NUTRI UNIT

NEW SIMPLIFIED FORM OF GRANT:
FINANCING NOT LINKED TO THE COSTS

CALL FOR PROPOSALS
and guide for applicants

Call reference: GP/EFSA/NUTRI/2021/01
Call title: Support to EFSA in the Safety Assessment of Novel Foods and Nutrient Sources

Restricted to the list of competent organisations adopted by EFSA Management Board according to Article 36 of European Parliament and Council Regulation (EC) No 178/2002

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INDICATIVE PROCEDURE TIMETABLE

Milestone	Date[1]	Comments
Launch date	30/11/2021	Date of call publication on EFSA's website.
Deadline for applicants to raise clarification questions to EFSA	09/2/2022	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	11/2/2022	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 Any proposal posted after the final deadline will automatically be rejected.	**17/2/2022**	Applicants can submit proposals: - either by post (registered mail) or by courier not later than **17/2/2022**, in which case the evidence of the date of dispatch shall be constituted by the postmark or the date of the deposit slip, to the address indicated below. The applicant submitting a proposal by post or by courier is requested to send an informative e-mail to EFSAProcurement@efsa.europa.eu. - or delivered by hand **not later than 12.30 hours (Italian time) on 17/2/2022** to the address indicated below. In this case, a receipt must be requested from EFSA as proof of submission, signed and dated by the staff member in EFSA Post Office who accepted the delivery. The EFSA Post Office is open from 8.30 to 12.30 Monday to Friday. It is closed on Saturdays, Sundays and EFSA holidays. Submission by post, courier or hand to this address: *European Food Safety Authority - EFSA* *For the attention of – Andrea LAMA, Finance Unit (Procurement Team)* *Via Carlo Magno 1/A, I – 43126 Parma, Italy* Proposals must be submitted using the double envelope system. The outer envelope should be sealed with adhesive tape, signed across the seal and carry the following information: - *"CALL FOR PROPOSALS GP/EFSA/PRES/2021/02 – NOT TO BE OPENED BY THE INTERNAL MAIL DEPARTMENT".* - name of the applicant - **the posting date should be legible on the outer envelope**
Notification of the evaluation results	February 2022	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.*
Grant agreement(s) signature	March 2022	Estimated.

[1] All times are in the time zone of the country of EFSA.

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1. GRANT OPPORTUNITY AND CONDITIONS[2]

1.1 LEGAL FRAMEWORK

Article 36 (1) of **the Regulation (EC) 178/2002**[3] **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 projects[4], the exchange of expertise and best practices in the fields within the Authority's mission.

The Commission Regulation (EC) 2230/2004[1] 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 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**[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**.

This Call is based on **EFSA's 2021 Work Programme for grants and operational procurements** as presented in Annex XIa of the Programming Document 2021 – 2023, available on the EFSA's website[6].

On the 19th December 2006 the Management Board, acting on a proposal from the Executive Director, drew up a **list of competent organisations designated by the Member States** which may assist EFSA, either individually or in networks, with its mission. This list is regularly updated by EFSA's Management Board.

[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 attached to this Call.

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

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

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

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

1.2 BACKGROUND AND OBJECTIVE OF THE CALL

1.2.1 BACKGROUND

The safety assessment of novel foods (NF) (defined by EU legislation as "foods or ingredients that have not been used for human consumption to a significant degree in the EU before 15 May 1997") is carried out by EFSA, particularly the Panel on Nutrition, Novel Foods and Food Allergens (NDA Panel) and its Working Group on Novel Foods (WG NF), on the basis of the following regulatory framework:

- Regulation (EU) 2015/2283[7] introduces a centralised assessment and authorisation procedure for novel foods as of January 2018. All applications for the authorisation of NF shall be submitted to the European Commission (EC) who may then request EFSA to carry out a safety assessment.
- EFSA will adopt its opinion in 9 months[8] from the date of receipt of a valid application from the EC. The final output provided by EFSA on the safety of the concerned NF serves as the scientific basis for the EC to take EU authorisation decision for the placing of the NF on the EU market.
- Data requirements for applications (technical dossiers) are outlined in EFSA Guidance[9] on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283.

Before January 2018, Member State (MS) competent authorities were responsible for the initial risk assessment of Novel Food dossiers according to Regulation (EC) No 258/97. An applicant would have submitted a dossier to a specific MS competent authority, which would have carried out the initial risk assessment and would have then shared it with the EC and other MS competent authorities. If safety issues were identified by other MS, then the EC would have requested EFSA to perform the risk assessment of that novel food. Therefore, MS competent authorities were directly involved in the evaluation of novel food dossiers with one third of the EU member states actively contributing to the process either by performing initial risk assessment or commenting on the initial risk assessment report. This indicates that at the time, several member states had risk assessment expertise and scientific and technical competencies in the area of NF in their competent authorities or through their national committees.

Regulation (EU) 2015/2283 defines novel food categories (referring to foods that were not used for human consumption to a significant degree within the Union before 15 May 1997) as follows:

(i) food with a new or intentionally modified molecular structure,
(ii) food consisting of, isolated from or produced from microorganisms, fungi or algae;
(iii) food consisting of, isolated from or produced from material of mineral origin;
(iv) food consisting of, isolated from or produced from plants or their parts, except when the food has a history of safe food use within the Union
(v) food consisting of, isolated from or produced from animals or their parts,
(vi) food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae;

[7] REGULATION (EU) 2015/2283 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001

[8] Excluding stop-the-clock times needed for requesting supplementary information to applicants

[9] EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2016. Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283. EFSA Journal 2016;14(11):4594, 24 pp. doi:10.2903/j.efsa.2016.4594

(vii) food resulting from a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism, or level of undesirable substances;
(viii) food consisting of engineered nanomaterials (as defined as defined in Art. 3(2.f) of Regulation (EU) 2015/2283);
(ix) vitamins, minerals, and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013
(x) food used exclusively in food supplements within the Union before 15 May 1997, where it is intended to be used in foods other than food supplements

Since the coming into force of Regulation (EU) 2015/2283 and the centralization in EFSA of the safety assessment activities related to NF,

- EFSA is facing a continuous increase in the number of NF mandates, from 84 received in the period 2003-2017, to over 150 received since 2018
- despite EFSA allocated considerable new resources to the risk assessment process for Novel foods, the combination of an extremely high workload and the 9-months legal deadline for finalising the scientific assessment is overstretching both internal capacity and contribution of external experts, to a level that would be difficult to sustain on a long term
- EFSA has put in place schemes to increase collaboration with external experts (e.g. Individual Scientific Assistance (ISA) scheme for specific tasks)
- the scientific and technical capacity of NF assessment which was present at MS level up to 2018 doesn't contribute anymore to the EU risk assessment and may gradually get lost.

To increase and optimise the capacity of NF and nutrient sources (NS) assessment, EFSA is exploring the opportunity:

- To benefit from the existing scientific and technical capacity in safety assessment in the framework of Regulation (EC) No 258/97, which is present at Member State (MS) level and also available in universities or organisations (included in the Art. 36),
- To benefit from specific expertise available in universities or scientific organisations (included in the Art. 36), especially for highly specific novel food categories (e.g. micro-algae, products of microbial fermentation),
- To task preparatory work for the safety assessment of NFs to support the EFSA WG NF for the drafting of relevant sections of the draft opinions.

1.2.2 OBJECTIVE OF THE CALL

The overall objective of the present call is **the identification of several partners - Art. 36 organisations** - to which EFSA can entrust at any time during the next 4 years the tasks of contributing to the **preparatory work for the safety assessment of novel foods and nutrient sources** performed by EFSA. With the partners selected following this call for proposals EFSA would sign **with each of them a 4 years Framework partnership agreement (FPA)**. Once the FPAs are signed, as soon as EFSA has a specific need of support, it would identify, based on a mechanism presented later in this call, which of the partners is best placed to carry out the work and will sign with that partner a specific agreement specifying timeline and the exact work to be carried out.

The preparatory work that can be entrusted to the partners through the specific agreement may cover one or more specific scientific areas as required for the safety assessment of NF and NS (nutrient sources) dossiers:

1. Product characterization
2. Intake assessment

3. Absorption, Distribution, Metabolism and Excretion (ADME) & Bioavailability
4. Nutritional assessment
5. Toxicological information
6. Human studies
7. Allergenicity

This support also implies acquaintance and adherence with applicable guidance documents[10] for the safety assessment of novel foods.

Note 1: From the above it implies that the successful partner DOES NOT HAVE TO COVER all 7 areas, on the contrary, it is sufficient if the successful partner covers at least one of the above 7 areas.
Note 2: The present call for proposals comes with an innovative and very simplified grant management, where the grant amounts paid to the partner are based on the predefined sums that are not linked to the costs. This means there is no need of co-financing from the partner, and no need of estimated budget or timesheets to record the work. The agreed sums are set at level that is 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 innovative grant form, during the application period, please raise the clarification questions in line with point 3.3.

1.3 DESCRIPTION OF THE TASKS TO BE PERFORMED BY THE FPA PARTNER UNDER THE SPECIFIC AGREEMENTS

1.3.1 ENTRUSTED TASKS AND TIMELINE

The current EFSA risk assessment process for novel foods and nutrient sources includes the following **4 steps to be carried out within 9 months**[6] from the date of receipt of a valid application from the EC:

1) the preparatory work done by the NF team with the support of experts in the first assessment of the dossier and in the identification of scientific data gaps in the opinion,
2) the drafting of the different sections of the specific novel food opinion in collaboration with the EFSA WG NF,
3) the finalisation of the draft scientific opinion by the EFSA WG NF and
4) the discussion and possible adoption of the scientific opinion by the EFSA NDA Panel.

The FPA partner will be tasked to support the above-mentioned step 1 of the EFSA risk assessment process for Novel foods. The preparatory work resulting in a technical report would then be used by the experts of the EFSA WG NF as a basis for the preparation of the relevant sections of the draft scientific opinion.

In particular, the FPA partner should undertake, in the respective areas of its competence, the following tasks:

[10] Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283; https://www.efsa.europa.eu/en/efsajournal/pub/4594
Guidance on safety evaluation of sources of nutrients and bioavailability of nutrient from the sources (Revision 1); https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2021.6552

(A) Check compliance of the dossier/data with EFSA applicable guidance documents and EFSA internal checklists.
(B) Critically analyse and review the data (e.g. reports of experimental activities conducted) submitted in the dossier.
(C) Extract critical data from the dossier, and from literature search where applicable. The data extracted should be factual, concisely summarising the overall data and key findings/study observations, indicating the relevance of critical data, highlighting uncertainties and inconsistencies identified, outlining data gaps and missing information to be requested to the applicant, if any. This information should be presented concisely in a structured summary report according to the specific template provided by EFSA.
(D) On some occasions following the evaluation of the initially submitted dossier, there may be requests to applicants for submission of additional data/studies identified under (C). In these cases, the FPA partner may be requested to carry out within the specified timeline the above-mentioned tasks for the additional data submitted. The partner should ensure the availability of the resources also for this additional step. This extra work is already foreseen by default and reflected in the below specified grant amount that EFSA is to pay to the partner for the performed work.
(E) If needed participation of the partner in the Working group of Novel Foods in the role of a hearing expert to provide clarifications on the technical report. The partner should ensure the availability of the resources also for this additional step. This extra work is already foreseen by default and reflected in the below specified grant amount that EFSA is to pay to the partner for the performed work.

EFSA in addition to the documents pertaining to the relevant section(s) of the dossier will also provide a template to be followed for the drafting of the technical report. Documents provided by the applicant in the dossier generally includes but are not limited to: certificate of analyses, analytical reports, documents referring to the manufacturing process, intake assessment reports, nutritional assessment reports, fully study reports for animal and human studies, allergenicity reports and relevant scientific publications.

In order to properly consider the preparatory work in the context of the whole assessment of the NF and taking into consideration the legal framework, the technical report for any of 7 areas shall be prepared within timelines specified below in table 1, in section 1.4, so depending on the number of areas entrusted to the partner (could be just one area, or even all 7 areas) and the level of complexity of the dossier (low, medium, high). For example, if the partner is to carry out assessment of all 7 areas of dossier, and the dossier is marked by EFSA as highly complex for each of 7 areas, the partner will have three months (see Table 1) from the receipt of the dossier from EFSA to carry out all the work (for all tasks (A), (B), (C), (D) detailed above) see at the bottom of Tab 1. This is crucial to ensure a proper flow of information to the WG in the context of the risk assessment process to be able to comply with the legal deadlines. The period during which the applicant is preparing the requested additional information[11] for step (D) is not counted in this time available for the partner.

After the delivery of the technical report the partner might be requested to provide clarifications on specific aspects of the document itself as well as for the revision of additional data, if any.

[11] As specified in the Annex A of the Administrative guidance for the processing of applications for regulated products (update 2021) https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/sp.efsa.2021.EN-6471

1.3.2 STRUCTURE OF THE DOSSIER AND AREAS OF EXPERTISE

The dossier and the relevant scientific opinion are following a specific pre-defined structure that is also indicative of the type of expertise required to perform the preliminary assessment. Specific requirements for the preparation and presentation of a dossier for NF are included in the specific guidance (EFSA, 2016; EFSA, 2021)[12]. The structure is summarized as follows:

1. Product characterization
    a. Identity (physico-chemical, microbiological, botanical characterization)
    b. Manufacturing Process
    c. Compositional data
    d. Specifications
2. Intake assessment
    a. The history of use of novel food and/or its source
    b. The proposed use(s) and use levels and anticipated intake
3. Absorption, Distribution, Metabolism and Excretion (ADME)
    a. including nutrient bioavailability studies
4. Nutritional assessment
5. Toxicological information
    a. Genotoxicity
    b. Sub-chronic toxicity
    c. Chronic toxicity and carcinogenicity
    d. Reproductive and developmental toxicity
6. Human studies
7. Allergenicity

The requested areas of expertise are therefore strictly connected with the different sections of the dossier. As already mentioned in part 1.2.2, **the partner can provide specific expertise for one or more of 7 areas and therefore can be entrusted with the preparation of a technical report for one or more sections from the same dossier.**

The full process can be summarised as follows:

i. EFSA is getting a NF dossier from the EU Commission for assessment
ii. EFSA verifies the suitability of the dossier and assess the level of complexity of each dossier section: 3 possibilities: low, medium, high complexity
iii. When the eligibility of the dossier is established, EFSA identifies, based on the mechanism specified below the partner for each section of the dossier.
iv. EFSA awards the grant to the selected partner, according to section 1.3.3, and sign with them a specific agreement.
v. The partner provides EFSA with the technical report(s) within timelines specified below in table 1, so depending on the number of areas entrusted to the partner (could be just one area, or even all 7 areas) and the level of complexity of the dossier (low, medium, high).

[12] Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283; https://www.efsa.europa.eu/en/efsajournal/pub/4594
Guidance on safety evaluation of sources of nutrients and bioavailability of nutrient from the sources (Revision 1); https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2021.6552

vi. EFSA verifies the quality of the work performed and if satisfactory EFSA pays the agreed grant amount to the partner (follow-up activities might be requested – See 1.3.1).

1.3.3 SELECTION OF PARTNER TO ENTRUST THE TASKS & RESULTING GRANT AGREEMENT

The organisations applying for this call **must indicate precisely** in their proposal for which **area/s of expertise and field/s of application they apply**. Organisations can apply for all possible areas/fields combinations or only for one or some of them. Each area/field combination claimed for in the proposal will be individually evaluated by EFSA according to the award criteria indicated in part 2.5.

Framework Partnership Agreement:
A framework partnership agreement, of up to 4 years, will be proposed by EFSA to each organisation for which at least one area/field combination claimed for has met the award criteria thresholds. The proposed framework partnership agreement will indicate precisely for which area/field combination(s) it applies, and the respective ranking(s) obtained by the organisation on the basis of the comparison of the scores obtained by all organisations awarded for the same area/field combination(s). The combination of areas/fields for all beneficiaries will be presented in a matrix, please find an example further below. An FPA sets out the framework conditions and is subsequently implemented through Specific Agreements.

Cascade / matrix mechanism: The points awarded in the evaluation will constitute the ranking in order to establish cascades of FPA beneficiaries for the various combinations of areas of expertise/fields of application which EFSA envisages to entrust. When in EFSA the need to entrust tasks arises, a specific request will be sent to the beneficiary ranked first in the cascade in question in order to conclude a specific agreement for the work to be carried out. In case the first ranked beneficiary does not accept the proposed specific agreement or doesn't reply in 5 working days, the beneficiary ranked second will be consulted. In case the second ranked beneficiary does not accept the proposed specific agreement or doesn't reply in 5 working days, the beneficiary ranked third will be consulted etc.

The matrix will be used in the case several areas of expertise or more novel foods dossiers are to be covered by one specific agreement. Here an example:

	Area of expertise (AoE) 1	AoE 2	AoE 3	AoE 4	AoE 5	AoE 6	AoE 7
Field of application (FoA) 1							
FoA 2	1. Beneficiary A: awarded score = 99 2. Beneficiary B: awarded score = 87 3. Beneficiary C: awarded score = 70		1. Beneficiary D: awarded score = 94 2. Beneficiary C: awarded score = 89 3. Beneficiary B: awarded score = 73	1. Beneficiary B: awarded score = 98			
FoA 3							
FoA 4	1. Beneficiary D: awarded score = 75						
FoA 5							
FoA 6							
FoA 7							
FoA 8							

Example 1	EFSA needs to perform assessment of AoE 3 in field of application 2. The first beneficiary in the cascade will be contacted (Beneficiary D: awarded score = 94)
Example 2	EFSA needs to perform AoE 1 and 3 assessement and in field of application 2. Beneficiary B will be contacted since it has the highest total score (87+73=160)
Example 3	EFSA needs to perform AoE 1,3,5 assessment in FoA 2. Beneficiary B will be contacted since it has the highst total score and also because it is the only beneficiary that can perform the EFSA request.

Exception to cascade and matrix rule:
EFSA may depart from the cascade and matrix rule if for a particular dossier there is high need of specific ability or experience, which cannot be anticipated from the results of the present call for proposals.

Specific Agreements:
Specific Agreements will be awarded to a FPA beneficiary on the basis of the cascade and matrix mechanisms described above, or following a specific assignment by derogation to a cascade/matrix. Each Specific Agreement will set out the specific conditions for performing the respective assignment.

1.3.4 PERFORMANCE OF ENTRUSTED TASKS:

The tasks entrusted through the specific agreements will be conducted by one or more staff members of the partner extra-muros (in the premises of the beneficiary).

Should EFSA during implementation of a specific agreement identify that a staff member of the beneficiary working on an entrusted 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.

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.

During the performance of the entrusting tasks, the staff of the partner:

- Shall carry out their duties and conduct themselves with the interests of EFSA in mind. They shall neither seek nor take instructions from any government, authority, organisation, or person outside EFSA in relation to the execution of the specific tasks entrusted through the specific agreement. They shall carry out the duties assigned to them objectively and impartially.
- Shall be fully subject to the EFSA Policy on Independence [1] and the Decision of the Executive Director on Competing Interest Management [2]. Before signature of the specific agreement they will submit a Declaration of Interest which will be screened according to the rules applicable to the external experts contributing to the EFSA's work (Articles 6-8) and the rules applicable to screening of Declarations of Interest in the context of procurement and grant awarding procedures (Article 15-16).
- Shall refrain from any unauthorised disclosure of information received in the line of duty, unless that information has already been made public or is accessible to the public. Under specific agreements in this field, EFSA will grant the staff of the partner/beneficiary access to confidential information in order to perform the tasks. They will therefore be required to sign a confidentiality agreement before commencing the performance of tasks (Annex 9).

The working language for performance of tasks will be English.

1.4 EFSA GRANT CONTRIBUTION

This call will result into several FPAs signed. EFSA reserves the right to award specific agreements under this group of FPAs up to an indicative maximum of 400.000 euro in 4 years duration of FPAs. EFSA reserves the right not to award specific agreements under the FPA without any compensation to be paid to the applicants/beneficiaries.

The grant amount of each specific agreement will be established based on the complexity of the dossier sections and on the number/type of dossier sections that will be entrusted to the identified partner. It implies that many scenarios with different grant amount can be envisaged, in line with the preestablished mechanism indicated in table 1.

Table 1 – Preparatory work in form of a technical report on one/some specific sections of the dossier

	Task/expertise	No. of working days needed (complexity) [€]		
		(Low)	(Medium)	(High)
a	Product characterization (Identity, compositional data and manufacturing process)	6 [2,880]	10 [4,800]	14 [6,720]
b	Intake assessment (history of use, proposed uses and use levels and anticipated intake)	4 [1,920]	6 [2,880]	8 [3,840]
c	ADME	1 [480]	2 [960]	3 [1,440]
d	Toxicology	6 [2,880]	10 [4,800]	14 [6,720]
e	Nutritional assessment	4 [1,920]	6 [2,880]	8 [3,840]
f	Human studies	4 [1,920]	6 [2,880]	8 [3,840]
g	Allergenicity	1 [480]	2 [960]	3 [1,440]
	Gran total (whole dossier)	26 [12,480]	42 [20,160]	58 [27,840]

Deadlines for the availability of the technical reports are depending on the number of working days (wd) needed to complete the task(s).

- **From 1 to 20 wd** - two months
- **From 21 wd** - three months

Examples:

A) For dossier X, the partner is entrusted:

1. the analysis of a), judged by EFSA as high complexity = 6,720 euro (14 wd)

2. the analysis of d), judged by EFSA as medium complexity = 4,800 euro (10 wd)
3. the analysis of f), judged by EFSA as low complexity = 1,920 euro (4 wd).

Grant amount would be 13,440 euro in this case. Deadline is set three months (28 wd) after the dossier is made available to the beneficiary

B) For dossier Y, the partner is entrusted:

1. the analysis of c), judged by EFSA as high complexity = 1,440 euro (3 wd)
2. the analysis of d), judged by EFSA as high complexity = 6,720 euro (14 wd)

Grant amount would be 8,160 euro in this case. Deadline is set two months (17 wd) after the dossier is made available to the beneficiary

C) For dossier Z, the partner is entrusted the whole dossier except c and f that is not included in the dossier:

1. the analysis of a), judged by EFSA as high complexity = 6,720 euro (14 wd)
2. the analysis of b), judged by EFSA as low complexity = 1,920 euro (4 wd)
3. the analysis of d), judged by EFSA as medium complexity = 4,800 euro (10 wd)
4. The analysis of e), judged by EFSA as low complexity = 1,920 euro (4 wd)
5. the analysis of g), judged by EFSA as medium complexity = 960 euro (2 wd).

Grant amount would be 16,320 euro in this case. Deadline is set three months (34 wd) after the dossier is made available to the beneficiary.

Upon execution of the work, and approval by EFSA of the technical report, 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 the costs.**

1.5 ELIGIBLE ORGANISATIONS

To be eligible to submit a proposal under this Call, at the day of the deadline for submission of proposals, the applicant 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/.

An applicant interested in joining the list should contact its national Focal Point, which will explain the procedure. Contact details of the Focal Points are available on the EFSA website here.

In order to achieve the main objective of the call, proposals can be submitted by one eligible organisation or by a consortium of eligible organisations. In case of a consortium, one of the partners must be identified in the proposal as the consortium leader. The applicant is responsible for identifying consortium partners. Subcontracting is allowed subject to the conditions specified in point 1.7 below. Subcontractors don't need to be eligible Art.36 organisations.

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.

A) Proposals submitted by consortium:

- **The Applicant** submits the proposal/grant application to EFSA on behalf of the consortium. The applicant is the leading entity of the consortium. There can be only one applicant in project proposal/grant application;

- **The Partner of the applicant** is the other entity in the consortium. There is no limit to number of partners of the applicant.

Applicant with its partners need to be art36 organisations.

Once the grant is awarded, the framework partnership agreement (FPA) is signed between EFSA and the applicant. Partner/s of applicant do not sign the FPA directly but instead sign a mandate (template provided by EFSA) to authorise the applicant to sign the FPA, any future amendments of FPA, and specific agreements on their behalf.

As soon as the FPA is signed, the applicant becomes the Coordinator and partner/s become co-beneficiary/ies. The coordinator and co-beneficiary/ies are referred to together as the beneficiaries. The beneficiaries are jointly and severally liable for the technical implementation of the project/tasks as described in the proposal / the call which becomes annex 1 of the FPA. If a beneficiary fails to implement its part of the project/tasks, the other beneficiaries become responsible for implementing that part.

The coordinator has the following important roles:

- Takes part in implementing the project/tasks;
- Monitors the action/task is implemented properly;
- Acts as intermediary for communication between the consortium and EFSA;
- Receives and answers all claims EFSA might have in relation to implementation of the project/tasks;
- Requests and reviews any documents or information required by EFSA and verifies their completeness and correctness before passing them to EFSA;
- Informs EFSA and its partner/s of any event that is likely to substantially affect implementation of the project/tasks;
- Submits the deliverables and reports to EFSA;
- Requests and receives payments from EFSA and distributes the funds to its 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 co-beneficiary/ies:

- Take part in implementing the project/tasks;
- Forward to the coordinator the data needed to draw up reports, financial statements and other documents required under the FPA;

- Inform the coordinator of any event or circumstances likely to substantially affect or delay the implementation of the project/tasks.

B) Proposals submitted by a sole applicant:

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

As soon as the FPA is signed, the applicant becomes the beneficiary. The beneficiary is liable for the technical implementation of the project/tasks as described in the proposal/the call which becomes annex 1 of the FPA.

The beneficiary:

- Takes part in implementing the project/tasks;
- Monitors the action/task is implemented properly;
- Communicates with EFSA;
- Receives and answers all claims EFSA might have in relation to the implementation of the project/tasks;
- 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/tasks;
- Submits the deliverables and reports to EFSA;
- Requests and receives payments from EFSA;

1.7. POSSIBILITY OF IMPLEMENTING CONTRACTS AND SUBCONTRACTING

Implementation agreements:
Where the implementation of the project requires the award of specific agreements (implementation agreements), e.g. delivery of services and/or goods or equipment necessary for the implementation of the action, the beneficiary must award the agreement 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 grant 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/EU[13] 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. 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:

- 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;

[13] 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)

- Recourse to subcontracting is 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;
- **Core tasks must not be subcontracted**. Only ancillary and assistance tasks can be subcontracted. The only core task foreseen in this Call is the overall management and supervising of the work entrusted from EFSA to the beneficiary.

1.8 PAYMENTS

Final payment after approval by EFSA of the final technical report.

In case the partner cannot finalize the work due to stop the clock-time by EFSA, if such stop continues for a period estimated to be > 4 months according to the indicative timelines as specified in the Annex A of the Administrative guidance[11], EFSA exceptionally can agree to a request for an **interim payment** of 70% of the grant amount specified in the Specific agreement, after approval by EFSA of the draft technical report.

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 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 FPA and Specific 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 PUBLICITY

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.

1.11 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 Privacy Statement 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.[14]

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).

Processing of personal data by the beneficiary
In case the implementation of activities under this FPA or subsequent specific agreements entails the processing of personal data, the beneficiary shall comply with the relevant rules in Article II.7.2 of the Grant Agreement (Annex 2) as a data processor of EFSA.

1.12 PUBLIC ACCESS TO DOCUMENTS

[14] 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

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.

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;
- proposal is submitted on the EFSA application form (Annex 3);
- proposal 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 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, if any, is justified in the proposal.

Documents to be provided:

- **LEGAL ENTITY FORM (Annex 4)** (download template here)
  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 (Annex 5)** (download template here)
  to be completed only by the applicant and in case of consortium only by the coordinator.

There is no need to submit these 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 application form the reference of the call under which the form/s were submitted to EFSA.

Only applicable if the applicant is a consortium:

- **PARTNERSHIP STATEMENT**:
  The applicant and partner/s must provide EFSA with a signed statement indicating their involvement. No template is provided by EFSA.

2.3 EXCLUSION CRITERIA

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 of EU Financial Regulation.

Documents to be provided:

- **THE DECLARATION ON HONOUR FOR EXCLUSION CRITERIA (Annex 6)**: template is published with this Call; to be completed/signed individually by the applicant and in case of consortium by each partner.

2.4 SELECTION CRITERIA

The purpose of the selection criteria is to verify the financial and operational capacity of the applicant and in case of consortium also of its partner/s.

Financial capacity:
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
- participate in its funding.

Operational capacity:
The applicant or the organization must have the professional resources, competencies and qualifications necessary to complete the proposed project:

Requirement 1:
The applicant should have expertise in one or more of the 7 areas of expertise listed in the table below and provide the respective evidence as indicated.

NOTE: The applicant is requested to consult the EFSA Guidance on Novel foods for the specific requirements of the relevant area(s) of expertise (e.g. type of studies requested for a NF dossier) and provide evidence of its expertise accordingly.[15]

	Scientific and technical areas of expertise	**Evidence to be provided**
1	Product characterization (Identity, compositional analyses and manufacturing process)	- You may apply for 1 or more of the 7 areas of expertise. For each area of expertise that you apply for (1 to 7), evidence with at least 2 CVs that you possess, as organisation, the required capacity in the area applied for. Each of 2 experts must have at least 3 years of post-graduate work experience in that area and fulfil the English language requirement specified below. - For each area of expertise that you apply for (1 to 7), evidence with at least one main activity performed in the past 7 years that you possess, **as organisation**, the required capacity in the area applied for. In addition, also please provide for each area of expertise applied for the details on/references to reports/publications/ patents produced (PDF or hyperlink to the document) by the organisation in the course of the past 7 years. -
2	Intake assessment (proposed uses and use levels and anticipated intake)	
3	ADME (Absorption, Distribution, Metabolism and Excretion)	
4	Nutritional assessment	
5	Toxicology	
6	Human studies	
7	Allergenicity	

The area(s) of expertise of interest for Requirement 1 shall be clearly specified in the CV and in the list of relevant activities performed by the organisation.

Requirement 2:

The applicant should have experience in one or more of the fields of application listed in the table below referring to the various NF category and provide the respective evidence as indicated. Expertise in these fields may come also from non-food areas.

	Field of application	**Evidence to be provided**
1	(food with a) New or intentionally modified chemical composition / molecular structure / chemicals and chemical complexes	For each field of applications 1-8:

[15] EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2016. Guidance on the preparation and presentation of an application for authorization of a novel food in the context of Regulation (EU) 2015/2283. EFSA Journal 2016;14(11):4594, 24 pp. doi:10.2903/j.efsa.2016.4594

2	(food consisting of, isolated from or produced from) Microorganisms, fungi or algae (including microalgae);	- You may apply for 1 or more of 8 fields of application. For each field of application that you apply for (1 to 8), evidence with at least 2 CVs that you possess, as organisation, the required capacity in the field applied for. Each of 2 experts must have at least 3 years of post-graduate work experience in that field and fulfil the English language requirement specified below; - For each field of application that you apply for (1 to 8), evidence with at least one main activity performed in the past 7 years that you possess, **as organisation**, the required capacity in the field applied for. In addition also please provide for each field of application applied for details on/references to reports/publications/ patents produced (PDF or hyperlink to the document) by the organisation in the course of the past 7 years.
3	(food consisting of, isolated from or produced from) Material of mineral origin;	
4	(food consisting of, isolated from or produced from) Plants or their parts,	
5	(food consisting of, isolated from or produced from) Animals or their parts	
6	(food consisting of, isolated from or produced from) Cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae;	
7	(food consisting of) Engineered nanomaterials (as defined Art. 3(2.f) of Regulation (EU) 2015/2283);	
8	Nutrients including vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Regulation (EU) No 609/2013	

The field (s) of application of interest for Requirement 2 shall be clearly specified in the CV and in the list of relevant activities performed by the organisation.

Requirement 3:

Mastering ENGLISH language. All experts proposed to work on EFSA assignments need to have an excellent level of spoken and written English. For non-native speakers, this should be evidenced by either
- having worked in at least one international project where English is used for meetings
- having published at least one scientific publication or made at least one oral presentation in conferences in English
- teaching in English AND/OR Certificate B2 level.

This requirement is inferred from the information included in the CVs and list of activities.

ADDITIONAL documents to be provided by the applicant:

- **DECLARATION ON HONOUR ON SELECTION CRITERIA (Annex 7);**
- **SIMPLIFIED FINANCIAL STATEMENT (Annex 8)**
  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;
- **INSTITUTIONAL AND INDIVIDUALS DECLARATION OF INTERESTS**
  Template available here. EFSA will request **Institutional** DoI only from the awarded beneficiary, prior to the signature of FPA. EFSA will request **Individual** DoI only from the awarded beneficiary, prior to the signature of each specific grant agreement. The requirement to submit institutional DOIs will be specified in the event of proposal for grant award in the award letter and they will have to be provided and assessed by the EFSA authorising officer before FPA

signature. **Institutional and Individual DoIs do not need to be provided with your proposal.** In case of a consortium and/or in case of subcontracting, such declarations will need to be completed separately and submitted for each partner and for each identified subcontractor (institutional DoIs) and for each individual member of the project team (individual DoIs) coming from consortium partners or subcontractors.

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 following award criteria are applicable in this call:

For each area of expertise and field of application combination, the proposals which have satisfied the below indicated quality thresholds will be ranked according to the award criteria obtained in order to form the cascade of beneficiaries to whom an FPA will be awarded.

AWARD CRITERIA A) Area of expertise (Max. 70 points for each area applied for, pass-mark 35 points). For each area of expertise you apply for (1 to 7) please

- Describe the resources, both in terms of quantity (number of proposed experts), and quality (years of experience, quality of experience,) 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. Please provide also a list of activities, publications and/or reports performed in the past 7 years considered relevant for the EFSA assignment in the area that you apply for.
  (max. 40 points, pass-mark 20 points)
- Describe how the assigned task is to be distributed among experts, how it is coordinated and how you will ensure the quality control of the executed work. In case you apply for more than one area, please describe also the interactions and possible synergies across experts in the different areas. **(max. 20 points, pass-mark 10 points)**
- 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. In particular, explaining how the newly assigned experts will guarantee the same level of quality of expertise throughout the life of FPA. **(max. 10 points)**

AWARD CRITERIA B) Field of application (Max. 30 points for field of application, pass-mark 15 points). For each field of application you apply for (1 to 8) please:

- Describe the resources, both in terms of quantity (number of proposed experts), and quality (years of experience, quality of experience) 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. Please provide also a list of activities, publications and/or reports performed in the past 7 years considered relevant for the EFSA assignment in the field of application that you apply for. **(max. 20 points)**

- Describe how the assigned task is to be distributed among experts, how it is coordinated and how you will ensure the quality control of the executed work. **(max. 5 points)**
- 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. In particular, explaining how the newly assigned experts will guarantee the same level of quality of expertise throughout the life of FPA **(max. 5 points)**

Based on the above scoring, for each area of expertise / field of application combination there will be a ranking of proposals. In case there is a specific assignment to be entrusted by EFSA, the ranking resulting from the above scoring will be respected, with possible derogations mentioned under point 1.3.3.

3. SUBMITTING PROPOSALS

3.1 APPLICATION FORM & CHECKLIST

The proposal must be submitted using the **EFSA APPLICATION FORM (Annex 3).** The application form is published together with this call. The application form must be:

- duly completed and
- supported with all the requested annexes;
- signed by a duly authorised legal representative of the applicant.

By submitting a proposal, the applicant and in case of consortium also partner/s accept/s the procedures and conditions described in this Call and in the documents referred to in it.

In addition to a full paper version of the application, the applicant must submit the application also on a CD or USB. The electronic version must be identical to the paper version. In case of any discrepancies between the electronic and paper version, the latter will prevail. All documents presented by the applicant become the property of EFSA and are deemed confidential.

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 are required. These supporting documents are an integral part of the proposal. For more information on the relevant supporting documents to be submitted, please refer to part 2 of this Call. 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 SUBMISSION MODALITIES

Proposals are to be submitted as indicated in the second page of this document in the Indicative procedure timetable.

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.

3.4 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.