



## CALL FOR PROPOSALS AND GUIDE FOR APPLICANTS

**Call reference:** EUBA-EFSA-2024-NIF-01

**Call title:** Contribution to the Risk Assessment of Novel Foods and Nutrient Sources in the EU.

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 and key messages:** EFSA is responsible for EU risk assessments of materials from farm to fork. With this Call for Proposals, EFSA is launching a new opportunity to involve [competent organisations](#) in the assessment of Novel Food (NF) dossiers submitted to EFSA under Regulation (EU) 2015/2283 and the preparation of scientific opinions (specific sections or in full) for the NF regulatory domain. The objective of this call is to identify and award a four-year Framework partnership agreement (FPA) to one or more competent organisations or consortia thereof that can provide capacity and expertise (chemistry, microbiology, biotechnology, food technology, nutrition, ADME, exposure and toxicology) that are relevant for the assessment of NF technical dossiers.



## INDICATIVE PROCEDURE TIMETABLE

Milestone	Date <sup>1</sup>	Comments
<b>Launch date</b>	11/06/2024	Date of call publication on EFSA's website.
<b>Deadline for applicants to raise clarification questions to EFSA</b>	14/10/2024	If, after having read this Call for proposals and guide for applicants, you have any questions, you may address them to <a href="mailto:EFSAProcurement@efsa.europa.eu">EFSAProcurement@efsa.europa.eu</a> by indicating the Call reference.
<b>Deadline for EFSA to reply to clarification questions</b>	16/10/2024	Replies will be provided on EFSA's webpage where this Call is published and which the applicants are requested to consult regularly.
<b>Deadline for submission of proposals</b>	21/11/2024 At 17:00 (CEST)	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. <b>Hard copy paper applications will not be accepted.</b>
<b>Notification of the evaluation results</b>	DECEMBER 2024	Estimated <i>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.</i>
<b>Grant agreement(s) signature</b>	DECEMBER 2024/ JANUARY 2025	Estimated

<sup>1</sup> All times are in the time zone of the country of the EFSA.



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**ANNEXES**

Annex 1: Draft grant agreement

Documents to be submitted with proposals (to be downloaded from the EU Funding and Tender portal Submission Service, see section 2 'Selecting proposal')

Annex 2: Administrative Declaration

Annex 3: Declaration on honour on exclusion criteria

Annex 4: Declaration on honour on selection criteria

Annex 5: Selection criteria template (all requirements including CVs)

Annex 6: Award criteria template



## 1. GRANT OPPORTUNITY AND CONDITIONS<sup>2</sup>

### 1.1 LEGAL FRAMEWORK

Article 36 (1) of the Regulation (EC) 178/2002<sup>3</sup> 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 to facilitate a scientific cooperation framework by the coordination of activities, the exchange of information, the development and implementation of joint projects<sup>4</sup>, 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 [here](#).

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 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 tasks defined in Article 4(3), 5th point - preparing the Authority's scientific opinions, including preparatory work relating to the assessment of authorisation dossiers.

Article 5(2) of the Commission Regulation (EC) 2230/2004<sup>5</sup> 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.

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<sup>2</sup> 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.

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

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

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



This call is based on EFSA's Founding regulation<sup>6</sup> and EFSA's 2024 Work Programme for grants and operational procurements as presented in Annex XII of the Programming Document 2024-2026, available on the EFSA's website<sup>7</sup>.

## 1.2 BACKGROUND AND OBJECTIVES OF THE CALL

### BACKGROUND

EFSA is responsible for EU risk assessments of materials from farm to fork. With this Call for Proposals, EFSA is launching a new opportunity to involve [Article 36 organisations](#) in the assessment of Novel Food (NF) and Nutrient Sources (NS) dossiers submitted to EFSA under Regulation (EU) 2015/2283 and the preparation of draft opinions (specific sections thereof or in full) for the NF regulatory domain. Indicatively EFSA expects an average of 20 dossiers per year to be outsourced to the beneficiaries.

### OBJECTIVES OF THE CALL

The objective of this call is to identify and award a four-year Framework partnership agreement (FPA) to a maximum of three MS competent organisations (or consortia consisting of MS competent organisations) in cascade, that can provide both capacity and all expertise that is relevant to NF and NS technical dossiers (chemistry, microbiology, biotechnology, food technology, nutrition, ADME<sup>8</sup>, exposure and toxicology) and necessary for evaluating the dossiers submitted by applicants.

The involvement of the beneficiaries in the risk assessment workflow is explained in section 1.3.1.

Only competent organisations are eligible to apply to this Call (see section 1.5). The applicants must provide the following full complement of expertise and services to EFSA.

- i. Scientific expertise in the areas relevant to Novel Foods and Nutrient Sources
- ii. Centralised scientific coordination
- iii. Centralised administrative coordination

The roles and responsibilities of involved organisations are defined in Section 1.6.

## 1.3 TASKS TO BE PERFORMED BY THE FPA BENEFICIARY(-IES) UNDER SPECIFIC AGREEMENTS

EFSA will supply the technical dossier validated by the EC and following completeness check by FDP, additional data from Additional Data Requests raised during the risk assessment, the applicable guidance documents and the templates for the draft scientific opinions.

### 1.3.1 Involvement of the FPA beneficiary in the risk assessment workflow and indicative timelines

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<sup>6</sup> 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.

<sup>7</sup> <https://www.efsa.europa.eu/sites/default/files/2024-01/programming-document-2024-2026.pdf>

<sup>8</sup> Absorption, Distribution, Metabolism and Excretion



Based on the current application process described here for novel foods and nutrient sources, the workflow foreseen within the frame of this Framework Partnership Agreement is summarised in Figure 1.

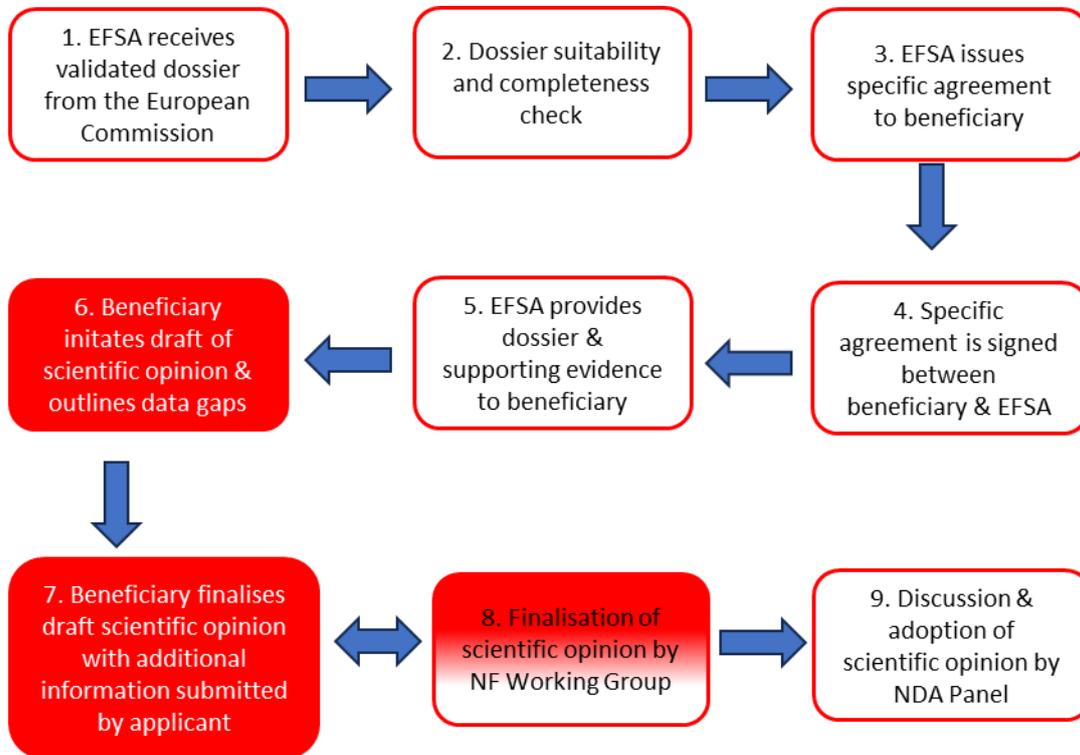


Figure 1. Workflow for scientific assessment of NF applications within the frame of the FPA. The steps relate to EFSA's procedures (i.a. tollgates and underlying regulatory framework).

The beneficiary will contribute to steps 6 & 7 of Figure 1. In addition, the possibility of contribution of the beneficiary to the discussions of the Working Group as Hearing Experts is foreseen (Step 8). The following tasks (i.-vi. below) are foreseen. One EFSA scientific officer(s) of the Novel Foods Team will be assigned as project manager for each dossier outsourced and will be the reference person for the beneficiary on all the matters related to the handling of the novel food/nutrient sources dossier. Regular reporting to NF Team counterpart(s) is needed to keep track of progresses and comply with EFSA procedures and the legal framework (Regulation (EU) 2015/2283). The following list of tasks delineates those to be carried out and those that are envisaged to be carried out by the beneficiary, alone or in conjunction with EFSA.

- i. EFSA to check suitability and completeness of the data provided in the dossier with the Guidance documents for NF and NS (and Guidance documents referred to therein) and EFSA's internal checklists. (Steps 1 & 2)
- ii. Beneficiary to analyse critically the data (e.g. chemical and microbiological data, intake assessment, reports of animal and human studies in the area of ADME, toxicology and nutrition, and allergenicity data) submitted in the dossier, and outline (if any) data gaps which would necessitate for a request by EFSA for Additional Information to the applicant. (Step 6)
- iii. Beneficiary to analyse critically the literature search performed by the applicant and check for relevant missing publications or reports that are in the public domain. (Step 6)
- iv. Beneficiary to assess all the information under ii) and iii) and prepare accordingly a draft of all the sections for a first full draft of the scientific opinion. This should be based on the information assessed and according to the template for scientific opinion provided by EFSA. (Steps 6 & 7)



- v. In case additional information identified under (ii) is requested by EFSA to the applicant, the beneficiary is requested to assess the data submitted by the applicant in reply to the questions within 2 weeks. However, if the reply to the questions or the submitted data are incomplete or unclear, the beneficiary will communicate to EFSA on the need to raise a clarification request to the applicant. Once the additional information is complete and/or once the clarification has been provided, the beneficiary is requested to update the draft opinion with the information received within 3 weeks. (Step 7)
- vi. When needed, participation of a representative of the beneficiary in one or more Working Group meetings in the role of a hearing expert to provide clarifications on the draft opinion may be requested. This participation will be reimbursed under EFSA rules for hearing experts, and not under this grant. (Step 8)

The tasks i. – vi. are linked to the lifecycle of an application. Tasks v-vi may be required to complete the final deliverable. When required, completion of these tasks will be considered as the final deliverable. When tasks v-vi are not required, the intermediate deliverable (completion of tasks i-iv) will be treated as the final deliverable.

The beneficiary will be requested to deliver the first full draft of the scientific opinion indicatively within 4 (four) months after getting access to the technical dossier (to complete tasks i-iv). It should be noted that in case of identification of data gaps that require the submission of additional data or of the need for clarifications, EFSA has a clock stop mechanism in place to suspend the scientific evaluation until the missing information has been submitted and is considered satisfactory. This may require the preparation of an accordingly updated draft of the scientific opinion once the additional data/clarifications have been received. In addition to the time allocated to the preparation of the draft scientific opinion, EFSA may request participation of a representative of the beneficiary in one or more Working Group meetings in the role of a hearing expert to provide clarifications on the draft opinion. In the absence of clock stops, the total time available from successful completeness check of the dossier to adoption of the scientific opinion by the NDA Panel (i.e., the legal deadline) is 9 months.

#### **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.

The envelope EFSA has available to award grants under this call for proposals is **€ 3,500,000**. Applicants should note that in the Funding and Tender opportunities portal submission service under Administrative Form (Part A) there is an obligatory field regarding the budget (section 3). Applicants must insert the total envelope (please choose relevant option for your call) in the 'Requested grant amount' field.

##### **1.4.1 Framework Partnership Agreement:**

This Call for proposals aims to conclude a maximum of three Framework Partnership Agreements (FPA) in cascade 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 maximum duration of this Framework Partnership Agreement is 4 years.



**Cascade mechanism:** The points awarded in the evaluation will constitute the ranking in order to establish a cascade of beneficiaries. EFSA will consult the beneficiary ranked first to conclude a specific agreement for work to be carried out.

The beneficiary should confirm their acceptance of the terms described in the specific agreement within 10 calendar days, and, where requested, submit the CVs and Individual Declarations of Interest of staff members fulfilling the expertise requirements. In case the beneficiary does not accept the terms described in the specific agreement, they should reply within 10 calendar days. In case of a negative reply EFSA will contact the second beneficiary in the cascade and the above timescales for replying would be applicable.

#### **Specific Agreements:**

Specific Agreements will be awarded to a FPA beneficiary based on the cascade mechanism described above. Each Specific Agreement will set out the specific conditions for performing the respective assignment and will define the exact timing of deliverables/milestones.

The ownership of the delivered outputs as a result of these tasks will be vested solely in EFSA and EFSA will be solely responsible of the results of the tasks performed. Only with EFSA's prior written permission the beneficiary will be allowed to use the outputs resulting from the entrusted tasks.

The working language for performance of tasks will be English.

Should EFSA, during the implementation of a specific agreement, identify that a staff member of the beneficiary working on a task is not performing according to expectations, EFSA has the right to request a replacement of staff member from the beneficiary. The beneficiary in such a case must ensure there is a smooth handover between the outgoing and new staff member and at the same time the beneficiary shall endeavour to minimise any negative impact from such a change of staff on the execution of the entrusted task.

#### **1.4.2 EFSA grant contributions**

The present Call for proposals comes with a simplified grant management, where the grant amounts paid to the beneficiary are based on predefined sums that are not linked to the costs of the action. This means there is no need of co-financing from the beneficiary, and no need of estimated budget or timesheets to record the work. The agreed sums are set at a level to positively encourage 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.

This Call will result in one or more FPAs to be signed (up to three). This includes the following estimations.

- i. Novel Foods and Nutrient Sources dossier assessments, including drafting of sections contributing to the scientific opinions and assemblage of the draft opinions (3,000,000 euro)
- ii. Centralised scientific coordination (250,000 euro)
- iii. Centralised administrative coordination (250,000 euro)

The breakdown is given as an indication; EFSA reserves the right to shift budget across tasks depending on the actual needs. EFSA reserves the right not to award Specific Agreements under the FPA without any compensation to be paid to the beneficiaries.

The grant amount of each Specific Agreement will be established based on the complexity of the dossier entrusted to the beneficiary. It implies that many scenarios with different grant amounts can be envisaged, in line with the preestablished mechanism indicated in Table 1.



Table 1 – Evaluation of technical dossiers, drafting of sections and assemblage of opinion based on complexity

	Task/expertise	Complexity of tasks €		
		(Low)	(Medium)	(High)
a	Product characterization (Identity, compositional data, food technology and manufacturing process)	3,600	6,000	8,400
b	Intake assessment (history of use, proposed uses and use levels and anticipated intake)	1,200	2,400	3,600
c	ADME	2,400	3,600	4,800
d	Toxicology	3,600	6,000	8,400
e	Nutritional assessment	2,400	3,600	4,800
f	Human studies	2,400	3,600	4,800
g	Allergenicity	600	1,200	1,800
h	Draft Opinion assemblage	3,600	6,000	8,400

Complexity is assigned based on EFSA experience, considering the work needed to complete one opinion. As a result, different permutations across the different tasks will be possible depending on the complexity of the different parts of the technical dossier, and, where necessary, the need for additional literature search is identified. It is important to note that each Specific Agreement is set up to cover an entire draft scientific opinion and therefore covers all tasks from a to h, and that each task has its fixed price depending on the complexity of the dossier. Under this FPA, choosing individual tasks will not be possible.

In addition, each Specific Agreement will benefit from an additional €4,000 for the centralised scientific coordination and €4,000 for the centralised administrative coordination.

#### Examples:

Example 1: For Specific Agreement X the beneficiary is entrusted on the following technical dossier, as judged by EFSA.

Tasks a, c, g, h: medium complexity

Tasks b, d, e, f: low complexity

The Specific Agreement amounts to 26,400 euro for the scientific work plus 8,000 euro for the coordination activities.

Example 2: For Specific Agreement Y the beneficiary is entrusted on the following technical dossier, as judged by EFSA.

Tasks a, c, h: high complexity

Tasks b, d, e, f: medium complexity

Task g: low complexity

The Specific Agreement amounts to 37,800 euro for the scientific work plus 8,000 euro for the coordination activities.



EFSA will generally issue 12-months Specific Agreement to account for possible additional data, if applicable which may be required to complete the final deliverable. Upon execution of the work, and approval by EFSA of the final deliverable, EFSA will pay the agreed amount. There will be no verification of actually incurred costs, no statement of the costs to be submitted to EFSA, as the form of grant awarded under this Call is based on financing not linked to costs.

It should be noted that in case of additional data requests being sent to the applicant(s) this will lead to a stop of the clock-time by EFSA of the assessment. If the additional data requests have an impact on the scientific assessment performed by the beneficiary, and if this leads to a stop of the clock-time of more than four months, then the Specific Agreement is put on hold and the beneficiary will be paid for the work performed up to that point, pending evaluation of the tasks performed by EFSA. Should the stop-the-clock period exceed one year, then an additional €3,000 for the re-initiation of the scientific coordination and scientific work on the technical dossier will be paid by EFSA.

Specific Agreements signed before expiry of FPA will continue until their completion, which could - if necessary - be up to 12 months after FPA expiry (including any clock-stops). In exceptional cases, this period could be longer than 12 months.

### 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 the EFSA Management Board and is available for consultation using this link <https://efsa.force.com/competentorganisations/s/>.

To achieve the main objective of the call, proposals can be submitted by **one eligible organisation or by a consortium of eligible organisations. EFSA would prefer to sign the Framework Partnership Agreements with consortia, however organisations applying as such (i.e., not being part of any consortium) will not be excluded if all criteria are met.** In case of proposals coming from consortia, one of the partners must be identified in the proposal as the consortium leader ("the applicant"). The applicant is responsible for identifying consortium partners.

**If you are searching for consortium partners, please contact your national Focal Point. The list of the EFSA Focal Points is available at the following address:** <https://www.efsa.europa.eu/en/partnersnetworks/eumembers> (section: Focal Points members and observers).

### 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 a sole applicant:

- **The Applicant** submits the proposal to EFSA. There can be only one applicant in the proposal.

As soon as the grant agreement is signed, the applicant becomes the beneficiary. The beneficiary is liable for the technical implementation of the project as described in the proposal which becomes Annex 1 of the grant agreement.

#### The beneficiary:

- Communicates with EFSA;



- Receives and answers all claims EFSA might have in relation to the 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 of any event that is likely to substantially affect the implementation of the project;
- Submits the deliverables and reports to EFSA;
- Requests and receives payments from EFSA;
- Nominates one member who will be responsible for control over scientific outputs within the consortium for each of task/expertise areas described in Table 1.

### 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 that 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;
- Nominates one member within the consortium who will be responsible for control over scientific outputs within the consortium for each of task/expertise areas described in Table 1.
- 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;
- Ensures that the beneficiaries participate to the training provided by EFSA to ensure that the style and formatting of EFSA opinions to be adopted by the EFSA NDA Panel are being implemented;
- 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.

**EFSA's roles and responsibilities**

EFSA has the following important roles and responsibilities towards the beneficiaries.

- Provide access to the full technical dossiers to the beneficiaries within 3 working days of the signing of the Specific Agreement;
- Provide IT support to ensure access to relevant EFSA documents;
- Provide the templates to be used for drafting the sections of the scientific opinions and their assemblage;
- Provide appropriate training to ensure that the style and formatting of EFSA opinions to be adopted by the NDA Panel are being implemented.

**1.7 POSSIBILITY OF SUBCONTRACTING**

Subcontracting is not permitted under this call for proposals (i.e., staff members working in the project must be employed by the organisation awarded the grant).

**1.8 PAYMENTS**

**Final payment** follows approval by EFSA of the final deliverable. With the final payment, the Specific Agreement is concluded.

It should be noted that in case of additional data requests being sent to the applicant(s) this will lead to a stop of the clock-time by EFSA of the assessment. If the additional data requests have an impact on the scientific assessment performed by the beneficiary, and if this leads to a stop of the clock-time of more than four months, then the Specific Agreement is put on hold and the beneficiary will be paid an **interim payment** for the work performed up to that point, pending evaluation of the tasks performed by EFSA. Should the stop-the-clock period exceed one year, then an additional €3,000 for the re-initiation of the scientific coordination and scientific work on the technical dossier will be paid by EFSA as **interim-payment**.

**1.9 GRANT 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 [EFSAProcurement@efsa.europa.eu](mailto:EFSAProcurement@efsa.europa.eu).

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.

### 1.10 ESTIMATED BUDGET AND ELIGIBLE COSTS

For the submission of a proposal under this Call for proposals, leading to the signature of an FPA, no estimated budget is required.

### 1.11 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

### 1.12 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 [Privacy Statement](#) on the EFSA website as well as in Article 15 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.<sup>9</sup>

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/protecting/protect\\_en.cfm#BDCE](http://ec.europa.eu/budget/explained/management/protecting/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 15 of the Grant Agreement (Annex 1) as a data processor of EFSA.

### **1.13 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.

### **1.14 Hungarian public interest trusts established under Hungarian Act IX of 2021**

Following the Council Implementing Decision (EU) 2022/2506, as of 16th December 2022, no legal commitments (including the grant agreement itself as well as subcontracts, purchase contracts, financial support to third parties etc.) can be signed with Hungarian public interest trusts established under Hungarian Act IX of 2021 or any entity they maintain.

Affected entities may continue to apply to calls for proposals. However, in case the Council measures are not lifted, such entities are not eligible to participate in any funded role (beneficiaries, affiliated entities, subcontractors, recipients of financial support to third parties).

## **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;

<sup>9</sup> 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



- 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**

The following requirements will be verified.

- 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 – not applicable

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.

**2.3 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 HONOUR ON EXCLUSION CRITERIA**

Annex 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 separate forms. The applicant must upload the form in the relevant field under Part B and Annexes of the Funding and Tenders Portal. If applying in consortium, the consortium leader must convert all declarations on honour on exclusion for all partners 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. <b>2.4A</b>	Requirements and requested evidence
<b>1</b>	<b>Financial capacity</b>



	<p>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.</p>
	<p>The applicant and in case of consortium also its partner/s must have stable and sufficient financial resources to:</p> <ul style="list-style-type: none"> <li>• maintain their activity throughout the period during which the project is being carried out, and</li> </ul> <p>If the Authority considers that financial capacity is weak, it may:</p> <ul style="list-style-type: none"> <li>– request further information;</li> <li>– decide not to give pre-financing;</li> <li>– decide to give pre-financing paid in instalments;</li> <li>– decide to give pre-financing covered by a bank guarantee;</li> <li>– where applicable, require the joint and several financial liability of all the co-beneficiaries.</li> </ul> <p>If the EFSA Authorising Officer considers that the financial capacity is insufficient, the application may be rejected.</p>
	<p>Requested evidence:</p>
	<p><b>Documents to be provided by the applicant:</b></p> <p><b>DECLARATION ON HONOUR ON SELECTION CRITERIA</b> 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.</p> <ul style="list-style-type: none"> <li>• <b>SIMPLIFIED FINANCIAL STATEMENT</b> available <a href="#">here</a> only required for private bodies if the grant requested from EFSA is &gt;60.000 €. The template published with the Call should be completed for at least the last two closed financial years.</li> <li>• <b>AUDIT REPORT</b> only required for private bodies if the grant requested from EFSA is &gt;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.</li> </ul> <p>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.</p> <p>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.</p> <ul style="list-style-type: none"> <li>• <b>LETTER OF COMMITMENT:</b> 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 contribute to the project; no template is provided by EFSA.</li> </ul>



The applicant must convert the **Declaration on honour on selection criteria, the Simplified Financial statement (if applicable) and the letter of commitment** (if applicable) into one single pdf and upload the single document in the relevant field under Part B and Annexes of the Funding and Tenders Portal.

## **B. Professional and operational capacity**

### A. Requirements

The applicant or in case of a consortium, the consortium as a whole, must have the professional resources, competencies, qualifications and capacity necessary to complete the proposed project:

#### **1. Requirements for the organisation:**

The applicant should provide evidence of expertise (at least 3 years) in the field of:

- 1.1 Centralised scientific coordination for the execution of the contract
- 1.2 Centralised administrative coordination for the execution of the contract

#### **2. Requirements for the team of experts:**

2.1 The applicant should provide a team of experts with at least a bachelor degree and three years of relevant post-university working experience. The team as a whole should cover the expertise in all the below areas. For **each of the expertise areas (a-g), one member who will coordinate and be responsible for control over scientific outputs should be proposed**. This person should have an excellent level of spoken and written UK English. For non-native speakers, this should be demonstrated by an Official certificate of English proving a C1 level OR at least 3 years of work in an English-speaking environment.

- a. Chemical product characterisation, e.g.
  - Physico-chemical analysis of chemicals as, and in, novel foods
  - Characterisation of impurities
  - Analysis of formulations and compositional data
- b. Biological product characterisation, e.g.
  - Microbiological analysis
  - Assessing microorganism characterisation data
  - Molecular biology
  - Fermentation and biotechnological processes
- c. Intake assessment, e.g.
  - History of use
  - Proposed uses and use levels and anticipated intake
- d. ADME, e.g.
  - Assessment of toxicokinetic studies
- e. Toxicology, e.g.
  - Expertise in the conduct of toxicological studies in laboratory animals and other animal species
  - Genotoxicity



- Pharmacology, toxicology (reproductive and developmental, neurotoxicology, immunotoxicology)
  - Immunotoxicology, including allergenicity
- f. Human nutrition
- g. Epidemiology and human studies

**3. Environmental management (the answers to this section are for information purposes and will not be considered under any criteria, neither selection nor award criteria):**

Environmental protection is an integral part of EFSA's governance. EFSA has established, implemented and maintains a certified environmental management system in accordance with the international standard ISO 14001 and the European EMAS regulation. Environmental impacts of EFSA's activities are identified, managed and monitored in order to improve environmental performance. This commitment to environmental sustainability requires us to consider a life-cycle perspective when purchasing our services.

For this reason, we are asking you some information on the environmental management of your activities, to be provided filling in **Annex 5 (Selection criteria)**.

B. Requested evidence

**EVIDENCE REQUESTED FOR REQUIREMENT 1:**

Evidence of a recently finalised research project (within the last 3 years) and of a new or ongoing research project relevant to the topics of this grant.

**EVIDENCE REQUESTED FOR REQUIREMENT 2:**

- 1) **CURRICULUM VITAE** of the experts to be involved in the project, including a brief description of the expertise and a list of publications relevant to the project for each person proposed. If individual team members are not yet assigned for the proposed project, applicants should provide details of the staff profiles necessary for the project; EFSA strongly recommends submitting the CVs in the EU CV format which can be accessed [here](#).
- 2) **CURRICULUM VITAE** of the staff responsible for the centralised overall scientific coordination and for the centralised administrative coordination for the execution of the contract.
- 3) Official certificate of English proving a C1 level, if applicable.
- 4) In addition to the CVs, the applicant should summarise in one page, **the names of the members who will coordinate and be responsible for control over scientific outputs for each of the expertise areas** (a-g) described above.
- 5) In addition to the CVs, the applicant should also summarise on one page, the names of **all** the individual project team members.

**EVIDENCE REQUESTED FOR REQUIREMENT 3:**

Annex 5 – Selection criteria, Information on environmental management

**For requirements 1-3 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 including CVs), in the relevant field under Part B and Annexes of the Funding and Tenders Portal.**



## DECLARATION OF INTERESTS (DoIs)

Institutional DoI is not requested for this grant.

Individual DOIs may be requested for members of the project team having influence and/or control over scientific outputs (i.e. the individuals listed above under requirement B3), in advance of the signature of each specific agreement. Template available [here](#). **Individual DoIs do not need to be provided with your proposal at this stage.** Please refer to [EFSA's policy on independence](#) and the [Decision of the Executive Director on Competing Interest Management](#) for more detailed information.

## 2.5 AWARD CRITERIA

The award criteria serve to assess the quality of the proposals in relation to the objectives of the Call. The proposals that have satisfied the below indicated quality thresholds will be ranked according to the award criteria obtained to form the cascade of beneficiaries to whom an FPA will be awarded. The following award criteria are applicable in this call.

### AWARD CRITERIA (Max. 100 points)

**1. Quality of resources.** Describe the resources, both in terms of quantity (number of proposed experts), and quality (years of experience, quality of experience), including risk mitigating actions, that you have available for tasks to be entrusted from EFSA, and how you intend to make it quickly (in terms of days) available after the task is entrusted via signed specific agreement. Also provide a list of activities, publications and/or reports performed in the past five years demonstrating the quality in appraising study reports in accordance with the relevant principles and methodologies (e.g., applicable OECD TGs, analytical techniques, etc.) for each of the areas that are listed under 2.4. Professional and operational capacity. **(max. 40 points, pass-mark 28 points)**

**2. Timeliness of delivery.** Describe how the resources will ensure delivery of the drafted assessments of the individual areas of a technical dossier relevant for the draft opinion and how they will ensure the assemblage of the draft opinion and its delivery to EFSA within four months from receipt of the dossier, including risk mitigating actions **(max. 20 points, pass-mark 14 points)**

**3. Quality of the centralised scientific and administrative coordination.** Describe how the assigned task is to be distributed among experts involved, how it is coordinated and how you will ensure the quality control of the executed work, including mention to potential risks and risk mitigating actions **(max. 20 points, pass-mark 14 points)**

**4. Quality of continuity.** Describe how you will guarantee that the experts will be available at the time of need during FPA 4 years life, and which measures you will take in the case there will be fluctuation changes to the proposed pool of experts, including mention to potential risks and risk mitigating actions. In particular, explain how the newly assigned experts will guarantee the same level of quality of expertise throughout the life of the FPA **(max. 20 points, pass-mark 14 points)**

Based on the above scoring, each proposal will be ranked if it passes all the pass-marks and scores in total a minimum of 70 points out of maximum possible 100 points. A Framework Partnership Agreement will be signed with the three highest ranked proposals. In case there is a specific assignment to be entrusted by EFSA, the ranking resulting from the above scoring will be respected.

**For the award criteria a template (Annex 6) is available to download in the 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.**

## **2.6 PROCESS FOLLOWING THE ASSESSMENT AGAINST AWARD CRITERIA**

Following their ranking in the first three positions, EFSA reserves the right to invite applicants to adapt their 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.

In case some applicants fail to adapt the proposal, EFSA reserves the right to reject the proposal. The budget made available in this way may be used for projects of next applicants.

The applicants will be notified, once the evaluation has been finalized, whether they are among the first three ranked or not.

## **3. SUBMITTING PROPOSALS**

### **3.1 SUBMISSION MODALITIES**

You must submit your proposal electronically via the [EU Funding & Tenders Portal](#) 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 [this link](#) (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 [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 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 [Submit a proposal – electronic submission system](#). On the same page useful links to the [User guide of the submission system](#) and an [FAQ on proposal submission](#) 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.

## 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.