



TENDER SPECIFICATIONS

Reference: OC/EFSA/ED/2020/01

Subject: Development of roadmaps for action on:

LOT 1 - Building a European partnership for next generation, systems-based environmental risk assessment;

LOT 2 - New approach methodologies in risk assessment;

LOT 3 - Risk assessment of combined exposure to multiple chemicals.

Procurement procedure: Open call (Article 164(1) (a) of the Financial Regulation)

Project/Process code: D01.01-ED-21

Budget Line: 3210

Tender specifications purpose:

1. specify what EFSA will buy under the contract resulting from this procurement procedure;
2. announce the criteria which EFSA will use to identify the successful contractor;
3. guide tenderers in the preparation and sending of their offer;
4. form annex 1 of the contract resulting from this procurement procedure and be binding for contract implementation.

Additional guidance:

Please read the [EFSA Guidance for tenderers](#) available on the EFSA website, designed to assist potential tenderers in their understanding of EFSA procurement procedures.

Provide EFSA with feedback:

If you considered applying to this call for tenders but finally decided not to, please provide EFSAProcurement@efsa.europa.eu with your feedback on the call and reasons for not applying. Feedback will be treated confidentially and will only be used for improving future EFSA procurement calls.



PROCEDURE TIMETABLE

Milestone	Date ¹	Comments
Launch date	01/12/2020	Date Contract Notice is sent to Official Journal
Deadline for sending request for clarification to EFSA	18/02/2021 at 14:30 (CET)	Requests for clarification may only be submitted through the e-Tendering website as described in the Invitation Letter. EFSA is not obliged to reply to clarifications received less than 6 working days before the deadline for submission of offers.
Deadline for EFSA to reply to clarification questions	19/02/2021	
"Receipt Time Limit" - Closing date and time for receipt of offers	26/02/2021 at 14:30 (CET)	Refer to the Invitation letter and part 3 of these tender specifications regarding how to submit your offer.
Opening session	01/03/2021 at 14:30 (CET)	EFSA - Via Carlo Magno 1A, Parma, 43126, Italy. Requests to attend the virtual opening session to be held using Microsoft Teams must be made 2 working days in advance of the virtual opening session. Refer to Invitation letter for details.
Notification of evaluation results	Estimated April 2021	The outcome of the procurement procedure will be communicated to all tenderers exclusively using the e-mail address indicated in their offer. Please check regularly the inbox in question.
Contract signature	Estimated April 2021	

¹ All times are in the time zone of Italy, the country in which EFSA is based.



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PART 1 TECHNICAL SPECIFICATIONS - WHAT DOES EFSA NEED TO BUY THROUGH THIS PROCUREMENT PROCEDURE?

1.1 BACKGROUND

1.1.1 About EFSA

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. The EFSA's overall mission is two-fold: to deliver independent, high-quality and timely scientific advice on risks in the food chain, from farm to fork, in an integrated manner and to communicate on those risks, in an open manner to all interested parties and the public at large. EFSA works with Member States, European bodies, international and third country organisations to share information, data and best practices, identify emerging risks and develop coherent communications on risks in the food chain. As the risk assessor, EFSA produces scientific opinions and advice that form the basis for European policies and legislation. Its remit covers food and feed safety, nutrition, animal health and welfare, plant protection and plant health. EFSA also considers, through environmental risk assessments, the possible impact of the food chain on the biodiversity of plant and animal habitats.

Grants and procurement calls are launched by EFSA as part of EFSA's scientific cooperation strategy. These calls for external support help the Authority to respond more effectively and flexibly to its growing workload, particularly in the core areas of data collection, provision of scientific advice and evaluation of regulated products.

1.1.2. About this procurement

Article 30 of the General Food Law (Regulation (EC) No 178/2002²) lays down the requirement of EFSA exercising vigilance to identify at an early stage, any potential source of scientific divergences between its scientific opinions and those issued by other European bodies carrying out similar tasks with the aim to resolve such divergences.

Article 32d of the "Transparency Regulation" (Regulation (EU) 2019/1381 of the European Parliament and of the Council³) states that the European "*Commission, in exceptional circumstances of serious controversies or conflicting results, may request the Authority to commission scientific studies with the objective of verifying evidence used in its risk assessment process. The studies commissioned may have a wider scope than the evidence subject to verification*". EFSA's grant and procurement budget embeds for this purpose verification studies on an annual basis from 2021 onwards. However, in the absence of a specific request under Article 32d of Regulation (EU) 2019/1381 by the European

² 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 European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1-24.

³ Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC. OJ L 231, 6.9.2019, p. 1-28.



Commission, EFSA will dedicate part of its grant and procurement budget for the purpose of preparedness for verification studies.

The areas of work would be those for which scientific studies are required and regulatory efforts are justified, to ensure that regulatory science does not fall behind scientific developments and potential new research methodologies of regulatory interest. Investing in commissioning scientific studies and projects to address scientific and methodological knowledge gaps in its regulatory areas, generating data and evidence, developing methodologies and communication science in a coordinated manner with larger EU and Member State research and innovation programmes (e.g. Horizon 2020, Horizon Europe), translating and complementing research findings into implementable risk assessment methodologies can strengthen the cooperation between EFSA and other EU/national institutions and reduce knowledge and communication gaps. This may thereby prevent triggering Article 30 requests on scientific divergences which have the potential to develop to Article 32d requests.

To support this investment EFSA established a process for identifying and prioritising scientific themes and developing their related roadmaps for action. The main components of this process are:

- i) A “theme paper” which provides for each scientific theme directions for preparedness for future risk assessment requirements, avoidance of scientific divergences and eventually verification studies in collaboration and consultation with partners (e.g. JRC, Member States, EU Agencies and, if relevant, international partners and stakeholders).
- ii) A “roadmap for action” which provides for each scientific theme a full understanding on e.g. ongoing activities, knowledge gaps, societal interests and concerns as well as collaboration opportunities and potential partners. Each roadmap will provide for EFSA and its partners a basis for prioritisation and decision making for high-value (> 1 million euro), multi-annual (>2-5 years) studies or project calls (grants or procurements) to be launched under a scientific theme over a 6 years period.

In line with EFSA’s consideration on the future of science⁴ and EFSA’s 2027 strategic development⁵, EFSA prioritised four scientific themes for 2021, and roadmaps for action are required for three themes in the frame of this procurement:

- (1) building a European partnership for next generation, systems-based environmental risk assessment
- (2) new approach methodologies (NAMs) in risk assessment, and
- (3) risk assessment of combined exposure to multiple chemicals.

The technical offers submitted in response to this call for tenders shall take the directions provided in the relevant theme papers into account (**Annexes 3-5**).

⁴ Refer to <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.e170622>

⁵ Refer to <https://www.efsa.europa.eu/sites/default/files/event/mb-82/mb191218-7-p.pdf>



This call is based on EFSA's 2021-2023 draft Work Programme for grants and operational procurements as presented in Annex IX of the draft Programming Document 2021 – 2023, available on the EFSA's website⁶.

1.2 OBJECTIVES AND DIVISION IN LOTS

The aim of this procurement procedure is to conclude on three direct contracts for the execution of specific tasks over a clearly defined period, as defined in these tender specifications.

The overall purpose of the contracts resulting from this call for tenders is to deliver roadmaps for action which provide recommendations for future multi-annual, multi-partner studies or projects for each lot (see below) building on EFSA's vision (Annexes 3-5), and supporting EFSA's preparedness for future risk assessment requirements and prevent possible divergence on sensitive matters.

Each roadmap for action must:

- map ongoing and planned developments in the respective regulatory and scientific area, identify and prioritise working areas;
- identify data gaps, potential research overlaps, challenges and technical/non-technical barriers;
- identify and rank opportunities for collaboration with potential partners in the respective scientific area;
- identify opportunities for communication in the respective scientific area;
- be substantiated by data acquired through desk-work, in dialogue with relevant stakeholders, and based on market analysis.

This tender is divided into three lots, these being:

- **Lot 1** – Development of a roadmap for action on building a European partnership for next generation, systems-based environmental risk assessment
- **Lot 2** – Development of a roadmap for action on new approach methodologies in risk assessment
- **Lot 3** – Development of a roadmap for action on risk assessment of combined exposure to multiple chemicals

As a tenderer, you may submit an offer for one or more lots but the offer should indicate clearly for which lot you are applying. In case you decide to apply for several lots, a separate technical and financial offer for each lot must be provided. Each tender must cover all specific objectives and tasks of the lot to which it refers.

⁶ Refer to https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/amp2123.pdf



OBJECTIVES FOR LOT 1

- **Development of roadmap for action on building a European partnership for next generation, systems-based environmental risk assessment**

The **main objective** of the roadmap for action for this lot is to identify and connect relevant partners⁷ from various sectors, across regulatory silos, and build a platform (partnership) where cooperation and harmonisation of methodologies will take place to facilitate the transition to next generation, systems-based regulatory environmental risk assessment (ERA) by 2030. The following objectives should be read alongside the theme paper 'Building a European partnership for next generation, systems-based environmental risk assessment (PERA)' (**Annex 3**).

The **specific objectives** for lot 1 are:

Objective 1: Refining the problem formulation proposed in the offer

- Provide a refined problem formulation to address the objectives of the theme paper (Annex 3) aiming to:
 - build PERA by 2022;
 - transition successfully to next generation, systems-based ERA by 2030.
- Provide a refined workplan (milestones, timelines, etc.) describing and potentially refining the methodology proposed in the offer and that will be used to achieve all subsequent objectives (2-7).

Objective 2: Mapping relevant activities and organisations for PERA and next generation, systems-based ERA

- Map all relevant ongoing and planned activities related to ERA that are of relevance to PERA and next generation, systems-based ERA (including research projects and innovation programmes, associated timelines, and organisations responsible for/involved in these projects/programmes) at national level, European level and international level. Identify potential overlaps with research and innovation programmes of regulatory relevance. As a minimum, the mapping should include the EC, EU Member States' national bodies, relevant EU Agencies (e.g. ECDC, ECHA, EEA, EMA, etc.) and relevant EU institutions and their work programmes (e.g. the JRC and Horizon 2020 and Horizon Europe, in particular PARC⁸ and the Partnership on Biodiversity), international organisations (e.g. U.S. FDA, U.S. EPA, OECD and those listed in the theme

⁷ Partners as defined in the theme paper Building a European Partnership for next generation, systems-based Environmental Risk Assessment, are e.g. European national competent authorities/agencies, EU Member States, EU Agencies, Commission Services, policy makers, risk managers, risk assessors, scientific community, with expertise in environmental risk assessment of regulated products in the EU and civil society.

⁸ Draft proposal for a European Partnership under Horizon Europe, Partnership for the Assessment of Risk from Chemicals (PARC). Refer to:
https://ec.europa.eu/info/sites/info/files/research_and_innovation/funding/documents/ec_rtd_he-partnerships-chemical-risk-assessment.pdf



- paper), and potential relevant projects being conducted in academic institutions;
- ii) Based on objective 2.i (above), list all relevant organisations that could serve as potential partners of PERA along with the knowledge, expertise, data, tools and methodologies they would bring either to PERA or for the transition to next generation, systems-based ERA, or both;
 - iii) Based on objective 2.ii (above), identify the needs of the potential partners of PERA in the field of regulatory ERA and for the development and implementation of systems-based approaches for next generation ERA, as well as the needs of PERA customers;
 - iv) Assess differences, commonalities and complementarities of any existing ERA partnerships of relevance to PERA and next generation, systems-based ERA identified above, with PERA;
 - v) Assess the relevance of existing systems-based approaches for ERA identified above, and their adequacy/suitability for next generation, systems-based ERA;
 - vi) Assess the strengths and weaknesses of IT platforms that can support PERA identified above.

Objective 3: Identifying areas requiring further development (e.g. requiring further scientific development and/or implementation of specific policies)

- i) Identify relevant working areas additional to what is included in the theme paper necessary to establish a systems-based approach for next generation ERA. Provide a clear justification on their relevance by taking the directions/opportunities into account as outlined in the theme paper (Annex 3);
- ii) Identify any further development that is needed in the working areas identified in the theme paper (i.e. scientific development and/or implementation of specific policies);
- iii) Identify directly relevant discontinuities and knowledge gaps with a clear justification on their relevance to reach the desired vision by 2030 and impact for EFSA;
- iv) Perform an analysis of the relevance and added value of the working areas that are listed in the theme paper as well as those additional ones that have been identified (see objective 3i, above) to achieve EFSA's vision as defined in the theme paper (Annex 3);
- v) Identify processes/methodologies and any other consideration of conducting ERA that can be improved within the frame of regulated products under different EU legislations and/or can benefit from sharing/accessing data, tools and methodologies;
- vi) Identify potential synergies that can add value to ERA methodologies in EU frameworks. These could include, for example, the possibility of combining predictive models and monitoring data in an integrated systems-based approach;



- vii) Explore opportunities for the use of artificial intelligence (AI)⁹ approaches in the area of ERA, including data extraction and integration of information from different sources. The tenderer needs to be available to be interviewed by a contractor (still to be identified through a separate call for tenders) preparing the roadmap for action on artificial intelligence in evidence management in risk assessment.

Objective 4: Identifying challenges and blockers

- i) Identify potential challenges and blockers to build PERA and for the transition to next generation, systems-based ERA based on the outcome of Objective 2 and 3;
- ii) Assess the impact of challenges and blockers (see objective 4.i, above) for EFSA's vision as defined in the theme paper (Annex 3) and potential partners;
- iii) Explore feasible alternatives to overcome challenges and blockers (see objective 4.i, above).
- iv) Explore if the outcome of objectives 2, 3 and 4 result in a revised problem formulation for the implementation of PERA and transition to next generation systems-based ERA, previously defined under objective 1, and provide recommendations for integrating the identified gaps (e.g. work areas).

Objective 5: Assessing cooperation/collaboration opportunities

- i) Identify opportunities for pertinent cooperation/collaboration with potential partners outlined in the theme paper and any additional potential partner(s) identified;
- ii) Perform an analysis of the added value and benefits of pertinent cooperation/collaboration opportunities (see objective 5.i, above), as well as possible challenges of the identified potential partnership(s).

Objective 6: Prioritising working areas and possible partners

- i) Prioritise/rank working areas based on new EU policy targets (in terms of the Green Deal and associated strategies and action plans), and development needs and opportunities identified in previous objectives;
- ii) Prioritise/rank key opportunities, and possible partners based on the outcomes of objective 5.i, above. Also consider the [Article 36 list of competent organisations](#)¹⁰ designated by EU Member States to assist EFSA with tasks within the field of its mission;

⁹ Artificial Intelligence has been defined by the European Commission as "Artificial Intelligence refers to systems that display intelligent behaviour by analysing their environment and taking action — with some degree of autonomy — to achieve specific goals. We are using AI on a daily basis, for example to block email spam or speak with digital assistants. Growth in computing power, availability of data and progress in algorithms have turned AI into one of the most important technologies of the 21st century." Refer to https://ec.europa.eu/knowledge4policy/publication/coordinated-plan-artificial-intelligence-com2018-795-final_en#:~:text=Delivering%20on%20its%20strategy%20on,use%20of%20AI%20in%20Europe

¹⁰ Refer to <https://efsa.force.com/competentorganisations/s/>



- iii) Based on the information collected and assessed under the other objectives, provide a list of possible actions to be implemented by EFSA and at least five high level recommendations for multi-annual, multi-partner studies or projects, each supported by a SWOT or equivalent analysis.

Objective 7: Identifying communication opportunities

- i) Identify opportunities for communication in the area of systems-based ERA at European level, relying on social research methods and tools that provide societal insights (incl. awareness, understanding, risk perceptions, expectations, sentiment analysis). Such insights should be generated to inform any future communication and engagement efforts in this area of work.

OBJECTIVES FOR LOT 2

- **Development of roadmap for action on new approach methodologies in risk assessment**

The **main objective** of the roadmap for action for this lot is to define EFSA priorities regarding the incorporation of new approach methodologies (NAMs) in regulatory hazard assessments and risk characterisations of chemicals in food and feed, and to define a multiannual strategy for increasing the use of NAMs in EFSA human health risk assessment to minimise the need for animal-based verification studies, so that by 2027 the large majority of EFSA requests for additional data are based on NAMs. The following objectives should be read alongside the theme paper on new approach methodologies in risk assessment (**Annex 4**).

The **specific objectives** for lot 2 are:

Objective 1: Refining the problem formulation proposed in the offer

- i) Provide a refined problem formulation to address the objectives of the theme paper (Annex 4) to be achieved focusing on:
 - a) understanding mechanistic-based risk characterisation of chemicals and evolution of the risk assessment paradigm to identify susceptible population groups;
 - b) identifying key issues for understanding and evaluating the outcome of NAM-based studies and their relevance for the risk assessment;
 - c) principles for 'validation and acceptance' in the regulatory science context of non-standardised studies with ad-hoc design.
- ii) Provide a refined workplan (milestones, timelines, etc) describing and potentially refining the methodology proposed in the offer and that will be used to achieve all subsequent objectives (2-7).



Objective 2: Mapping relevant activities and organisations for NAMs

- i) Map all relevant ongoing and planned NAMs activities (including research projects, and associated timelines) regarding the validation of NAMs and the incorporation of “valid methods” although not validated yet NAM-based results in regulatory risk assessments¹¹;
- ii) Map research and innovation programmes of regulatory relevance for NAMs activities (including timelines). As a minimum, the mapping should include the EC, EU Member States’ national bodies, relevant EU Agencies (e.g. ECHA, EEA, ECDC, EMA, etc) and relevant EU institutions and their work programmes (e.g. the JRC and Horizon 2020 and Horizon Europe, in particular PARC¹² under Horizon Europe), as well as in international organisations (e.g. OECD, FAO, WHO or U.S. FDA, U.S. EPA and Health Canada) including activities under APCRA and those by international scientific societies, and potential relevant projects being conducted in academic institutions. Examples of areas of interest are described in the theme paper (Annex 4) and include, among others, developments in OMICs approaches, organs on a chip, organoids, work on adverse outcome pathways;
- iii) For the relevant ongoing and planned NAMs activities (see objective 2.i, above) identify potential overlaps with research and innovation programmes of regulatory relevance (including timelines) of EU Member States’ national bodies, relevant EU Agencies (e.g. ECHA, EEA, ECDC, EMA, etc) and relevant EU institutions and their work programmes (e.g. the JRC and Horizon 2020 and Horizon Europe in particular PARC¹²).

Objective 3: Identifying areas requiring further scientific development

- i) Identify relevant working areas that are included in the theme paper or additional ones, necessary to implement the use of NAMs in human health risk assessment, to minimise the need for animal-based verification studies. Provide a clear justification on their relevance by taking the directions/opportunities into account as outlined in the relevant theme paper (Annex 4);
- ii) Identify any further development that is needed in the working areas identified in the theme paper (i.e., scientific development and/or implementation of specific policies);
- iii) Identify directly relevant discontinuities and knowledge gaps with a clear justification on their relevance to reach the desired vision by 2027 and impact for EFSA related to the use of NAMs for regulatory risk assessments, focusing on aspects related to the evolution towards a mechanistic paradigm using NAM-based studies for risk assessments relevant for human health;

¹¹ See glossary, in EFSA SC (2018) <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5327>

¹² Draft proposal for a European Partnership under Horizon Europe, Partnership for the Assessment of Risk from Chemicals (PARC). Refer to: https://ec.europa.eu/info/sites/info/files/research_and_innovation/funding/documents/ec_rtd_he-partnerships-chemical-risk-assessment.pdf



- iv) Perform an analysis of the relevance and added value of the working areas that are listed in the theme paper as well as those additional ones that have been identified (see objective 3i, above) to achieve EFSA's vision as defined in the theme paper (Annex 4);
- v) Explore opportunities for the use of artificial intelligence (AI)¹³ approaches in the area of NAMs including data extraction and integration of information from different sources. The tenderer needs to be available to be interviewed by a contractor (still to be identified through a separate call for tenders) preparing the roadmap for action on artificial intelligence in evidence management in the risk assessment.

Objective 4: Identifying challenges and blockers

- i) Identify potential challenges and blockers focusing on critical elements for the consideration as "valid methods" and the integrating non-standardised NAM-based studies in the regulatory context to perform improved risk assessments based on mechanistic understanding;
- ii) Assess the impact of challenges and blockers (see objective 4.i, above) for EFSA's vision as defined in the theme paper (Annex 4);
- iii) Explore feasible alternatives to overcome challenges and blockers (see objective 4.i, above).

Objective 5: Assessing cooperation/collaboration opportunities

- i) Identify opportunities and potential partners and evaluate means/tools (workshops, conferences, sharing databases etc) for pertinent cooperation/collaboration with potential partners outlined in the theme paper and any additional potential partner identified;
- ii) Perform an analysis of the added value and benefits of pertinent cooperation/collaboration opportunities (see objective 5.i, above), as well as possible challenges of the identified potential partnerships, and including any prioritisation considerations. Conduct a specific assessment of the OECD and ECVAM workplans for the next years and identify in those workplans the elements related to NAMs with specific interest for implementing EFSA's vision (as outlined in the theme paper, Annex 4). Present a SWOT or equivalent analysis for supporting the prioritisation of cooperation/collaboration opportunities by EFSA.

¹³ Artificial Intelligence has been defined by the European Commission as "Artificial Intelligence refers to systems that display intelligent behaviour by analysing their environment and taking action — with some degree of autonomy — to achieve specific goals. We are using AI on a daily basis, for example to block email spam or speak with digital assistants. Growth in computing power, availability of data and progress in algorithms have turned AI into one of the most important technologies of the 21st century."

Refer to https://ec.europa.eu/knowledge4policy/publication/coordinated-plan-artificial-intelligence-com2018-795-final_en#:~:text=Delivering%20on%20its%20strategy%20on,use%20of%20AI%20in%20Europe



Objective 6: Prioritising working areas and possible partners

- i) Prioritise/rank working areas based on the outcomes of objectives 1 and 3 above;
- ii) Prioritise/rank key opportunities for cooperation and possible partners based on the outcomes of objective 5 above. Consider also the [Article 36 list of competent organisations](#)¹⁴ dedicated by Member States to assist EFSA with tasks within the field of its mission;
- iii) Based on the information collected and assessed under the other objectives provide:
 - a) Explore if the outcome of objectives 2, 3 and 4 results in a revised problem formulation for the implementation of NAMs in EFSA risk assessments previously defined under objective 1, and provide recommendations for integrating the identified gaps (e.g. work areas);
 - b) a list of possible actions to be implemented by EFSA and at least five high level recommendations for multi-annual, multi-partner projects, each supported by a SWOT or equivalent analysis.

Objective 7: Identifying communication opportunities

- i) Identify opportunities for communication along the risk assessment process related to the use of NAMs and NAM-based mechanistic risks assessment outcomes, by using research methods and tools that provide societal insights (incl. awareness, understanding, risk perceptions, expectations, sentiment analysis). Such insights should be generated to inform any future communication and engagement efforts in this area of work;
- ii) The proposal should further specify how insights generated under point 7 i) can be used to inform:
 - a. a communication plan targeting risk managers and the public, highlighting the benefits/opportunities for addressing risk assessment data gaps using NAMs and for the incorporation of mechanistic understanding in the risk characterisation;
 - b. a communication plan targeting researchers developing NAMs to provide information and increase their interest in the validation of the NAM methods for regulatory use.

Examples of communication plans using such insights should be developed.

¹⁴ Refer to <https://efsa.force.com/competentorganisations/s/>



OBJECTIVES FOR LOT 3

- **Development of roadmap for action on the risk assessment of combined exposure to multiple chemicals (RACEMiC)**

The **main objective** of the roadmap for action for this lot is to develop and implement a harmonised approach for the assessment of human health risks resulting from both dietary and non-dietary exposure to multiple chemicals. The following objectives should be read alongside the theme paper on the risk assessment of combined exposure to multiple chemicals (RACEMiC) (**Annex 5**).

The **specific objectives** for lot 3 are:

Objective 1: Refining the problem formulation proposed in the offer

- Provide a refined problem formulation for the routine implementation of human health risk assessment of combined dietary and non-dietary exposure to multiple chemicals across EFSA's domains of activity. This includes a refinement of the scope and objectives described in the theme paper (Annex 5) focusing on:
 - methods development, tools harmonisation, data consolidation and implementation;
 - a stepwise implementation, starting with the routine risk assessment of dietary exposure to multiple pesticides, the subsequent integration of non-dietary exposure to pesticides, and ultimately the extension to other chemicals;
- Provide a refined workplan (milestones, timelines, etc) describing and potentially refining the methodology proposed in the offer and that will be used to achieve all subsequent objectives (2-7).

Objective 2: Mapping relevant activities and organisations for combined exposure to multiple chemicals

- Map all relevant ongoing and planned activities related to the human health risk assessment of combined exposure to multiple chemicals (including research projects and innovation programmes of regulatory relevance for human health risk assessment, associated timelines and the organisations responsible for/involved in these projects/programmes), at national level, European level and international level. As a minimum, the mapping should include the EC, EU Member States' national bodies, relevant EU Agencies (e.g. ECHA, EEA, EMA, etc) and relevant EU institutions and their work programmes (e.g. the JRC and Horizon 2020 and Horizon Europe, in particular PARC¹⁵), as well as in international organisations (e.g. U.S. FDA, U.S. EPA, OECD and those listed in

¹⁵ Draft proposal for a European Partnership under Horizon Europe, Partnership for the Assessment of Risk from Chemicals (PARC). Refer to: https://ec.europa.eu/info/sites/info/files/research_and_innovation/funding/documents/ec_rtd_he-partnerships-chemical-risk-assessment.pdf



the theme paper) and potential relevant projects being conducted in academic institutions;

- ii) Identify potential overlaps with research and innovation programmes of regulatory relevance (including timelines) of EU Member States' national bodies, relevant EU Agencies (e.g. ECHA, EEA, EMA, etc) and relevant EU institutions and their work programmes (e.g. the JRC and Horizon 2020 and Horizon Europe in particular PARC¹⁵).

Objective 3: Identifying areas requiring further scientific development

- i) Identify relevant working areas additional to what is included in the theme paper necessary to implement combined exposure to multiple chemicals in human health risk. Provide a clear justification on their relevance by taking the directions/opportunities into account as outlined in the relevant theme paper (Annex 5);
- ii) Identify any further development that is needed in the working areas identified in the theme paper (i.e., scientific development and/or implementation of specific policies);
- iii) Identify directly relevant discontinuities and knowledge gaps with a clear justification on their relevance to reach the desired vision by 2030 and impact for EFSA;
- iv) Perform an analysis of the relevance and added value of the working areas that are listed in the theme paper as well and those additional ones that have been identified (see objective 3i, above) to achieve EFSA's vision as defined in the theme paper (Annex 5);
- v) Explore opportunities for the use of Artificial Intelligence (AI)¹⁶ approaches for combined exposure to multiple chemicals in human health risk assessment including data extraction and integration of information from different sources. The tenderer needs to be available to be interviewed by a contractor (still to be identified through a separate call for tenders) preparing the roadmap for action on artificial intelligence in evidence management in risk assessment.

Objective 4: Identifying challenges and blockers

- i) Identify potential challenges and blockers for the implementation of human health risk assessment of combined exposure to multiple chemicals based on the outcome of objective 2 and 3;

¹⁶ Artificial Intelligence has been defined by the European Commission as "Artificial Intelligence refers to systems that display intelligent behaviour by analysing their environment and taking action — with some degree of autonomy — to achieve specific goals. We are using AI on a daily basis, for example to block email spam or speak with digital assistants. Growth in computing power, availability of data and progress in algorithms have turned AI into one of the most important technologies of the 21st century." Refer to: https://ec.europa.eu/knowledge4policy/publication/coordinated-plan-artificial-intelligence-com2018-795-final_en#:~:text=Delivering%20on%20its%20strategy%20on,use%20of%20AI%20in%20Europe



- ii) Assess the impact of challenges and blockers (see objective 4.i, above) for EFSA's vision as defined in the theme paper (Annex 5);
- iii) Explore feasible alternatives to overcome challenges and blockers (see objective 4.i, above).
- iv) Explore if the outcome of objective 2, 3 and 4 result in a revised problem formulation for the implementation of human health risk assessment of combined exposure to multiple chemicals in EFSA assessments previously defined under objective 1, and provide recommendations for integrating the identified gaps (e.g. work areas).

Objective 5: Assessing cooperation/collaboration opportunities

- i) Identify opportunities and potential partners (incl. possible consortia), and evaluate means/tools (workshops, conferences, sharing databases etc) for pertinent cooperation/collaboration with potential partners outlined in the theme paper and any additional potential partner identified;
- ii) Perform an analysis of the added value and benefits of pertinent cooperation/collaboration opportunities (see objective 5.i, above), as well as possible challenges of the identified potential partnerships.

Objective 6: Prioritising working areas and possible partners

- i) Prioritise/rank working areas based on the outcomes of objectives 1 to 4 above;
- ii) Prioritise/rank key opportunities and possible partners based on the outcomes of objective 5 above; Consider also the [Article 36 list of competent organisations](#)¹⁷ dedicated by Member States to assist EFSA with tasks within the field of its mission;
- iii) Based on the information collected and assessed under the other objectives provide a list of possible actions to be implemented by EFSA and at least five high level recommendations for multi-annual, multi-partner studies or projects, each supported by a SWOT or equivalent analysis.

Objective 7: Identifying communication opportunities

- i) Identify opportunities for communication along in the area of risk assessment process related to combined exposure to multiple chemicals in human health risk assessment, relying on social research methods and tools that provide societal insights (incl. awareness, understanding, risk perceptions, expectations sentiment analysis). Such insights should be generated to inform any future communication and engagement efforts in this area of work.

¹⁷ Refer to <https://efsa.force.com/competentorganisations/s/>



1.3 TASKS, DELIVERABLES, TIMELINE AND PAYMENTS

TASKS AND DELIVERABLES FOR LOT 1

- **Development of a roadmap for action on building a European partnership for next generation, systems-based environmental risk assessment**

No.	Tasks & deliverables	Can be subcontracted? ¹⁸	Deadline
1	<p>Task: Prepare an inception report that covers:</p> <ul style="list-style-type: none"> a) A refined problem formulation as described above in Section 1.2 (lot 1) under Objective 1. b) The refined workplan and refined methodology proposed in the offer with a detailed description of the tasks, methods and tools to be used for achieving all objectives (2-7), including the description of all information sources and approaches followed for data collection and integration. c) The refined methodology on how to identify and select the profiles of scientific/regulatory experts and other experts and/or relevant institutions, as needed, to be interviewed in order to provide direction and information for the development of the roadmap. This should also include the proposed content of the interview questions/survey. <p>The contractor will receive the following documents below at the kick-off meeting. The contractor shall consider these documents when addressing all objectives:</p> <ul style="list-style-type: none"> - comments from international bodies/organisations and stakeholders on the theme paper (Annex 3) received during the last phase of the consultation process. - EFSA 2021-2027 draft strategy. <p>Deliverable:</p> <ul style="list-style-type: none"> 1. Inception report (max. 20 pages, excluding annexes). The inception 	Yes	Within 1 month from kick-off meeting

¹⁸ If a subcontractor provides the whole or a very large part of the financial capacity OR executes the whole or a very large part of the tasks, EFSA may demand the subcontractor to sign the contract.



	<p>report shall be submitted in English in both MS-Word and Adobe Acrobat (PDF) format with the charts in MS-Excel.</p> <p>A revised version of the deliverable reflecting agreed changes at the first interim meeting will be submitted at the latest 15 days after the interim meeting #1.</p>		
2	<p>Task: Prepare a report (interim report #1) containing: Findings/results of Objective 2 as well as data sources, as described above in Section 1.2 (lot 1).</p> <p>Deliverable: 1. Interim report #1 describing execution and results of objective 2 and plan for next steps.</p> <p>The report shall be submitted in English in both MS-Word and Adobe Acrobat (PDF) format with the charts in MS-Excel.</p> <p>A revised version of the deliverable reflecting agreed changes at the interim meeting #2 will be submitted at the latest 15 days after the interim meeting #2.</p>	Yes	Within 2.5 months from kick-off meeting
3	<p>Task: Prepare a report (interim report #2) containing:</p> <ul style="list-style-type: none"> a) a revised version of the findings/results of Objective 2 updated according to the comments provided by EFSA and agreements reached during interim meeting #2. b) the findings/results for Objectives 3 and 4, as described above in Section 1.2 (lot 1), integrated with the revised version of the findings/results for Objective 2. This should include a justified proposal for a revised problem-formulation. <p>Deliverable: 1. Interim report #2 describing points a) and b) and the plan for next steps.</p> <p>The report shall be submitted in English in both MS-Word and Adobe Acrobat (PDF) format with the charts in MS-Excel.</p> <p>A revised version of the deliverable reflecting agreed changes at the interim meeting #3</p>	Yes	Within 4 months from kick-off meeting



	will be submitted at the latest 15 days after the interim meeting #3.		
4	<p>Task: 1) Prepare a report (Interim report #3) containing:</p> <ul style="list-style-type: none"> a) a revised version of the findings/results for Objectives 2, 3 and 4, updated according to the comments provided by EFSA and agreements reached during interim meetings #3 b) the findings/results for Objectives 5 and 6, as described above in Section 1.2 (lot 1) with a justified proposal for prioritisation of work areas and activities and possible partners as described in Objective 6 of Section 1.2 (lot 1). c) The recommendations for at least 5 multi-annual, multi-partner studies or projects (Objective 6) should include at least the following sections: scope, objectives, challenges, and expected impact as well as a proposed timescale for the implementation of the studies or projects. <p>Deliverable: 1. Interim report #3 describing points a) to c) as mentioned above and the plan for next steps.</p> <p>The report shall be submitted in English in both MS Word and Adobe Acrobat (PDF) format with the charts in MS-Excel.</p> <p>A revised version of the deliverable reflecting the changes agreed at the interim meeting #4 will be submitted at the latest 15 days after the interim meeting #4.</p>	Yes	Within 5 months from kick-off meeting
5	<p>Task: Prepare a complete draft roadmap report containing:</p> <ul style="list-style-type: none"> a) the revised version of the findings/results for Objectives 1, 5 and 6 updated according to the comments provided by EFSA and agreements reached during interim meeting #4 integrated with the revised version of the findings/results for Objectives 2, 3 and 4. b) the findings/results of Objective 7 as described above in Section 1.2 (lot 1). 		Within 6 months from kick-off meeting



	<p>c) an overview of the literature data consulted to date, and a summary of the outcome and conclusions from interviews and surveys conducted.</p> <p>2) Prepare a draft set of presentation slides (approximately 20) summarising the methodology, main components and recommendations for actions/studies/projects of the roadmap for action.</p> <p>Deliverable:</p> <ol style="list-style-type: none"> 1. Draft roadmap report (max. 90 pages, excluding annexes) describing execution and results of all objectives (1 to 7), drafted based on a template provided by EFSA (external report) and contain the compiled results/findings described in the inception report and in the interim reports #1, #2 and #3 and updated according to the agreements in interim meetings 2. Draft presentation of approximately 20 slides. <p>The draft roadmap shall be submitted in English in both MS-Word and Adobe Acrobat (PDF) format with the charts in MS-Excel.</p> <p>The presentation shall be submitted in English in both MS-PowerPoint and Adobe Acrobat (PDF) format.</p> <p>A revised version of the deliverables reflecting the changes agreed at the interim meeting #5 will be submitted at the latest 15 days after the interim meeting #5.</p>		
6	<p>Task: Prepare a final roadmap report updated according to the comments provided by EFSA and agreements reached during interim meeting #5, including an executive summary.</p> <p>The final roadmap shall report on all the completed tasks as defined in Section 1.2 (lot 1) and should have the same structure as the draft roadmap and address all objectives.</p> <p>Deliverable:</p>	Yes	Within 7 months from kick-off meeting



	<p>The final roadmap report (max. 90 pages, excluding annexes) shall include the executive summary (max 2 pages) drafted based on a template provided by EFSA (external report).</p> <p>The roadmap shall be submitted in English in both MS-Word and Adobe Acrobat (PDF) format with the charts in MS-Excel.</p>		
7	<p>Task: Prepare a final set of presentation slides summarising the methodology, and main components of the roadmap for actions updated according to the comments provided by EFSA and agreements reached during interim meeting #5 (final meeting).</p> <p>Deliverable:</p> <ol style="list-style-type: none">1. A presentation of approximately 20 slides2. A recorded presentation. <p>The presentation shall be submitted in English in both MS-PowerPoint and Adobe Acrobat (PDF) format.</p>	Yes	Within 7 months from kick-off meeting
No.	Meetings	Deadline for finalisation	
<p>The contractor is responsible for organising the meetings and taking minutes using the appropriate EFSA template of every meeting held with EFSA and for <u>sending them to EFSA within 5 working days after the meeting, for revision and agreement</u>. The minutes must be approved by EFSA to be considered as agreed.</p> <p>All meetings are to be attended by at least the project manager and the expert/s responsible for the specific task/s under discussion, including sub-contractors, if applicable.</p> <p>In addition to the meetings below, the contractor will be asked to include in its work plan indicatively a 2 hour meeting every second week throughout the entire duration of the contract to discuss on the progress of the tasks/deliverables; any issues or risks should be highlighted during these meetings.</p> <ol style="list-style-type: none">a. A 2 hour meeting every second week to discuss the progress of the upcoming deliverables, when no other interim meetings are scheduled within two weeks, for a 'checkpoint with EFSA' throughout the entire duration of the contract.b. 2-3 meetings (approximately 2 hours each) to be interviewed by a contractor that will be identified by EFSA following a separate call for tenders and tasked to develop a roadmap for action on artificial intelligence (AI) for evidence management in risk assessment. The aim of the interviews is to explore and align the AI needs stemming from this specific roadmap with the roadmap development on AI. The name of the contractor that will work on the AI roadmap will be made available at the kick-off meeting.			



1	<p>Kick-off meeting: via teleconference – one day¹⁹</p> <p>The purpose of the kick-off meeting is to:</p> <ul style="list-style-type: none"> - verify the contractor's understanding of the terms of reference; - provide clarification on the additional supporting material provided; - discuss the proposed approach and methodology to carry out the services requested by EFSA (incl. the fine-tuning of the methodology, timelines and structure of the various deliverables) that will be documented in the inception report and in the roadmap; - to have a joined discussion with the contractor developing the roadmap on artificial intelligence (AI) on methods and timelines foreseen for the development of the AI roadmap, and how best to cooperate with each other to capture potential opportunities for the use of AI on building a European partnership for next generation, systems-based environmental risk assessment. <p>During this meeting, in addition to operational implementation, the administrative and financial matters related to contract implementation will be discussed.</p>	Within 2 weeks after entry into force of contract
2	<p>Interim meeting #1: via teleconference – half day</p> <p>The purpose of the meeting is to discuss/review the inception report.</p>	Within 1.5 months from kick-off meeting
3	<p>Interim meeting #2: via teleconference - half day</p> <p>The purpose of the meeting is to discuss/review the interim roadmap report #1</p>	Within 3 months from kick-off meeting
4	<p>Interim meeting #3: via teleconference - half day</p> <p>The purpose of the meeting is to discuss/review the interim roadmap report #2</p>	Within 4.5 months from kick-off meeting
5	<p>Interim meeting #4: via teleconference - half day</p> <p>The purpose of the meeting is to discuss/review the draft roadmap report #3</p>	Within 5.5 months from kick off meeting
6	<p>Interim meeting #5: via teleconference – half day</p> <p>The purpose of the meeting is to discuss/review the full draft roadmap report.</p>	Within 6.5 months from kick off meeting
7	<p>Final meeting: via teleconference– half day</p> <p>The purpose of the final meeting is to present and discuss the final roadmap as well as the presentation slides.</p>	Within 8 months from kick off meeting

¹⁹ One day = 8 hours, half day = 4 hours



No.	Payments	Linked to EFSA approval of deliverable No.
1	Interim payment 1 of 40%	3 – Interim report no.2 due 4 months from kick-off meeting
2	Payment of the balance of 100% - 40% of the interim payment	All other deliverables

No.	Summary of deliverables and timeline	Deadline for finalisation
1.	Kick off meeting	Within 2 week after entry into force of contract
2.	Inception report	Within 1 month from kick-off meeting
3.	Interim meeting 1	Within 1.5 months from kick-off meeting
4.	Interim report #1	Within 2.5 months from kick-off meeting
5.	Interim meeting 2	Within 3 months from kick-off meeting
6.	Interim report #2	Within 4 months from kick-off meeting
7.	Interim meeting 3	Within 4.5 months from kick-off meeting
8.	Interim report #3	Within 5 months from kick-off meeting
9.	Interim meeting 4	Within 5.5 months from kick-off meeting
10.	Draft complete roadmap report	Within 6 months from kick-off meeting
11.	Interim meeting 5	Within 6.5 months from kick-off meeting
12.	Final complete report - including executive summary, presentation slides	Within 7 months from kick-off meeting
13.	Final meeting	Within 8 months from kick-off meeting



TASKS AND DELIVERABLES FOR LOT 2

- **Development of a roadmap for action on new approach methodologies in risk assessment**

No.	Tasks & deliverables	Can be subcontracted? ²⁰	Deadline
1	<p>Task: Prepare an inception report that covers:</p> <ul style="list-style-type: none"> a) A refined problem formulation as described above in Section 1.2 (lot 2) under Objective 1. b) The refined workplan and refined methodology proposed in the offer with a detailed description of the tasks, methods and tools to be used for achieving all objectives (2-7), including the description of all information sources and the approaches followed for the data collection and integration. <p>The contractor will receive the following documents below at the kick-off meeting. The contractor shall consider these documents when addressing objectives 1-7:</p> <ul style="list-style-type: none"> c) comments from international bodies/organisations and stakeholders on the theme paper (Annex 4) received during the last phase of the consultation process. d) EFSA 2021-2027 draft strategy. <p>Deliverable: Inception report (max. 20 pages, excluding annexes). The inception report shall be submitted in English in both MS-Word and Adobe Acrobat (PDF) format with the charts in MS-Excel.</p> <p>A revised version of the deliverable reflecting the changes agreed at the first interim meeting will be submitted at the latest 15 days after the interim meeting #1.</p>	Yes	Within 1 month from kick-off meeting
2	<p>Task: Prepare a report (interim report #1) containing:</p> <p>the findings/results for objectives 2, and 4, as described above in Section 1.2 (lot 2).</p>	Yes	Within 2.5 months from kick-off meeting

²⁰ If a subcontractor provides the whole or a very large part of the financial capacity OR executes the whole or a very large part of the tasks, EFSA may demand the subcontractor to sign the contract.



	<p>Deliverable: Interim report #1 describing execution and results of objectives 2, and 4, and plan for next steps.</p> <p>The report shall be submitted in English in both MS-Word and Adobe Acrobat (PDF) format with the charts in MS-Excel.</p> <p>A revised version of the deliverable reflecting the changes agreed at the interim meeting #2 will be submitted at the latest 15 days after the interim meeting #2.</p>		
3	<p>Task: Prepare a report (Interim report #2) containing:</p> <p>a) the revised version of the findings/results for objectives 2, and 4, updated according to the comments provided by EFSA and the agreements reached during interim meeting #2</p> <p>b) the findings/results for objectives 3 and 5 as described above in Section 1.2 (lot 2), integrated with the revised version of the findings/results for objectives 2, and 4.</p> <p>Deliverable: Interim report #2 describing points a) and b) as mentioned above and the plan for next steps.</p> <p>The report shall be submitted in English in both MS-Word and Adobe Acrobat (PDF) format with the charts in MS-Excel.</p> <p>A revised version of the deliverable reflecting the changes agreed at the interim meeting #3 will be submitted at the latest 15 days after the interim meeting #3.</p>	Yes	Within 4 months from kick-off meeting
4	<p>Task: Prepare a report (Interim report #3) containing:</p> <p>a) a revised version of the findings/results for objectives 2, 3, 4 and 5 updated according to the comments provided by EFSA and the agreements reached during interim meeting #3.</p> <p>b) The findings/results for objective 6 as described above in Section 1.2 (lot 2) with a justified proposal for prioritisation of NAM work areas and activities and possible partners.</p> <p>c) a list of possible actions to be implemented by EFSA and at least five high level recommendations for multi annual, multi partner studies or projects for the implementation of NAMs according to</p>	Yes	Within 5 months from kick-off meeting



	<p>Objective 6, as described above in Section 1.2 (lot 2). These recommendations should include at least the following sections: scope, objectives, challenges, and expected impact as well as a proposed timescale for the implementation of the studies or projects.</p> <p>d) a justified proposal for a revised problem formulation previously defined on the implementation of NAMs in EFSA risk assessments (see Objective 1, lot 2), having taken into account the results/findings for objectives 1-4, as needed.</p> <p>Deliverable: Interim report #3 describing points a) to d) as mentioned above and the plan for next steps. The report shall be submitted in English in both MS-Word and Adobe Acrobat (PDF) format with the charts in MS-Excel. A revised version of the deliverable reflecting the changes agreed at the interim meeting #4 will be submitted at the latest 15 days after the interim meeting #4.</p>		
5	<p>Task:</p> <p>1) Prepare a complete draft roadmap report containing:</p> <ul style="list-style-type: none"> a) The revised version of the findings/results for objectives 1 and 6 updated according to the comments provided by EFSA and agreements reached during interim meeting #4, integrated with the revised version of the findings/results for objectives 2 to 5. b) draft communication plans on the use of NAMs in regulatory assessments for risk managers, the public and researchers as described under Objective 7 as described above in Section 1.2 (lot 2). c) an overview of the literature data consulted to date, and a summary of the outcome and conclusions from information searches and surveys conducted. <p>2) Prepare a draft set of presentation slides (approximately 20) summarizing the methodology, main components and recommendations for actions/studies/projects of the roadmap for action</p> <p>Deliverable:</p>	Yes	Within 6 months from kick-off meeting



	<p>1. Draft roadmap report describing execution and results of all objectives (1 to 7), drafted based on a template provided by EFSA (external report), containing the complied results/findings described in the inception report and in the interim reports #1 #2 and #3 and updated according to the agreements in the interim meetings.</p> <p>The draft roadmap shall be submitted in English in both MS-Word and Adobe Acrobat (PDF) format with the charts in MS-Excel</p> <p>2. Draft presentation of approximately 20 slides.</p> <p>The presentation shall be submitted in English in both MS-PowerPoint and Adobe Acrobat (PDF) format.</p> <p>A revised version of the deliverables reflecting the changes agreed at the interim meeting #5 will be submitted at the latest 15 days after the interim meeting #5.</p>		
6	<p>Task: Prepare a final roadmap, including an executive summary</p> <p>The final roadmap shall report on all the completed tasks as defined in Section 1.2 (lot 2) and should have the same structure as the draft roadmap. It shall take on board the EFSA comments and remarks made on the draft roadmap.</p> <p>Deliverable: The final roadmap report (max. 90 pages, excluding annexes) revised according to EFSA comments, and shall include the executive summary (max 2 pages). The roadmap shall be submitted in English in both MS-Word and Adobe Acrobat (PDF) format with the charts in MS-Excel</p>	Yes	Within 7 months from kick-off meeting
7	<p>Task: Prepare a final set of presentation slides summarizing the methodology, and main components of the roadmap for actions updated according to the comments provided by EFSA and agreements reached during interim meeting #5</p> <p>Deliverable:</p> <ol style="list-style-type: none"> 1. A presentation of approximately 20 slides 2. A recorded presentation <p>The presentation shall be submitted in English in both MS-PowerPoint and Adobe Acrobat (PDF) format.</p>	Yes	Within 7 months from kick-off meeting



No.	Meetings	Deadline for finalisation
	<p>The contractor is responsible for organising the meetings and taking minutes using the appropriate EFSA template of every meeting held with EFSA and for <u>sending them to EFSA within 5 working days after the meeting, for revision and agreement</u>. The minutes must be approved by EFSA to be considered as agreed.</p> <p>All meetings are to be attended by at least the project manager and the expert/s responsible for the specific task/s under discussion, including sub-contractors, if applicable.</p> <p>In addition to the meetings below, the contractor will be asked to include in its work plan indicatively:</p> <ol style="list-style-type: none"> A 2-hour meeting every second week to discuss the progress of the upcoming deliverables, when no other interim meetings are scheduled within two weeks, for a 'checkpoint with EFSA' throughout the entire duration of the contract. 2-3 meetings (approximately 2 hours each) to be interviewed by a contractor that will be identified by EFSA following a separate call for tenders and tasked to develop a roadmap for action on artificial intelligence (AI) for evidence management in risk assessment. The aim of the interviews is to explore and align the AI needs stemming from this specific roadmap with the roadmap development on AI. The name of the contractor that will work on the AI roadmap will be made available at the kick-off meeting. 	
1	<p>Kick-off meeting: via teleconference – one day²¹</p> <p>The purpose of the kick-off meeting is to:</p> <ul style="list-style-type: none"> - verify the contractor's understanding of the terms of reference; - provide clarification on the additional supporting material provided; - discuss the proposed approach and methodology to carry out the services requested by EFSA (incl. the fine-tuning of the methodology, timelines and structure of the various deliverables) that will be documented in the inception report and in the roadmap; - to have a joined discussion with the contractor developing the roadmap on artificial intelligence on methods and timelines foreseen for the development of the AI roadmap, and how best to cooperate with each other to capture potential opportunities and regulatory needs for the use of AI in NAMs. <p>During this meeting, in addition to operational implementation, the administrative and financial matters related to contract implementation will be discussed.</p>	Within 2 weeks after entry into force of contract
2	<p>Interim meeting #1: via teleconference – half day</p> <p>The purpose of the meeting is to discuss/review the inception report.</p>	Within 1.5 months from kick-off meeting
3	<p>Interim meeting #2: via teleconference – half day</p> <p>The purpose of the meeting is to discuss/review the interim report #1</p>	Within 3 months from kick-off meeting

²¹ One day = 8 hours, half day = 4 hours



4	Interim meeting #3: via teleconference – half day The purpose of the meeting is to discuss/review the interim report #2.	Within 4.5 months from kick-off meeting
5	Interim meeting #4: via teleconference – half day The purpose of the meeting is to discuss/review the interim report #3.	Within 5.5 months from kick off meeting
6	Interim meeting #5: via teleconference – half day The purpose of the meeting is to discuss/review the full draft roadmap report.	Within 6.5 months from kick off meeting
7	Final meeting: via teleconference – half day The purpose of the final meeting is to present and discuss the final roadmap as well as the presentation slides and communication material.	Within 8 months from kick off meeting
No.	Payments	Linked to EFSA approval of deliverable No.
1	Interim payment 1 of 40 %	3 – Interim report no.2 due 4 months from kick-off meeting
2	Payment of the balance of 100% - 40% of the interim payment	All other deliverables

No.	Summary of deliverables and timeline	Deadline for finalisation
1.	Kick off meeting	Within 2 weeks after entry into force of contract
2.	Inception report	Within 1 month from kick-off meeting
3.	Interim meeting 1	Within 1.5 months from kick-off meeting
4.	Interim report #1	Within 2.5 months from kick-off meeting
5.	Interim meeting 2	Within 3 months from kick-off meeting
6.	Interim report #2	Within 4 months from kick-off meeting
7.	Interim meeting 3	Within 4.5 months from kick-off meeting
8.	Interim report #3	Within 5 months from kick-off meeting
9.	Interim meeting 4	Within 5.5 months from kick-off meeting
10.	Draft complete roadmap report	Within 6 months from kick-off meeting
11.	Interim meeting 5	Within 6.5 months from kick-off meeting
12.	Final complete report - including executive summary, presentation slides	Within 7 months from kick-off meeting
13.	Final meeting	Within 8 months from kick-off meeting



TASKS AND DELIVERABLES FOR LOT 3

- **Development of a roadmap for action on risk assessment of combined exposure to multiple chemicals**

No.	Tasks & deliverables	Can be subcontracted? ²²	Deadline
1	<p>Task: Prepare an inception report containing:</p> <p>a) A refined problem formulation as described above in Section 1.2 (lot 3) under Objective 1.</p> <p>b) The refined workplan and refined methodology proposed in the offer with a detailed description of the tasks, methods and tools to be used for achieving all objectives (2-7) including the description of all information sources and the approaches followed for the data collection and integration.</p> <p>c) The refined methodology on how to identify and select the profiles of the scientific/regulatory and other experts and/or relevant institutions, as needed, to be interviewed in order to provide direction and information for the development of the roadmap. This should also include the proposed content of the interview questions/survey.</p> <p>The contractor will receive the following documents below at the kick-off meeting. The contractor shall consider these documents when addressing all objectives:</p> <ul style="list-style-type: none"> - comments from international bodies/organisations and stakeholders on theme paper (Annex 5) received during the last phase of the consultation process. - Action plan of DG SANTE and EFSA on the cumulative risk assessment of pesticides and their residues, mentioned in the theme paper on risk assessment of combined exposure to multiple chemicals (Annex 5). Relevant for lot 3. - EFSA 2021-2027 draft strategy. 	Yes	Within 1 month from kick-off meeting

²² If a subcontractor provides the whole or a very large part of the financial capacity OR executes the whole or a very large part of the tasks, EFSA may demand the subcontractor to sign the contract.



	<p>Deliverable:</p> <p>1. Inception report (max. 20 pages, excluding annexes).</p> <p>The inception report shall be submitted in English in both MS-Word and Adobe Acrobat (PDF) format with the charts in MS-Excel.</p> <p>A revised version of the deliverable reflecting the changes agreed at the first interim meeting will be submitted 15 days after the interim meeting #1.</p>		
2	<p>Task: Prepare a report (interim report #1) containing:</p> <p>the findings/results for Objective 2, as described above in Section 1.2 (lot 3).</p> <p>Deliverable:</p> <p>1. Interim report #1 describing execution and results of Objective 2, and plan for next steps.</p> <p>The report shall be submitted in English in both MS-Word and Adobe Acrobat (PDF) format with the charts in MS-Excel.</p> <p>A revised version of the deliverable reflecting agreed changes at the interim meeting #2 will be submitted at the latest 15 days after the interim meeting #2.</p>	Yes	Within 2.5 months from kick-off meeting
3	<p>Task: Prepare a report (interim report #2) containing:</p> <p>a) a revised version of the findings/results for Objective 2, updated according to the comments provided by EFSA and agreements reached during interim meeting #2</p> <p>b) the findings/results for Objectives 3 and 4 as described above in Section 1.2 (lot 3), integrated with the revised version of the findings/results for Objectives 2. This should include a justified proposal for a revised problem-formulation.</p> <p>Deliverable:</p> <p>1. Interim report #2 describing points a) and b) and the plan for next steps.</p>	Yes	Within 4 months from kick-off meeting



	<p>The report shall be submitted in English in both MS-Word and Adobe Acrobat (PDF) format with the charts in MS-Excel.</p> <p>A revised version of the deliverable reflecting agreed changes at the interim meeting #3 will be submitted at the latest 15 days after the interim meeting #3.</p>		
4	<p>Task: Prepare a report (interim report #3) containing:</p> <p>a) a revised version of the findings/results for Objectives 2, 3 and 4 updated according to the comments provided by EFSA and the agreements reached during interim meeting #3.</p> <p>b) the findings/results for Objectives 5 and 6, as described above in Section 1.2 (lot 3), with a justified proposal for prioritisation of work areas and activities and possible partners as described in Objective 6 of Section 1.2 (lot 3).</p> <p>c) a list of possible actions to be implemented by EFSA and at least five high level recommendations for the implementation of cumulative risk assessment areas and activities according to Objective 6, as described above in Section 1.2 (lot 3). These recommendations should include at least the following sections: scope, objectives, challenges, and expected impact as well as a proposed timescale for the implementation of the studies or projects.</p> <p>Deliverable:</p> <p>1. Interim report #3 describing points a) to c) and the plan for next steps.</p> <p>The report shall be submitted in English in both MS-Word and Adobe Acrobat (PDF) format with the charts in MS-Excel.</p> <p>A revised version of the deliverable reflecting the changes agreed at the interim meeting #4 will be submitted at the latest 15 days after the interim meeting #4.</p>	Yes	Within 5 months from kick-off meeting
5	<p>Task:</p> <p>1) Prepare a complete draft roadmap report containing:</p>	Yes	Within 6 months from kick-off meeting



	<p>a) the revised version of the findings/results for Objectives 1, 5 and 6 updated according to the comments provided by EFSA and agreements reached during interim meeting #4 integrated with the revised version of the findings/results for Objectives 2, 3 and 4.</p> <p>b) the findings/results of Objective 7 as described above in Section 1.2 (lot 3).</p> <p>c) an overview of the literature data consulted to date, and a summary of the outcome and conclusions from information searches and surveys conducted.</p> <p>2) Prepare a draft set of presentation slides (approximately 20) summarizing the methodology, main components and recommendations for actions/studies/projects of the roadmap for action.</p> <p>Deliverable:</p> <p>1. Draft roadmap report (max. 90 pages, excluding annexes) describing execution and results of all objectives (1 to 7), drafted based on a template provided by EFSA (external report), and containing the complied results/findings described in the inception report and in the interim reports #1 #2 and #3 and updated according to the agreements in the interim meetings.</p> <p>2. Draft presentation of approximately 20 slides. The draft roadmap shall be submitted in English in both MS-Word and Adobe Acrobat (PDF) format with the charts in MS-Excel</p> <p>The presentation shall be submitted in English in both MS-PowerPoint and Adobe Acrobat (PDF) format.</p>		
6	<p>Task: Prepare a final roadmap report updated according to the comments provided by EFSA and agreements reached during interim meeting #5, including an executive summary.</p> <p>The final roadmap shall report on all the completed tasks as defined in Section 1.2 (lot</p>	Yes	Within 7 months from kick-off meeting



	<p>3) and should have the same structure as the draft roadmap and address all the objectives.</p> <p>The final roadmap shall be presented by the contractor during the final meeting.</p> <p>Deliverable: The final roadmap report (max. 90 pages, excluding annexes) shall include the executive summary (max 2 pages) drafted based on a template provided by EFSA (external report).</p> <p>The roadmap shall be submitted in English in both MS-Word and Adobe Acrobat (PDF) format with the charts in MS-Excel.</p>		
7	<p>Task: Prepare a final set of presentation slides summarizing the methodology, and main components of the roadmap for actions updated according to the comments provided by EFSA and agreements reached during interim meeting #5.</p> <p>Deliverable:</p> <ol style="list-style-type: none">1. A presentation of approximately 20 slides2. A recorded presentation <p>The presentation shall be submitted in English in both MS-PowerPoint and Adobe Acrobat (PDF) format.</p>	Yes	Within 7 months from kick-off meeting
No.	Meetings	Deadline for finalisation	
<p>The contractor is responsible for organising the meetings and taking minutes using the appropriate EFSA template of every meeting held with EFSA and for <u>sending them to EFSA within 5 working days after the meeting, for revision and agreement</u>. The minutes must be approved by EFSA to be considered as agreed.</p> <p>All meetings are to be attended by at least the project manager and the expert/s responsible for the specific task/s under discussion, including sub-contractors if applicable.</p> <p>In addition to the meetings below, the contractor will be asked to include in its work plan indicatively a 2 hour meeting every second week throughout the entire duration of the contract to discuss on the progress of the tasks/deliverables; any issues or risks should be highlighted during these meetings.</p> <ol style="list-style-type: none">a. A 2 hour meeting every second week to discuss the progress of the upcoming deliverables, when no other interim meetings are scheduled within two weeks, for a 'checkpoint with EFSA' throughout the entire duration of the contract.b. 2-3 meetings (approximately 2 hours each) to be interviewed by a contractor that will be identified by EFSA following a separate call for tenders and tasked to develop a roadmap for action on artificial intelligence (AI) for evidence management in risk assessment. The aim of the interviews is to explore and align the AI needs stemming from this specific roadmap with the roadmap development on AI. The name of the contractor that will work on the AI roadmap will be made available at the kick-off meeting.			



1	<p>Kick-off meeting: via teleconference – one day²³ The purpose of the kick-off meeting is to:</p> <ul style="list-style-type: none"> - verify the contractor's understanding of the terms of reference; - provide clarification on the additional supporting material provided; - discuss the proposed approach and methodology to carry out the services requested by EFSA (incl. the fine-tuning of the methodology, timelines and structure of the various deliverables) that will be documented in the inception report and in the roadmap; - to have a joined discussion with the contractor developing the roadmap on artificial intelligence (AI) on methods and timelines foreseen for the development of the AI roadmap, and how best to cooperate with each other to capture potential opportunities for the use of AI on risk assessment of combined exposure to multiple chemicals <p>During this meeting, in addition to operational implementation, the administrative and financial matters related to contract implementation will be discussed.</p>	Within 2 weeks after entry into force of contract
2	<p>Interim meeting #1: via teleconference – half day</p> <p>The purpose of the meeting is to discuss/review the inception report.</p>	Within 1.5 months from kick-off meeting
3	<p>Interim meeting #2: via teleconference - half day</p> <p>The purpose of the meeting is to discuss/review the interim roadmap report #1.</p>	Within 3 months from kick-off meeting
4	<p>Interim meeting #3: via teleconference - half day</p> <p>The purpose of the meeting is to discuss/review the interim roadmap report #2.</p>	Within 4.5 months from kick-off meeting
5	<p>Interim meeting #4: via teleconference - half day</p> <p>The purpose of the meeting is to discuss/review the interim roadmap report #3.</p>	Within 5.5 months from kick off meeting
6	<p>Interim meeting #5: via teleconference - half day</p> <p>The purpose of the meeting is to discuss/review the full draft roadmap report.</p>	Within 6.5 months from kick off meeting
7	<p>Final meeting: via teleconference – half day</p> <p>The purpose of the final meeting is to present and discuss the final roadmap as well as the presentation slides</p>	Within 8 months from kick off meeting
No.	Payments	Linked to EFSA approval of deliverable No.
1	Interim payment 1 of 40 %	3 – Interim report no.2 due 4 months from kick-off meeting
2	Payment of the balance of 100% - 40% of the interim payment	All other deliverables

²³ One day = 8 hours, half day = 4 hours



No.	Summary of deliverables and timeline	Deadline for finalisation
1.	Kick off meeting	Within 2 weeks month after entry into force of contract
2.	Inception report	Within 1 month from kick-off meeting
3.	Interim meeting 1	Within 1.5 months from kick-off meeting
4.	Interim report #1	Within 2.5 months from kick-off meeting
5.	Interim meeting 2	Within 3 months from kick-off meeting
6.	Interim report #2	Within 4 months from kick-off meeting
7.	Interim meeting 3	Within 4.5 months from kick-off meeting
8.	Interim report #3	Within 5 months from kick-off meeting
9.	Interim meeting 4	Within 5.5 months from kick-off meeting
10.	Draft complete roadmap report	Within 6 months from kick-off meeting
11.	Interim meeting 5	Within 6.5 months from kick-off meeting
12.	Final complete report - including executive summary, presentation slides	Within 7 months from kick-off meeting
13.	Final meeting	Within 8 months from kick-off meeting

The working language for contract implementation including execution of tasks, meetings and deliverables shall be English. Any written deliverables must be to a high standard of English which does not require proof reading. For further details regarding deliverable acceptance criteria for EFSA, see Annex 6.

1.4 INFORMATION ON THE CONTRACT

Nature of expense: services

Type of contract: direct

Maximum number of contractors in each lot: 1 per lot

Place of performance: contractor's premises

Duration of tasks in each lot: 8 months from kick-off meeting.



Budget information

The maximum budget EFSA has available per lot is:

Lot 1 500.000 €

Lot 2 500.000 €

Lot 3 500.000 €

Any offer exceeding these maximums will be excluded from further assessment during evaluation.

Important information for British tenderers:

As a consequence of the UK withdrawal from the European Union on 31 January 2020 and entry into force the Withdrawal Agreement ratified by the UK and the European Union, the UK will have a special status with the European Union until the end of the Transition Period (31 December 2020).

During the Transition Period, economic operators established in the UK may continue to bid for EFSA calls for tenders. For any contracts awarded to UK established economic operators prior to the end of the Transition Periods, these contracts should be implemented in accordance with their contractual terms until their end-date, including any modifications where necessary. For any procurement procedures ongoing (i.e. no contract signed yet) at the end of the Transition Period, economic operators established in the UK will no longer be entitled to participate and will be excluded from any ongoing procedure for which the contract has not yet been signed. This provision applies to the lead tenderer and any partners in a consortium which may be established in the UK. This provision does not apply to the use of subcontractors established in the UK.

1.5 OWNERSHIP, INTELLECTUAL PROPERTY RIGHTS, USE OF RESULTS

As regards any product or delivery commissioned by EFSA and developed by the contractor in the context of the contract resulting from this call for tenders, as well as source codes of IT applications and models developed for EFSA, the intellectual property rights will be owned by EFSA only in its capacity as financial source of the 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 contract, unless the contractor requests EFSA ex-ante authorisation and obtains from EFSA a written consent in this regard.

In addition, the contractor selected as a result of the present procurement procedure shall be solely responsible and liable for the following:

- To ensure that terms and conditions asserted by any copyright holder of publications or information referred to in the final deliverable for EFSA are fully satisfied;
- To make the necessary arrangements enabling EFSA to reproduce and make non-commercial use of publications and information referred to in the final deliverable it commissioned. As needed, the contractor shall consult with copyright licensing authorities (i.e. at national level) for guidance on purchasing



copyright licenses to reproduce any publications provided to EFSA. The contractor remains solely responsible and liable for obtaining all necessary authorizations and rights to use, reproduce and share the publications provided to EFSA

PARTS OF RESULTS PRE-EXISTING THE CONTRACT

If the results are not fully created for the purpose of the contract this should be clearly pointed out in the tender. Information should be provided about the scope of pre-existing materials, their source and when and how the rights to these materials have been or will be acquired.

EFSA does not acquire ownership or any license of pre-existing rights not incorporated in the deliverables. The full ownership is limited to the deliverables, which might include licensed pre-existing rights on excerpts, parts, texts etc., if fully or partially incorporated in the final deliverables.

The draft contract in Annex 2 contains further provisions on ownership of intellectual property rights. All quotations or information the tenderer provides in the technical and financial offer for EFSA which originates from other sources to which third parties may claim rights, have to be clearly marked in the offer in a way allowing easy identification (source publications, including date & place, creator, number, full title etc.). The tenderer shall take account of the above specification on ownership and copyrights in their technical and financial offer.

Use of results

EFSA is committed to the publication of contract deliverables - such as supporting evidence in the form of datasets, raw data, protocols etc. in the Knowledge Junction in order to improve transparency, reproducibility and evidence reuse. The [Knowledge Junction](#)²⁴ repository of EFSA runs on the EU-funded Zenodo research-sharing platform where uploaded items receive a unique Digital Object Identifier to make them citable. Any part of the output resulting from this contract may be published (at EFSA's discretion) on the Knowledge Junction repository, with attribution to the contractor, and several deliverables can be cross-linked among them and to the published final Report on Wiley Online Library.

1.6 PERSONAL DATA AND CONFIDENTIALITY

Processing of personal data by EFSA as contracting authority

Information on the processing of personal data by EFSA as contracting authority in charge of the present procurement procedure is available in the [Privacy Statement](#) on the EFSA website as well as in Article II.9.1 of the draft contract in Annex 2.

Please note that your personal data as a tenderer or selected contractor may be registered in the Early Detection and Exclusion System (EDES) if you are in one of the situations mentioned in Article 136 of the Financial Regulation. The relevant Privacy Statement is

²⁴ <http://www.efsa.europa.eu/en/press/news/190117> and <https://zenodo.org/communities/efsa-kj/?page=1&size=20>



available on the European Commission's website, here:
http://ec.europa.eu/budget/explained/management/protecting/protect_en.cfm#BDCE.

Processing of personal data by the selected contractor

In case tasks and activities under this call relate to the processing of personal data, Article II.9.2 of the draft contract in Annex 2 shall be observed.

For further information on data protection, please refer to the [EFSA guidance for tenderers](#) on the EFSA website, page 13.

Confidentiality

EFSA will disregard general statements that the whole tender or substantial parts of it contain confidential information. Tenderers need to mark clearly the information they consider confidential and explain why it may not be disclosed. EFSA reserves the right to make its own assessment of the confidential nature of any information contained in the tender.



PART 2 EVALUATION - HOW WILL YOUR OFFER BE ASSESSED?

In case you apply as a group of economic operators in a joint offer or if your offer envisages the use of subcontractors, please refer to the [EFSA Guidance for tenderers](#).

2.1 OPENING OFFERS

The aim of the public opening session is to check whether the offer received was dispatched by the deadline for tender receipt and that the tenders are electronically protected until the official opening.

2.2 ORDER OF EVALUATION

Tenderers should note that the content of their offers will be assessed in the following pre-defined order: Exclusion criteria (Access to EU Market); Selection criteria (Technical & Professional capacity); Compliance with tender specifications; Award Criteria (Quality and Price).

Following the above assessment and identification of the winning tender, the following will be assessed only for the tenderer proposed for contract award: Selection criteria Professional Conflict of Interest – Institutional and Individual Declarations of Interest); Exclusion criteria (Declaration on Honour on exclusion criteria); Selection criteria (Declaration on Honour on selection criteria); Selection criteria (Economic & Financial capacity).

Evidence under sections 2.3 and 2.4 does not have to be submitted to EFSA if it has already been submitted in response to a previous EFSA call. In such case the evidence must be exactly the same as requested in these tender specifications and not older than 12 months. Please specify the reference of the EFSA call for tenders under which you have already submitted the evidence to EFSA if you chose to rely on such evidence.

2.3 GROUNDS FOR EXCLUSION

Eligibility – access to EU Market

Only offers from tenderers established in eligible countries will be allowed to the next step of the evaluation. Please refer to the [EFSA Guidance for tenderers](#) for further details.

Evidence requested in your offer:

Tenderers must submit the Administrative data forms (including LEF and BAF) available [here](#).

Exclusion

Tenderers must not be in one of the exclusion situations listed in article 136 of the Financial Regulation, explained in the [EFSA Guidance for tenderers](#).

Evidence requested in your offer:

Tenderers must declare that they are not in one of the exclusion situations by providing a signed and dated Declaration on Honour on exclusion criteria, available [here](#). In case of a joint offer from a group of economic operators, or in case of



subcontracting, such declaration should be submitted for each member of the group and for each identified subcontractor.

Further supporting evidence in support of this declaration may be requested from the successful tenderer prior to signature of the contract. Such requested evidence will be specified in the award letter and may have to be provided to EFSA before the contract is signed.

2.4 SELECTION CRITERIA

In addition to the evidence requested below, EFSA has the right, during the evaluation process, to request further evidence on the tenderer's compliance with the economic, financial, technical and professional capacity requirements.

A) Economic and financial capacity

The tenderer must have generated an overall annual turnover of at least 500,000 € in each of the last 3 closed financial years (2019, 2018 and 2017).

Evidence requested in the offer:

Tenderers must declare they fulfil the economic and financial capacity by providing a signed and dated Declaration on Honour on selection criteria, available [here](#). In case of a joint offer from a group of economic operators, such declaration should be completed by the leading partner only.

EFSA will request proof of annual turnover from the successful tenderer prior to signature of the contract. Such requested evidence will be specified in the award letter and must be provided to EFSA before the contract is signed. This evidence will be evaluated on a consolidated basis.

During contract implementation, in case of request for the addition of new subcontracting or assignment of the contract to a new legal entity, the economic and financial capacity will be checked for the last 3 most recent closed financial years and not necessarily the financial years published with the call.

B) Technical and professional capacity

SELECTION CRITERIA FOR LOT 1

- **Development of roadmap for action on building a European partnership for next generation, systems-based environmental risk assessment**

1. The tenderer must have the following **minimum professional capacity** to perform the contract:

a) extensive and demonstrable experience in:

- environmental risk assessment regulatory requirements and methodologies in several EU regulations, such as chemicals, biocides, GMOs, human and veterinary medicinal products and feed additives products, etc;
- development of roadmaps or other types of similar strategic documents (e.g. prioritising research needs);



- carrying out consultation activities (design and conduct interviews, surveys, etc.);
 - collecting and managing data relating to the field of the contract, handling large amounts of information, research and work programmes, and producing summary reports;
 - working with public authorities in more than two EU countries;
 - working with information sources and experts /networks in relation to the subjects covered by the present contract;
 - building partnerships/research consortia.
- b) ability to provide a team of at **least 7** experts to ensure that the deadlines of the deliverables will be met and will be compliant with these specific expertise requirements below:
- **1 senior expert** acting as project manager with at least 10 years of subject matter expertise in project management in the area of public health/food, feed safety or environmental sciences or environmental risk assessment. The project manager shall be responsible for the overall contact and the management and coordination of the implementation of all services requested by EFSA in this call for tender. The project manager will be the interface for all commercial and contractual matters and the overall contact point for the services requested by EFSA. He/she shall work and liaise with ensuring the coherence for the overall work, must be included overseeing control of delivered service, client orientation and conflict resolution. He/she should have experience in the coordination of at least 2 large-scale projects (≥100.000 €) and multidisciplinary projects and in the management of teams of at least 5 people.
 - **1 senior expert** with at least 10 years of subject matter expertise in environmental/chemical risk assessment methodologies and at least 2 years of experience in regulatory work with European Union or international public organisations. Deep hands on experience with very good and proved regulatory expertise and expertise in the relevant field.
 - **1 expert** with at least 7 years of work experience in systems thinking/theory/integrated systems-based approaches applied to environmental assessments and at least 1 year of experience of experience in regulatory work with European Union or international public organisations. Very hands on professionals with good regulatory and scientific expertise in the relevant field. Capable of assisting with project design, and project work stream planning and scientific project calls.
 - **1 expert** with at least 5 years of work experience as information specialist, able to carry out interviews, literature searches, and research and market analyses.
 - **2 junior experts** with at least 2 years of work experience in environmental risk assessment methodologies.



- **1 junior expert** with at least 3 years of work experience in using social research methods and tools to gather, analyse and report findings that can be used to inform communication activities (e.g. market research, using interviews, surveys, focus groups or another mix of qualitative/quantitative methods).
- c) The team of experts must have overall a very good level of spoken and written standard UK English. For non-native English speakers, the knowledge of English shall be demonstrated by: (i) extensive experience (minimum five years) in international projects where English is the working language; or (ii) at least three years of work/study in an English speaking environment; or (iii) certificate of English proving at least a C1 level;
- 2. The tenderer must have the following **minimum technical capacity** to perform the contract:
 - a) The tenderer must have access to relevant databases for performing literature searches (e.g. Web of science, Scopus) and a range of public resources (e.g. CORDIS database²⁵; EU regional policy programmes²⁶; P2P network database²⁷; LIFE projects²⁸);
 - b) The tenderer must have an architecture for digital collaboration, including video/tele-meeting facilities for progress meetings, and a common document management system such as Office 365 for simultaneous handling of documents.

SELECTION CRITERIA FOR LOT 2

- **New approach methodologies in risk assessment**

1. The tenderer must have the following **minimum professional capacity** to perform the contract:
 - a) extensive and demonstrable experience in:
 - the development of roadmaps or other types of similar strategic documents
 - chemical risk assessment in the food and feed area and the development and design of NAM studies
 - Knowledge on the use of NAM-based results in regulatory risk assessment,
 - knowledge on study design and execution of NAM-based experiments.

²⁵ Refer to <https://cordis.europa.eu/projects/en>;

²⁶ Refer to https://ec.europa.eu/regional_policy/en/projects

²⁷ Refer to <https://www.era-learn.eu/network-information/networks>

²⁸ Refer to <https://ec.europa.eu/environment/life/project/Projects/index.cfm>



- Knowledge in the validation, harmonisation and standardisation of test methods (e.g. by OECD, ECVAM, ISO, etc.)
 - in depth knowledge on current developments on NAMs at EU and international levels
 - working with information sources and experts /networks in relation to NAMs and chemical risk assessment in food and feed
 - working with public authorities in more than two EU countries
 - carrying out consultation activities (design and conduct interviews, surveys, etc.), collecting and managing data relating to the field of the contract
 - handling large amounts of information,
 - research and work programmes
 - producing summary reports
- b) ability to provide a team of at **least 7** experts to ensure that the deadlines of the deliverables will be met and will be compliant with these specific expertise requirements below:
- **1 senior expert** acting as project manager with at least 10 years of subject matter expertise in project management in the area of public health/food safety. The project manager shall be responsible for the overall contact and the management and coordination of the implementation of all services requested by EFSA in this call for tender. The project manager will be the interface for all commercial and contractual matters and the overall contact point for the services requested by EFSA. He/she shall work and liaise with ensuring the coherence for the overall work, must be included overseeing control of delivered service, client orientation and conflict resolution. He/she should have experience in the coordination of at least 2 large-scale projects (≥100.000 €) and in the management of teams of at least 5 people.
 - **1 senior expert** with at least 10 years of subject matter expertise in chemical risk assessment methodologies for toxicological hazard assessment and at least 2 years of experience in regulatory work with European Union or international public organisations and knowledge on the process for validation and standardisation of test methods for regulatory assessments. Deep hands on experience with very good and proved regulatory expertise and expertise in the relevant field.
 - **1 expert** with at least 7 years of work experience in the design and execution of NAM based studies for toxicological hazard assessment. Very hands on professionals with good regulatory and scientific expertise in the relevant field. Capable of assisting with project design, and project work stream planning and research calls.
 - **1 expert** with at least 5 years of work experience as information specialist, familiar with data extractions and 'Big Data' methods, design and



harmonisation of templates for data collection and data integration. Analytical, structured and committed professional.

- **2 junior experts** with at least 2 years of work experience chemical risk assessment methodologies and/or use of NAMs for toxicological hazard assessment.
 - **1 junior expert** with at least 3 years of work experience in using social research methods and tools to gather, analyse and report findings that can be used to inform communication activities (e.g. market research, using interviews, surveys, focus groups or another mix of qualitative/quantitative methods)
- c) The team of experts must have overall a very good level of spoken and written standard UK English. For non-native English speakers, the knowledge of English shall be demonstrated by: (i) extensive experience (minimum five years) in international projects where English is the working language; or (ii) at least three years of work/study in an English speaking environment; or (iii) certificate of English proving at least a C1 level.
2. The tenderer must have the following **minimum technical capacity** to perform the contract
- a) The tenderer must have access to relevant databases for performing literature searches (e.g. Web of science, Scopus), a range of public resources (e.g. CORDIS database²⁹; P2P network database³⁰;
 - b) The tenderer must have an architecture for digital collaboration, including video/tele-meeting facilities for progress meetings, and a common document management system such as Office 365 for simultaneous handling of documents.

SELECTION CRITERIA FOR LOT 3

Roadmap for action risk assessment of combined exposure to multiple chemicals

1. The tenderer must have the following **minimum professional capacity** to perform the contract:
- a) extensive and demonstrable experience in:
 - the development of roadmaps or other types of similar strategic documents,
 - human health risk assessment of chemicals in food and feed,
 - toxicological hazard assessment and dietary and non-dietary exposure assessment, preferably to multiple chemicals,

²⁹ Refer to <https://cordis.europa.eu/projects/en>;

³⁰ Refer to <https://www.era-learn.eu/network-information/networks>



- working with public authorities in more than two EU countries,
 - working with information sources and experts /networks in relation to the subjects covered by the present contract,
 - carrying out consultation activities (design and conduct interviews, surveys, etc.),
 - collecting and managing data relating to the field of the contract, handling large amounts of information, research and work programmes and producing summary reports.
- b) ability to provide a team of at **least 7** experts compliant with these specific expertise requirements below:
- **1 senior expert** acting as project manager with at least 10 years of subject matter expertise in project management in the area of public health/food safety. The project manager shall be responsible for the overall contact and the management and coordination of the implementation of all services requested by EFSA in this call for tender. The project manager will be the interface for all commercial and contractual matters and the overall contact point for the services requested by EFSA. He/she shall work and liaise with ensuring the coherence for the overall work, must be included overseeing control of delivered service, client orientation and conflict resolution. He/she should have experience in the coordination of at least 2 large-scale projects (≥100.000 €) and in the management of teams of at least 5 people.
 - **1 senior expert** with at least 10 years of subject matter expertise in human health risk assessment of chemicals within a regulatory process, preferably for different types of chemicals, and at least 2 years of experience in regulatory work with a European Union or international public organisations. Deep hands on experience with very good and proved regulatory expertise and expertise in the relevant field.
 - **1 expert** with at least 7 years of work experience in toxicological hazard assessment of chemicals, incl. toxicokinetics and dose-response modelling, and at least 1 year of experience with a European Union institution or other international public organisations. Very hands on professionals with good regulatory and scientific expertise in the relevant field. Capable of assisting with project design, and project work stream planning and research calls.
 - **1 expert** with at least 7 years of work experience in exposure assessment to chemicals, incl. use of statistical software, handling and analysis of relatively large datasets (e.g. > 10.000 records) and probabilistic methodologies, and at least 1 year of experience with a European Union institution or other international public organisations. Very hands on professionals with good regulatory and scientific expertise in the relevant field. Capable of assisting with project design, and project work stream planning and research calls.



- **1 expert** with at least 5 years of work experience as information specialist, able to carry out interviews, research and market analysis. Analytical, structured and committed professional.
 - **1 junior expert** with at least 2 years of work experience in human health risk assessment.
 - **1 junior expert** with at least 3 years of work experience in using social research methods and tools to gather, analyse and report findings that can be used to inform communication activities (e.g. market research, using interviews, surveys, focus groups or another mix of qualitative/quantitative methods)
- c) The team of experts must have overall a very good level of spoken and written standard UK English. For non-native English speakers, the knowledge of English shall be demonstrated by: (i) extensive experience (minimum five years) in international projects where English is the working language; or (ii) at least three years of work/study in an English speaking environment; or (iii) certificate of English proving at least a C1 level.
2. The tenderer must have the following **minimum technical capacity** to perform the contract
- a) The tenderer must have access to relevant databases for performing literature searches (e.g. Web of science, Scopus) and a range of public resources (e.g. CORDIS database³¹; EU regional policy programmes³²; P2P network database³³ LIFE projects³⁴;
 - b) The tenderer must have an architecture for digital collaboration, including video/tele-meeting facilities for progress meetings, and a common document management system such as Office 365 for simultaneous handling of documents.

Evidence requested from the tenderers for each lot applied for:

- Requirement a): A list of all relevant activities and details on at least three major projects or publications related to the subject matter of this contract, carried out in the course of the past 5 years by the proposed members of the Project team;
- Requirements b): Detailed CVs of the Project team members proposed for the assignment taking into account the minimum expertise requirements detailed above, including the knowledge of English; EFSA strongly recommends submitting the CVs in the EU CV format which can be accessed [here](#);

³¹ Refer to <https://cordis.europa.eu/projects/en>;

³² Refer to https://ec.europa.eu/regional_policy/en/projects

³³ Refer to <https://www.era-learn.eu/network-information/networks>

³⁴ Refer to <https://ec.europa.eu/environment/life/project/Projects/index.cfm>



- Requirement c): A list of available tools and resources and a statement confirming access to the relevant literature databases and specifying the name of the databases.

- **Declaration on Honour on selection criteria** available [here](#). To be signed by the tenderer (in case of joint offer signed by the leading partner only);
- **Confirmatory statement of resources** (*only applicable for joint offers or offers with subcontracting*): a statement signed by each partner/subcontractor confirming they will provide the necessary resources for the performance of the contract;

C) Professional conflicting interest

In accordance with article 167(1)(c) of the Financial Regulation and paragraph 104 of the recitals, if EFSA, based on the assessment of the technical and professional capacity evidence, concludes that the tenderer has a professional conflicting interest and therefore does not possess the professional capacity to perform the contract to an appropriate quality standard, the tenderer may be rejected.

Evidence requested in the offer for each lot applied for:

The tenderer proposed for contract award will be requested, prior to and as a condition of contract signature, to provide:

Institutional declaration of interests available [here](#) In case of a group of economic operators and/or in case of subcontracting, such declaration will need to be completed separately and submitted for each partner and for each identified subcontractor and;

Individual declarations of interests available [here](#) for each member of the proposed project team.

Institutional and Individual DoIs do not need to be provided with your offer. The requirement to submit Institutional and Individual DoIs will be specified in the award letter and will have to be provided and assessed by the EFSA Authorising Officer before and as a condition of contract signature. Please refer to [EFSA's policy on independence](#) and the [Decision of the Executive Director on Competing Interest Management](#) for detailed information.

With the exception of declarations of interest, evidence must be included in the offer for partners in a joint offer and/or subcontractors only if the capacity of those entities is necessary to satisfy the minimum economic, financial, technical and professional capacity requirements.

If any of the declarations or information provided proves to be false, EFSA may impose administrative sanctions (exclusion or financial penalties) on the entity providing the false declarations/information.

For the purposes of the evaluation related to exclusion and selection criteria EFSA may also refer to publicly available information, in particular evidence that it can access on a national database free of charge.

2.5 COMPLIANCE WITH TENDER SPECIFICATION AND MINIMUM REQUIREMENTS



Your offer will be assessed for compliance with the tender specifications before its assessment against the award criteria.

Tenders do not comply with the tender specifications and will be rejected if they:

- ☐ do not comply with minimum requirements laid down in the tender specifications;
- ☐ propose a solution different from the one imposed;
- ☐ propose a price above the fixed maximum set in the specifications;
- ☐ are submitted as variants, when the specifications do not authorise them;
- ☐ do not comply with applicable obligations under environmental, social and labour law established by Union law, national law and collective agreements or by the international environmental, social and labour law provisions listed in Annex X to Directive 2014/24/EU³⁵ and compliance with data protection obligations resulting from Regulation (EU) 2016/679 and Regulation (EU) 2018/1725³⁶.

The grounds for rejection is not linked to the award criteria so there is no evaluation. The tenderer will be informed of the grounds for rejection without being given feedback on the content of the tender other than on the non-compliant elements.

2.6 AWARD CRITERIA

Tenders will be evaluated against the below award criteria. The award criteria serve to identify the **most economically advantageous offer**.

A) QUALITY AWARD CRITERIA FOR EACH LOT

QUALITY AWARD CRITERIA FOR LOT 1: Development of roadmap for action on building a European partnership for next generation, systems-based environmental risk assessment

1. UNDERSTANDING OF THE ASSIGNMENT AND TASKS REQUIRED (max. 35 points - minimum threshold 60% i.e. 21/35 to pass minimum quality threshold for this criteria)

This is intended to assess the extent to which the offer demonstrates a clear understanding of the assignment and project objectives covering all the aspects of the technical specifications.

The tenderer should:

- Describe how they propose to provide the services described in the technical specifications and to perform the work necessary for achieving the objectives requested in this open call;

³⁵ OJ L 94 of 28.03.2014, p. 65

³⁶ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of individuals with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295/39 21.11.2018, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R1725&from=EN>



- Demonstrate awareness on how to develop a network from various regulatory sectors to build partnerships;
- Demonstrate awareness of EFSA needs in the area of systems-based regulatory environmental risk assessment taking into account the information in the theme paper (Annex 3) and in the tender specifications;
- Demonstrate that the proposal is within the scope of this Open Call.

2. METHODOLOGY PROPOSED FOR IMPLEMENTATION (max. 25 points - minimum threshold 60%, i.e. 15/25 to pass minimum quality threshold for this criterion)

The degree to which the proposed methodology shows the capacity to address the tasks underlined in the tender specifications, including convincing justification for the choice of proposed methodology highlighting advantages and disadvantages.

The tenderer should:

- Provide quality parameters and details of the approach to follow to identify the partners of relevant sectors that should be part of PERA. **2 points**
- Provide methodology on how to identify and select the sectors, institutions and disciplines experts be chosen, how interviews with selected experts should be conducted **5 points**
- Describe what databases and resources are proposed to gather the relevant information; **5 points**
- Describe what methods are proposed to map activities and identify overlaps, knowledge gaps, challenges and blockers in relation to Objective 3, 4, 5 and 6; **5 points**
- Describe how to assure that activities and milestones identified to achieve a next generation ERA are feasible and can be addressed by PERA once it is established; **3 points**
- Provide a logical and well-structured step by step explanation of methodology; **5 points**

3. PROJECT MANAGEMENT AND ORGANISATION OF THE TASKS WITHIN PROJECT TEAM AND RESPECT OF TIMELINES (max. 20 points – minimum threshold 60% i.e. 12/20 to pass minimum quality threshold for this criterion)

This is to assess the extent to which the team set-up is suitable for the implementation of the assignment, and to meet the agreed deadlines for deliverables. More specifically **the tenderer should provide:**

- Clear and detailed information on distribution of the tasks among the project team; in case of joint offer & subcontractors, clarity on who does what, when and why (justify why the partner/subcontractor is proposed to do the particular task/work-package); **5 points**
- Clarity of organization of project into work packages, including project phases, timelines, milestones, deliverables, providing a Gantt chart; **10 points**
- Clear and detailed information on the frequency and type of communication with EFSA and internal team communication (in case of joint offers & subcontractors also the frequency and type of communication between partners and/or subcontractor), the role of project leader in the coordination and tasks allocation in relation to the methodology and tools proposed; **5 points**



4. RISK MANAGEMENT (10 points - minimum threshold 60% i.e. 6/10 to pass minimum quality threshold for this criteria)

This is to assess the risk management awareness of the tenderer, in particular the ability to identify any potential risks to the achievement of the project objectives, assess risk impact & likelihood, and ability to foresee effective mitigating actions. **The tenderer should:**

- Identify risks associated with the proposed methodology, technical problems, and project management issues (e.g. measures to ensure meeting deadlines, and mitigation strategies for continuity of the service in case of absence of the member of the team), which might appear during the implementation of the assignment; how will the tenderer manage output deficiencies; **5 points**
- Propose risk mitigation actions and explain their likely effectiveness; **5 points**

5. MEASURES TO GUARANTEE QUALITY OF DELIVERABLES (10 points - minimum threshold 60% i.e. 6/10 to pass minimum quality threshold for this criteria)

This is to assess the quality assurance mechanisms put in place to guarantee the high quality of deliverables. **The tenderer should explain:**

- Role of team leader / leading partner in quality assurance; **5 points**
- Special additional measures for quality assurance proposed for this particular project; language quality check. **5 points**

QUALITY AWARD CRITERIA FOR LOT 2: New approach methodologies in risk assessment

1. UNDERSTANDING OF THE ASSIGNMENT AND TASKS REQUIRED (max. 35 points - minimum threshold 60% i.e. 21/35 to pass minimum quality threshold for this criteria)

- This is intended to assess the extent to which the offer demonstrates a clear understanding of the assignment and project objectives covering all the aspects of the technical specifications.

The tenderer should:

- Describe how they propose to provide the services described in the technical specifications and to perform the work necessary for achieving the objectives requested in this open call;
- Demonstrate awareness regarding the development, validation process in the EU and internationally, and current situation regarding the use of NAMs in the regulatory context;
- Demonstrate awareness of EFSA needs in the area of NAMs taking into account the information in the theme paper (Annex 4) and in the tender specifications;
- Demonstrate that the proposal is within the scope of this Open Call.

2. METHODOLOGY PROPOSED FOR IMPLEMENTATION (max. 25 points - minimum threshold 60%, i.e. 15/25 to pass minimum quality threshold for this criterion)



The degree to which the proposed methodology shows that the tenderer has the capacity to implement his knowledge in the area of NAMs and regulatory chemical risk assessment in order to address the tasks underlined in the tender specifications. In particular **the tenderer should:**

- Provide an appropriate methodology for addressing all objectives and include convincing justification for the choice of the proposed methodology **5 points**
- Specify and justify the selection of information sources such as databases and other resources proposed to gather the relevant information; **3 points**
- Provide details of the methods proposed to map activities, identify overlaps, knowledge gaps, challenges and blockers in relation to Objective 3, 4 and 5, and to perform the prioritization of working areas and possible partners; **5 points**
- Provide convincing evidence to ensure that the activities and milestones identified are feasible; **4 points**
- Describe the methods/tools to identify communication opportunities **3 points**
- Provide a logical and well-structured step by step explanation of methodology; **5 points**

3. PROJECT MANAGEMENT AND ORGANISATION OF THE TASKS WITHIN PROJECT TEAM AND RESPECT OF TIMELINES (max. 20 points – minimum threshold 60% i.e. 12/20 to pass minimum quality threshold for this criterion)

This is to assess the extent to which the team set-up is suitable for the implementation of the assignment and to meet the agreed deadlines for deliverables. More specifically **the tenderer should provide:**

- Clear and detailed information on distribution of the tasks among the project team according to their knowledge and expertise in the area; in case of joint offer & subcontractors, clarity on who does what, when and why (justify why the partner/subcontractor is proposed to do the particular task/work-package); **5 points**
- Clarity of organization of project into work packages, including project phases, timelines, milestones, deliverables, providing a Gantt chart; **10 points**
- Clear and detailed information on the frequency and type of communication with EFSA and internal team communication (in case of joint offers & subcontractors also the frequency and type of communication between partners and/or subcontractor), the role of project leader in the coordination and tasks allocation in relation to the methodology and tools proposed. **5 points**

4. RISK MANAGEMENT (10 points - minimum threshold 60% i.e. 6/10 to pass minimum quality threshold for this criteria)

This is to assess the risk management awareness of the tenderer, in particular the ability to identify any potential risks to the achievement of the project objectives, assess risk impact & likelihood, and ability to foresee effective mitigating actions. **The tenderer should:**

- Identify risks associated with the proposed methodology, technical problems, and project management issues (e.g. measures to ensure meeting deadlines,



and mitigation strategies for continuity of the service in case of absence of the member of the team) which might appear during the implementation of the assignment; **5 points**

- Propose risk mitigation actions and explain their likely effectiveness. **5 points**

5. MEASURES TO GUARANTEE QUALITY OF DELIVERABLES (10 points - minimum threshold 60% i.e. 6/10 to pass minimum quality threshold for this criteria)

This is to assess the quality assurance mechanisms put in place to guarantee the high quality of deliverables. **The tenderer should explain:**

- Role of team leader / leading partner in quality assurance; **5 points**
- Special additional measures for quality assurance proposed for this particular project. **5 points**

QUALITY AWARD CRITERIA FOR LOT 3: Roadmap for action risk assessment of combined exposure to multiple chemicals

1. UNDERSTANDING OF THE ASSIGNMENT AND TASKS REQUIRED (max. 35 points - minimum threshold 60% i.e. 21/35 to pass minimum quality threshold for this criteria)

This is intended to assess the extent to which the offer demonstrates a clear understanding of the assignment and project objectives covering all the aspects of the technical specifications.

The tenderer should:

- Describe how they propose to provide the services described in the technical specifications and to perform the work necessary for achieving the objectives requested in this open call;
- Demonstrate awareness regarding methods development, tools harmonisation, data consolidation and implementation of human health risk assessment of combined exposure to multiple chemicals, dietary and non-dietary, across EFSA's domains of activity;
- Demonstrate awareness of EFSA needs in the area of combined exposure to multiple chemicals into account the information in the theme paper (Annex 5) and in the tender specifications;
- Demonstrate that the proposal is within the scope of this Open Call.

2. METHODOLOGY PROPOSED FOR IMPLEMENTATION (max. 25 points - minimum threshold 60%, i.e. 15/25 to pass minimum quality threshold for this criterion)

The degree to which the proposed methodology shows that the tenderer has the capacity to implement his knowledge in the area of combined exposure to multiple chemicals, dietary and non-dietary, and regulatory chemical risk assessment in order to address the tasks underlined in the tender specifications. In particular **the tenderer should:**

- Provide a proper methodology for addressing all objectives and include convincing justification for the choice of the proposed methodology; **2 points**



- Specify and justify the selection of information sources such as databases and other resources proposed to gather the relevant information; **5 points**
- Provide details of the methods proposed to map activities, identify overlaps, knowledge gaps, challenges and blockers in relation to Objective 3, 4 and 5, and to perform the prioritization of working areas and possible partners; **5 points**
- Provide convincing evidence to ensure that the activities and milestones identified are feasible; **5 points**
- Describes the methods/tools to identify communication opportunities; **3 points**
- Provide a logical and well-structured step by step explanation of methodology; **5 points**

3. PROJECT MANAGEMENT AND ORGANISATION OF THE TASKS WITHIN PROJECT TEAM AND RESPECT OF TIMELINES (max. 20 points – minimum threshold 60% i.e. 12/20 to pass minimum quality threshold for this criterion)

This is to assess the extent to which the team set-up is suitable for the implementation of the assignment and to meet the agreed deadlines for deliverables. More specifically **the tenderer should provide:**

- Clear and detailed information on distribution of the tasks among the project team; in case of joint offer & subcontractors, clarity on who does what, when and why (justify why the partner/subcontractor is proposed to do the particular task/work-package); **5 points**
- Clarity of organization of project into work packages, including project phases, timelines, milestones, deliverables, providing a Gantt chart; **10 points**
- Clear and detailed information on the frequency and type of communication with EFSA and internal team communication (in case of joint offers & subcontractors also the frequency and type of communication between partners and/or subcontractor), the role of project leader in the coordination and tasks allocation in relation to the methodology and tools proposed. **5 points**

4. RISK MANAGEMENT (10 points - minimum threshold 60% i.e. 6/10 to pass minimum quality threshold for this criteria)

This is to assess the risk management awareness of the tenderer, in particular the ability to identify any potential risks to the achievement of the project objectives, assess risk impact & likelihood, and ability to foresee effective mitigating actions. **The tenderer should:**

- Identify risks associated with the proposed methodology, technical problems, and project management issues (e.g. measures to ensure meeting deadlines, and mitigation strategies for continuity of the service in case of absence of the member of the team) which might appear during the implementation of the assignment; **5 points**
- Propose risk mitigation actions and explain their likely effectiveness; **5 points**

5. MEASURES TO GUARANTEE QUALITY OF DELIVERABLES (10 points - minimum threshold 60% i.e. 6/10 to pass minimum quality threshold for this criteria)



This is to assess the quality assurance mechanisms put in place to guarantee the high quality of deliverables. **The tenderer should explain:**

- Role of team leader / leading partner in quality assurance; **5 points**
- Special additional measures for quality assurance proposed for this particular project; **5 points**

FOR ALL LOTS, the sum of all quality award criteria gives a maximum possible total of 100 points.

For each lot applied for, tenderers must provide a detailed technical offer addressing all points in the technical specifications and each of the quality award criteria. Repetition of mandatory requirements in the technical specifications without providing detail in the technical offer will only result in a very low score.

For each lot applied for, offers must score at least **60%** for each criterion, and at least **70%** of maximum possible total points against the quality award criteria.

Tenders that do not reach these minimum quality thresholds will be eliminated from subsequent stages of the evaluation process.

B) PRICE AWARD CRITERION FOR EACH LOT

Tenders which passed the quality thresholds will be further assessed to ensure:

- I. the price offer is made within the maximum budget for financial offers indicated in the tender specifications and;
- II. the financial offer satisfies the formal requirements of the tender specifications.

C) THE BEST PRICE-QUALITY RATIO FOR EACH LOT

Tenders for which financial offers were made within the maximum budget and satisfied the formal requirements indicated in the tender specification will be retained for the identification of the tender with the best price-quality ratio based on the following formula:

TOTAL SCORE OF THE EVALUATED OFFER (C) =

30 * Cheapest price offer/price of tender X

+

70 * Total quality score (out of 100) for all quality award criteria of tender X/100



PART 3 - HOW TO SUBMIT YOUR OFFER USING e-SUBMISSION

You must submit your tender electronically via the e-Submission application available from the e-Tendering website before the time limit for receipt of tenders.

The e-Submission application allows economic operators to respond to call for tenders by preparing their tenders electronically in a structured and secured way and submitting their tenders electronically. The e-Tendering is the starting point for launching the e-Submission application.

Make sure you submit your tender on time: you are advised to start completing your tender early. To avoid any complications with regard to late receipt/non-receipt of tenders within the deadline, please ensure that you submit your tender several hours before the deadline. A tender received after the deadline indicated in the procurement documents will be rejected.

Registration in the Participant Register

Any economic operator willing to submit a tender must be registered in the [Participant Register](#) - an online register of organisations and natural persons participating in European Commission's calls for tenders or proposals.

On registering each participant obtains a Participant Identification Code (PIC, 9 - digit number) which acts as its unique identifier in the Participant Register. A participant needs to register only once – the information provided can be further updated or re-used by the participant in other European Commission's calls for tenders or calls for proposals.

At any moment during the procurement procedure the Research Executive Agency Validation Services (hereafter *the EU Validation Services*) may contact the participant and ask for supporting documents on legal existence and status [and financial capacity].

The requests will be made through the register's messaging system to the e-mail address of the participant's contact person indicated in the register. It is the responsibility of the participant to provide a valid e-mail address and to check it regularly.

The documents that may be requested by *the EU Validation Services* are listed in the [EU Grants and Tenders Rules on Legal Entity Validation, LEAR appointment and Financial Capacity assessment](#).

Please note that a request for supporting documents by the *EU Validation Services* in no way implies that the tenderer has been successful.

How to Submit your Tender in e-Submission

You can access the e-Submission application via the corresponding call for tender in TED e-Tendering, as specified in the Invitation Letter.



In order to have access to e-Submission, you will need to "Subscribe to call for tenders" on TED e-Tendering first. To subscribe, you will need to login with your an [EU Login](#)³⁷. In case you don't have an [EU Login](#), you can [create an account](#) at any moment. For more information see the [EU login help](#). After logging in with your EU Login password, the e-Tendering will then display a button 'submit your tender' and you will be able to access the e-Submission.

The e-Submission "[quick guide for economic operators](#)" is available after logging in with your EU Login password.

Information to be filled in

In the e-Submission application, fill in and upload all necessary fields and documents as appropriate. All tenders must be clear, complete and consistent with all the requirements laid down in the tender specifications, including:

- **Signed declaration on Honour on Exclusion criteria.** All members of a joint tender, including subcontractors – if applicable – must upload the signed and dated declaration on honour on exclusion criteria using the template available [here](#).
- **Signed declaration on Honour on Selection criteria.** In case of a joint offer from a group of economic operators, such declaration should be completed by the leading partner using the template available [here](#).
- **Exclusion criteria.** If requested in the tender specifications, the tenderer and all members of a joint tender including subcontractors – if applicable – must provide the documentary evidence for exclusion criteria.
- **Selection criteria.** If requested in the tender specifications, the tenderer and all members of a joint tender including subcontractors – if applicable –, must provide the documentary evidence for selection criteria.
- **Technical tender.** It must address all the requirements laid down in the tender specifications.
- **Financial tender** The complete financial tender, including the breakdown of the price as provided in the tender specifications.

For detailed instructions on how to submit your tender, consult the Quick Reference Guide for Economic Operators where you will find:

- Technical requirements to use e-Submission
- Step-by-step guide to help you submit your tender
- Important advices and information on how to get technical support

Please make sure all required documents and evidence are submitted with your tender.

³⁷ Previously called European Commission authentication system (ECAS)



Documents to be signed and dated while creating your Tender

The following documents must be signed and dated during the creation of your tender in e-Submission:

- **Declaration on honour(s).** All members of a joint tender, including subcontractors must sign and date the declaration on Exclusion criteria. Only the leader in a joint tender must sign and date the declaration on Selection criteria. The declaration on honour(s) must be converted to PDF format and then signed by the authorised representatives with advanced electronic signature based on qualified certificates or by hand.

Re-submission of a tender

After submitting a tender, but within the time limit for receipt of tenders, you may still submit a new version of your tender. **If you submit a new Tender you must include all your Tender documents, including the Qualification and Tender documents.**

You must formally notify EFSA that the previous tender is withdrawn. The notification letter must be signed by the legal representative who signed the original tender stating the call reference and the Tender ID you wish to withdraw. The notification must be uploaded in e-submission together with the new version of all tender documents. You are kindly requested to also e-mail the notification letter to EFSAProcurement@efsa.europa.eu.

Withdrawal of tenders

If after submitting a tender, you wish to completely withdraw your tender, you must formally notify EFSA that you wish to withdraw your submitted Tender(s) as indicated above.

Alternative tender

You are entitled to send several tenders to one call for tenders.

Deadline for receipt of tenders

The tender (including all documents) must be fully uploaded and received before the deadline for receipt of tenders indicated in the invitation to tender.

Please note that you are responsible to ensure that your full tender reaches the destination in due time.

In case of problems with the submission of the electronic tender, we recommend that you call the helpdesk in reasonable time before the time limit for receipt. The time it takes to submit the tender and upload all your documents may vary considerably depending on the number of concurrent submissions by other economic operators, the size of your tender



and the type of internet service you are using. We recommend that you upload the documents the day before the deadline.

If the contracting authority detects technical faults in the functioning of the electronic equipment used for submitting and receiving tenders due to which it is impossible to electronically submit and receive tenders, you will be informed of the extension of the time limit by the contracting authority at the e-Tendering link.

For more information or technical support on e-Submission, please visit the [e-Submission help site](#).

Contact

- The original hand signed tender report must be scanned and sent by email immediately after submission, to the following address: EFSAProcurement@efsa.europa.eu.
- Notifications for re-submission or withdrawal of tenders must be sent to: EFSAProcurement@efsa.europa.eu

When communicating state the reference to the call for tenders and, if applicable, the Tender ID.



ANNEX 1 - FINANCIAL OFFER TEMPLATE FOR EACH LOT APPLIED FOR

Tenderers are requested to use this template for preparing their financial offer. **A separate financial offer should be completed and submitted for each lot applied for.** In doing so tenderers confirm they are aware of the following facts:

- As referred to in part 1.4, the maximum budget EFSA has available for this assignment is **500.000 €**. Any offer exceeding this maximum will not be retained for contract award.
- Prices must be quoted in Euro using the conversion rates published in the C series of the Official Journal of the European Union on the day when the invitation to tender was issued. This information is also available on the website of the European Central Bank at the following URL: <http://www.ecb.int/stats/eurofxref/>.
- Pursuant to the provisions of Article 9 of the Italian Law n. 17 dated 10/01/2006 and under Article 151 of Council Directive 2006/112/EC, EFSA is exempt from all duties, taxes and other charges, including VAT. For this reason, all prices given in the financial breakdown should be free of VAT and other taxes or duties.
- The price offered below is understood to be all-inclusive. For example, any additional costs which can be incurred by the contractor in performing the contract, such as overheads, travel, subsistence/accommodation expenses, etc. should also be factored into the all-inclusive price. In addition, if the deliverables incorporate pre-existing rights, the tenderer should factor into their total price the cost of licensing those pre-existing rights to EFSA.
- It is the responsibility of each tenderer to ensure that the total amount of the tender inserted in the relevant field of the e-Submission application corresponds to the amount indicated in the uploaded financial offer. In case of discrepancies, only the amount indicated in the financial offer will be taken into account.

<p>ALL INCLUSIVE TOTAL PRICE</p> <p>to be used for the evaluation and for contract implementation in the case of award.</p>	<p>..... €</p>
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Tenderer name:

Name of person signing the financial offer:

His/her position in the company:

His/her signature:

Date:



ANNEX 2 - DRAFT CONTRACT

The contract which results from this procurement procedure will be based on the model annexed to these tender specifications.