TENDER SPECIFICATIONS

Reference: OC/EFSA/ED/2021/01
Subject: Development of roadmaps for action on:
LOT 1 – Advancing the environmental risk assessment of chemicals for insect pollinators
LOT 2 – Applying OMICS and bioinformatics approaches: towards next generation risk assessment

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	05/10/2021	Date Contract Notice is sent to Official Journal
Deadline for sending request for clarification to EFSA	10/01/2022 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	12/01/2022	
"Receipt Time Limit" - Closing date and time for receipt of offers	**18/01/2022 at 14:30 (CET)**	Refer to the Invitation letter and part 3 of these tender specifications regarding how to submit your offer.
Opening session	19/01/2022 at 14:30 (CET)	Requests to attend the virtual opening session must be made 2 working days in advance of the opening session. Refer to Invitation letter for details.
Notification of evaluation results	Estimated March 2022	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 2022	

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

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. 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 relevant 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 environment (including biodiversity, ecosystems and ecosystem services) and health of plants and animals.

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 to allow 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 178/2002[2]) 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 Council[3]) 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

[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.

European 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 communicating science in a coordinated manner with larger EU and national 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 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 – for each scientific theme – provides 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 – for each scientific theme – provides a full understanding on e.g. ongoing activities, knowledge gaps, societal interests and concerns as well as collaboration opportunities and potential partners. Each roadmap must provide for EFSA and its partners a basis for prioritisation and decision making for high-value (> 1 million euro) and 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 2020, EFSA launched its first wave of scientific themes, for which the associated roadmaps are currently (2021) under development.[4] The scientific themes covered are:

- Building a European partnership for next generation, systems-based environmental risk assessment (PERA);
- New approach methodologies (NAMs) in risk assessment;
- Risk assessment of combined exposure to multiple chemicals (RACEMiC);
- Artificial intelligence (AI) in the evidence management phase of the risk assessment.

In line with EFSA's considerations on the future of science[5] and EFSA's 2027 strategic development[6], EFSA recently launched two additional scientific themes for 2021, for which roadmaps for action need to be developed in the frame of the present procurement. The additional scientific themes are:

[4] https://etendering.ted.europa.eu/cft/cft-display.html?cftId=7613
[5] Refer to https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.e170622
[6] Refer to https://www.efsa.europa.eu/en/corporate-pubs/efsa-strategy-2027-science-safe-food-sustainability

LOT 1 – Advancing the environmental risk assessment of chemicals for insect pollinators; LOT 2 – Applying OMICS and bioinformatics approaches: towards next generation risk assessment.

The technical offers submitted in response to this call for tenders shall take the directions provided in the respective theme papers into account (as provided in **Annexes 3-4**, respectively).

This call is based on EFSA's 2021 Work Programme for grants and operational procurements as presented in Annex IXa of the Programming Document 2021 – 2023, available on the EFSA's website[7].

1.2 OBJECTIVES AND DIVISION IN LOTS

The aim of this procurement procedure is to conclude on two 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 and multi-partner studies or projects for each lot (see below) building on EFSA´s vision (Annexes 3-4), 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 developmental areas;
- Identify data and methodological 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 and dissemination of information with EFSA's partners and other actors 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 two lots, these being:

LOT 1 – Advancing the environmental risk assessment of chemical pesticides for insect pollinators

LOT 2 –Applying OMICS and bioinformatics approaches: towards next generation risk assessment

As a tenderer, you may submit an offer for one or the two lots, but the offer should indicate clearly for which lot you are applying. In case you decide to apply for both 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.

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

OBJECTIVES FOR LOT 1

- **Development of roadmap for advancing the environmental risk assessment of chemical pesticides for insect pollinators**

The **main objective** of the roadmap for action for this lot is to identify recent relevant research and risk assessment developments that might need consideration when conducting environmental risk assessments (ERAs) **of chemical pesticides** for insect pollinators.
The roadmap also has to identify relevant ERA development needs for insect pollinators that require additional research input. This information must be relevant for consolidating, updating and harmonising methodologies for the ERA of chemical pesticides for insect pollinators, and for developing and implementing a systems-based approach for the ERA for insect pollinators.

The development of this roadmap for action will need to consider the work being done under:

- The development of a roadmap for action on **'Building of a European partnership for next generation, systems-based ERA (PERA)**[8] (please refer to **Annex 8** for the theme paper on PERA)
- The development of the EU Bee Partnership Platform[9]
- EFSA Bee guidance and its ongoing revision[10,11]

A key action of the EFSA strategy 2021-2027 (EFSA, 2021[12]) is to refine regulatory ERAs by developing and implementing a systems-based approach for the ERA of regulated products, including chemical pesticide, under EFSA's remit (see theme papers for more details). EFSA has already put together a framework for the development of a systems-based approach for honey bees (EFSA SC Panel, 2021[13]). This approach is based on interlinking monitoring data and modelling methods for the risk assessment of chemical pesticides, considered alone or in combination with other stressors; this approach can be used for pre- and post-market authorisations of plant protection products (PPPs).. This approach, while being developed for honey bees, could in principle also be considered for use in other insect pollinators and organisms.

For the development of the roadmap for action for this lot 1, the following objectives are to be specifically considered, and these should be read alongside the theme paper 'Advancing the Environmental Risk Assessment of Chemicals to Better Protect Insect Pollinators (IPol-ERA)' (see **Annex 3**).

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

Objective 1: Develop a protocol for project implementation

[8] The roadmap for action on PERA started to be developed in 2021 and the final roadmap is expected in March 2022. Further information on this roadmaps will be made available to the contractor for this roadmap during the kick off meeting of the project.
[9] https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2021.EN-6694
[10] https://www.efsa.europa.eu/en/news/guidance-bees-and-pesticides-work-plan-published
[11] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2013.3295
[12] https://www.efsa.europa.eu/sites/default/files/2021-07/efsa-strategy-2027.pdf
[13] https://www.efsa.europa.eu/en/efsajournal/pub/6607

Provide a protocol that outlines:

i. The problem formulation (i.e. what the project aims to address) and possible refinements of the problem formulation;
ii. Which methods will be used for addressing the problem (i.e. how the project will be carried out and according to which timelines). This part of the protocol would also include 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).

The contractor must follow EFSA's Draft framework for protocol development for EFSA' scientific assessments[14] for the development of the protocol.

Objective 2: Map relevant activities and organisations for a joint IPol-ERA partnership, for advancing the ERA for chemical pesticides for insect pollinators and to transition to a next generation systems-based ERA for insect pollinators

i. Map all relevant organisations that could be part of a joint IPoL-ERA partnership, as well as ongoing and planned activities related to the subject matter of the current project (including research projects and innovation programmes, associated timelines, and organisations responsible for/involved in these projects/programmes) at national, European and international levels. 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, Horizon 2020, Horizon 2020-funded European Green Deal Calls, the EU Bee Partnership, EU Partnership for the Assessment of Risks from Chemicals (PARC), the European co-funded Partnership on Biodiversity (BiodivERsA), as well as international organisations (e.g. U.S. EPA, OECD, etc. see Annex 3), and potential relevant projects being conducted in academic institutions. The mapping of activities should be done in close communication and cooperation with EFSA's Insect Pollinator Cluster[15].

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, Horizon 2020 and Horizon Europe, etc.);

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

i. Identify any additional and relevant specific objective(s) and/or risk assessment development area(s), other than those already included in the theme paper, necessary to advance the ERA of chemicals pesticides for insect pollinators. Provide a clear justification on their relevance by taking the vision/opportunities into account as outlined in the theme paper (**Annex 3**) and investigate and provide proposals on how they can be developed;

ii. Identify any additional element/s that is/are needed within each of the risk assessment development areas identified in the theme paper (i.e. scientific

[14] https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2020.EN-1843

[15] EFSA's Insect Pollinator Custer is being developed and planned to be established by the time the contractor starts with the work for this roadmap.

development and/or implementation of specific policies) and investigate and provide proposals on how they can be developed;

iii. Identify relevant discontinuities and knowledge gaps with a clear justification on their relevance to reach the desired vision, and impact for EFSA, by 2030;

iv. Perform an analysis of the relevance and added value of the development areas that are listed in the theme paper as well as the additional ones identified (see Objective 3i, above) to achieve EFSA's vision as defined in the theme paper (Annex 3);

v. Explore complementarities with the MUST-B project[16], the EU Bee Partnership and the ongoing revision of the EFSA's Bee guidance[17,18], as well as national and international relevant projects and activities.

Objective 4: Identify challenges and blockers

i. Identify potential challenges and blockers for advancing the ERA of chemical pesticides for insect pollinators and for implementing a systems-based ERA approach, based on the outcomes of Objective 2 and 3;

ii. Assess the impact of challenges and blockers (see Objective 4.i, above) for the implementation of EFSA's vision as defined in the theme paper (Annex 3);

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 advancing the ERA of chemical pesticides for insect pollinators as defined under Objective 1 (also see EFSA's Draft framework for protocol development for EFSA' scientific assessments[14]), and provide recommendations for integrating identified gaps (e.g. risk assessment development areas).

Objective 5: Assess 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 those already outlined in the theme paper and any additional potential partner(s);

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 the outcomes of Objectives 1 to 4 above;

16 https://www.efsa.europa.eu/fr/efsajournal/pub/6607
17 https://www.efsa.europa.eu/en/news/guidance-bees-and-pesticides-work-plan-published
18 https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2013.3295

ii. From the outcomes of 6i.) prioritise/rank working areas based on new EU policy targets (in terms of the Green Deal and associated strategies and action plans), development needs, and opportunities identified in previous Objectives;

iii. 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[19] designated by EU Member States to assist EFSA with tasks within the field of its mission;

iv. 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 on multi-annual, multi-partner studies or projects, each supported by a SWOT or equivalent analysis.

Objective 7: Identify communication opportunities

i. Identify opportunities for communication and dissemination of information with EFSA's partners and other actors. This could include communication plans targeting risk managers, researchers and the public, highlighting the benefits/opportunities in the area of ERA of chemical pesticides for insect pollinators This would use 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 for applying OMICS and bioinformatics approaches: towards next generation risk assessment

The **main objective** of the roadmap for action for this lot is to define EFSA priorities for the wide integration of omics and associated bioinformatics approaches in food regulatory science (by 2030) to support the transition into next generation risk assessment. Advancing in this theme will also promote the implementation of the EFSA 2021-2027 strategy[12] (key actions under Expected Operational Result 2.1.3)

For the development of the roadmap for action for this lot 2, the following specific objectives are to be specifically considered, and these should be read alongside the theme paper 'Application of OMICS and BIOINFORMATICS Approaches: Towards Next Generation Risk Assessment' (**Annex 4**).

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

Objective 1: Develop a protocol for project implementation

Provide a protocol that outlines:

[19] Refer to https://efsa.force.com/competentorganisations/s/

i. The problem formulation (i.e. what the project aims to address) and possible refinements of the problem formulation;
ii. Which methods will be used for addressing the problem (i.e. how the project will be carried out and according to which timelines). This part of the protocol would also include 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).

The contractor must follow EFSA's Draft framework for protocol development for EFSA' scientific assessments[14] for the development of the protocol.

Objective 2: Map relevant activities and organisations for the application of Omics and associated bioinformatics in regulatory assessments

i. Map all relevant ongoing and planned activities related to the use of Omics and/or related bioinformatics in regulatory assessments (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. 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, Horizon 2020, Horizon 2020-funded European Green Deal Calls, the EU Partnership for the Assessment of Risks from Chemicals (PARC), as well as international and third Countries organisations (e.g. U.S. US FDA OECD, WHO, Health Canada, etc. see **Annex 4**), and potential relevant projects being conducted in academic institutions, especially concerning larger academic initiatives or consortia (as for example the Public Health Alliance for Genomic Epidemiology).

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, ECDC etc.) and relevant EU institutions and their work programmes (e.g. the JRC, Horizon 2020 and Horizon Europe, etc.);

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

i. Identify any additional and relevant specific objective(s) and/or risk assessment development area(s), other than those already included in the theme paper, necessary to advance the use of omics and associated bioinformatics approaches in food risk assessments. Provide a clear justification on their relevance by taking the vision/opportunities into account as outlined in the theme paper (**Annex 4**) and investigate and provide proposals on how they can be developed;

ii. Identify any additional element/s that is/are needed within each of the risk assessment development areas identified in the theme paper (i.e. scientific development and/or implementation of specific policies) and investigate and provide proposals on how they can be developed;

iii. Identify relevant discontinuities and knowledge gaps with a clear justification on their relevance to reach the desired vision and impact for EFSA, by 2030;

iv. Perform an analysis of the relevance and added value of the development 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 complementarities with national and international relevant projects and activities.

Objective 4: Identifying challenges and blockers

i. Identify potential challenges and blockers for advancing the application of omics and associated bioinformatic approaches to support the transition into next generation risk assessments 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 4**);

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 results in a revised problem formulation for the application of omics and associated bioinformatic approaches to support the transition into next generation risk assessments as defined under Objective 1 (also see EFSA's Draft framework for protocol development for EFSA' scientific assessments[1414]), and provide recommendations for integrating the identified gaps (e.g. risk assessment development 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 those already outlined in the theme paper and any additional potential partner(s);

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 the outcomes of Objectives 1 to 4 above;

ii. From the outcomes of 6i.) prioritise/rank working areas based on new EU policy targets (in terms of the Green Deal and associated strategies and action plans), development needs, and opportunities identified in previous Objectives;

iii. Prioritise/rank key opportunities and possible partners based on the outcomes of Objective 5 above; Consider also the Article 36 list of competent organisations[19] dedicated by Member States to assist EFSA with tasks within the field of its mission;

iv. 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 and dissemination of information with EFSA's partners and other actors. This could include communication plans targeting risk managers, researchers and the public, highlighting the benefits/opportunities in the area of Omics and Bioinformatics approaches in the food safety risk assessment. This would use 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.

1.3 TASKS, DELIVERABLES, TIMELINE AND PAYMENTS

TASKS AND DELIVERABLES FOR LOT 1

- **Development of a roadmap for action for advancing the environmental risk assessment of chemical pesticides for insect pollinators**

No.	Tasks & deliverables	Can be subcontracted?[1][8]	Deadline
1	**Task:** Prepare an inception report that includes: a. A problem formulation and possible refinements of the problem formulation, as described above in Section 1.2 (lot 1). b. A project implementation protocol for refining the workplan and 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/consulted 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. The contractor will receive the following documents at the latest at the kick-off meeting. The contractor shall consider these documents when addressing all objectives: - comments received through a consultation with EFSA's partners and other stakeholders on the	Yes	Within 1 month from kick-off meeting

	theme paper (Annex 3). - Information on the PERA roadmap and relevant Bee guidance documents **Deliverable 1:** 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. 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.		
2	**Task:** Prepare a report (interim report #1) containing: a. Findings/results of **Objective 2** as well as data sources, as described above in Section 1.2 (lot 1). **Deliverable 2:** Interim report #1 describing execution and results of Objective 2 and 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 agreed changes at the interim meeting #2 will be submitted at the latest 15 days after the interim meeting #2.	Yes	Within 2.5 months from kick-off meeting
3	**Task:** Prepare a report (interim report #2) containing: 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. **Deliverable 3:** Interim report #2 describing points a) and b) 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 agreed changes at the interim meeting #3 will be submitted at the latest 15 days after the interim meeting #3.	Yes	Within 4 months from kick-off meeting
4	**Task:** 1) Prepare a report (Interim report #3) containing:	Yes	Within 5 months from kick-off

	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. **Deliverable 4:** Interim report #3 describing points a) to c) 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.		meeting
5	**Task:** Prepare a complete draft roadmap report containing: 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)**.** c. an overview of the literature data consulted to date, and a summary of the outcome and conclusions from interviews and surveys conducted. d. 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. **Deliverable 5:** a) 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	Yes	Within 6 months from kick-off meeting

	report and in the interim reports #1, #2 and #3 and updated according to the agreements in interim meetings. The draft roadmap shall be submitted in English in both MS-Word and Adobe Acrobat (PDF) format with the charts in MS-Excel. b) Draft presentation of approximately 20 slides. The presentation shall be submitted in English in both MS-PowerPoint and Adobe Acrobat (PDF) format. 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.		
6	**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. 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. **Deliverable 6:** 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). The roadmap shall be submitted in English in both MS-Word and Adobe Acrobat (PDF) format with the charts in MS-Excel.	Yes	Within 7 months from kick-off meeting
7	**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). **Deliverable 7**: a) A presentation of approximately 20 slides The presentation shall be submitted in English in both MS-PowerPoint and Adobe Acrobat (PDF) format. b) A recorded presentation (video file).	Yes	Within 7 months from kick-off meeting
No.	**Meetings**		**Deadline for finalisation**
The contractor is responsible for organising the meetings and taking minutes using the appropriate EFSA template of every meeting held with EFSA and for sending them to EFSA within 5 working days after the meeting, for revision and agreement. The minutes must be approved by EFSA to be considered as agreed.			

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.

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.

1	Kick-off meeting: via teleconference – one day[20] The purpose of the kick-off meeting is to: • 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; During this meeting, in addition to operational implementation, the administrative and financial matters related to contract implementation will be discussed.	Within 2 weeks after entry into force of contract
2	Interim meeting #1: via teleconference – half day The purpose of the meeting is to discuss/review the inception report.	Within 1.5 months from kick-off meeting
3	Interim meeting #2: via teleconference - half day The purpose of the meeting is to discuss/review the interim roadmap report #1	Within 3 months from kick-off meeting
4	Interim meeting #3: via teleconference - half day The purpose of the meeting is to discuss/review the interim roadmap 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 draft roadmap 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 mont hs 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.	Within 8 months from kick off meeting

No.	Payments	Linked to EFSA approval of deliverable No.
1	Interim payment of 40%	1,2,3
2	Payment of the balance of 60%	4,5 a) and

[20] One day = 8 hours, half day = 4 hours

		b),6,7 a) and b)

Summary of deliverables and timeline	Deadline for finalisation
Kick off meeting	Within 2 weeks after entry into force of contract
Inception report	Within 1 month from kick-off meeting
Interim meeting 1	Within 1.5 months from kick-off meeting
Interim report #1	Within 2.5 months from kick-off meeting
Interim meeting 2	Within 3 months from kick-off meeting
Interim report #2	Within 4 months from kick-off meeting
Interim meeting 3	Within 4.5 months from kick-off meeting
Interim report #3	Within 5 months from kick-off meeting
Interim meeting 4	Within 5.5 months from kick-off meeting
Draft complete roadmap report	Within 6 months from kick-off meeting
Interim meeting 5	Within 6.5 months from kick-off meeting
Final complete report - including executive summary, presentation slides	Within 7 months from kick-off meeting
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.

TASKS AND DELIVERABLES FOR LOT 2
Development of a roadmap for action for applying OMICS and bioinformatics approaches: towards next generation risk assessment

No.	Tasks & deliverables	Can be subcontracted?[18]	Deadline
1	**Task:** Prepare an inception report that includes: a. A problem formulation and possible refinements of the problem formulation, as described above in Section 1.2 (lot 2). b. A project implementation protocol for refining the workplan and 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	Yes	Within 1 month from kick-off meeting

	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/consulted 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. The contractor will receive the following documents below at the latest at the kick-off meeting. The contractor shall consider these documents when addressing all objectives: -comments received through a consultation with EFSA's partners and other stakeholders on the theme paper (Annex 4). **Deliverable 1:** 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. 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.		
2	**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 2). **Deliverable 2:** Interim report #1 describing execution and results of Objective 2 and 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 agreed changes at the interim meeting #2 will be submitted at the latest 15 days after the interim meeting #2.	Yes	Within 2.5 months from kick-off meeting
3	**Task:** Prepare a report (interim report #2) containing: 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.	Yes	Within 4 months from kick-off meeting

	b. the findings/results for **Objectives 3 and 4**, as described above in Section 1.2 (lot 2), integrated with the revised version of the findings/results for Objective 2. This should include a justified proposal for a revised problem-formulation. **Deliverable 3:** Interim report #2 describing points a) and b) 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 agreed changes at the interim meeting #3 will be submitted at the latest 15 days after the interim meeting #3.		
4	**Task:** 1) Prepare a report (Interim report #3) containing: 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 2) with a justified proposal for prioritisation of work areas and activities and possible partners as described in **Objective 6** of Section 1.2 (lot 2). 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. **Deliverable 4:** Interim report #3 describing points a) to c) 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.	Yes	Within 5 months from kick-off meeting

5	**Task:** Prepare a complete draft roadmap report containing: 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 2)**.** c) an overview of the literature data consulted to date, and a summary of the outcome and conclusions from interviews and surveys conducted. d) 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. **Deliverable 5:** a) 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 . The draft roadmap shall be submitted in English in both MS-Word and Adobe Acrobat (PDF) format with the charts in MS-Excel. b) Draft presentation of approximately 20 slides. The presentation shall be submitted in English in both MS-PowerPoint and Adobe Acrobat (PDF) format. 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.		Within 6 months from kick-off meeting
6	**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.	Yes	Within 7 months from kick-off meeting

	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. **Deliverable 6:** 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). The roadmap shall be submitted in English in both MS-Word and Adobe Acrobat (PDF) format with the charts in MS-Excel.		
7	**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). **Deliverable 7**: a) A presentation of approximately 20 slides The presentation shall be submitted in English in both MS-PowerPoint and Adobe Acrobat (PDF) format. b) A recorded presentation (video file).	Yes	Within 7 months from kick-off meeting

No.	Meetings	Deadline for finalisation
The contractor is responsible for organising the meetings and taking minutes using the appropriate EFSA template of every meeting held with EFSA and for sending them to EFSA within 5 working days after the meeting, for revision and agreement. The minutes must be approved by EFSA to be considered as agreed. 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. 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.		
1	Kick-off meeting: via teleconference – one day[20] The purpose of the kick-off meeting is to: • 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; During this meeting, in addition to operational implementation, the administrative and financial matters related to contract implementation will be discussed.	Within 2 weeks after entry into force of contract

2	Interim meeting #1: via teleconference – half day The purpose of the meeting is to discuss/review the inception report.	Within 1.5 months from kick-off meeting
3	Interim meeting #2: via teleconference - half day The purpose of the meeting is to discuss/review the interim roadmap report #1	Within 3 months from kick-off meeting
4	Interim meeting #3: via teleconference - half day The purpose of the meeting is to discuss/review the interim roadmap 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 draft roadmap 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.	Within 8 months from kick off meeting
No.	**Payments**	**Linked to EFSA approval of deliverable No.**
1	Interim payment 1 of 40%	1, 2, 3
2	Payment of the balance of 60%	4,5 a) and b),6,7 a) and b)

Summary of deliverables and timeline	Deadline for finalisation
Kick off meeting	Within 2 weeks after entry into force of contract
Inception report	Within 1 month from kick-off meeting
Interim meeting 1	Within 1.5 months from kick-off meeting
Interim report #1	Within 2.5 months from kick-off meeting
Interim meeting 2	Within 3 months from kick-off meeting
Interim report #2	Within 4 months from kick-off meeting
Interim meeting 3	Within 4.5 months from kick-off meeting
Interim report #3	Within 5 months from kick-off meeting
Interim meeting 4	Within 5.5 months from kick-off meeting
Draft complete roadmap report	Within 6 months from kick-off meeting

Interim meeting 5	Within 6.5 months from kick-off meeting
Final complete report - including executive summary, presentation slides	Within 7 months from kick-off meeting
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.

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 €

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

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[21] 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 PROTECTION AND CONFIDENTIALITY

Processing of personal data in the context of this contract shall comply with Regulation (EU) 2018/1725 ('the EDPR')[22]. The EDPR constitutes the specific data protection legal framework applicable to EU institutions, bodies, offices and agencies, including EFSA and is aligned with the rules and principles under the General Data Protection Regulation (EU) 2016/679 (GDPR), applicable in the European Union.
In terms of the EDPR, EFSA acts as the controller for processing of personal data under the contract and the selected contractor, any consortium partner and subcontractor, as the processor or sub-processor.

[21] http://www.efsa.europa.eu/en/press/news/190117 and https://zenodo.org/communities/efsa-kj/?page=1&size=20
[22] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32018R1725

Processing of personal data by EFSA as contracting authority (controller)
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 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 (processor/sub-processor)
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

Tender bids will be treated confidentially in accordance with the case law of the European Courts, which confirms the existence of a presumption of non-disclosure in case of a request for public access to documents in accordance with Regulation (EC) No 1049/2001. This does not prevent that specific parts of the submitted tender may be subject to disclosure when applicable law so requires. Unless there is an overriding public interest in disclosure, EFSA will refuse full access to the submitted tender, redacting the parts that contain confidential information, the disclosure of which would undermine the protection of commercial interests and intellectual property of the tenderer.
Accordingly, EFSA will disregard general statements that the whole tender or substantial parts thereof are confidential information. Tenderers need to mark clearly the specific parts of their tender bid they consider confidential providing an explanation why the information should not be disclosed, which may be subject to EFSA's further assessment in accordance with applicable law.

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 300,000 € in each of the last 3 closed financial years (2020, 2019 and 2018).

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

Advancing the environmental risk assessment of chemical pesticides for insect pollinators

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

a. Extensive and demonstrable experience in:

- Entomology;
- Ecology;
- Regulatory requirements and methodological aspects pertaining to the ERA of chemical pesticides;
- Development of roadmaps or other types of similar strategic documents (e.g. prioritising research needs);
- Performing consultation and engagement activities (especially, the design and conduct of interviews and surveys);

- Collecting, collating and managing data related to the subject matter of the contract; handling large amounts of information, research and work programmes; and scientific reporting;
- 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 6** experts to ensure that the deadlines of the deliverables and quality of the outputs will be met and will be compliant with these specific expertise requirements below:

- **1) 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 ERA of chemicals. 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. The expert shall work and liaise with ensuring the coherence for the overall work and must be in charge of overseeing the delivered service, client orientation and conflict resolution. The expert 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;

- **2) 1 expert** with at least 7 years of subject matter expertise in entomology/ ecology applied to insect pollinators and some experience on ERA methodologies, and at least 2 years of experience in regulatory work with the European Union or international public organisations;

- **3) 1 expert** with at least 7 years of work experience in systems thinking/theory/integrated systems-based approaches (e.g., applied to environmental assessments) and at least 1 year of experience in regulatory work with the European Union or international public organisations;

- **4) 1 expert** with at least 5 years of work experience in using social research methods and tools to gather, analyse and report findings of primary and secondary research (e.g. market research, literature reviews using interviews, surveys, focus groups or another mix of qualitative/quantitative methods). Experience in applying the above to inform communication and engagement activities is required. If such experience is not available within the same profile, an expert with at least 3 years of experience in applying findings from social research to communication and engagement activities is to be added to the team.
- **5) 1 junior expert** with at least 2 years of work experience in ERA methodologies for chemical pesticides of including ecotoxicology;
- **6) 1 junior expert** in ecology with at least 2 years of work experience with terrestrial arthropods.

c. The senior and experts project team members must have individually a very good level of spoken and written standard UK English. For non-native English speakers , the knowledge of English shall be demonstrated by: extensive

experience (minimum five years) in international projects or consortia where English is the working language OR evidence demonstrating active participation at conferences and meetings in English OR at least three years of work/study in an English speaking environment OR an official certificate of English proving at least a C1 level OR at least 5 publications written in English;

2. The tenderer must have the following **minimum technical capacity** to perform the contract:

d. 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 database[23]; EU regional policy programmes[24]; P2P network database[25]; LIFE projects[26]);

e. 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

Applying Omics and bioinformatics approaches: towards next generation risk assessment

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

a. extensive and demonstrable experience in:
- The development and application of omics and bioinformatics methodologies;
- Knowledge on the use of Omics and bioinformatics data/results for the risk assessment in the public health or food and feed areas;
- In depth knowledge on current developments on omics and bioinformatics at EU and international levels;
- Development of roadmaps or other types of similar strategic documents (e.g. prioritising research needs);
- Performing consultation and engagement activities (in particular the design and conduct of interviews and surveys);
- Collecting, collating and managing data related to the subject matter of the contract; handling large amounts of information, research and work programmes; and scientific reporting;
- 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.

b. Ability to provide a team of at **least 6** experts to ensure that the deadlines of the deliverables will be met and will be compliant with these specific expertise requirements below:

- **1) 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 or

[23] Refer to https://cordis.europa.eu/projects/en;
[24] Refer to https://ec.europa.eu/regional_policy/en/projects
[25] Refer to https://www.era-learn.eu/network-information/networks
[26] Refer to https://ec.europa.eu/environment/life/project/Projects/index.cfm

food/feed 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. The expert 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. The expert 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;

- **2) 1 expert** with at least 7 years of expertise in the development and application of omics and bioinformatics approaches for risk assessment in the area of public health or food/feed safety and at least 2 years of experience in regulatory work with European Union or international public organisations;
- **3) 1 expert** with at least 7 years of practical work experience in the design and execution of omics-based studies for regulatory assessments and at least 2 years of experience in regulatory work with European Union or international public organisations;
- **4) 1 expert** with at least 5 years of work experience in bioinformatics methodologies, familiar with bioinformatic 'Big Data' extraction, integration, analysis and design and harmonisation of templates for data collection;
- **5) 1 expert** with at least 5 years of work experience in using social research methods and tools to gather, analyse and report findings of primary and secondary research (e.g. market research, literature reviews using interviews, surveys, focus groups or another mix of qualitative/quantitative methods). Experience in applying the above to inform communication and engagement activities is required. If such experience is not available within the same profile, an expert with at least 3 years of experience in applying findings from social research to communication and engagement activities is to be added to the team.
- **6) 1 junior expert** with at least 2 years of work experience in omics and/or bioinformatics methodologies.

c. The senior and experts project team members must have individually a very good level of spoken and written standard UK English. For non-native English speakers , the knowledge of English shall be demonstrated by: extensive experience (minimum five years) in international projects or consortia where English is the working language OR evidence demonstrating active participation at conferences and meetings in English OR at least three years of work/study in an English speaking environment OR an official certificate of English proving at least a C1 level OR at least 5 publications written in English;

2. The tenderer must have the following **minimum technical capacity** to perform the contract:

d. 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 database[23]; EU regional policy programmes[24]; P2P network database[26]; LIFE projects[26]);

e. 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 in the offer:

Evidence requested from the tenderers for each lot applied for:

Requirement a): A list of all relevant activities/experience and details on at least three major projects or publications to support the required extensive and demonstrable experience, and carried out in the course of the past 5 years by the proposed members of the Project team (Annex 5a for Lot 1 and Annex 5b for Lot 2);
Requirements b) and c): 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; Tenderers should also provide a one page summary of the names of the individual Project Team members and fill in the table indicating the name of the expert proposed for each of the profiles outlined above, in the technical and professional capacity section (Annex 6a for Lot 1 and Annex 6b for Lot 2).
Requirement c): an official certificate of English proving at least a C1 level, where applicable
Requirement d) and e): A list of available tools and resources (Annex 7a for Lot 1 and Annex 7b for Lot 2) and a signed statement confirming access to the relevant databases under requirement d) and specifying the name of the databases and disposal of an architecture for digital collaboration under requirement e).
□ **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 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/EU[27] and compliance with data protection obligations resulting from Regulation (EU) 2016/679 and Regulation (EU) 2018/1725[28].

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

[27] OJ L 94 of 28.03.2014, p. 65

[28] 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

QUALITY AWARD CRITERIA FOR LOT 1: Development of roadmap for action on Advancing the ERA of chemical pesticides for insect pollinators

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 perform the work necessary for achieving the objectives requested in this Open Call;
- Demonstrate awareness regarding the risk assessment methodologies for insect pollinators in the EU and internationally, and current situation in the regulatory context;
- Demonstrate awareness of EFSA needs in the area of the ERA of chemicals for insect pollinators taking into account the information in the theme paper (Annex 3) and 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 an appropriate methodology for addressing all objectives and include convincing justification for the choice of the proposed methodology **max.5 points**
- Specify and justify the selection of information sources such as databases and other resources proposed to gather the relevant information; **max.3 points**
- Provide details of the methods proposed to map activities, identify overlaps, knowledge gaps, challenges and blockers in relation to Objectives 3, 4 and 5, and to perform the prioritization of working areas and possible partners in relation to Objective 6; **max.5 points**
- Provide convincing evidence to ensure that the activities and milestones identified are feasible; **max.4 points**
- Describe the methods/tools to identify communication and dissemination of information opportunities; **max.3 points**
- Provide a logical and well-structured step by step explanation of methodology; **max.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. **The tenderer should:**

- Provide a 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); **max.5 points**
- Provide clarity of organisation of the project into work packages, including project phases, timelines, milestones, deliverables, providing a Gantt chart; **max.10 points**
- Provide 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; **max.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; **max.5 points**
- Propose risk mitigation actions and explain their likely effectiveness; **max.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 the role of team leader / leading partner in quality assurance; **max.5 points**
- Special additional measures for quality assurance proposed for this particular project; language quality check. **max.5 points**

QUALITY AWARD CRITERIA FOR LOT 2: Development of roadmap for action for applying Omics and bioinformatics: towards next generation 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 application of omics and associated bioinformatics approaches and current situation regarding their use in the regulatory context;
- Demonstrate awareness of EFSA needs in the area of using Omics and associated bioinformatics approaches for food and feed assessments 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 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 an appropriate methodology for addressing all objectives and include convincing justification for the choice of the proposed methodology **max.5 points**
- Specify and justify the selection of information sources such as databases and other resources proposed to gather the relevant information; **max.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 in relation Objective 6; **max.5 points**
- Provide convincing evidence to ensure that the activities and milestones identified are feasible; **max.4 points**
- Describe the methods/tools to identify communication and dissemination of information opportunities **max.3 points**
- Provide a logical and well-structured step by step explanation of methodology; **max.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. **The tenderer should:**

- Provide a 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); **max.5 points**
- Provide clarity of organisation of the project into work packages, including project phases, timelines, milestones, deliverables, providing a Gantt chart; **max.10 points**
- Provide 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; **max.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; **max.5 points**
- Propose risk mitigation actions and explain their likely effectiveness; **max.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 the role of team leader / leading partner in quality assurance; **max.5 points**
- Special additional measures for quality assurance proposed for this particular project; language quality check. **max.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

Tenders which passed the quality threshold 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

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:

WEIGHTED 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. It is not possible to submit a tender through eSubmission after the time-limit for receipt of tenders indicated in the contract notice and/or the TED eTendering website.

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[29]. 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*.**

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:

[29] Previously called European Commission authentication system (ECAS)

- **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.

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. It is not possible to submit a tender through eSubmission after the time-limit for receipt of tenders indicated in the contract notice and/or the TED eTendering website.

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.

Contact

-
- 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

Tenderers are requested to use this template for preparing their financial offer for each of the lots. 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. Tenderers from countries outside the euro zone have to quote their prices in euro. The price quoted may not be revised in line with exchange rate movements. It is for the tenderer to bear the risks or the benefits deriving from any variation.
- 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 in to 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.

ALL INCLUSIVE TOTAL PRICE **to be used for the evaluation and for contract implementation in the case of award.**	..... €

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.

ANNEX 3 – LOT 1 THEME PAPER

Science Studies and Project Identification & Development Office (SPIDO)

Disclaimer: This document does not present a future theme as part of EFSA´s work programme, or any future position of EFSA. It aims to support the development of future themes and its content can be subject to change.

Theme (concept) paper

Advancing the Environmental Risk Assessment of Chemicals to Better Protect Insect Pollinators (IPol-ERA)

1. Vision

By 2030, the methodology followed for the environmental risk assessment of chemicals across EFSA's activities will be further advanced to better safeguard the protection of insect pollinators (including wild and managed pollinators), their diversity, ecological functions and ecosystem services they provide, including pollination.

2. Background

In the frame of the **Farm to Fork Strategy**[30], one of the main priorities of the European Commission is to reduce by 50% the overall use of – and risk from – chemical pesticides by 2030, especially for the most hazardous ones. This policy priority, along with those outlined in the **European Green Deal**[31] (in particular by its **EU Biodiversity Strategy**[32] **-** and **EU Pollinators Initiative**[33] **- and the EU Chemicals Strategy for Sustainability**[34] emphasising the vital role of pollinators for healthy ecosystems and food security), highlight the necessity to reverse their decline and activate all levers to protect biodiversity and the particularly vulnerable ecosystems.

The EU Biodiversity Strategy also aims to bring back at least 10% of agricultural area under high-diversity landscape features to provide space for wild animals, plants, pollinators and natural pest regulators. These areas will play the role of compensatory areas in agro-ecosystems that should not be subject to any chemical

[30] https://ec.europa.eu/food/farm2fork_en
[31] https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en
[32] https://ec.europa.eu/environment/strategy-offline/biodiversity-strategy-2030_en
[33] https://ec.europa.eu/environment/nature/conservation/species/pollinators/policy_en.htm
[34] https://ec.europa.eu/environment/strategy/chemicals-strategy_en

application/exposure. In addition, the **EU Pollinators Initiative**[35] objectives state that **by 2030** scientific knowledge about the magnitude, causes and consequences of **insect pollinator** decline will have improved, that the main known causes of this decline will be addressed and managed, and societal awareness and collaboration amongst stakeholders strengthened.

In the first instance, EFSA will prioritise the work for pesticides, with subsequent integration of the tools and methodologies developed to other relevant chemicals. Prioritisation of other chemicals will also be developed building on the experience gained in the area of pesticides.

This stepwise progress will be all the stronger due to the support and cooperation accompanying this ambition from interested partners, such as the European Commission and Parliament, Member States, stakeholders and other agencies of the European Parliament's ENVI committee.

3. Scope and objectives

EFSA's project on advancing the environmental risk assessment for insect pollinators (IPoL-ERA), with the cooperation of interested ENVI agencies and the support of the Joint Research Centre (JRC), intends to take a series of actions to support the European Commission's ambition in reducing pesticide risk/use, promoting environmentally safer alternatives to control agricultural pests and diseases, safeguarding the protection of insect pollinators and in assessing the role of landscape reservoir (such as insect pollinator refuges) to mitigate risks to insect pollinators.

The **overarching objective** is to contribute to the further advancement of the environmental risk assessment of chemicals (such as plant protection products, biocides, veterinary drugs, fertilisers) for insect pollinators, in order to address current risk assessment challenges and ensure preparedness for future challenges.

Specific emphasis (**specific objectives**) will be put on:

1. The consolidation, update and harmonisation of risk assessment methodologies by considering their possible alignment across sectorial legislative frameworks, in close coordination with the outcome of the roadmap for action on "Building a European Partnership for next generation systems based environmental risk assessment" (PERA)[36];
2. The consideration of more context-dependent (i.e. characteristics of receiving environments) and real-world scenarios;
3. The development and implementation of a systems-based approach for IPol-ERA;
4. The promotion of data/expertise sharing and multidisciplinary collaborations through partnerships.

The **initial focus** will be on **chemical pesticides**, as the further advancement of IPol-ERA for this group of chemicals is key in supporting the European Commission's mission to reduce the overall risk/use of pesticides and safeguarding the protection of insect pollinators.

[35] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52018SC0302R(01)&from=EN

[36] The roadmap for action on the project 'Building a European Partnership for next generation systems based environmental risk assessment' (PERA) will be completed in March 2022

EFSA's IPoL-ERA will be informed by and complement other relevant EFSA theme papers and associated activities/projects:

- Building of a European partnership for next generation, systems-based ERA (PERA);
- New approach methodologies (NAMs) in risk assessment;
- Risk assessment of combined exposure to multiple chemicals (RACEMiC).

4. Risk assessment development areas

The further advancement of insect pollinator environmental risk assessments will require the implementation of a portfolio of activities clustered in **development areas**. Currently, the six following interrelated risk assessment development areas are proposed for further consideration and action:

1. Engaging towards a joint IPol-ERA partnership

This development area aims to:

- Broaden the scope of the EU Bee Partnership (EUBP) currently focused on honey bees to insect pollinators, and involve new relevant partners to build an IPol-ERA partnership at EU level for data and expertise sharing on insect pollinators;
- Build linkages with relevant and complementary partnerships (e.g. One Health platform, EU Partnership for the Assessment of Risk from Chemicals [PARC], EU Partnership for Biodiversity [BiodivERsA] and PERA);
- Support the setting of research priorities for developing environmental risk assessment methodologies in line with IPol-ERA objectives (e.g. through the establishment of an EU steering network composed of Member States, stakeholders, EFSA, EU ENVI agencies and scientists from ongoing relevant research projects);
- Address risk assessment issues (e.g. through the establishment of a scientific expert Working Group with expertise in the environmental risk assessment of chemicals for insect pollinators, as well as other required technical expertise in biology and ecology, as needed).

Note that the IPol-ERA partnership will feed the risk assessment development areas for insect pollinators listed below, where relevant, and will be integrated in PERA.

2. Assessing ecological consequences of chemical effects on insect pollinators

This development area will increase the knowledge about chemical effects on insect pollinators and their impacts on ecosystems (including ecological traits of species and ecosystem structure and functions). The improved knowledge will provide the scientific basis to support the definition of specific protection goals.

- Determine the impact of chemical effects on insect pollinators and the ecosystems (i.e. pollination function, genetic resources, food chain structure) they contribute to, both in relation to the normal operating range of insect pollinator populations in EU ecosystems and to the effects caused by the chemicals they are exposed to;

- Describe the options for specific protection goals in line with the EFSA method for supporting risk managers in their decision making processes[37,38]
- Define quantitative links between effect levels of chemicals and their impacts, at population and community levels, in EU ecosystems for the various options for specific protection goals.
- Explore the possibility to develop qualitative and quantitative Adverse Outcome Pathways (AOPs) to extrapolate across multiple levels of biological organisation.

3. Advancing hazard and exposure characterisation

This development area has the objective of increasing knowledge about exposure scenarios in terms of where insect pollinators are exposed in ecosystems, the type of exposure (e.g. contact, dietary, sources of exposure), as well as about the types of adverse effects (e.g. acute, chronic, sub-lethal).

- Generate and collect data on chemical effects on insect pollinators (acute, chronic and sub-lethal toxicity, toxicokinetics and toxicodynamics (TK/TD), field effect data including potential for recovery);
- Determine interspecies sensitivity by e.g. analysing literature data, performing experimental work, considering models;
- Explore new and alternative approaches/methods for hazard assessment (e.g. *in silico* tools to predict chemical toxicity: read-across methods, [quantitative] structure-activity relationship [Q]SAR models, biologically-based models [such as kinetic-dynamic and dynamic energy budget models], ecological structure activity relationships (ECOSAR) predictive models and OMICs) and assess their relevance and reliability for regulatory purposes; test them against current approaches using relevant test case studies; promote their regulatory uptake and use; and make these approaches/methods available to all through existing relevant open-source databases (such as EFSA's chemicals hazard database, the OpenFoodTox[39]);
- Generate and collect data on routes and sources of chemical exposure to insect pollinators (by reviewing relevant information reported in databases, dossiers and scientific literature, and liaising with relevant scientific expert groups, when needed) and develop/refine methods for exposure estimation;
- Investigate the role of the different sources and routes of exposure (contact and dietary); in particular, investigate the relevance of the exposure via contaminated soil for insect pollinators (e.g. most solitary bees are ground nesting).

4. Advancing risk assessment of combined exposure to multiple chemicals in insect pollinators

This development area will target the development and implementation of risk assessment approaches to address combined hazard/exposure to multiple chemicals with the following high-level activities:

- Prioritise, develop and implement methodologies for hazard characterisation of multiple chemicals in insect pollinators considering combined toxicity for acute, chronic and sublethal effects (concentration-addition, response-addition and interactions);

[37] https://www.efsa.europa.eu/en/efsajournal/pub/1821
[38] https://www.efsa.europa.eu/en/efsajournal/pub/4499
[39] https://zenodo.org/record/4740174#.YO_25OgzbD4

- Prioritise, develop and implement methodologies for exposure assessment (environmental fate, occurrence of multiple chemicals);
- Support the development and implementation of fit-for-purpose monitoring programmes/activities. This would include the improvement of analytical methods by expanding the number of pesticide residues analysed and by improving their analytical limits (detection and quantification limits) in various relevant matrices;
- Prioritise, develop and implement harmonised methodologies for risk characterisation that enable consideration of combined exposure to multiple chemicals.

5. Developing landscape scale population level based environmental risk assessment tools that account for environmental stressors

This development area aims to advance the development of spatially and temporally explicit tools in support of landscape scale population level based IPol-ERA that also account for environmental stressors. The following high-level activities are proposed:

- Develop spatially- and temporally-explicit tools (e.g. population models) to consider adverse effects associated with chemical exposure at higher levels of biological organisation (population, community, ecosystem) and the relevant spatio-temporal scales;
- Assess the importance of landscape features/heterogeneity/connectivity, type of management of local fields, spatial and temporal population dynamics, and recovery potential of insect pollinators at a landscape scale;
- Develop methodologies to assess indirect effects on insect pollinators (e.g. reduced beneficial weeds/host plants, shelter, food sources) due to herbicide usage at a landscape scale;
- Ensure the calibration, testing and validation (e.g. plausibility check of model predictions) of new tools;
- Consider the complex of environmental stressors (such as competition between managed and wild bees, biological agents, resources and abiotic factors such as climate/weather land structure, invasive alien species) that can potentially impact insect pollinators and assess their relevance for insect pollinator risk assessment.

6. Developing and implementing a systems-based approach and promoting its use and uptake in a regulatory context

This development area will build on previous development areas and integrate their outcomes to contribute to the development of a more holistic environmental risk assessment framework for insect pollinators that follows systems-based approaches. Hence, the objective is the implementation of holistic and integrated risk assessment tools and methodologies and make them operational for use in a regulatory context.

The following high-level activities are proposed:

- Develop approaches to facilitate the integration of empirical data (e.g. landscape features), risk assessment tools and methodologies (including fit-for-purpose modelling, risk assessment of combined exposure to multiple chemicals) and monitoring/surveillance[40];

[40] https://www.efsa.europa.eu/en/consultations/call/public-consultation-draft-efsa-scientific-committee-opinion-1

- Develop tools for the integration of environmental monitoring, surveillance and pesticide data in prospective insect pollinator risk assessments;
- Integrate in the ERA risk indicators to monitor the health of insect pollinators in agro-ecosystems;
- Develop user-friendly tools (e.g. IT integrated support systems) for use by risk assessors, risk managers, applicants and other stakeholders for addressing their respective needs (e.g. regulatory assessment, consideration of risk mitigation measures, alternative options for pest management, best agricultural practices, etc.);
- Build capacity in the use of the new tools/approaches and their future implementation.

5. Opportunities

- Develop an EU-level approach/network for environmental monitoring for insect pollinators;
- Identify emerging insect pollinator risk assessment needs, and bridge risk assessment gaps;
- Co-develop and implement innovative/complementary tools and methods for insect pollinator risk assessments;
- Advance and harmonise insect pollinator risk assessments, across regulatory silos;
- Adapt existing models/simulations or build new ones to understand colony effects on honeybees (and bumblebees) and population effects of solitary species and other insect pollinators;
- Move beyond honey bees as a model species, not only including bumblebees but also solitary bees and other taxa of insect pollinators in regulatory risk assessments;
- Identify, prioritise and promote research and innovation needs for insect pollinator risk assessments, and align research and innovation in insect pollinator risk assessments with EU/national Research & Innovation investments to improve coherence and reduce overlap between national and EU funding in ERA research;
- Address new policy targets, the 'one substance – one assessment' concept[41], and societal needs;
- Identify elements to improve best management practices to reduce impact on biodiversity and pollinators.
- Strengthen cooperation opportunities with other EU institutions working on pollinator activities and with relevant Horizon 2020 research projects.

6. Cooperation

Developing IPoL-ERA will help strengthen the cooperation to share and promote knowledge, expertise, methods and data (to minimize redundancies in data generation, collection, analysis and technology transfer) with interested and relevant national

[41] https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/EFSA-ECHA-position-paper-OSOA.pdf

institutions, EU Agencies and EU institutions (e.g. ECHA, EEA, EMA, JRC) and international partners (e.g. the US EPA, and other non-EU regulatory partners).

A stronger interagency and international cooperation will also strengthen the reliability and transparency of insect pollinator risk assessments, prevent duplication of efforts and enhance effective dialogue between risk assessors and managers, and other relevant partners at European, national and regional level, while building public trust.

With the incorporation of research findings from research projects developed in support of IPoL-ERA into regulatory guidance, EFSA will support decision and policy makers in identifying and implementing key elements of the EU Green Deal. To achieve this goal, a close cooperation with key European players is needed, such as with DG JRC, ECHA, EEA and EU Member States to ensure key research areas are identified and EU Biodiversity Strategy targets are adequately addressed and can be successfully delivered (such as reducing harmful pesticides by 50%, increasing biodiversity-rich landscape features on agricultural land and halting and reversing the decline of insect pollinators).

In addition, close follow up of the work and planned deliveries for the Horizon 2020-funded European Green Deal Calls, in particular those covering area 6: Farm to fork, area 7: Biodiversity and ecosystems and area 8: Zero-pollution, toxic-free environments, will be needed to ensure synergies and avoid duplication of efforts. Close cooperation with partners and stakeholders (e.g., beekeepers and their networks, nature conservation sector and civil society organisations) is also needed to identify additional priorities and complementarity of research work, e.g. with the EU Bee Partnership[42], EU Partnership for the Assessment of Risks from Chemicals [PARC][43] and the European co-funded Partnership on Biodiversity [BiodivERsA][44]and other future Horizon Europe Cluster 6 research projects.

7. Impact for EFSA and partners

- Increases preparedness for more comprehensive environmental risk assessments; using new tools and methodologies to better characterise the impact of chemicals to non-target insect pollinators;
- Enhances future networking and cooperation opportunities with partners in the Commission (JRC) and EU agencies (such as EEA, ECHA and EMA);
- Promotes the development of an updated risk assessment paradigm, with further interagency cooperation on the development and implementation of a systems-based environmental risk assessment for regulated substances/compounds or products;
- Strengthens the position of EFSA as an important partner for the development of methodologies to characterise the impact of chemicals present in agro-ecosystems to insect pollinators, at EU level and also internationally;
- Demonstrates EFSA's awareness to societal interests, increasing and reinforcing its visibility and commitment to environmental protection and preventing biodiversity loss;

[42] https://www.efsa.europa.eu/en/supporting/pub/en-1423
[43] https://ec.europa.eu/info/sites/default/files/research_and_innovation/funding/documents/ec_rtd_he-partnerships-chemical-risk-assessment.pdf
[44] https://www.biodiversa.org/1759

- Facilitates contributions from national competent authorities, EU Member States international partners, stakeholders and the scientific community for transparent and informed discussions and developments in the area of advancing the environmental risk assessment for insect pollinators.

ANNEX 4 – LOT 2 THEME PAPER

Science Studies and Project Identification & Development Office (SPIDO)

Disclaimer: This document does not present a future theme as part of EFSA´s work programme, or any future position of EFSA. It aims to support the development of future themes and its content can be subject to change.

Theme (concept) paper

Application of OMICS and BIOINFORMATICS Approaches: Towards Next Generation Risk Assessment

1. Vision

By 2030, it is expected that EFSA will routinely apply omics and associated bioinformatic approaches in relevant risk assessments (RAs), allowing for an enhanced food chain analytics and strengthen the utilisation of data. This will support the transition into a next generation food safety RA that will be leaner, automated and based on the mechanisms behind adverse effects, greatly enhancing our ability to assess food/feed-related hazards and risks.

2. Background

As outlined in the EU **Farm to Fork Strategy**[45], the use of innovative technologies in regulatory science is critical to transition to sustainable food systems. Innovative and evolving technologies/methods such as some of the omics-based approaches (e.g. genomics and associated bioinformatic tools, as explained below in section 3) are

[45] https://ec.europa.eu/food/farm2fork_en

increasingly applied in regulatory science, whereas several others (e.g. transcriptomics, proteomics, metagenomics, epigenomics, metabolomics, exposomics) have hardly been exploited in a regulatory context. Building on existing knowledge such as the conclusions from the 2015 Global Summit on Regulatory Science ("Regulatory bioinformatics")[46] and the 2018 EFSA colloquium on omics, these technologies have the potential to produce new evidence for next generation food/feed risk assessments and contribute to EFSA's preparedness for the future in providing fit for purpose scientific advice.

A clear example of successfully implementing omics in RA is the use of genomics data from whole genome sequencing (WGS). WGS data are used for outbreak investigations and antimicrobial resistance (AMR) monitoring legislation,[47] and WGS data requirements are included in EFSA risk guidance documents, e.g. for microorganisms used as feed additives or as production organisms,[48] and microorganisms used for the production of food enzymes.[49] The implementation of other omics technologies (e.g. metabolomics, proteomics, epigenomics) will help to shift away from only using traditional tests (such as descriptive toxicity assays or compositional analysis of food and feed), and capitalize on the understanding of mechanisms behind adverse effects or changes in composition (e.g. in novel foods or future generations synthetic biology products). However, a number of challenges and uncertainties are known regarding the harmonization and wide incorporation of several omics and associated bioinformatics approaches in routine RAs, including establishing and applying fit for purpose validated quality assurance systems/procedures. These challenges are mainly on (i) data generation (including quality and reproducibility); (ii) data collection and storage (; (iii) implementation of robust bioinformatic analytical tools and their validation; (iv) implementation of the FAIR principles for data;[50] (v) interpretation of the results building confidence in regulation. Developing a theme on the application of omics and associated bioinformatics tools in RA will address the mapping of omics case studies of relevance to EFSA to better understand the current and future challenges, promote the consolidation of these technologies in regulatory science and help build the needed confidence for wide implementation while addressing important knowledge gaps.

3. Scope and objectives

EFSA, in cooperation with other European and international institutions, intends to advance on the use of omics and associated bioinformatics approaches to support the transition into next generation risk assessments. Within the context of this theme paper, omics refers to the experimental approaches for collective characterisation and quantification of biological data as a whole for risk assessment purposes, while bioinformatics refers to the methods and software tools to collect, store, process, analyse, mine, and integrate omics or other types of qualitative and quantitative biological datasets (e.g. clinical data, low-throughput molecular assays, other models such as IVIVE – in vitro/in vivo extrapolation, epidemiological data).

The **overarching objective** is to promote and widely integrate these approaches in food regulatory science to deliver more fit for purpose and faster scientific advice providing

[46] https://www.sciencedirect.com/science/article/pii/S0273230016301349
[47] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020D1729&from=EN
[48] https://www.efsa.europa.eu/en/efsajournal/pub/5206
[49] https://www.efsa.europa.eu/en/efsajournal/pub/5741
[50] https://www.nature.com/articles/sdata201618

risk assessors with the necessary knowledge and tools to effectively address current RA challenges and ensure preparedness for future ones.
At this stage, it is highly desired to establish some proof of concepts to identify ways on how to apply omics and bioinformatics as standard approaches in risk assessment.

Specific objectives include:

5. The increased capability to produce more precise and comprehensive mechanism-based scientific advice;
6. The consolidation of omics and associated bioinformatic approaches in RA processes across several EFSA scientific domains;
7. Exploitation of new high throughput methodologies and large amounts of publicly available big data to address RA knowledge gaps;
8. The promotion of engagement with stakeholders and applicants by the application of RA methodologies using common and agreed open-source/open-access bioinformatic tools;
9. The facilitation of collaborations for data/expertise sharing through partnerships.

4. Risk assessment development areas

The potential of applying omics and associated bioinformatic approaches is transversal to many of EFSA's scientific domains, which prompts for a broad set of RA development areas (possible working areas) that are complementary to those defined in the theme on New Approach Methodologies (NAMs) prioritised in 2020 for the use omics in chemical RAs as an alternative approach to animal tests. While some of the following possible working areas rely more on omics and some others on bioinformatics, most of them require an interplay of the two.
Possible working areas to be covered are:

1. **Support the creation, curation and usage of publicly available omics data repositories as pillars to support a mechanistic-based risk assessment**
   Promote the development and usage of databases containing omics data (e.g. toxicogenomics databases, genomic databases, gene expression databases, proteomics databases or metabolomics databases) to enrich and improve different aspects of the food safety assessment, such as:
   - Faster and more comprehensive RA of plants, microorganisms, innovative/novel foods, etc.
   - Aiding the prompt identification and characterisation of compounds that could constitute emerging risks[51]
   - Adding a new layer of evidence in EFSA scientific opinions which in turn will improve the quality of scientific outputs

2. **Improving and facilitating the use of genomics and whole genome sequence analysis**

[51] An *emerging* risk is defined by EFSA as: "a risk resulting from a newly identified *hazard* to which a significant *exposure* may occur, or from an unexpected new or increased significant exposure and/or susceptibility to a known hazard."

- In currently applied areas (e.g. AMR and virulence analysis in regulated products, outbreak investigation, AMR monitoring)
- Extend its use to other regulatory areas (e.g. animal/plant health), determination of sensitivity/susceptibility of specific groups) by filling data and methodological gaps

3. Incorporating metagenomics into RA in areas relevant for animal, human and environmental health such as:

- Impact of contaminants/pesticides on biodiversity (i.e. bacterial soil communities)
- Safety assessment of foods and chemicals that might have an influence on the human microbiome (e.g. food/feed additives and innovative/novel foods)
- Detection, monitoring and surveillance of microorganisms and genetic traits (e.g. AMR, pathogens)

4. Incorporating other omics technologies (epigenomics, transcriptomics, metabolomics, proteomics) for e.g.:

- Improved and high-throughput characterisation of protein adverse effects like toxicity and allergenicity (including proteins from novel sources)
- More comprehensive safety assessment of complex GMOs (e.g. microorganisms and plants) such as those obtained through future generation synthetic biology approaches
- Enhanced assessment and characterisation of food and feed, including safety of consumption, nutritional properties and intake biomarkers.
- Support the development of on-site omics tests (field kits), based on biomarkers, to increase quantitative data collection
- Develop methodologies for integrated analysis of multiple omics datasets to strengthen the base of evidence.

5. Facilitating the transition into a more holistic food exposure assessment using the exposomics approach and associated bioinformatic tools e.g. using metabolomics:

- To check for mass consumption of specific metabolites in wastewater samples
- On blood samples to quantitatively assess food exposure
- For the identification of novel biomarkers for the mass screening of contaminants, nutrients, exposures

5. Opportunities

- **Contribute to the wide incorporation of omics and bioinformatics into RA processes and to the transition into next generation food RA**

  Several upcoming European and International projects will be focused on the incorporation of omics and bioinformatics into RA processes. For example, the ASPIS research cluster under Horizon 2020 and Horizon Europe's PARC sets, among other activities, to establish the state-of-the-art baseline for the use of omics in toxicological risk assessment. Likewise, the SAFFI China-EU project sets to discover unexpected contaminants using omics and bioinformatics approaches. EFSA, in synergy with these large-scale activities can contribute towards the common goal of transitioning towards next generation food RA. Importantly, EFSA considers the future research developments in this very fast-

evolving field as opportunities which will be promptly translated into RA methodologies.

- **Exploit the big data in publicly available databases and build new collaborations**

  Many public sector initiatives in Europe, America or Asia started already five to ten years ago to consolidate 'big data' gathered from high-throughput approaches such as omics into structured, publicly available databases. The exploitation of these databases, not extensively used by EFSA so far, will lead to the build-up of new collaborations with the actors involved in the curation and maintenance of these databases, opening new interesting opportunities for further developments.

- **Provide open-source/open-access bioinformatic tools/pipelines for data analysis to streamline and lean the entire RA process**

  Use of such tools/pipelines can contribute to reduce the needs of resources from regulatory bodies and applicants and can also act as a 'glue' facilitating the engagement, constructive dialogue and efficient use of standardised methodologies between industry, academia and regulatory bodies.

- **Benefit from the remarkable progress achieved in fields other than toxicology and exposure**

  For instance, the *Human Cell Atlas* initiative[52] aims to profile each different cell of the human body through single cell sequencing. This initiative was born from and is promoted by the community of developmental and cancer biology. However, the data of the human cell atlas can be used to enhance e.g. *in silico* toxicological predictions for food RA.

- **Take advantage of and align with EFSA activities in artificial intelligence (AI) and New Approach Methodologies (NAMs)**

  In 2020 EFSA prioritized the AI and NAM themes. These two themes can work in synergy with the omics and bioinformatics theme, complementing and learning from each other's gains and achievements. Developing these three themes not as isolated efforts but as a joint action can maximise the overall accomplishments.

6. Cooperation

Developing the theme on omics and bioinformatics will strengthen cooperation (through reinforcement of existing collaborations or creation of new ones) with key actors in Europe and internationally such as with Members states (MS), EC (e.g. DG JRC), other EU agencies (e.g. ECHA, ECDC, EMA) as well as with relevant international organisations (e.g. OECD, WHO, OIE, FAO, PHA4GE) and Third countries' regulatory bodies such as EFTA countries, Canada (Health Canada and CFIA), China (CFSA), Japan (FSCJ), USA (EPA and FDA, USDA) etc to, for instance, co-develop case studies for establishing proof of concepts for the use of omics and bioinformatics in chemical risk assessments to build confidence in regulation. Such collaborations will prevent duplication of efforts, facilitate

[52] https://www.humancellatlas.org/

the sharing of knowledge and expertise as well as help setting up platforms for common use of data, methods and tools, all contributing towards enhancing public trust.

For WGS, different ongoing collaborations under the 'One Health' approach can be strengthened, e.g. i) for outbreak investigations: collaborating with MSs, EURLs, ECDC and international stakeholders (including FDA) for improving systems interoperability and data sharing; ii) for AMR: working with the 'MSs-zoonoses Network' and the EURL-AR for the implementation of the new AMR Monitoring Legislation; different activities on AMR surveillance, RA, etc., are being planned; and a stronger collaboration with the JRC could be stablished. New collaborations could be established in the future with WHO, who are also supporting the use of WGS for AMR. There is clearly potential for establishing further cooperation, e.g. expanding the use of metagenomics for AMR that is a field in which FDA has several activities on-going. In general, collaboration could be established with other leading institutions in the field of genomics.

Similar cooperation could be established with EU agencies (in conjunction with Member States) that also have activities in the area of omics and bioinformatics; e.g. the exploration of omics approaches is fundamental for human health risk assessments carried out by ECHA and it is defined as a main objective in EMA's 2025 strategy to support developments of human medicines (e.g. biomarkers identification using omics approaches). In addition, existing collaborations with international organisations can be further enhanced such as the one with the OECD on the reporting of omics data from various sources or with the FDA for microbial contaminant detection.[53,54]

The integration of omics data and methods in the food and feed regulatory science framework across different domains will support risk managers and decision makers in the implementation of central EU strategies such as the Farm to Fork strategy as well as international initiatives such as the WHO Strategy on Global Food Safety. For example, through the exploration of omics data for an accelerated safety and nutritional value assessment of aquaculture products or future generation synthetic biology products in the context of building sustainable food systems.

Important cooperation opportunities can also be exploited through the follow up of ongoing and planned research project activities relevant for several work areas within EFSA's remit to identify additional priorities and ensure complementarity and avoid potential duplication of activities while enabling EFSA to become a key contributor in such activities. For example, Horizon 2020-funded work on the use of omics for healthy diets (e.g. in preventive personalised nutrition which also addresses societal concerns for improved nutrition[55]), for facilitating the identification, targeting and conservation of biodiversity "hot-spots" in the land and oceans in the context of the European Green Deal[56] or the EU Partnership for the Assessment of Risks from Chemicals [PARC][57]

7. Impact for EFSA and partners

- Produces new evidence for next generation RAs to enhance the quality of scientific guidance and RA methodologies

[53] https://www.accessdata.fda.gov/scripts/fdatrack/view/track_project.cfm?program=cfsan&id=CFSAN-OARSA-Sequencing-based-analytical-methods-for-microbial-contaminant-detection

[55] https://preventomics.eu/

[56] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/bg-02-2018

[57] https://ec.europa.eu/info/sites/default/files/research_and_innovation/funding/documents/ec_rtd_he-partnerships-chemical-risk-assessment.pdf

- Increases capability to address future challenges such as the assessment of complex, novel products into the food chain requiring more holistic safety evaluations
- Positions EFSA as an important partner in the global efforts to implement omics and bioinformatics as standard approaches in risk assessment, through establishing proof of concepts and standards in data analysis and interpretation
- Utilises omics and bioinformatic tools in food/feed RAs that have the necessary qualities (e.g. reliable, generating reproducible results, standardised, fit for purpose) to be effectively used in RA
- Increases capability to produce more precise and comprehensive, fit for purpose and faster scientific advice allowing for a mechanistic-based assessment of adverse effects
- Enables the use of -yet largely unexploited- massive amounts of publicly available 'big datasets' in RAs to address knowledge gaps
- Promotes engagement with stakeholders and applicants by the application of RA methodologies using common and agreed open-source/open-access bioinformatic tools (e.g. bioinformatic analytical pipelines)
- Prompts for the development of centralised infrastructures to store and analyse omics data

ANNEX 5. MINIMUM PROFESSIONAL CAPACITY

Annex 5.a: LOT 1 Advancing the environmental risk assessment of chemicals for insect pollinators

List of projects and publications* covering the requirement under 1.a.	
Entomology	
Ecology	
Regulatory requirements and methodological aspects pertaining to the ERA of chemical pesticides	
Development of roadmaps or other types of similar strategic documents (e.g. prioritising research needs)	
Performing consultation and engagement activities (especially, the design and conduct of interviews and surveys)	
Collecting, collating and managing data related to the subject matter of the contract; handling large amounts of information, research and work programmes; and scientific reporting	
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	

*Note= the same project/publication can be listed to demonstrate several requirements. A minimum of three projects/publications is required.

ANNEX 5. b: LOT 2 Applying OMICS and bioinformatics approaches: towards next generation risk assessment

List of at projects and publications* covering the requirement under 2.a.	
The development and application of omics and bioinformatics methodologies	
Knowledge on the use of Omics and bioinformatics data/results for the risk assessment in the public health or food and feed areas	
In depth knowledge on current developments on omics and bioinformatics at EU and international levels	

Development of roadmaps or other types of similar strategic documents (e.g. prioritising research needs)	
Performing consultation and engagement activities (in particular the design and conduct of interviews and surveys)	
Collecting, collating and managing data related to the subject matter of the contract; handling large amounts of information, research and work programmes; and scientific reporting	
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	

*Note= the same project/publication can be listed to demonstrate several requirements. A minimum of three projects/publications is required.

ANNEX 6 – EXPERTISE OF THE PROPOSED TEAM

Annex 6.a: LOT 1 Advancing the environmental risk assessment of chemicals for insect pollinators

Expert profile	Expert's name (add link to CV)	English level*	Other
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 ERA of chemicals. 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. The expert shall work and liaise with ensuring the coherence for the overall work and must be in charge of overseeing the delivered service, client orientation and conflict resolution. The expert 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 expert with at least 7 years of subject matter expertise in entomology/ ecology applied to insect pollinators and some experience on ERA methodologies, and at least 2 years of experience in regulatory work with the European Union or international public organisations.			
1 expert with at least 7 years of work experience in systems thinking/theory/integrated systems-based approaches (e.g., applied to environmental assessments) and at least 1 year of experience in regulatory work with the European Union or international public organisations.			
1 expert with at least 5 years of work experience in using social research methods and tools to gather, analyse and report findings of primary and secondary research (e.g. market research, literature reviews using interviews, surveys, focus groups or another mix of qualitative/quantitative			

methods). Experience in applying the above to inform communication and engagement activities is required. If such experience is not available within the same profile, an expert with at least 3 years of experience in applying findings from social research to communication and engagement activities is to be added to the team.			
1 junior expert with at least 2 years of work experience in ERA methodologies for chemical pesticides of including ecotoxicology.			
1 junior expert in ecology with at least 2 years of work experience with terrestrial arthropods.			

*For non-native English speakers assigned as senior or experts project team members, the knowledge of English shall be demonstrated by: extensive experience (minimum five years) in international projects or consortia where English is the working language OR evidence demonstrating active participation at conferences and meetings in English OR at least three years of work/study in an English speaking environment OR an official certificate of English proving at least a C1 level OR at least 5 publications written in English showing the necessary language skills. This information has to be available from the expert's CV.

ANNEX 6. b: LOT 2 Applying OMICS and bioinformatics approaches: towards next generation risk assessment

Expert profile	**Expert's name** (add link to CV)	**English level***	**Other**
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 or food/feed 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. The expert 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. The expert 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 expert with at least 7 years of expertise in the development and application of omics and bioinformatics approaches for risk assessment in the area of public health or food/feed safety and at least 2 years of experience in regulatory work with European Union or international public organisations.			
• **1 expert** with at least 7 years of practical work experience in the design and execution of omics-based studies for regulatory assessments and at least 2 years of experience in regulatory work with European Union or international public organisations.			
1 expert with at least 5 years of work experience in bioinformatics methodologies, familiar with bioinformatic 'Big Data' extraction, integration, analysis and design and harmonisation of templates for data collection.			
1 expert with at least 5 years of work experience in using social research methods and tools to gather, analyse and report findings of primary and secondary research (e.g. market research, literature reviews using interviews, surveys, focus groups or another mix of qualitative/quantitative methods). Experience in applying the above to inform communication and engagement activities is required. If such experience is not available within the same profile, an expert with at least 3 years of experience in applying findings from social research to communication and engagement activities is to be added to the team.			
1 junior expert with at least 2 years of work experience in omics and/or bioinformatics methodologies.			

*For non-native English speakers assigned as senior or experts project team members, the knowledge of English shall be demonstrated by: extensive experience (minimum five years) in international projects or consortia where English is the working language OR evidence demonstrating active participation at conferences and meetings in English OR at least three years of work/study in an English speaking environment OR an official certificate of English proving at least a C1 level OR at least 5 publications written in English showing the necessary language skills. This information has to be available from the expert's CV.

ANNEX 7 TOOLS AND RESOURCES

ANNEX 7. a: LOT 1 Advancing the environmental risk assessment of chemicals for insect pollinators

List of available tools and resources

ANNEX 7. b: LOT 2 Applying OMICS and bioinformatics approaches: towards next generation risk assessment

List of available tools and resources

ANNEX 8 – THEME PAPER IN SUPPORT OF THE DEVELOPMENT OF A ROADMAP FOR ACTION FOR 'BUILDING A BUILDING A EUROPEAN PARTNERSHIP FOR NEXT GENERATION, SYSTEMS-BASED ENVIRONMENTAL RISK ASSESSMENT'

Science Studies and Project Identification & Development Office (SPIDO)

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Theme (concept) paper – Building a European Partnership for next generation, systems-based Environmental Risk Assessment

Revised theme paper in light of the comments received from the European Commission (DG SANTE), ENVI Agencies, EU Member States and EFSA's Scientific Committee members in the phases 1 & 2 of EFSA's consultation process

Vision:

By 2022, the European Partnership for Environmental Risk Assessment (PERA) has:

- Brought together partners of relevant sectors across regulatory silos and improved the **cooperation** on regulatory environmental risk assessment (ERA) between these partners.

By 2030, PERA has:

- Facilitated the transition to next generation, systems-based ERA through the co-development of new and complementary **tools** and **methods**, and the sharing of **data** (including their findability, accessibility, interoperability, and reuse) and **expertise**.

Background:

In line with sectoral legal requirements, the ERA of regulated products (such as biocides, chemicals, pesticides, pharmaceuticals, feed additives and genetically modified organisms) is typically performed on a single substance/compound or product basis, for a specific type of use, in the European Union (EU). While the EU has made substantial progress on achieving environmental protection with the exiting ERA paradigm, frameworks for the ERA of single substances/compounds or products are increasingly challenged by the scientific community and society. Such frameworks are claimed to have fallen out of step with **scientific knowledge** and **progress**.[58] Moreover, they are not always in line with new policy

[58] E.g. https://science.sciencemag.org/content/367/6476/360

targets[59] and society needs[60] that demand for **more sustainable solutions** to protect the environment.

In addition, environmental policies in different sectors have developed independently and at different times, and are implemented by different institutions, leading to inconsistencies between different regulatory frameworks and potential policy gaps. For regulatory ERAs this fragmentation can lead to **inconsistencies** in assessments and decisions across regulated substances/compounds or products.

Today's regulatory ERAs call for a **systems-based approach** that formulate ERA issues/problems and associated protection goals holistically; address the cumulative effects of multiple regulated substances/compounds or products and stressors; analyse upstream and downstream life-cycle implications; evaluate a range of alternative solutions; involve a broad range of stakeholders; and use interdisciplinary scientific approaches. This approach would improve the scientific basis for regulatory ERA and decision-making, create opportunities for new partnerships and enhance cooperation across regulatory silos[61].

Considering the broad array of regulatory ERAs performed under different sectoral regulatory frameworks, there are many commonalities (e.g. hazard assessment, common parameters) for which a more coherent and harmonised approach would be beneficial when characterising environmental risks. Also, next generation ERAs should be designed in a manner that facilitate their integration in EU environmental impact and sustainability assessments, and policy assessments performed by relevant partners in the context of other regulatory frameworks/policies.

Scope and objectives:

The purpose of **PERA** is to provide an overarching platform that:

- Facilitates the transition to next generation, systems-based ERA that addresses new policy targets and society needs;
- Connects relevant partners (e.g. national competent authorities/agencies, EU Member States, EU Agencies, Commission Services, policy makers, risk managers, risk assessors, scientific community and civil society) from various sectors, across regulatory silos, and improves cooperation between these partners;
- Accelerates the development of new/complementary tools and methods, and the uptake of innovative tools and methods for regulatory ERA;
- Promotes and facilitates the sharing of data (including their findability, accessibility, interoperability and reuse) and expertise, and the establishment of a EU-wide cross-disciplinary network of risk assessors and risk managers (e.g. community of practice);
- Improves efficiency and transparency.
- Overcomes the challenges of a fragmented regulatory/policy landscape.

With the instigation of PERA, the "virtual centre of excellence" and platform for the ERA of regulated substances/compounds or products, as suggested by the Scientific Advice Mechanism (SAM) of the Group of Chief Scientific Advisors in 2018 for pesticides[62], will be implemented.

Working areas:

[59] E.g. EU Green Deal covering the farm to fork strategy for sustainable food, the chemical strategy for sustainability, the biodiversity strategy, the zero pollution action plan, the circular economy action plan, and the soil thematic strategy

[60] E.g. children striking over climate change, people of Europe demanding for more sustainable food systems

[61] https://ehp.niehs.nih.gov/doi/10.1289/EHP1465

[62] https://op.europa.eu/en/publication-detail/-/publication/5306df12-79b9-11e8-ac6a-01aa75ed71a1/languageen/format-PDF/source-94583924

The adoption of a **systems-based approach** for next generation ERA will require the implementation of a portfolio of activities clustered in working areas. Each of these working areas will cover a set of activities with operational SMART objectives that must be defined by PERA partners.
The following non-exhaustive list of potentially interrelated **working areas** is proposed for PERA:

- Formulating ERA issues/problems and (specific) protection goals holistically to address overall system impacts[63];
- Assessing environmental risks resulting from exposure to regulated substances/compounds or products at relevant levels of biological organisation (individual, population, community, ecosystem) and spatio-temporal scales[64];
- Assessing cumulative environmental effects resulting from exposure to multiple regulated substances/compounds or products, and stressors[65];
- Developing and designing tools and methods (including post-market environmental monitoring) for evaluating the efficiency of risk mitigation measures;
- Monitoring regulated substances/compounds, or products in different environmental compartments and matrices, and along the food/feed chain[66];
- Integrating of pre- and post-registration data of regulated substances/compounds or products, and other environmental monitoring, surveillance and pesticide/pharmacovigilance data[67];
- Comparing environmental risks of regulated substances/compounds or products with a range of alternative solutions;
- Developing more coherent, harmonised and interoperable regulatory ERA approaches;
- Developing a common currency for the assessment of environmental impacts;
- Integrating regulatory ERAs in EU environmental impact and sustainability assessments, or policy assessments performed by relevant partners in the context of other regulatory frameworks/policies;
- Developing and implementing the safe and sustainable by design concepts for regulatory ERA[68];
- Identifying areas where revised or new guidelines are needed for the ERA of future/new candidate (innovative, greener) regulated substances/compounds or products;
- Assessing groups/classes of chemical products for authorisation renewal based on the type of active substance, mode of action, and/or use;
- Implementing the FAIR (findability, accessibility, interoperability, and reuse) principles for digital ERA data;
- Building on relevant projects;
- Building linkages with relevant/complementary partnerships (e.g. One Health platform[69], EU bee partnership[70], EU Partnership for the Assessment of Risk from Chemicals [PARC][71], EU Partnership for Biodiversity[72]);

[63] https://ehp.niehs.nih.gov/doi/10.1289/EHP1465;
https://www.sciencedirect.com/science/article/abs/pii/S0273230017301952
[64] https://projects.au.dk/almass/; https://link.springer.com/article/10.1007/s10646-018-1962-0;
https://www.sciencedirect.com/science/article/pii/S0048969715304939;
https://www.sciencedirect.com/science/article/pii/S0048969715308597;
https://www.sciencedirect.com/science/article/abs/pii/S0273230017301952
[65] Human health effects will be addressed in the SPIDO theme paper on multiple chemicals risk assessment
[66] https://science.sciencemag.org/content/367/6476/388
[67] https://science.sciencemag.org/content/357/6357/1232
[68] https://science.sciencemag.org/content/367/6476/397
[69]https://onehealthplatform.com/home
[70] https://www.efsa.europa.eu/en/supporting/pub/en-1423

- Drawing on experience from related fields, including in non-EU jurisdictions.

Not all working areas and regulated substances/compounds or products proposed in the scope of PERA may be equally relevant for all PERA partners. Moreover, not all PERA partners may be directly involved in regulatory ERAs; instead, they may perform/contribute to environmental impact and sustainability assessments, and policy assessments. Therefore, PERA partners will need to prioritise working areas and type of regulated substances/compounds or products based on their remit. Thus, working areas and specific types of regulated substances/compounds or products may be addressed at different timeframes by different PERA partners.
In this respect, EFSA may focus its initial work on **pesticides**. This will allow EFSA to use this group of substances to pilot and assess the establishment of PERA and evaluate the suitability of the proposed methodology, as well as cooperation with its partners. The work on pesticides will also support the European Commission (EC) in its ambition to reinforce/strengthen the ERA of pesticides, as outlined in the EU farm to fork strategy[73], EU biodiversity strategy[74] and EC report on the evaluation of Regulation (EC) No 1107/2009[75], and of biocides, as outlined in the EU chemical strategy for sustainability. Thereafter, EFSA may consider other relevant regulated substances/compounds or products, including chemical substances/compounds or products regulated by other frameworks in the EU.

Opportunities:
Systems-based approaches are not new and have gained broad interest in the international scientific community. However, a systems-based ERA for regulated substances/compounds or products has not yet been developed and thus integrated in regulatory assessments. In recent years, the EU has made substantial efforts towards the development of a holistic and integrated risk assessment approach of multiple stressors in bees (MUST-B)[76,77] that could serve as a model case study for the further advancement of regulatory ERA.
The European Green Deal announced the development of a chemical strategy for sustainability in 2020, which will require the EU Agencies and scientific bodies to move towards a process of "one substance – one assessment". This will overcome some of the challenges of a fragmented regulatory/policy landscape.
PERA will provide an overarching platform that can:

- Improve interagency cooperation on regulatory ERA and other types of assessment, and cooperation between risk assessors and managers, and other relevant partners at European, national and regional level;
- Advance and harmonise regulatory ERAs, across regulatory silos;
- Address new policy targets, the "one substance – one assessment" concept, and society needs;
- Co-develop new/complementary tools and methods, and implement innovative tools and methods for regulatory ERA;
- Improve the sharing of data (including their findability, accessibility, interoperability and reuse) and expertise;
- Identify current and emerging ERA needs, and bridge ERA gaps;

[71] https://ec.europa.eu/info/sites/info/files/research_and_innovation/funding/documents/ec_rtd_he-partnershipschemical-risk-assessment.pdf
[72] https://ec.europa.eu/info/sites/info/files/research_and_innovation/funding/documents/european_partnership_for_rescuing_biodiversity_to_safeguard_life_on_earth.pdf
[73] https://ec.europa.eu/info/sites/default/files/communication-annex-farm-fork-green-deal_en.pdf
[74] https://ec.europa.eu/info/sites/info/files/communication-annex-eu-biodiversity-strategy-2030_en.pdf
[75] https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_report_2020_en.pdf
[76] https://www.efsa.europa.eu/en/topics/topic/bee-health
[77] https://b-good-project.eu/about; https://www.poshbee.eu/

- Identify, prioritise and promote research and innovation needs for regulatory ERA, and align research and innovation in ERA with EU/national Research & Innovation investments to improve coherence and reduce overlap between national and EU funding in ERA research;
- Build linkages with relevant/complementary partnerships and projects.

Cooperation:

PERA will facilitate the advancement of regulatory ERA by promoting cooperation with relevant partners (such as national competent authorities/agencies, EU Member States, EU Agencies, Commission Services, policy makers, risk managers, risk assessors, scientific community and civil society).

PERA will also build linkages with relevant/complementary partnerships and projects, such as the new European Partnership for the Assessment of Risks from Chemicals (PARC)[78] to be launched under Horizon Europe in 2022. The innovative research projects to be supported by this partnership will focus on human health aspects, but are expected to include environmental aspects that are relevant for regulated ERA, in particular in the areas of environmental media monitoring and sources of human exposure to chemicals.

The European Commission launched in mid-September a €1 billion call for research and innovation projects that respond to the climate crisis and help protect Europe's unique ecosystems and biodiversity. The Horizon 2020-funded European Green Deal Call, has 8 thematic areas including area 6: Farm to fork, area 7: Biodiversity and ecosystems and area 8: Zero-pollution, toxic-free environments that aim to launch large consortia to work on these issues.

Impact for EFSA and other PERA partners:

- Strengthen interagency cooperation on ERA for regulated substances/compounds or products and other types of assessment, and cooperation with national competent authorities/agencies, EU Member States, Commission Services, policy makers, risk managers, risk assessors, scientific community and civil society;
- Harmonise regulatory ERAs, across regulatory silos;
- Facilitate the development of new/complementary tools and methods, and uptake of innovative tools and methods for the further advancement of ERA within the context of regulatory science;
- Improve the sharing of data (including their findability, accessibility, interoperability and reuse) and expertise;
- Deliver rapid methodological improvements, foster data sharing and make better use of available expertise for the ERA of specific groups of regulated substances/compounds, or products to demonstrate the value of PERA;
- Pave the way for the transition to next generation, system-based ERA that addresses new policy targets, including the "one substance – one assessment" concept, and society needs, that aim to better protect the environment and halt biodiversity loss (including farmland biodiversity);
- Position EFSA and other PERA partners as important partners for the implementation of next generation ERA in regulatory science at EU level, and internationally;
- Increase researchers' interest in regulatory ERA and science.

[78] https://ec.europa.eu/info/sites/info/files/research_and_innovation/funding/documents/ec_rtd_he-partnershipschemical-risk-assessment.pdf