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CALL FOR PROPOSALS AND GUIDE FOR APPLICANTS

Call reference: EUBA-EFSA-2023-PLANTS-01 **Call title:** PERA - Advancing the ERA of Plant Protection Products towards a system-based approach

Restricted to **the list of competent organisations** established by the Authority's Management Board in application of article 2 the Commission Regulation (EC) No 2230/2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organisations operating in the fields within the Authority's remit.

Brief description of the call objectives: to address different needs in the area of the Environmental Risk Assessment of Plant Protection Products, in particular in the area of terrestrial ecotoxicology. Data will be collected and generated to further improve the current knowledge.

Key words: environmental risk assessment of pesticides, exposure, hazard, modelling, agricultural landscape, system-based approach



INDICATIVE PROCEDURE TIMETABLE

Milestone	Date ¹	Comments
Launch date	0 <u>6</u> 7/07/2023	Date of call publication on EFSA's website.
Deadline for applicants to raise clarification questions to EFSA	<u>2130</u> /10/2023	If, after having read this Call for proposals and guide for applicants, you have any questions, you may address them to EFSAProcurement@efsa.europa.eu by indicating the Call reference.
Deadline for EFSA to reply to clarification questions	<u>2396703</u> /11/2023	Replies will be provided on EFSA's webpage where this Call is published and which the applicants are requested to consult regularly.
Deadline for submission of proposals	<u>3009</u> /11/2023 At 17:00 (<u>BrusselsXL</u> <u>timeCEST</u>)	Applicants can submit proposals by following the instructions in section 3.1 of this call for proposals. All applications must be submitted through the EU Funding and Tenders portal, following the instructions provided. Hard copy paper applications will not be accepted.
Notification of the evaluation results	Dec `23 / Jan `24	Estimated Attention: outcome of the present call will be communicated to all applicants to the e-mail address indicated in their proposal. Accordingly, applicants who have submitted proposals under the present call are strongly invited to check regularly the inbox in question.
FPA signature	Jan <u>/Feb</u> 2024	Estimated

 $^{^{\}rm 1}\,{\rm All}$ times are in the time zone of the country of the EFSA.



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Annex 2: Administrative Declaration

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Annex 6: Award criteria template and Estimated budget template (Estimated budget template Not applicable for this call for proposals)

Annex 7: Summary professional capacity

Annexes:

Annex 1: Draft grant agreement

Annex 2: Estimated budget template Not applicable

Annex 3: Financial statement and monthly timesheet template Not applicable

Annex 4: Confidentiality Agreement

Annex 5: Summary for evidence requested to prove the professional and operational capacity



1. GRANT OPPORTUNITY AND CONDITIONS²

1.1 LEGAL FRAMEWORK

Article 36 (1) of the Regulation (EC) 178/2002³ 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, stipulates that the Authority shall promote the European networking of organisations operating in the fields within the Authority's mission. The aim of such networking is, in particular, to facilitate a scientific cooperation framework by the coordination of activities, the exchange of information, the development and implementation of joint projects⁴, the exchange of expertise and best practices in the fields within the Authority's mission. The list of competent organisations designated by the Member States, which may assist EFSA with its mission, is approved and regularly updated by EFSA's Management Board. The full list of Article 36 organisations can be found <u>here</u>.

EFSA's founding regulation was amended by 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.

The Commission Regulation (EC) 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of the European Parliament and Council Regulation (EC) 178/2002 with regard to the network of organisations operating in the fields within the EFSA's mission specifies in Article 4 that tasks may be entrusted by the Authority to organisations on the list of competent organisations.

The present call specifically focuses on the below tasks defined in Article 4(3):

- producing scientific data or works contributing to the risk assessment tasks, including assessment tasks in the field of human nutrition in relation to Community legislation, for which the Authority is responsible; this type of task must correspond to precise problems identified in the course of the work of the Authority, and in particular that of its Committee and permanent Scientific Panels, and must not duplicate Community research projects or data or contributions which it is the industry's duty to provide, especially in the context of authorisation procedures;
- 2. preparing the harmonisation of risk assessment methods;
- 3. sharing data of common interest, e.g. the establishing of databases;
- 4. the tasks referred to in Articles 6 and 18(3)(b) of Regulation (EC) No 1829/2003.

Article 5(2) of the Commission Regulation (EC) $2230/2004^5$ of 23 December 2004 specifies that the financial support to the networking organisations shall take the form of subsidies (grants) awarded in accordance with the EFSA's financial regulation and implementing rules.

The present Call for proposals and guide for applicants (hereinafter referred to as "the Call") is procedurally governed by Title VIII of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union.

 $^{^{2}}$ The applicant is reminded that this Call and guide for applicants contains a selection of the most important conditions for the grant implementation. For the full set of conditions, the applicant is invited to consult the draft grant agreement in Annex 1 of this Call.

³ <u>http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF</u>

⁴ Project is frequently referred to in this Call as "action", in line with EU Financial Regulation terminology.

⁵ <u>http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:379:0064:0067:EN:PDF</u>



This call is based on EFSA Founding regulation⁶ and EFSA's 2023 Draft Work Programme for grants and operational procurements as presented in Annex XII of the Programming Document 2023 – 2025, available on the EFSA's website⁷.

1.2 BACKGROUND AND OBJECTIVES OF THE CALL

BACKGROUND

Environmental risk assessment (ERA) of plant protection products (PPPs) is required by Regulation EU 1107/2009⁸, which regulates the placing on the market of these products in the European Union.

In line with EFSA Strategic objectives 2027⁹ on how to ensure preparedness for future risk analysis needs, more up-to-date scientific guidance and methodological approaches need to be developed. For regulatory environmental risk assessment (ERA) opportunities identified so far are e.g. to integrate several aspects related to the landscape (e.g. landscape architecture and ecology) and to combine prospective and retrospective assessments. Fit-for-purpose methods need to be developed, and basic data collected and generated. This includes developing clear and effective tiered approach risk assessment schemes, promoting the uptake of new tools (e.g. mechanistic effect modelling) and methods (e.g. adverse outcome pathways (AOPs), new approach methodologies (NAMs), etc.).

This call aims to establish a framework to collect and generate data for progressing on the integration of species ecology and landscape features in the risk assessment, to gain knowledge on the environmental exposure to pesticides with different application scenarios, and to identify novel strategies and tools for assessing potential pesticides effects at higher level of biological organisation i.e. at population and community level. The main focus is on terrestrial ecotoxicology for which drafting or updating guidance have been identified as priority¹⁰, in particular, the revision of current SANCO Guidance Document on Terrestrial Ecotoxicology (EC, 2002)¹¹ on some specific organisms (e.g. NTAs, NTTPs and in-soil organisms), data may however be useful also in other areas of RA.

Beyond incorporating into risk assessment to the most updated scientific knowledge, EFSA intends also to investigate the possibilities to allow data exchange and data re-use among different actors, ultimately supporting data flows between modelling and monitoring approaches.

OBJECTIVES OF THE CALL

The overall objective of the present call is the identification of partners among Article 36 organisations which can support EFSA PLANTS unit on activities regarding, in particular, the ERA of plant protection products (PPP).

The call for proposals will result in the signature of a Framework Partnership Agreement (FPA) to develop, in collaboration with EFSA, specific projects over the next four years in support of **advancing the methodology of ERA of PPPs**.

Specifically, it aims at creating a pool of expertise (working in consortium) from different organisations to support EFSA with the execution of projects in main working areas.

The working areas can include several specific sub-areas which will be developed as work-package (WPs) via the definition of specific grant agreements. They are described in summary in the Table 1 and in detail in Section 1.3.

https://www.efsa.europa.eu/sites/defaultdash /files/2022-01/amp2325.pdf

⁶ Regulation (EC) 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, as amended by 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.

⁸ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

⁹ https://www.efsa.europa.eu/en/corporate-pubs/efsa-strategy-2027-science-safe-food-sustainability

¹⁰ https://food.ec.europa.eu/system/files/2023-06/pesticides_ppp_app-list-guidance_priority-list.pdf

¹¹ Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002 rev 2 final 17 October 2002



Table 1 summary of the areas and sub-areas to be covered under this FPA

Main Areas	Specific sub- areas
AREA#1 Characterisation of the exposure of PPPs in different environmental	• Definition of the exposure for different pesticide application techniques, including innovative pesticide application and consideration of any ongoing activities on this subject.
matrices	 Modelling and experimental work for determining levels of exposure and exposure scenarios depending on crop characteristics and application techniques (e.g., drift deposition values on different environmental matrices-etc).
	 Better understanding via experimental work on the PPPs bioavailability to soil organisms and plants.
AREA#2 Characterisation of the hazards to	 Literature search (based on the principles of extensive and systematic reviews) to compile data to assess:
terrestrial NTOs among different levels of biological organisation,	 extrapolation from lab to higher tier studies
and across species	 extrapolation among different levels of biological organisation and across species (e.g. Species Sensitivity Distribution analysis), including analysis on interspecies sensitivity, background variability, etc.
	• Exploring the application and implementation of NAMs in ERA, e.g (eco)genomics
AREA#3 Collection and evaluation of methodologies and tools (e.g. mechanistic effect models) for	 Systematic search and review of models for use in the ERA of pesticides, including data extraction and their assessment according to Good Modelling Practices (GMP)¹².
regulatory risk assessment.	 Assessment of model suitability for the regulatory RA of pesticides and development of a curated repository of assessed models for use by risk assessors (e.g., a living list/repository in a knowledge junction).
	Sensitivity analysis/parametric study on these models
	Training on the selected models
AREA#4 Exploring the integration and interconnection of data from	 Collect the needs and benefits from MSs and stakeholders for sharing data, methods and tool in a common risk assessment platform for PPP.
different sources, methods, tools and objectives via the development of a common platform for risk assessments.	 Develop the RA platform design (conceptual design) and the activities to integrate data, risk assessment scenarios, monitoring data, pesticide application equipment, mitigation measures, modelling and any available tools for risk assessment etc.

After signing a FPA, specific agreements including details of the projects, methodological approaches, tasks, deliverables and timelines will be defined and agreed with EFSA.

¹² EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2014. Scientific Opinion on good modelling practice in the context of mechanistic effect models for risk assessment of plant protection products. EFSA Journal 2014;12(3):3589, 92 pp. doi:10.2903/j.efsa.2014.3589



The beneficiary shall consider EFSA activities in the areas covered by this FPA ^{13,14,15} ¹⁶ (EFSA will made available all the necessary materials) as well as any other ongoing activities. By performing the work, the beneficiary shall adhere to the EFSA methods and standards (e.g. the principle of the systematic literature searches¹⁷). The beneficiary, shall also consider any cross-cutting activities

A preliminary and indicative high-level estimation of project duration and distribution over the four years of the FPA has been indicated by EFSA and described in the following section.

In applying to this call the applicant is invited to consider this preliminary time estimation described under indicative timelines below in and elaborate an overall proposal based on his/her own experience. In this proposal it is expected to get an overview on how the applicant will plan the activities (i.e. a workplan) belonging to the main areas and sub-areas of this FPA, including justifications when there are major deviations from the indicative EFSA proposal. In particular, considering the complexity of this FPA, the applicant within his proposal shall develop a detailed workplan, reporting the following elements:

- 1. Indication of timelines, roles and tasks distribution within the consortium, resources etc.
- 2. Tentative planning of meetings with EFSA during the FPA.
- 3. Opportunities for collaboration with other organisations working on the same topics such as for example PARC project (<u>https://www.eu-parc.eu/</u>) in order to avoid work duplication and identify synergies. This shall also include consideration of cross-cutting issues e.g. with human risk assessment, where possible
- 4. Check points to revise and agree on yearly basis with the EFSA the indicative workplan in order to reconsider priorities during the FPA.

1.3 TASKS, DELIVERABLES, TIMELINES, MEETINGS AND PAYMENTS

In general, the tasks will involve gathering and analysing data from literature as well as generating raw data via experimental work (both laboratory and field work), developing protocols.

For all the activities EFSA will provide to the beneficiary the relevant templates and access to a dedicated project Teams channel.

The beneficiary shall provide project management (e.g. implementation, execution and monitoring of the activities that will be defined with grant specific agreements) for the duration of the FPA and develop project monitoring tool (e.g. dashboard) where EFSA and the beneficiary can monitor the progress of the activities.

The beneficiary will also be also requested to address dissemination and communication of project results (e.g. annual info sessions to member states, stakeholders, European commission etc.) in collaboration with EFSA.

1.3.1 AREA#1 - Characterisation of the exposure of PPPs in different environmental matrices

The scope of the activities under this area is to advance the characterisation of the environmental exposure, in particular of non-target organisms, by gaining a better understanding of the exposure in different environmental compartments and matrices like soil and plants following the use of PPP. The level of exposure of these compartments/matrices depends, among other, on how the pesticides are applied (pesticide application equipment). In order to define the link between the exposure and the effects to non-target organisms, it is important to understand which organisms could be exposed,

¹³ <u>https://etendering.ted.europa.eu/cft/cft-display.html?cftId=8625</u>

¹⁴ <u>https://www.efsa.europa.eu/en/supporting/pub/e200503</u>

¹⁵ <u>https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2022.e200505</u>

<u>16 Services - 48237-2023 - TED Tenders Electronic Daily (europa.eu)</u>

¹⁷ European Food Safety Authority; Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 2010; 8(6):1637. [90 pp.]. doi:10.2903/j.efsa.2010.1637. Available online: www.efsa.europa.eu



when and where in both the off-crop and in-crop areas. This can be the basis of the development of a problem formulation as first step of the risk assessment.

The activities could be divided in different sub-activities for addressing the different needs, as shown in Table 1.

TASKs of AREA#1

Tasks will be defined in detail with specific grant agreements. For this area's activities, the beneficiary shall be able to perform the following tasks:

- Gathering and collate data aiming at describing the exposure in the environment for the different type of application techniques, including innovative application techniques (e.g. unmanned aerial spraying or drones) and agricultural practices;
- Gathering and collate data aiming at investigating the bioavailability of active substances for example by defining the influence of soil properties ((e.g. Organic Carbon) and physico-chemical properties on soil organism toxicity and translocation into plants;
- Developing protocols for field experimental studies aiming at measuring exposure in different matrices e.g. spray and dust drift and crop interception experiments;
- Developing protocols for laboratory experimental tests to investigate the bioavailability and the influence on the toxicity on soil organisms (e.g. starting with earthworms) for substances presenting a range of physical-chemical proprieties (Koc, Pow). This should serve as a basis for identify a possible correction factor for lipophilic compounds for the standard risk assessments;
- Developing test protocols for laboratory experimental work to investigate the translocation of active substance in terrestrial plants;
- Coordinate/perform (field and lab) experimental work;
- Analysing raw data to define exposure factors;

DELIVERABLES AREA#1

Deliverables will be defined in detail with the specific grant agreement. Under this area it is expected that the beneficiary will provide:

- Protocols outlining methodological approaches to perform literature search, to perform experimental work, to carry out data analysis and how to present the results;
- Reports, including data collected, raw data from experimental work, analysis, results, and conclusions.

INDICATIVE TIMELINES of AREA#1

Timelines will be defined in detail with the specific grant agreement. It is expected that the activities under this area are performed over the duration of the FPA. EFSA has indicatively estimated a duration of each specific grant agreement that can vary from 12 to 36 months.

1.3.2 AREA#2 - Characterisation of the hazards to terrestrial NTOs among different levels of biological organisation, and across species

The scope of the activities under this area is to gather from literature and dossier studies (laboratory and higher tier studies) toxicity data on the hazard on non-target organisms (e.g., non-target arthropods, terrestrial non-target plants, soil organisms). For this purpose, data should be collected via systematic literature search and also considering the PPP dossiers, according to a data model to be agreed with EFSA. Analysis such as interspecies sensitivity and background variability (e.g. abundance) should be performed. Ongoing activities shall be considered (e.g., EFSA OpenFoodTox



database^{18,19} and current developments, PARC etc.). Additionally, under the scope of this area, further work for refining and operationalising experimental test protocols (e.g. lower or higher tier tests on wild pollinators) in the area of terrestrial ecotoxicology can be carried out.

TASKs of AREA#2

Tasks will be defined in detail with specific grant agreements. For this area's activities, the beneficiary shall be able to perform the following tasks:

- Developing protocols for the literature search (based on the principles of extensive and systematic reviews).
- Gathering and collate data on the hazard of active substances for non-target organisms to perform an analysis of interspecies sensitivity and background variability (e.g. population sizes, or abundance) as well as extrapolation from lab to field;
- Perform literature search for exploring the application and implementation of NAMs in ERA e.g. (eco)genomics technologies;
- Develop recommendations for the design of new experimental test protocols (e.g. lower or higher tier tests) in the area of terrestrial ecotoxicology in view of international acceptance.

DELIVERABLES of AREA#2

Deliverables will be defined in detail within the specific grant agreement. Under this area it is expected that the beneficiary will provide:

- Protocols outlining methodological approaches e.g., to perform literature search, data analysis and presentation of the results;
- Reports, including data collected from literature, data analysis, results, and conclusions.

INDICATIVE TIMELINES of AREA#2

Timelines will be defined in detail with the specific grant agreement. It is expected that the activities under this area are performed over the first half of the duration of the FPA. EFSA has indicatively estimated a duration for specific grant agreement in this area of 24 months.

1.3.3 AREA#3 - Investigating the use of mechanistic effect models, including population models in regulatory environmental risk assessment

The scope of the activities under this area is to develop a repository of mechanistic and effect models ready to use (i.e. a list of knowledge junction) for regulatory risk assessment. Existing models should be collected and evaluated for their suitability for ERA, including a sensitivity analysis.

TASKs of AREA#3

Tasks will be defined in detail with specific grant agreements. For this area's activities, the beneficiary shall be able to perform the following tasks:

- To develop a protocol for the systematic retrieval of existing (effect) models developed to characterise environmental risks of pesticide use;
- To develop a protocol implementing a refined/extended set of criteria for the regulatory evaluation of models according to the EFSA GMP¹² opinion in order to address the specific model typologies and by considering any further development on this subject;
- To set up a repository for the selected models via a systematic search according to the agreed protocol and evaluate the retrieved models against the (refined) GMP criteria;
- To provide training on effect models in the context of the regulatory ERA of pesticides.

¹⁸ Dorne JLCM, Richardson J, Livaniou A, Carnesecchi E, Ceriani L, Baldin R, Kovarich S, Pavan M, Saouter E, Biganzoli F, Pasinato L, Zare Jeddi M, Robinson TP, Kass GEN, Liem AKD, Toropov AA, Toropova AP, Yang C, Tarkhov A, Georgiadis N, Di Nicola MR, Mostrag A, Verhagen H, Roncaglioni A, Benfenati E, Bassan A. EFSA's OpenFoodTox: An open source toxicological database on chemicals in food and feed and its future developments. Environ Int. 2021 Jan;146:106293. doi: 10.1016/j.envint.2020.106293. Epub 2020 Dec 8. PMID: 33395940.

¹⁹ <u>https://zenodo.org/record/5076033</u>



DELIVERABLES of AREA#3

Deliverables will be defined in detail with the specific grant agreement. Under this area it is expected that the beneficiary will provide:

- Protocols outlining methodological approaches e.g. to perform literature search;
- Reports including the evaluation of the retrieved models for their suitability for ERA of PPPs, a clear indication of the input parameters
- repository of evaluated models (i.e., a list of knowledge junction <u>https://www.efsa.europa.eu/en/press/news/170303</u>).
- Training on models

INDICATIVE TIMELINES of AREA#3

Timelines will be defined in detail with the specific grant agreement. It is expected that the activities under this area are performed over the second half of the duration of the FPA, in order to take into account any development on this subject by the EFSA working group on effect models in ERA. EFSA has indicatively estimated a duration for specific grant agreement in this area of 24 months.

1.3.4 AREA#4 - Exploring the integration and interconnection of data from different sources, methods, tools and objectives via the development of a common platform for risk assessments of PPP

The scope of this activity is to explore the integration of data (e.g. environmental scenarios, monitoring data, ecology data such as information on habitat/communities, exposure, modelling, pesticide application equipment, mitigation measures). The purpose is to identify needs and possibilities, and the cost benefits, in discussion with member states, EU agencies, and stakeholders, under consideration of on-going developments at EU level. As second objective, a conceptual model and architecture on how operationalising the identified needs (e.g. a platform with an interoperable environment) should be developed e.g. outline structure, IT requirements, costs etc.

TASKs of AREA#4

Tasks will be defined in detail with specific grant agreements. For this area's activities, the beneficiary shall be able to perform the following tasks:

- To collect, analyse and report feedback from MS and stakeholders on needs and benefits integrate various sources of data and tools for RA;
- To identify different options pending on feasibility in terms of timelines (e.g. short, medium long term), IT requirements and costs.

DELIVERABLES of AREA#4

Deliverables will be defined in detail with the specific grant agreement. Under this area it is expected that the beneficiary will:

- Collect and collate information;
- Provide a protocol outlining methodological approach;
- Draft reports including the conceptual model, the architecture, timelines, IT requirements and costs.

INDICATIVE TIMELINES of AREA#4

Timelines will be defined in detail with the specific grant agreement. It is expected that the activities under this area are performed over the second half of the duration of the FPA. EFSA has indicatively estimated a duration for specific grant agreement in this area of 24 months.



Work Package / Objective	Tasks	Deliverables	Indicative timeline
Overarching tasks	 Task 1: inception report The beneficiary shall draft an inception report with a detailed workplan for activities under in the areas 1 to 4 based on what has been submitted with this proposal and by considering the feedback form EFSA at the kick-off meeting. At the kick-off meeting Task 2: project management and communication Planning, implementation and reporting of the activities for the areas 1 to 4 and communication Task 3: liaise with the science matter unit (regular meetings during the development of specific agreements) and draft the minutes of the meetings	Deliverable 1: inception report, including a detailed workplan and a proposal for a for a tool to monitor the activities Deliverable 2 (to be defined via specific agreements): -annual reports on the progress of the activities under the FPA as agreed with the specific grant agreements, including outcome of check point and -a project monitoring tool e.g. dashboard to monitor the progress of the activities (EFSA shall not pay any fee to access the tool) -communication plan, delivery of presentations during events organised in collaboration with EFSA Deliverable 3: minutes of the	 Deliverable 1 month after the kick-off meeting Deliverable 2 over the duration of the FPA to be defined in specific agreement Deliverable 3 One week after each meeting
Area 1	 TASKs (to be defined via specific agreements): Gathering and collate data aiming at describing: exposure in the environment for the different type of application techniques influence of soil properties and physico-chemical properties of the substance on soil organism toxicity and on translocation in plants <u>Developing protocols for experimental studies aiming at:</u> measuring exposure in the field in different matrices investigating bioavailability and toxicity on soil organisms in relation to physico-chemical properties of PPP investigating translocation in plants Coordinate/perform (field) experimental work Analysing raw data to define exposure factors 	 meetings with EFSA Deliverable (to be defined via specific agreements): Protocols outlining methodological approaches to perform literature search, experimental work, data analysis and presentation of the results Experimental work Reports, including data collected, raw data from experimental work analysis, results, and conclusions. 	To be defined in specific agreements



Area 2	 Perform literature search for exploring the application and implementation of NAMS in ERA e.g. (eco)genomics technologies Drafting reports TASKs (to be defined via specific agreements): Perform a data collection and data analysis on hazard for non-target organisms (lab and higher tier studies) via systematic literature search and /or using dossier studies Develop recommendations for the design of new experimental test protocols (e.g. lower or higher tier tests) in the area of terrestrial ecotoxicology 	Deliverable (to be defined via specific agreements): - Protocols outlining methodological approaches e.g. to perform literature search, data analysis and presentation of the results - Reports, including data collected, data analysis, results, and conclusions.	To be defined in specific agreements
Area 3	 TASKs (to be defined via specific agreements): To Develop protocol for the literature search on existing effect models on non-target organisms To refine the criteria for model evaluation based on the EFSA Good Modelling Practices opinion To perform the literature search according to the agreed protocol. Hence, to collect and evaluate existing effect models on non-target organisms To set up a repository for the selected models To Provide training on models in ERA. 	 Deliverable (to be defined via specific agreements): Protocols outlining methodological approaches e.g. to perform literature search, data analysis and presentation of the results Repots including the evaluation of the retrieved models for their suitability for ERA of PPPs, a clear indication of the input parameters and a repository (i.e., a list of knowledge junction) 	
Area 4	 TASKs (to be defined via specific agreements): To collect, analyse and report feedback from MS and stakeholders on needs to integrate various needs and sources of data To identify different options for a platform development pending on feasibility in terms of timelines (e.g. short, medium long term), IT requirements and costs 	 Deliverable (to be defined via specific agreements): Collect and collate information Provide an outline of methodological approach Draft reports including the conceptual model, the architecture, timelines, IT requirements and costs. 	

Subcontracting is allowed for non-core tasks only. Core tasks for this project are: project management, protocols development, data analysis and final reports including raw data. Implementation of agreed protocols such as for example performing experimental work can be outsourced. Please also refer to section 1.7 'Possibility of implementing contracts and subcontracting'.



No.	Meetings	Deadline for finalisation
1	 Kick-off meeting: half day²⁰ / teleconference The kick-off meeting is regarded as the start of the project and must take place no later than 1 month after the signature of the FPA. At this meeting, details of the project workplan will be discussed and the objectives, the final report structure, deliverables and timeframe will be clarified. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary. The presence at the kick-off meeting of a beneficiary's staff member responsible for administrative/finance issues of the project is advised as this will facilitate understanding by the beneficiary of the grant principles, related financial reporting requirements and significantly ease the financial management of the grant agreement, both for EFSA and the beneficiary. 	Within 1 month after entry into force of FPA
2	Interim/final meetings: To be defined with the deliverable 1 (inception report)	NA
No.	Payments	Linked to EFSA approval of deliverable No.
	For FPA The payment modalities applicable to each specific agreement are detailed in articles 4 and 5 of the draft specific agreement published under the framework partnership agreement (Annex 1 of the call for Proposals).	NA

Deliverables must be drafted in English and may be subject to publication at EFSA's discretion.

Please note that all reporting, minutes, outcome of the discussions could be submitted at EFSA's discretion to EFSA's Panel and Working Group members as well as to other stakeholders. Use of the grant deliverables may be subject to publication, subject to the terms and conditions set out in the draft grant agreement (Annex 1 of the call for proposals).

1.4 INFORMATION ON THE GRANT AGREEMENT

Applicants should note that the draft grant agreement is published with the call for proposals. If any applicant should have specific comments on the provisions of the draft grant agreement, these must be raised in a clarification, prior to the deadline for receipt of proposals so that a clear and transparent reply may be published for the benefit and information of all applicants.

1.4.1 Framework Partnership Agreements (FPA)

This Call for proposals aims to conclude a Framework Partnership Agreements (FPA) for the performance of the tasks described in these specifications. An FPA is a long-term cooperation between the Authority and one or several partners. It sets out the framework conditions and is subsequently implemented through Specific Agreements. The specific agreements will set out the specific conditions for performing the respective assignments.

The financial ceiling available for specific agreements under the framework partnership agreement is 10.000.000,00 [ten million euro] \in .

The maximum duration of this Framework Partnership Agreement is 4 years

 $^{^{20}}$ One day = 8 hours, half day = 4 hours



The duration of the specific grant agreements for the areas 1 to 4 will be typically between 12 and 36 months. The specific grant agreement related to project management (i.e. task 2: project management) will last 48 months. The FPA continues to apply to specific agreements after its expiry. The services relating to such specific agreements must be performed no later than 12 months after the expiry of the FPA.

This call will result in the signature of on FPA. EFSA reserves the right to award Specific Agreements under the FPA during its period of validity according to the estimates provided in the table below:

	Year 1	Year 2	Year 3	Year 4	Total
Total	3.000.000	2.000.000	3.000.000	2.000.000	10.000.000 €.
	€	€	€		

Where possible, in order to facilitate the planning of the beneficiaries, EFSA will share periodically the plan of the upcoming expected specific agreements.

1.5 ELIGIBLE ORGANISATIONS

To be eligible, applicants must be on the list of competent organisations designated by the Member States in accordance with Article 36 of Regulation (EC) 178/2002 and Commission Regulation (EC) 2230/2004. This list is regularly updated by EFSA Management Board and is available for consultation using this link https://efsa.force.com/competentorganisations/s/.

In order to achieve the main objective of the call, proposals must be submitted by a consortium of at least **three eligible organisations.** One of the partners must be identified in the proposal as the consortium leader. The applicant (consortium leader) is responsible for identifying consortium partners.

1.6 ROLES AND RESPONSIBILITIES

For proper understanding of this call it is important to have clarity on the terminology regarding involved organisations and their roles.

Proposals submitted by consortium:

- **The Applicant** submits the proposal to EFSA on behalf of the consortium. The applicant is the leading entity of the consortium.
- **The Partner** is the other entity in the consortium. There can be a minimum of one partner or more partners.

Once the grant is awarded, the grant agreement is signed between EFSA and the applicant (leading entity of the consortium).

Partners do not sign the grant agreement directly but instead sign a mandate (template provided by EFSA) authorising the applicant to sign the grant agreement and any future amendments on their behalf.

As soon as the grant agreement is signed, the applicant becomes the Coordinator and partner/s become co-beneficiary/ies. The coordinator and co-beneficiary/ies are referred to as the beneficiaries. The beneficiaries are jointly and severally liable for the technical implementation of the project as described in the proposal which becomes Annex 1 of the grant agreement. If a beneficiary fails to



implement its part of the project, the other beneficiaries become responsible for implementing that part.

The coordinator has the following important roles:

- Takes part in implementing the project;
- Monitors the action is implemented properly;
- Act as intermediary for communication between the consortium and EFSA;
- Receives and answers all claims EFSA might have in relation to implementation of the project;
- Requests and reviews any documents or information required by EFSA and verifies their completeness and correctness before passing them to EFSA;
- Informs EFSA and the partner/s of any event that is likely to substantially affect implementation of the project;
- Submits the deliverables and reports to EFSA;
- Requests and receives payments from EFSA and distributes the funds to partner/s without unjustified delays.

The coordinator may not delegate the above-mentioned tasks to the co-beneficiary/ies or subcontract them to any third party.

The other beneficiary/ies:

- Take part in implementing the project;
- Forward to the coordinator the data needed to draw up reports, financial statements and other documents required under the grant agreement;
- Inform the coordinator of any event or circumstances likely to substantially affect or delay the implementation of the project.

1.7 IMPLEMENTING CONTRACTS AND SUBCONTRACTING

Implementation contracts:

Where the implementation of the project requires the award of procurement contracts (implementation contracts), e.g. purchase of services and/or goods or equipment necessary for the implementation of the action, the beneficiary must award the contract to the entity offering the best value for money or the lowest price (as appropriate), avoiding conflicts of interests. The beneficiary is expected to clearly document the tendering procedure and retain the documentation for the event of an audit.

Entities acting in their capacity as contracting authorities within the meaning of Directive 2014/24/EU²¹ must comply with the applicable national public procurement rules.

Sub-contracting:

Sub-contractors are not consortium partners and are not party to the grant agreement/FPA. They do not have any contractual relationship with EFSA. Subcontractors are entities contracted by the beneficiary to carry out some specific tasks or activities. Subcontracting is allowed under these conditions:

• **Core tasks must not be subcontracted**. Only ancillary and assistance tasks can be subcontracted.

²¹ Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, p. 65-242)



- Subcontracts must be awarded to the entity offering best value for money or the lowest price (as appropriate), avoiding conflicts of interests;
- Subcontracting must only cover the implementation of a limited part of the action;
- Recourse to subcontracting must be justified having regard to the nature of the project and what is necessary for its implementation;
- Recourse to subcontracting during project implementation, if not envisaged from the outset in the proposal, is subject to prior authorisation in writing by EFSA, and must be formalised via an amendment to the grant agreement. Approval may be granted as long as it does not entail a change to the grant agreement which would call into question the decision awarding the grant or be contrary to the equal treatment of applicants;
- The conditions applicable to the beneficiaries under Articles II.6 (*Confidentiality*), II.7 (*Processing of Personal Data*), II.8 (*Visibility of Union Funding*) of the grant agreement are also applicable to the subcontractor.

1.8 GRANT PRINCIPLES

The financial help provided by EFSA under this Call is a grant governed by the EU Financial Regulation referred to in part 1.1. Accordingly, the grant awarded following this Call must comply with the following principles:

The form of grant awarded under this Call is based on financing not linked to the costs of the relevant operations in accordance with Article 125 (1)(a) of the EU Financial Regulation. Grants financed in this way require the fulfilment of conditions set out in sector specific rules of Commission decisions or the achievement of results measured by reference to previously set milestones or through performance indicators.

The present call for proposals comes with an innovative and simplified grant management, where the grant amounts paid to the partner are based on the pre-defined sums which are not linked to the actual costs of the action. This means there is no need for co-financing from the partner, and no need for completion of estimated budgets or timesheets to record the work. The agreed sums are set at a level designed to stimulate the mutually convenient partnership creation. The payment of agreed sums from EFSA will be carried out based on the acceptance by EFSA of the delivered work. If you have questions on this grant form, during the application period, please raise any clarification questions to <u>EFSAProcurement@efsa.europa.eu</u>.

The financial support provided by EFSA under this Call is a grant governed by the EU Financial Regulation referred to in part 1.1. Accordingly, the grant awarded following this Call must comply with certain grant principles established in the EU Financial Regulation, specifically:

• **Non-retroactivity**: A grant may be awarded for a project which has already begun only where the applicant can demonstrate in the grant application the need to start the action before the grant agreement is signed. In accordance with Article 193 of the Financial Regulation. The tasks entrusted by EFSA should not be performed before the signature of the grant Agreement.

Article 180(3) of the EU Financial Regulation specifically states that **the following grant principles are NOT applicable** where the grant takes the form of financing not linked to the costs pursuant to article 125(1)(a):

• **Co-financing**: In accordance with Article 190 of the Financial Regulation, grants shall involve co-financing.



- **No-profit**: In accordance with Article 192(3)(d) of the Financial Regulation, grants shall not have the purpose or effect of producing a profit within the framework of the project for the applicant or partner.
- **Non-cumulative**: In accordance with Article 191(3) of the Financial Regulation, in no circumstances shall the same costs be financed twice from the EU budget.

1.9 ESTIMATED BUDGET AND ELIGIBLE COSTS

Not applicable

1.10 PUBLICITY

All beneficiaries are expected to follow the rules on visibility of EFSA funding set out in Article II.8 of the grant agreement.

According to Article 38 of the EU Financial Regulation EFSA is bound to publish information on recipients of its grants at its website. Such publication shall take place no later than 30 June of the year following the financial year in which the grants were awarded and shall cover these data of the beneficiaries:

- name of the beneficiary
- address of the beneficiary
- subject of the grant
- amount awarded

With regards to publications of EFSA outputs that are integrating the preparatory work delivered in the context of this grant, the beneficiary could be mentioned in authorship lists indicating the affiliation to its organisation.

1.11 PROTECTION OF PERSONAL DATA IN RELATION TO GRANT PROCEDURES

Processing of personal data by EFSA

Information on the processing of personal data by EFSA in the context of this grant procedure is available in the <u>Privacy Statement</u> on the EFSA website as well as in Article II.7 of the draft grant agreement. Any personal data included in the Agreement must be processed by EFSA in accordance with Regulation (EU) No 2018/1725.²²

Applicants should note that personal data as applicant or selected beneficiary 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. For more information see the Privacy Statement on: http://ec.europa.eu/budget/explained/management/protect_en.cfm#BDCE).

Processing of personal data by the beneficiary

In case the implementation of activities under the grant agreement resulting from this call entails the processing of personal data, the beneficiary shall comply with the relevant rules in Article II.7.2 of the Grant Agreement (Annex 1) as a data processor of EFSA.

²² Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons 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



1.12 PUBLIC ACCESS TO DOCUMENTS

In the general implementation of its activities and for the processing of grant procedures in particular, EFSA observes Regulation (EC) N° 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

1.13 OPEN ACCESS

EFSA is committed to the publication of grant outputs in the <u>Knowledge Junction</u> in order to improve transparency, reproducibility and evidence reuse. The Knowledge Junction 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 the action under this grant may be published (at EFSA's discretion) on the Knowledge Junction with attribution to the beneficiary.



2. SELECTING PROPOSALS

The Evaluation Committee established by EFSA specifically for this call will evaluate the submitted proposals in five steps:

- 1. Verification of submission requirements (2.1)
- 2. Eligibility criteria (2.2)
- 3. Exclusion criteria (2.3)
- 4. Selection criteria (2.4)
- 5. Award criteria (2.5)

If the proposal fails at any step it is automatically excluded from further evaluation. EFSA may contact the applicant during the evaluation process if there is a need to clarify certain aspects or for the correction of clerical mistakes.

2.1 VERIFICATION OF SUBMISSION REQUIREMENTS

The following will be verified:

- proposal was submitted within the deadline for submission of proposals;
- administrative data for grant application form is duly signed by the authorised representative of the applicant;
- proposal is complete and includes all the supporting documents.

2.2 ELIGIBILITY CRITERIA

Criterion No. 2.2	Requirements and requested evidence	
1	Eligibility criteria	
	The following requirements will be verified:	
	 The applicant applies in a consortium with partner/s (a consortium of at least two entities); At the day of deadline for submission of proposals, the applicant and in case of consortium also its partner/s are on the list of competent organisations designated by the Member States in accordance with Art 36 of Regulation (EC) 178/2002 and Commission Regulation (EC) 2230/2004; Applicant and in case of consortium also its partner/s are involved in the execution of the project; Subcontracting, if any, is justified in the proposal. 	
	Requested evidence:	
	 ADMINISTRATIVE DECLARATION Annex 2, available to download in the Funding and Tenders Portal under Part B Templates. The applicant and partner(s) (if applicable) must complete and sign the form. The applicant must upload the signed form in the relevant field under Part B and Annexes of the Funding and Tenders Portal. Administrative data for 	



grant application (including Legal Entity and Financial Identification Forms): available <u>here</u>
 LEGAL ENTITY FORM: available <u>here</u> to be completed and signed by the applicant and in case of consortium also by its partner/s. For a public body the legal entity form should be provided together with a copy of the resolution or decision establishing the public body, or other official document establishing that public body. For a private body an extract from the official journal, copy of articles of association, extract of trade or association register, certificate of liability to VAT (if, as in certain countries, the trade register number and VAT number are identical only one of these documents is required).
FINANCIAL IDENTIFICATION FORM: available <u>here</u> to be completed only by the applicant and in case of consortium only by the coordinator.
Please note that there is no need to submit the Legal entity and Financial information forms if they have already been submitted under another EFSA procurement or grant procedure and provided that these forms are still valid. In this case simply indicate in the administrative data for grant application form the reference of the call under which the form/s were previously submitted to EFSA.
Please note that the administrative declaration includes also a partnership statement to be signed in case of consortium (compulsory for this call for proposals). Only applicable if the applicant is a consortium:
PARTNERSHIP STATEMENT: The applicant and partner/s must provide EFSA with a statement indicating their involvement in the action. The applicant and partner/s must sign the partnership statement. No template is provided by EFSA.

2.3 EXCLUSION CRITERIA

Criterion No. 2.3	Requirements and requested evidence
2	Exclusion criteria
	The following requirements will be verified:
	The applicant and partner/s must sign a declaration on their honour certifying they are not in one of the exclusion situations referred to in the Articles 136-140 of EU Financial Regulation.
	Requested evidence:
	THE DECLARATION ON HONOURSection A, available here: to be completed/signed individually by the applicant and in case of consortium by each partner. THE DECLARATION ON HONOUR ON EXCLUSION CRITERIAAnnex 3, available to download in the Funding and Tenders Portal under Part B Templates. The applicant and the partner(s) (if applicable) must complete and sign



into one single pdf and upload the single document in the relevant field under Part B and Annexes of the Funding and Tenders Portal.

2.4 SELECTION CRITERIA

A) Financial capacity

Criterion No. 2.4A	Requirements and requested evidence
1	Financial capacity
	The purpose of the selection criteria is to verify the financial capacity of the applicant and in case of consortium also of its partner/s.
	 The applicant and in case of consortium also its partner/s must have stable and sufficient financial resources to: maintain their activity throughout the period during which the project is being carried out, and
	Requested evidence:
	Documents to be provided by the applicant:
	 Annex 4, available to download in the Funding and Tenders Portal. Only the applicant (or consortium leader if applicable) is required to complete and sign the form. The applicant must upload the form in the relevant field under Part B and Annexes of the Funding and Tenders Portal. SIMPLIFIED FINANCIAL STATEMENT available here only required for private bodies if the grant requested from EFSA is >60.000 €. The template published with the Call should be completed for at least the last two closed financial years.
	 AUDIT REPORT only required for private bodies if the grant requested from EFSA is >750.000 €. In the event of an application grouping several applicants (consortium), the threshold applies to each applicant. If the audit report is not available AND a statutory report is not required by law, a self-declaration signed by the applicant's authorised representative certifying the validity of its accounts for the last 2 years available must be provided. The audit report should be produced by an approved external auditor certifying the accounts for the last two years available, where such an audit report is available or whenever a statutory report is required by law.
	The authorising officer responsible may, depending on a risk assessment, waive the obligation of providing an audit report for education and training establishments, and in the case of agreements with several beneficiaries, for applicants who do not bear any financial responsibility or who have accepted joint and several liabilities.



• LETTER OF COMMITMENT: applicable only when another public body financially contributes to the project (body other than EFSA, applicant or in case of consortium, its partners); to be signed by the contributing public body; it serves to confirm its commitment to financially contribu- to the project; no template is provided by EFSA.
The applicant must convert the Declaration on honour on selection criteria, the Simplified Financial statement (if applicable) and the letter of commitment applicable) into one single pdf and upload the single document in the relevant fier under Part B and Annexes of the Funding and Tenders Portal. Documents to be provided by the applicant:
- DECLARATION ON HONOUR - Section B, available <u>here</u> to be completed by the applicant or in case of consortium by the coordinator.
LETTER OF COMMITMENT: applicable-only when another public body financially contributes to the project (body other than EFSA, applicant or in case of consortium, its partners); to be signed by the contributing public body; it serves to confirm its commitment to financially contribu- to the project; no template is provided by EFSA;

B) Professional and operational capacity

Criterion No. 2.4.B	Requirements and requested evidence
1	Professional and operational capacity:
	Requirements:
	The applicant or in case of a consortium, the consortium as a whole, must have the professional resources, competencies and qualifications necessary to complete the proposed activities.
	 Requirements for the organisation: The applicant should provide evidence of expertise related to the areas to be covered by this FPA described in section 1.2 (table 1) and 1.3. In particular, the applicant should prove to have experience in the following fields: Project management and coordination with multiple partners Environmental science or related (e.g. biology, ecology, ecotoxicology, soil science, plant science, agronomy), chemistry, Environmental exposure and effect modelling Regulatory environmental risk assessment, preferably in the area of PPP, including experience in experimental research and data analysis Tool development and techniques requiring integration of different data and methods, including use of geographic information systems (GIS) Data management (e.g. collect, collate and analysing data following systematic literature search approaches), Write scientific reports
	2. Requirements for the team of experts: Given the complexity of the FPA, a multidisciplinary team is needed. Experts involved in the tasks shall prove to have a University degree (minimum bachelor's degree). One expert can cover more than one of the profiles requested and fields listed below,

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PhD stu	minimum number of experts should be at least 15. Experience gained during udies is counted as experience for the assessment of professional capacity of nembers.
	im of experts should include at least:
a.	One senior expert in project management with at least 10 years of experience preferably with experience in managing project in the area of environmental risk assessment/ecology/environmental sciences. They should have experience
b.	in the coordination of at least one large-scale project ($\geq 1,000,000 \in$); preferably they should also have experience in (a) multidisciplinary projects; (b) management of project teams of at least 5 people. One senior information specialist with 5 years of experience in collecting,
5.	appraising and synthetising information from the scientific literature in the area on environmental risk assessment and in setting up and managing databases.
c.	One senior expert in environmental chemistry with 5 years of experience, in particular with experience in 1) laboratory chemical analysis, 2) planning and conducting field experimental trials; 3) regulatory exposure assessment preferably in the area of PPP
d.	One senior expert in ecotoxicology with 5 years of experience, in with experience in 1) conducting experimental studies with terrestrial non-target organisms and linking exposure with the effects on non-target organisms; 2)
e.	Regulatory risk assessment preferably in the area of PPP One senior expert in agronomy with 5 years of experience, in particular in 1) plant protection, agronomic practices and technologies such as precision agriculture 2)Plant physiology with experience in the assessment of the fate of
f.	chemicals in the soil-plant continuum – preferably in the area of PPP One senior expert in statistical analysis with 5 years of experience, in particular in the area of environmental risk assessment
_	Nine junior experts with 3 years of experience to cover the all the fields of expertise listed below. Each expert should cover at least one filed.
1.	Ids of expertise: Environmental chemistry: experts with experience in 1) laboratory chemical analysis, 2) planning and conducting field experimental trials; 3) Regulatory
2.	exposure assessment preferably in the area of PPP Ecotoxicology: terrestrial ecotoxicologist, with experience in 1) conducting experimental studies with terrestrial non-target organisms and linking exposure with the effects on non-target organisms; 2) Regulatory risk assessment preferably in the area of PPP
3.	Agronomy: expert with experience in 1) plant protection, agronomic practices and technologies such as precision agriculture 2) Plant physiology with experience in the assessment of the fate of chemicals in the soil-plant continuum – preferably in the area of PPP
4.	Soil science: expert with experience in environmental soil chemistry and soil biology covering also aspects related to bioavailability of organic chemicals in soil and bioaccumulation in terrestrial non-target organisms
5.	Environmental modelling: expert with experience in mathematical modelling to describe the fate and behaviour of chemicals in the different environmental matrices, agricultural and ecological data
6.	Mechanistic effect modelling: expert with experience in mathematical models describing the effects of chemicals on different non-target organisms (e.g. mechanistic effect models at individual/population/landscape level)
7.	Data collection and statistical analysis: experts with experience in collecting,
8.	interpreting, analysing and summarising data Geographic Information System (GIS): expert with experience in collecting
8. 9.	Geographic Information System (GIS): expert with experience in collecting and analysing spatio-temporal data (e.g. climate, soil, land use/land cover) IT and digitalisation, such as AI, programming, database handling,

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Re	quested evidence:
•	EVIDENCE REQUESTED FOR REQUIREMENT 1 : A list of three major projects, including project reports relevant for each of the four main areas identified in sections 1.2 (table 1) and 1.3 of this call for proposal, carried out in the course of the past 10 years; Projects relevant for more than one main area can be counted for each relevant area i.e. one project can be relevant for two or more areas. The applicant shall provide a short description of the projects and reference to the reports. Information shall be reported according to the template available in the Annex <u>75</u> .
•	 EVIDENCE REQUESTED FOR REQUIREMENT 2: CURRICULUM VITAE of all the experts and other staff to be involved in the project including a brief description of the expertise, dates and duration of the relevant work experience. In addition: For the project coordinator a short description (max 1000 characters including spaces) of at least one managed large-scale project (≥1,000,000 €). For the information specialist expert, a short description (max 1000 characters including spaces) of at least three systematic literature searches performed For the senior experts a list of relevant publications in the last 10 years. For the junior experts a list of relevant publications and/or project they have contributed to.
	An indication on which of the to the four main areas identified in sections 1.2 (table 1) and 1.3 for each person proposed shall be provided. If individual team members are not yet assigned for the proposed project, applicant
	should provide details of the staff profiles necessary for the project project, applicate Applicant should also provide a one-page summary of the names of the individua Project team members and the profiles covered. Information shall be reported according to the template available in the Annex 25 .
•	LIST OF PROJECT TEAM MEMBERS NAMES – in addition to the CV's, the applicant should also summarise on one page, the names of the individual project team members. For requirements 2.4.B (including CVs), a template (Annex 5) is available to download in the Funding and Tenders Portal. The applicant must upload the completed template (a single pdf document of all requirements) in the relevant field under Part B and Annexes of the Funding and Tenders Portal
•	INDIVIDUAL DECLARATION OF INTERESTS Template available <u>here.</u> Individual DOIs will be requested from each member of the proposed project team (including staff of partners in the consortium and/or subcontractors) in advance of the signature of each specific agreement. <u>Individual DoIs do not need to be</u> provided with your proposal at this stage.

2.5 AWARD CRITERIA

Criterion	For the award criteria a template (Annex 6) is available to download in the
No. 2.5	Funding and Tenders Portal. The applicant must upload the completed template
	(a single pdf document of all criteria) in the relevant field under Part B and
	Annexes of the Funding and Tenders Portal.
	The award criteria serve to assess the quality of the proposals in relation to the objectives of the Call. The following award criteria are applicable in this call:

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1	UNDERSTANDING OF THE ASSIGNMENT AND TASKS REQUIRED. (max. 15 points)
	This is intended to assess the extent to which the proposal demonstrates a clear understanding of the assignment and project objectives covering all the aspects of the technical specifications.
	 The applicant should: a) Describe how they propose to perform the task described in the technical specifications and to perform the work necessary for achieving the objectives requested in this Open Call; b) Demonstrate ability in planning field and laboratory experimental work; c) Demonstrate that the proposal is within the scope of this Open Call.
2	METHODOLOGY PROPOSED FOR IMPLEMENTATION. (max. 30 points - minimum threshold 60%)
	This is intended to assess the extent to which the project is described in detail, as well as the proposed methodology is well described and of high quality with particular reference to the following:
	 a) Detailed and appropriate methodology for addressing activities belonging to the main areas/sub-areas described in section 1.3, including a logical and well-structured step by step explanation of the methodology; MAX 5 POINTS. b) Proposal for the selection of information sources such as databases and other resources proposed to gather the relevant information MAX 5 POINTS. c) Convincing evidence to ensure that the activities and milestones identified are feasible, including details on how data will be managed and how the experimental work will be planned MAX 10 POINTS.
	 d) Convincing evidence that the most suitable and most up to date IT tools and statistical methods will be used MAX 10 POINTS.
3	PROJECT MANAGEMENT AND ORGANISATION OF THE TASKS WITHIN CONSORTIUM AND RESPECT OF TIMELINES (max. 30 points -minimum threshold 60%)
	This is intended to assess the extent to which the project management is described in detail, with particular reference to the following:
	a) <u>Project programme description clarity.</u> Clear description of the project, including phases, clear timelines for the project tasks completion, detailed milestones for the main areas/subareas described in section 1.3 (e.g. via a project Gantt chart), expected outcomes and deliverables, proposed contingency plan in case of deviations from the project programme. MAX 10 POINTS.
	 b) <u>Task distribution</u>. Clear and detailed information on distribution of the tasks among the project team and consortium member; clarity on who does what, when and why (justify why the partner is proposed to do the particular task/work-package); MAX 5 POINTS.
	c) <u>Feasibility</u> of the proposed methodology of the project execution: MAX 5 POINTS.



 consortium (roles and responsibilities of the communication, frequency, mean/platform used); in case of subcontractors also the communication between the consortium and subcontractors; MAX 5 POINTS e) <u>Communication with EFSA.</u> Provide clear and detailed information on the frequency and type of communication with EFSA, the role of project leader in the coordination and tasks allocation in relation to the methodology and tools proposed; MAX 3 POINTS f) Dissemination activity. Provide clear proposal regarding a communication plan and activities to promote the project results MAX 2 POINTS
RISK MANAGEMENT (25 points -minimum threshold 60%)
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, with particular
reference to the following:
 a) Risk identification: risk associated with the proposed methodology; risk associated with uncertain access to data; risk associated to technical problems, specifically related to the experimental work; MAX 5 POINTS.
 b) Proposed risk mitigation actions and their likely effectiveness in terms of ensuring respect of timeline, scientific rigor and quality, and service continuity;
MAX 5 POINTS.
 c) Description of Quality Assurance/Quality Control principles for the experimental work and literature reviews; MAX 5 POINTS.
d) Description of internal review system for ensuring the quality of the written outputs, including the proof-reading of the reports; MAX 5 POINTS .
 e) Measures to ensure meeting deadlines including advancement monitoring tools; MAX 3 POINTS.
 f) Mitigation strategies for continuity of the service in case of absence of the member of the team; MAX 2 POINTS.

In order to be considered for a reserve list, the proposal must:

- score a minimum of 60 points out of maximum possible 100 points; and
- for criteria 2, 3, 4, score at least 60% of the points attributed to that criterion.

Proposals which have satisfied these quality thresholds will be ranked in a reserve list.

2.6 PROCESS FOLLOWING THE ASSESSMENT AGAINST AWARD CRITERIA

The applicant(s) will be notified, once the evaluation has been finalized, whether they are placed on the reserve list or not.

EFSA reserves the right to invite the 1st ranked applicant on the reserve list, to adapt its proposal based on the evaluators' comments in accordance with article 200(5) EU FR.

Following the successful conclusion of the adaptation phase, the award decision will be taken by EFSA. Subsequently, the grant agreement will be prepared.



If the 1st ranked applicant fails to adapt its proposal, EFSA reserves the right to reject the proposal. The budget made available in this way may be used for a project of the next ranked applicant on the reserve list.



3. SUBMITTING PROPOSALS

3.1 SUBMISSION MODALITIES

You must submit your proposal electronically via the <u>EU Funding & Tenders Portal</u> before the time limit for receipt of proposals (indicated on page 2 of this call). A webinar showing step-by-step the use of the EU funding and Tender Portal for Grant submission on a pilot EFSA call is available at <u>this link</u> (from minute 15:39 to minute 45:55).

Registration in the Participant Register

Applicants submitting a proposal 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 grant 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.

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 <u>EU Grants and</u> <u>Tenders Rules on Legal Entity Validation, LEAR appointment and Financial Capacity assessment</u>. Please note that a request for supporting documents by the EU Validation Services in no way implies that the grant application has been successful.

Submitting your proposal

The EU Funding & Tenders Portal allows applicants to respond to calls for proposals by preparing applications electronically in a structured and secured way and submitting proposals electronically.

To find more information on submitting your proposal, please read carefully the information on the page <u>Submit a proposal – electronic submission system</u>. On the same page useful links to the <u>User</u> <u>guide of the submission system</u> and an <u>FAQ on proposal submission</u> are provided.

Make sure you submit your application on time: you are advised to start completing your application early. To avoid any complications with regard to late receipt/non-receipt of applications within the deadline, please ensure that you submit your application several hours before the deadline. It is not possible to submit an application after the deadline.

APPLICATION SUBMISSION COMPLETENESS CHECKLIST

ELIGIBILITY CRITERIA: for details of which documents are needed see part 2.2 of the call:



- Administrative data forms signed (including Legal Entity and Financial Identification Forms) available <u>here.</u>
- Partnership Statement (only for consortium)
EXCLUSION CRITERIA: for details of which documents are needed see part 2.3 of the call:
- Declaration on honour section A, available here.
 SELECTION CRITERIA: for details of which documents are needed see part 2.4 of the call: Declaration on honour section B, available <u>here</u>. Simplified Financial Statement, available <u>here</u> only for private bodies if the grant requested from EFSA is >60.000 €. Letter of commitment applicable only when another public body financially contributes to the project Evidence for requirement 2.4.B.1 (Requirements for the organisation) and 2.4.B.2 (Requirement for the team of experts) – Annex 57 Summary professional capacity
 AWARD CRITERIA: Technical proposal covering award criteria, see part 2.5 of the call, in particular the applicant is requested to submit with the proposal a workplan detailing how the applicant will plan the activities as described in sections 1.2 and 1.3.

3.2 LANGUAGE OF THE PROPOSAL AND THE SUPPORTING DOCUMENTS

Proposals may be submitted in any official language of the European Union. However, as EFSA's working language is English, the submission of proposals in English would speed up the evaluation process.

Please note that some supporting documents (e.g. CVs) are required. These supporting documents are an integral part of the proposal. If these supporting documents are in a language other than English, in order to facilitate and speed up the evaluation, it would be appreciated if a reliable translation of the relevant parts of the documents into English is provided with the proposal.

3.3 EXPECTED DURATION OF PROCEDURE

In accordance with Article 194(2) of the Financial Regulation, the maximum time-limits for the procedure are as follows:

- All applicants will be informed of the decision regarding their application within 6 months of the deadline for submission of proposals.
- Signature of the grant agreement will take place within 3 months from the date the successful applicant/s has/have been informed of the decision on their application.