EXECUTIVE DIRECTORATE

Note to the Management Board

Proposal for Technical Part of Terms of Reference for 3rd Independent External Evaluation of EFSA

Background information

1. In accordance with its Founding Regulation, EFSA will be subject to its 3rd external evaluation in 2017.
2. Following initial discussion at the private session of the Management Board in October 2016 on the scope of the evaluation, a Management Board Steering Committee (ESC) was set up to draft the Terms of Reference (ToR) for the external evaluation. The mandate of the ESC, including its composition, is available at: https://www.efsa.europa.eu/en/about/howwework.
3. The ESC had 3 meetings to discuss the ToR. In line with the Founding Regulation, the attached ToR have been drawn up in close cooperation with the European Commission.

Content of document

4. The external evaluation needs to cover all EFSA's working practices and its impact and cannot focus on specific areas of interest only.
5. The external evaluation needs to address mandatory evaluation criteria (section 2) and for each criterion a number of evaluation questions have been drafted.
6. An intervention logic (Annex I of ToR) has been prepared, indicating the drivers, need, problems and objectives that the intervention (establishment of EFSA) was intended to solve at the time the intervention was designed. It also lists inputs, activities, outputs, results and impact. The intervention logic is crucial for addressing the evaluation criteria and the underlying evaluation questions.
7. Section 3 provides for a high-level methodology, leaving room for proposals by contractors in the reopening of competition.
8. Section 4 gives detail of the reporting and deliverables and section 5 indicates the organisation of the project and the timetable.
9. Section 7 specifies the expertise required from the evaluation team. One proposed expertise requirement is to have one person in the evaluator team with 7 years of experience in high-level management of a risk assessment/scientific organisation to be discussed by the Management Board.

Next steps

10. Once agreed, the technical ToR will be incorporated into the Call for Tenders, together with additional information on budget, duration, admissibility, exclusion, selection and award criteria. EFSA will launch the call for tender among 9 contractors which are part of DG SANCO's framework contract on evaluations.
11. The maximum budget for this assignment is 230,000 EUR. The timing envisaged for potential contractors to submit tenders would be 6 weeks. The evaluation of received offers and award of the contract would take approximately additional 6 weeks. It is envisaged that the contractor will have approximately 10.5 months to carry out the contract.
12. The Management Board is asked to adopt the proposed technical ToR.

TERMS OF REFERENCE/TECHNICAL PART

3rd Independent External Evaluation of EFSA

Contracting Authority: EFSA

1. Context/Introduction

The purpose of these Terms of Reference (ToR) is to describe the aim and scope of the evaluation study and give instructions and guidance to anyone wishing to submit a tender. The ToR, together with the offer submitted, will also serve as the contractor's mandate during the implementation of the evaluation study, after the selection of the successful tenderer. They will become part of the contract that will be concluded following the award of the contract.

1.1 Background

The European Food Safety Authority (EFSA) is a European agency funded by the European Union that operates independently of the European legislative and executive institutions (Commission, Council, Parliament) and EU Member States.

It was set up in 2002 following a series of food crises in the late 1990s to be a source of scientific advice and communication on risks associated with the food chain. The agency was legally established by the EU under the General Food Law - Regulation 178/2002.

The General Food Law created a European food safety system in which responsibility for risk assessment (science) and for risk management (policy) are kept separate. EFSA is responsible for the former area, and also has a duty to communicate its scientific findings to the public.

As the risk assessor, EFSA produces scientific opinions and advice that form the basis for European policies and legislation. The remit covers:

- Food and feed safety
- Animal health and welfare
- Plant protection
- Plant health
- Nutrition

1.2 Objectives of the initiative/intervention and intervention logic

The mission and tasks of EFSA are laid down in Articles 22 and 23 of Regulation (EC) No 178/2002 and can be summarised as follows:

- To provide EU risk managers with independent, high quality, up-to-date and fit-for-purpose scientific advice on questions related to food and feed safety, animal health and welfare, plant health, nutrition and sector-specific environmental aspects;
- To provide scientific and technical support, in particular in case of crisis, and to improve international cooperation;
- To be an independent source of information and communicate to the public on its outputs and the information on which they are based;
- To promote and coordinate the development of uniform assessment methodologies in the fields falling within its mission;
- To search for, collect, collate, analyse and summarise scientific and technical data within its mission;
- to identify, characterise and monitor current and emerging risks that have a direct or indirect impact on food and feed safety;

- To cooperate with competent Member States bodies in order to share information, promote their involvement in risk assessment processes and minimise divergences;
- To cooperate with the Commission and the Member States to promote the effective coherence between risk assessment, risk management and risk communication function;
- To carry out its mission and tasks with independence, transparency and openness to interested parties/stakeholders.

1.3 Description of the initiative/intervention

An Intervention logic is described in Annex I of this document.

1.4 Implementation – State of Play

EFSA's activities are described in a number of documents, available on EFSA's website (*inter alia* those listed under point 6. REFERENCE, below).

1.5 Evaluation and Monitoring Provisions

1.5.1 Monitoring Provisions

- EFSA Programming documents (2011; 2012; 2013; 2012-2016; 2015-2017; 2016-2018; 2017-2019): https://www.efsa.europa.eu/en/about/corporatedocs
- Annual activity reports (from 2011 till 2016): https://www.efsa.europa.eu/en/publications/corporate

1.5.2. Previous evaluations and other reports

- Second External Evaluation of EFSA. Final report (2012)[1];
- Recommendations from EFSA'S Management Board (2012)[2];
- European Court of Auditors Special Report No 15/2012: Management of conflict of interest in selected EU Agencies (2012)[3];
- European Court of Auditors Special Report No 12/2016. Agencies' use of grants: not always appropriate or demonstrably effective (2016)[4];
- Impact Assessment of Specific Measures Aimed at Increasing Transparency and Engagement in EFSA's Risk Assessment Process (2016)[5];
- External review of the impact of scientific grant and procurement projects on delivering EFSA's tasks (2014)[6];
- Commission Staff Working Document on the results of the Fitness Check of the General Food Law Regulation, expected to be published by June 2017;
- Management Evaluation on the implementation of the Management Board recommendation related to the second External Evaluation of EFSA, expected to be published by end of June 2017;

[1] http://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/efsafinalreport.pdf
[2] http://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/mbrecommendations2012.pdf
[3] http://www.eca.europa.eu/Lists/News/NEWS1210_11/NEWS1210_11_EN.PDF
[4] http://www.eca.europa.eu/Lists/ECADocuments/SR16_12/SR_GRANTS_EN.pdf
[5] https://www.efsa.europa.eu/sites/default/files/160615-i5.pdf
[6] http://www.efsa.europa.eu/en/supporting/pub/695e

- Ex-post Evaluation of the Policy on Independence and Scientific Decision-Making Processes of EFSA and of its Implementing Rules on Declaration of Interest, expected to be finalised by end March 2017;
- External report on reputation of EFSA among its stakeholders across the EU, expected to be finalised by end of March 2017;
- Outcome of the Internal Audit Service on the Performance Audit on the Evaluation of Regulated Products: "Assessment" phase in pesticides authorisation, expected to be finalised by end of March 2017.

2. Specifications of the assignment

2.1 Objectives of the evaluation

As stipulated in Article 61 of EFSA's Founding Regulation (EC) 178/2002, before 1 January 2005 and every six years thereafter, the Authority, in collaboration with the European Commission, shall commission an independent external evaluation to assess the working practices and the impact of the Authority on the basis of the terms of reference issued by the Management Board in agreement with the European Commission.

The objective of the assignment is to provide an independent evaluation of EFSA's working practices and impact of its activities.

The Contractor shall assess the Authority and its core activities in terms of relevance, effectiveness, efficiency, coherence, complementarity and EU added value, answering the evaluation questions.

An assessment will also be made on the extent to which the recommendations issued by EFSA's Management Board, following the 2011 External Evaluation, have been put into practice.

The Contractor should provide recommendations to EFSA in order to face forthcoming challenges. EFSA's Management Board will examine the outcome of the external evaluation and issue recommendations to the European Commission regarding any possible changes to the Authority and its working practices.

The external evaluation report and the recommendations by the Management Board will be published on the EFSA website and disseminated widely via various other EFSA channels.

2.2 Scope of the evaluation

The evaluation is based on EFSA's Founding Regulation No 178/2002 and takes into account other secondary legislations creating additional mandatory procedures for EFSA (e.g. authorisation procedures). The starting point of the evaluation will be the second External Evaluation[7] and the related recommendations of EFSA's Management Board[8]. The evaluation shall cover the six year period 2011-2016 and extend, as appropriate, to 2018 to take into account recent significant developments. The evaluation shall address and cover the whole scope of EFSA's mission and tasks as well as its functioning as provided for in its Founding Regulation. In particular, it should address:

- EFSA's working practices for the production of scientific advice and scientific and technical support and its communication thereof, also including EFSA's planning, priority setting and resource management;

[7] https://www.efsa.europa.eu/sites/default/files/assets/efsafinalreport.pdf

[8] http://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/mbrecommendations2012.pdf

- The impact of EFSA's work on all relevant partners and stakeholders[9] at national, community and global level;
- EFSA's cooperation and reputation at EU and global level; and
- EFSA's governance structure.

The evaluation will need to take into account the conclusions of the Fitness Check of the General Food Law Regulation, to ensure continuity and consistency of both exercises. The publication of the Commission Staff Working Document on the results of the Fitness Check is expected by June 2017.

2.3 Evaluation questions

Evaluation criteria

Relevance:	the extent to which EFSA's objectives are pertinent to the needs, problems and issues to be addressed
Effectiveness:	the extent to which EFSA's objectives are, or are likely to be, achieved
Efficiency:	the extent to which the intended results of EFSA are achieved at a reasonable cost (fund, expertise, time, etc.)
Coherence:	the extent to which the policy/operation of EFSA does not contradict other policies/operations, internal or external to the Agency, with similar objectives
Complementarity:	the extent to which several policies/operations contribute to reaching the same objective (other policies/interventions to be specified)
EU added value:	the extent to which the policies/operations of EFSA adds benefits to what would have resulted from Member States' policies/operations only

Evaluation questions

Relevance

1. How well do the original EFSA objectives of Reg. 178/2002 still correspond to the current needs in the EU?
2. To what extent are EFSA's organisational structure and working practices/processes fit to meet current needs and to adapt to future scientific and communication challenges?

Effectiveness

3. To what extent have the following three general objectives of EFSA been achieved?

   a) A sustainable scientific system has been created and maintained, able to respond to needs from risk managers and to address emerging risks by delivery of state-of-the-art, unbiased and fit-for-purpose scientific advice.

   The following aspects linked to the scientific production system should be separately assessed, including their respective contributions to ensure mutual beneficial cooperation between EFSA and national experts/national scientific bodies:

   - EFSA panel system addressing general scientific questions;
   - EFSA panel system addressing authorisation dossiers;

[9] For the purpose of this evaluation, partners include: European Commission, European Parliament, Member State competent authorities on the area of food and feed safety (institutions of members of the Advisory Forum, Focal Points, EFSA Scientific networks, Article 36 List, other Member State competent authorities), sister agencies, non-EU and international organisation with a similar mandate as EFSA; stakeholders include: consumer organisations, civil society groups and NGOs with an interest in food and feed safety, farmers and primary producers, food industry, the media, and the scientific and research community working in food and feed safety.

- EFSA peer-review system on pesticides dossiers;
- EFSA scientific staff providing technical advice.

b) Citizens trust in the European food safety system is enhanced by EFSA's scientific excellence, independence and transparency. Among other aspects, it should be assessed to what extent EFSA's communication services contribute to building citizens' trust.

c) Harmonization of methodologies and coherence of approaches on food/feed safety risks are improved at EU and global level by EFSA's networking and cooperation with EU and global risk assessment authorities. The contribution of EFSA to this harmonization should be assessed.

4. What factors influenced what was achieved or not achieved? The assessment should include, among other aspects, observed unintended effects, an analysis of the strengths and weaknesses of EFSA and the tools for pooling expertise, in particular the collaboration arrangements between EFSA and external expertise (national experts, national scientific bodies including Article 36 organisations).

Efficiency

5. To what extent is the Authority's governance model appropriate for ensuring the Authority's mission statement? The evaluation should look at strengths and weaknesses of the current EFSA model in order to identify any particular EFSA needs.
6. To what extent are the internal mechanisms for programming, monitoring, reporting and evaluating EFSA adequate for ensuring accountability and appropriate assessment of the overall performance of the Authority?
7. How do established procedures, layers of hierarchy, division of work between teams or units, IT systems, initiative for streamlining and simplification, etc minimise the administrative burden of the Authority and its stakeholders?
8. Does the Authority undertake prioritisation of certain topics or tasks and, if so, has this been appropriate?
9. To what extent are the current practices for collecting scientific data and evidence adequate for EFSA's risk assessment?
10. How do the funds spent for EFSA compare to the results achieved?
11. If funds are not proportionate to the results achieved, what factors influence any particular discrepancies?

Coherence/Complementarity

12. To what extent does EFSA's work contribute to the promotion of the EU food and feed safety regulatory standards on a global level? To what extent does EFSA's work contribute to the EU political priorities?
13. To what extent is the involvement of Member State risk assessment organisations in the provision of EFSA's scientific advice adequate for ensuring Member States' ownership of a harmonised European assessment outcome and to which extent has the involvement been complementary to other public actors' activities? Which factors weighed on this adequacy and complementarity?
14. To what extent is EFSA's work coherent with EU commitments at international level (e.g. CODEX, OIE, IPPC)? Which aspects are not coherent, if any, and why?
15. To which extent is there overlap/complementarity/coherence with the work of other EU Agencies, notably EMA, ECHA, ECDC?

EU Added Value

16. What is the additional value resulting from EFSA's existence, compared to what could be achieved by Member States at national level?
17. To what extent is EFSA recognised as a leading regulatory scientific authority at national, European and global level? Which factors have the most important influence on the scientific recognition and the reputation of EFSA?
18. What would be the most likely consequences at the EU level of stopping EFSA?

3. Methodology

The Contractor should carry out the evaluation along four main phases:

1. Inception phase
2. Data collection phase
3. Data analysis phase
4. Synthesis and quality control phase

Indicative values for staff time/resource allocation for the four phases would be: 10%, 30%, 35% and 25%, respectively.

Throughout all phases of the evaluation, the methodology should respect the principles of objectivity, reliability and evidence-based assessment and should comply with the requirements of the Better Regulation Guidelines[10].

The methodology for the evaluation should be tailored to meet the information needs, ensuring that an appropriate mix of methodological tools and techniques are chosen with an aim to:

- Properly answer all evaluation questions and to perform an overall assessment;
- Gather/collect data, assist in analyses and formulation of judgment (or reasoned assessment);
- Perform cross-checking and triangulation;
- Reinforce each other through appropriate combinations;
- Match contextual constraints like: availability of expertise and data, allocated resources, time schedule; and
- Perform economic analysis of business processes.

Evaluation of methodological tools and techniques shall be implemented to fulfil the following functions:

1. to help structure the evaluation (in inception phase);
2. to collect data (in data collection phase);
3. to analyse data (in data analysis phase); and
4. to aid the formulation of judgements (in synthesis and quality control phase).

Consequently, there will be four evaluation phases, as mentioned above: An appropriate mix of tools (without relying mainly on a survey) should be used to strengthen the evidence basis of the evaluation, the reliability of data, the validity of its reasoning, and the credibility of its conclusions. Solutions in respect of methodological tools should be tailor-made for each phase of the evaluation, using a combination of methodological tools and techniques, including those indicated as mandatory below:

[10] http://ec.europa.eu/smart-regulation/guidelines/toc_guide_en.htm

- Tools and techniques to be used for the inception phase:
  - Desk research: tool to collect existing information [mandatory];
  - Interviews with EFSA management [mandatory];
- Tools and techniques to be used for the data collection and analysis phases:
  - Desk research: tool to collect existing information [mandatory];
  - Interviews: tool to collect personal opinions and qualitative information;
  - Group interviews/focus groups: tool to collect information during the course of a structured discussion;
  - Surveys: tool (questionnaire) to collect information covering the perspective of different target groups. Survey questions may be modified for each target group;
  - Relevant number of representative case studies to address the substance of the evaluation questions but also to allow for solid considerations on cost/benefit relationships, including costs of compliance versus generated added-value. The case studies should be proposed by the Contractor, taking into account stakeholders' inputs and agreed with the Evaluation Steering Committee [mandatory];
- Tools and techniques to be used for the formulation of judgements (conclusions, recommendations) – synthesis and quality control phase:
  - Contractor's Expert Panels: tool to reach a collective judgement on the value of the authority and its effects [mandatory];
  - SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis;
  - Multi-criteria analysis: tool to structure and combine assessment of a variety of cases to support judgements in complex situations;
  - Cost-effectiveness analysis: as evidenced by the data collection phase [mandatory].

Please note that many different tools and techniques are available and the list above is only indicative (apart from the mandatory items indicated). The Contractor has the choice of mixing the methods (from the list above or others) used to gather and analyse information and for making the assessment. However, the following must be taken into account:

- The evaluation must be based on recognised evaluation techniques and methodologies and must be conducted in such a way that the results are supported by evidence and rigorous analysis. Soundness and robustness of findings must be ensured and justified. For this purpose, triangulation of methods is required.
- The choice and a detailed description of the methodology must form part of the offer submitted. Advantages, limitations and risks involved in using the proposed tools and techniques should be explained. There should be a clear link between the evaluation questions addressed and the corresponding methodology proposed. The evaluation questions can be further elaborated, e.g. by providing operational subquestions under each question. An evaluation matrix should be elaborated to include the evaluation questions, any subquestions, the corresponding indicator and judgement criteria, as well as data sources.
- Considerable emphasis should be placed on the analysis phase of the evaluation. In addressing the evaluation questions, quantitative indicators should be sought and used as far as possible. The Contractor must support findings and recommendations by explaining the degree to which these are based on opinion, analysis and objectively verifiable evidence. Where opinion is the main source, the degree of consensus and the steps taken to test the opinion should be given.

- It is not expected that all individual measures of the initiative/intervention be assessed, but the sample of measures examined should be drawn up in a manner suitable for each evaluation question addressed, and should be such as to enable the evaluators to draw general conclusions on the measures.
- The approach proposed by the Tenderer must be clearly set out in the offer. It should clearly identify:
    a. data to be collected
    b. consultation strategy
    c. analysis to be conducted
- All consultation activities run by the Contractor, all related documents, the list of stakeholders (a stakeholder mapping might be required) and the Privacy Statement need to be agreed by EFSA/the Evaluation Steering Committee. In its allocation of time, the Contractor needs to foresee sufficient time[11] for the approval by EFSA.

A risk analysis should be provided, which needs to be tailored for this assignment.

Annex II provides a Quality Assessment Checklist, which provides the assessment criteria which will be used to evaluate the quality of the deliverables, including the aspects on data collection, analyses and judgements, and usefulness and feasibility of recommendations. It is mandatory that the Contractor will perform a thorough quality check of each phase, prior to its delivery to EFSA, by at least two senior members of the Contractor (personnel category I), whereby one of them shall have at least 7 years experience in high-level management of a risk-assessment/scientific organisation.

[11] Time needed for different approval steps will be clarified in more details during the kick-off meeting.

4. Reporting and deliverables

4.1 General reporting requirements

The Contractor must ensure that all reports under the contract are clear, concise, comprehensive and of high editorial quality. Reports should be drafted in English, using simple and non-technical language for a non-specialised audience. Technical explanations shall be given in annexes.

Each report (except the final version of the Final Report) should have an **introductory page** providing an overview and mapping of the report. It should describe what parts of the document, on the one hand, have been carried over from previous reports or been recycled from other documents, and on the other hand, represent progress of the evaluation work with reference to the work plan.

All reports must be submitted in electronic format according to the timetable below to the responsible body. Electronic files must be provided in Microsoft® Word and Excel for Windows format, as applicable[12]. Additionally, besides Word, the Final Report must be delivered in Adobe® Acrobat pdf format.

Annex II provides a Quality Assessment Checklist, which provides the assessment criteria which will be used to evaluate the quality of the deliverables. The Checklist will be used for the final "sign off" of the Contractor's deliverables and includes a judgement on whether key aspects of the work conducted, meet the required standards and provides any related comments.

4.2 Inception Report

The report should describe:

- How the work will be organised by the Contractor, including a detailed work plan with, *inter alia*, timelines, milestones and all actors, and an adaptation and substantiation of the overall approach;
- The fully developed methodology to answer all the evaluation questions, including the proposed sampling strategy of deliverables;
- How the methodology proposed by the Contractor is going to be implemented in detail, after e.g. having further examined the sources of secondary and primary data that will be used for the evaluation; in particular, which data and methods will be used to answer particular evaluation questions. The inception report should set out in detail how the proposed methodology will be implemented, and in particular clearly lay out in tabular form how the method allows each evaluation question to be answered via establishment of judgement criteria and, within these, of evaluation indicators. A further column highlighting choice of relevant evaluation tools should complete the table.
- The areas and numbers of case studies to be conducted, ensuring representativeness of EFSA's tasks; and
- The proposed content of survey and interview questions, together with a list and number of respondents as outlined in the technical offer and as agreed at the kick-off meeting, as applicable.

An indication for the report length is up to **30** pages, annexes excluded.

[12] E.g. graphs, aggregated data and primary data to be submitted in Excel, unless agreed otherwise.

On the basis of discussions with the Contractor, changes and improvements may be requested. The final version of evaluation tasks/questions suggested by the Contractor and evaluation indicators to be used, will be validated by the Evaluation Steering Committee. The Contractor will submit a final version within two weeks.

4.3 Interim Report

With this report, the Contractor should already be in a position to provide:

a) Aggregated data for the period under evaluation (it is expected that the field work will be finalised or very close to finalisation at this stage);

b) Preliminary findings and conclusions regarding the evaluation, addressing the objectives of the review and the evaluation questions; and

c) Description of the way the data will be triangulated, existing data gaps filled in and further analysis conducted.

The report must, as a minimum, provide:

- An overview of the status of the evaluation project;
- A description of problems encountered and solutions found;
- A summary of initial findings and results of the data gathering;
- An assessment of the data, whether it meets expectations and will provide a sound basis for responding to the evaluation questions, highlighting limitations and possible bias therein;
- A conclusion on whether any changes are required to the work plan, or any other solutions should be sought in order to ensure that the required results of the evaluation are achieved. If any such issues are to be identified, they must be discussed in the meeting with the Evaluation Steering Committee dedicated to this report;
- A proposal for the final structure of the Final Report, as well as a structure of the Executive Summary.

An indication for the report length is up to **70** pages, annexes excluded.

The contractor will submit a revised interim report with the necessary updates of the report after discussion with the Evaluation Steering Committee.

4.4 Draft Final Report

This document should deliver the results of all tasks covered by these ToR.

The structure of the report should follow a broad classification into the following parts:

- **Main report:** must contain in a concise manner a description of the subject evaluated, the context of the evaluation, and the methodology used (including an analysis of its strengths, weaknesses and limitations). It must present, in full, the results of the analyses, conclusions and recommendations arising from the evaluation. An indication for the report length is up to **150** pages, annexes excluded
- **Annexes:** These must collate the technical details of the evaluation, and must include questionnaire templates, interview guides, any additional tables or graphics, and references and sources.

4.5 Final Report

The Final Report follows the same format as the draft Final Report. Furthermore, it is accompanied by an **Executive Summary** of no more than **6** pages.[13] The Executive Summary summarises the evaluation's main conclusions, the main evidence supporting them and the recommendations arising from them. After being agreed with EFSA, it should be translated into Italian, French and German by a professional translation agency. On top of that, **an abstract** of no more than 200 words should be provided in English. The purpose of the abstract is to act as a reference tool, helping the reader to quickly ascertain the evaluation's subject.

The Contractor should also provide a PowerPoint presentation of key aspects and findings of the study, together with speaking notes. At the request of EFSA, the Contractor should provide a maximum of two presentations to interested stakeholder groups. The copyright of the reports remains with EFSA.

The document must take into account the feedback from the Evaluation Steering Committee on the draft Final Report, insofar as these do not interfere with the autonomy of the Contractor in respect of the conclusions they have reached and the recommendations made.

EFSA will publish the Final Report, the Executive Summary, the Abstract, and the annexes on its website.

4.6 Progress Reports

The Contractor will deliver Progress Reports on a monthly basis, summarising on one page the progress of the evaluation work made with reference to the work plan. The Contractor will report particularly on difficulties (re-)encountered and mitigation measures taken or suggestions to changes required to the work plan to ensure that the required results of the evaluation are achieved. The Evaluation Steering Committee might call for a meeting if the Progress Report raises concerns about progress of the work.

5. Organisation, meetings and timetable

5.1 Organisation

The contract will be managed by EFSA who will be responsible for providing the external evaluator with access to information and for facilitating practical and technical aspects in the day-to-day interface with the contractor. The evaluation process will be guided by an Evaluation Steering Committee (composed of 4 members of the Management Board and 1 EC representative) whose responsibilities will include:

- Ensuring that the interests of the stakeholders/partners are taken into consideration
- Guiding the evaluation work in view of its scientific quality
- Safeguarding the technical quality of the evaluation from a methodological viewpoint
- Endorsing the reports submitted by the external evaluator
- Ensuring that the Contractor's independence is not compromised.

The mandate of the Evaluation Steering Committee is available at:
https://www.efsa.europa.eu/en/about/howwework

[13] 1 page = 1500 characters

5.2 Meetings

The Contractor will be expected to participate in four physical meetings in Parma or Brussels, as indicated in the table below, and at least one teleconference. For these meetings, **minutes should be drafted by the Contractor**, within 1 week of the meeting, to be agreed among the participants. The meetings should be attended by the Project Leader and at least one other expert from the team.

5.3 Timetable

The indicative starting date is **15 June 2017**. The contract will start after both parties have signed the document. The period of execution of the contract is **10.5 months**.

The following outline work plan and indicative timetable are envisaged:

Timeline	Date	Task
Launch of call	27 March 2017	Evaluation Steering Committee to agree to mandate and ToR.
Deadline for offers	8 May 2017	Framework Contractors to submit their offers to EFSA.
Contract signature & start of work	15 June 2017	EFSA to finalise evaluation of offers, sign award decision and contract. Contractor to sign specific contract and start work.
Kick-off meeting	19 June 2017	Organised in Parma with participation of the Contractor.
Inception Report [T0 + 1 month]	17 July 2017 20 July 2017	Contractor provides the Evaluation Steering Committee with the **Inception Report.** A meeting is organised in Brussels with participation of the Contractor.
If needed, updated Inception Report	25 July 2017	Contractor provides the updated Inception Report, if needed, in line with feedback from the Evaluation Steering Committee.
Interim Report [T0 + 5.5 months]	30 November 2017 13 December 2017	Desk and field research completed. Contractor provides the Evaluation Steering Committee with the **Interim Report.** A meeting is organised in Parma with participation of the Contractor.
If needed, updated Interim Report	12 January 2018	Contractor provides the updated Interim Report, max. 15 calendar days after having received the request for changes.
Draft Final Report [T0 + 8 months]	19 February 2018 26 February 2018	Contractor provides the Evaluation Steering Committee with the **Draft Final Report**. A meeting is organised in Brussels with participation of the Contractor.

If needed, updated Draft Final Report	5 March 2018	Contractor provides the updated Draft Final Report, if needed, in line with feedback from the Evaluation Steering Committee.
Discussion of Draft Final Report at MB meeting	Mid March 2018	
Final Report [T0 + 10.5 months]	30 April 2018 7 May 2018	Taking account of the Management Board's comments, the Contractor sends the **Final Report and Executive Summary** to the Evaluation Steering Committee. A meeting is organised in Brussels with participation of the Contractor.
If needed, updated Final Report	31 May 2018	Contractor provides updated Final Report and/or Executive Summary, max. 15 calendar days after having received the request for changes.
Discussion of Final Report at MB meeting	Mid June 2018	

6. References

Basic documents are listed in 6.1 and a list of other documents (not exhaustive) is provided in 6.2.

6.1 Basic documents

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the EFSA and laying down procedures in matters of food safety (2002). http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32002R0178.

EFSA website: www.efsa.europa.eu

Corporate documents and publications: http://www.efsa.europa.eu/en/about/corporatedocs

Annual Quality Manager's Reports (from 2011 until 2016):
http://www.efsa.europa.eu/en/publications/corporate

Workflow for scientific opinions:
http://www.efsa.europa.eu/interactive_pages/scientificprocess/ScientificProcess

EFSA's Register of Questions:
http://registerofquestions.efsa.europa.eu/roqFrontend/login?1

6.2 Documents and information to be provided after contract signature (not exhaustive)

- EFSA replies to the Special ECA Report on the Agencies use of grants not always appropriate or demonstrably effective (2016);
- ECA Clearing letter Follow-up of the ECA Recommendations made in its Special Report on "Management of conflict of interest in selected EU Agencies" (SR 152012) (2016);

- IAS Final Audit Report on Performance Evaluation and Career Development in EFSA (2012);
- IAC Data Protection Audit on EFSA video-surveillance system. Version: final (2012);
- IAC Audit Report on Internal Control Standards Implementation (2014);
- IAS Final Audit Report on Reporting and Building Blocks of Assurance in EFSA (2014);
- IAS Audit on Reporting and Building Blocks of Assurance in EFSA. Action Plan (2014);
- IAS Final Audit Report on Scientific Support to Risk Assessment and Evaluation of Regulated Products with Focus on Data Collection and Analysis in EFSA (2015);
- IAS Audit on Scientific Support to Risk Assessment and Evaluation of Regulated Products with focus on Data Collection and Analysis in EFSA. Reply to Action Plan (2015);
- IAC Corporate Governance audit on the Role of the Expert in the EFSA Scientific Decision-Making Processes. Final Report (2016);
- IAS Final Audit Report on IT governance and IT project management in EFSA (2016);
- PaRMa Project. Project Closure Report (2014);
- Australia Project 2014. Project Closure Report (2015);
- Agora Project. Project Closure Report (2015);
- PRIME Project. Project Closure Report (2016);
- STEP 2018 Project. Project Steering Committee (2017);
- Process Management Project (PMP). Project Steering Committee (2017);
- EFSA Journal Project. Closure report (2017);
- QMS implementation Assessment (2015);
- Stage 2 Assessment. ISO 9001.2015 (2015);
- Stage 1 Assessment. ISO 9001.2015 (2015);
- Pre-Assessment certification. 9001.2015 (2015).
- Preliminary Implementation Plan Transformation to an "Open EFSA" (2015);
- Final Phase Implementation plan to an "Open EFSA" (2016);
- Overview of the scientific processes of the EU agencies network for scientific advice (EU-ANSA) (2015);
- EFSA Stakeholder Engagement Approach (2016).
- Roadmap on the follow-up to the common approach on EU decentralised agencies

7. Requirements

7.1 Resources

The Contractor shall ensure that experts are adequately supported and equipped. Sufficient administrative, secretarial and interpreting resources must be available to enable senior experts to concentrate on their core evaluation tasks.

7.2 Expertise required from the evaluation team

The tenderer shall provide a team of experts in line with the profile requirements announced in the Framework Contract and in addition should be compliant with the following minimum expertise requirements:

i. 'Category I' experts: A minimum of two experts, complying with the following requirements:
   - one should be the Project Leader;
   - one should have at least 7 years experience in high-level management of a risk-assessment/scientific organisation; and
   - one should have at least 7 years experience in related ex-post evaluations at European public organisations[14].

ii. 'Category II' expert: A minimum of two experts are required complying with the following requirement:
   - one should have at least 4 years of experience in the application of quantitative and qualitative evaluation methods proposed for the implementation of the project,
   - one should have at least 4 years of experience in the areas of food safety legislation and risk assessment related to EFSA's remit.

iii. 'Category III' experts: A minimum of one expert is required for the performance of this project.

iv. 'Category IV' experts: no minimum is set.

The tenderer shall submit the detailed CVs of all team members proposed for the assignment, taking into account the minimum expertise requirements detailed above and in line with the Framework Contract provisions. EFSA strongly recommends submitting the CVs in the EU CV format which can be accessed here[15]. In addition, the classification by staff category (I, II, III and IV) should be clearly indicated, ideally using a separate table, together with an indication on which profile requirements/competences are met by which member of the team and what is the planned role/task of each member in the team.

7.3 Absence of conflict of interests

Tenderers should provide an Institutional and Individual Declaration of Interests using the templates available on the EFSA website (http://www.efsa.europa.eu/en/procurement/toolbox).

In case of a consortium submitting an offer, or in case of subcontracting, such declarations should be completed separately and included in the offer for each member of the consortium and for each subcontractor.

[14] European public organisations should be read as synonym of the Union public administration, including Union's institutions, bodies, offices and agencies as referred to in Article 15 of the Treaty on the Functioning of the European Union.
[15] http://europass.cedefop.europa.eu/en/documents/curriculum-vitae/templates-instructions

EFSA reserves the right to verify this information and to request further supporting evidence prior to the signature of the specific contract.

7.4 Intellectual Property Rights

As regards any product or delivery commissioned by EFSA and developed by the contractor in the context of the specific contract resulting from this reopening competition, the intellectual property rights[16] (IPR) will be owned by EFSA only, in its capacity as financial source of the specific contract. The contractor cannot file a trademark, patent, copyright or other IPR protection scheme in relation to any of the results or rights obtained by EFSA in performance of the specific contract, unless the contractor requests EFSA ex-ante authorisation and obtains from EFSA a written consent in this regard.

EFSA may authorise the contractor to publish results of the specific contract resulting from this reopening competition provided the contractor obtains ex-ante written consent from EFSA in this regard. In such a case the contractor must make due reference mentioning that the results were achieved within the context of the specific contract with EFSA.

Exploitation of results is further specified in Article I.8 of the Framework Contract.

7.5 Confidentiality requirements concerning information obtained from EFSA

The contractor is likely to receive confidential information from EFSA in the course of the implementation of the assignment. The contractor will respect confidentiality by any means and shall use the information exclusively for the purpose for which it was made available and in view of achieving the project deliverables. This comprises personal data made available or processed (i.e. individual's names and contact details). As a general principle of data protection, any processing or use of personal data shall be strictly related to the purpose for which they were collected.

Upon delivery to EFSA and completion of the specific contract, all confidential information and documents shall either be returned to EFSA or be deleted or anyway destroyed irrespective of whether these exist in computers, electronic media or similar devices or in paper format. Personal data collected from EFSA information systems shall never be used or processed for any other purposes.

By virtue of the framework contract, the contractor shall undertake to enforce the compliance with confidentiality principles vis-à-vis its staff allocated to the assignment under the specific contract with EFSA. Upon conclusion of the specific contract, EFSA may impose further requirements, such as Confidentiality Declarations by individuals allocated to the assignment.

[16] Including primary and collated data collected during this assignment

Annex I – Intervention logic

Needs	Problems	General objectives	Specific objectives	Inputs	Activities	Outputs	Results	Impact
- The reduction, elimination or avoidance of a risk to health by ensuring food safety should be based on scientific risk assessment - The scientific assessment of risks needs to be fit for purpose to be used by the risk managers as a basis for legislation - Scientific assessment and, more globally, the scientific system producing them need to be trusted (recognised as high quality, independent, transparent and open by all stakeholders) - The evidence/data basing the risk assessment needs to be sound and at EU level. - The scientific system needs to be inclusive/ cooperative at EU and global level - Scientific assessment methodology needs to be up-to-date and timely to meet pace of innovation	- System not able to face the demands of risk managers because of lack of scientific capacity - Problems of trust created by a lack of visible independence, in particular from risk managers - Scientific divergences with MS because of a system functioning in isolation (no link with national scientific bodies) - Insufficient public perception of transparency of the processes and insufficient structured framework to interact with stakeholders - Decreased consumer confidence in relation to food - Uncertain and heterogeneous cooperation with and involvement of Member States including the involvement of Member States experts - Weak effectiveness of the work of the former Scientific Committees - Lack of an effective and comprehensive system of collection and analysis of data at an EU level - Lack of an effective capability to identify emerging risks	- Establishment of a system with sufficient scientific capacity to deliver excellent, independent and fit for purpose advice to respond the demands/needs of risk managers - Contributing to the trust in the food safety system by its independence, transparency and openness - Building a system creating coherence and shared views on food/feed safety risks at EU and global level	- Establishment of an autonomous agency separated from the Commission with its own staff , budget and tools responsible for providing scientific advice and support to risk managers - Functioning of the agency based on independence and transparency - Independent right of the agency on communication - Cooperation of the agency with EC and MS to ensure the coherence of the RA, RM and risk communication functions - Networking with MS and openness to stakeholders contributing to shared scientific views	- Staff + expertise - Budget - Data, studies - Methodologies - Mandates, guidance - Data collection tools - Externalisation tools (e.g. grants and procurement) - IT - Tools for cooperation and networking with MS, EC, global scientific bodies - Communication tools - Openness and interaction with stakeholders - Crisis tools (preparedness and quick delivery)	- Delivering the scientific opinions and reports and the correlated management of SC/panels - Production of scientific guidance and new or adapted assessment methodologies - Data collection and analysis - Cooperation with MS and correlated tools (e.g. AF, Art.36) - Interaction with stakeholders - Implementation of independence - Transparency and openness - Cooperation with EC and correlated tools - Identification of Emerging risks - Support in crisis - International activities - Risk communication	- Scientific opinions - Scientific and Technical reports - Scientific Guidance - External reports (e.g. reports of a beneficiary of a grant) -Scientific studies - RA methodologies and models - Quick support in time of crisis through a special emergency risk assessment process - Data collection reports - Databases - Tools for mining data - Communication outputs - Independence rules and their implementations - Transparency and interaction with stakeholders rules and their implementation - Cooperation with and disseminating in scientific world - Cooperation and involvement of MS. - Information shared with MS, shared work with MS - Tools for preparedness of crisis and for supporting in case of crisis.	- Fit-for purpose scientific advice and support to risk managers - Higher scientific capacity of the system - High quality and sufficient data available - Transparent assessment system - More visibly independent / autonomous system - Increased and timely information on risk - Member States better informed, sharing the same scientific information/data and having more convergent scientific views. - Stakeholders better informed and involved, - Better preparedness for facing new risks and crisis	- Trusted science - Increased harmonisation of risk assessment methodologies and opinions at EU and global level - Internationally agreed food safety standards - Accessibility and reusability of data and new knowledge creation - Maintenance of high level of food and feed safety - Containment of crises

Annex II – Quality Assessment Checklist

Quality Assessment for Deliverables

This documents provides **a Quality Assessment checklist** to be completed, in order to:

- give a structured feedback to the Evaluator on the deliverables, and
- support and justify the approval of the final version of each deliverable.

The checklist can be quickly filled out by ticking boxes, but becomes most useful when also including comments in the open fields.

Quality Assessment for Evaluation of *[Deliverable]*

EFSA Unit [Unit]

Official(s) managing the evaluation: [Name(s)]

Evaluator: [Company/name]

Assessment carried out by(*):

Evaluation Steering Committee [ ]
Evaluation Function [ ]
Other (please specify) [ ]

(*) Multiple crosses possible

Date of assessment [DD/MM/YYYY]

Objective of the assessment	Aspects to be assessed	Fulfilled? Y, N, N/A	Comments
1. Scope of evaluation	Confirm with the Terms of Reference and the work plan that the contractor :		
	a. Has addressed the evaluation issues and specific questions	[ ]	
	b. Has undertaken the tasks described in the work plan	[ ]	
	c. Has covered the requested scope for time period, geographical areas, target groups, aspects of the intervention, etc.	[ ]	
2. Overall contents of report	Check that the report includes:		
	a. Executive Summary according to an agreed format	[ ]	
	b. Main report with required components	[ ]	
	▪ Title and Content Page ▪ A description of the intervention being evaluated, its context, the purpose of the evaluation, contextual limitations, methodology, etc. ▪ Findings, conclusions, and judgments for all evaluation issues and specific questions ▪ The required outputs and deliverables ▪ Recommendations as appropriate		
	d. All required annexes	[ ]	
3. Data collection	Check that data is accurate and complete		
	a. Data is accurate	[ ]	
	▪ Data is free from factual and logical errors ▪ The report is consistent, i.e. no contradictions ▪ Calculations are correct		

Objective of the assessment	Aspects to be assessed	Fulfilled? Y, N, N/A	Comments
	b. Data is complete ▪ Relevant literature and previous studies have been sufficiently reviewed ▪ Existing monitoring data has been appropriately used ▪ Limitations to the data retrieved are pointed out and explained. ▪ Correcting measures have been taken to address any problems encountered in the process of data gathering	[ ]	
4. Analysis and judgments	Check that analysis is sound and relevant		
	a. Analytical framework is sound ▪ The methodology used for each area of analysis is clearly explained, and has been applied consistently and as planned ▪ Judgements are based on transparent criteria ▪ The analysis relies on two or more independent lines of evidence ▪ Inputs from different stakeholders are used in a balanced way ▪ Findings are reliable enough to be replicable	[ ]	
	b. Conclusions are sound ▪ Conclusions are properly addressing the evaluation questions and are coherently and logically substantiated ▪ There are no relevant conclusions missing according to the evidence presented ▪ Findings corroborate existing knowledge; differences or contradictions with existing knowledge are explained ▪ Critical issues are presented in a fair and balanced manner ▪ Limitations on validity of the conclusions are pointed out	[ ]	
5.Usefulness of recommendations	a. Recommendations are useful ▪ Recommendations flow logically from the conclusions, are practical, realistic, and addressed to the relevant Commission Service(s) or other stakeholders	[ ]	

Objective of the assessment	Aspects to be assessed	Fulfilled? Y, N, N/A	Comments
	b. Recommendations are complete ▪ Recommendations cover all relevant main conclusions	[ ]	
6. Clarity of the report	a. Report is easy to read ▪ Written style and presentation is adapted for the various relevant target readers ▪ The quality of language is sufficient for publishing ▪ Specific terminology is clearly defined ▪ Tables, graphs, and similar presentation tools are used to facilitate understanding; they are well commented with narrative text	[ ]	
	b. Report is logical and focused ▪ The structure of the report is logical and consistent, information is not unjustifiably duplicated, and it is easy to get an overview of the report and its key results. ▪ The report provides a proper focus on main issues and key messages are summarised and highlighted ▪ The length of the report (excluded appendices) is proportionate (good balance of descriptive and analytical information) ▪ Detailed information and technical analysis are left for the appendix; thus information overload is avoided in the main report	[ ]	