

SCIENTIFIC EVALUATION OF REGULATED PRODUCTS DEPARTMENT

CALL FOR PROPOSALS **and guide for applicants**

Call reference: GP/EFSA/NUTRI/2017/01

Call title: Entrusting preparatory work for the safety assessment on Novel Foods and Traditional Foods from third countries

Project/Process code: Nutri-08/ Novel Applications

Budget line: B-3010

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.

INDICATIVE PROCEDURE TIMETABLE

Milestone	Date ¹	Comments
Launch date	14/07/2017	Date of publication on EFSA's website.
Deadline for applicants to raise clarification questions to EFSA	29/09/2017	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	06/10/2017	Replies will be provided on EFSA's webpage where this Call is published and which the applicants are requested to consult regularly.
Deadline for submission of proposals <u>Any proposal posted after the final deadline will be rejected</u>	13/10/2017	<p>You can submit your proposal:</p> <ul style="list-style-type: none"> - either by post (registered mail) or by courier not later than 13/10/2017, 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 13/10/2017 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. <p>Submission by post, courier or hand to this address: <i>European Food Safety Authority -EFSA For the attention of - Ms Rita De Bon, Finance Unit (Procurement Team) Via Carlo Magno 1/A, I -43126 Parma, Italy</i></p> <p>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:</p> <ul style="list-style-type: none"> - "CALL FOR PROPOSALS GP/EFSA/NUTRI/2017/01 - 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	November 2017	Estimated. <i>Attention: outcome of the present Call for proposals will be communicated to all applicants to the e-mail address indicated in their proposal. Accordingly, the applicants who have submitted a proposal under the present call are strongly invited to check regularly the inbox in question.</i>
Grant agreements signature	November 2017	Estimated

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

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1. GRANT OPPORTUNITY AND CONDITIONS²

1.1 LEGAL FRAMEWORK

Article 36 of the Regulation (EC) 178/2002³ of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety foresees the possibility to financially support networking of organisations operating in the fields within the EFSA's mission.

In particular, Article 36(1) 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, the development and implementation of joint projects⁴ and the exchange of expertise and best practices in the fields within the Authority's mission.

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.

The Commission Regulation (EC) 2230/2004⁵ 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 and in Article 5 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 Regulation also requires (recital 9) that tasks entrusted should be performed to high scientific and technical standards, efficiently (also with regard to deadlines) and independently, under the responsibility of EFSA.

In accordance with Article 4, tasks that may be entrusted by the Authority to organisations on the list of competent organisations, include those consisting in:

- collecting and analysing data with a view to facilitating risk assessment by the Authority, including assessment tasks in the field of human nutrition in relation to Community legislation, especially the compiling and/or processing of scientific data on any substance, treatment, food or feed, preparation, organism or contaminant which may be linked with a health risk, and the collection and/or analysis of data on the exposure of Member States' populations to a health risk associated with food or feed;
- producing scientific data or works contributing to the risk assessment tasks, including assessment tasks in the field of human nutrition in relation to Community legislation, for which the Authority is responsible; this type of task must

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>

correspond to precise problems identified in the course of the work of the Authority, and in particular that of its Committee and permanent Scientific Panels, and must not duplicate Community research projects or data or contributions which it is the industry's duty to provide, especially in the context of authorisation procedures;

- preparing the Authority's scientific opinions, including preparatory work relating to the assessment of authorisation dossiers;
- preparing the harmonisation of risk assessment methods;

The present Call for proposals and guide for applicants (hereinafter referred to as "the Call") is procedurally governed by Regulation (EU, EURATOM) 966/2012⁶ of the European Parliament and of the Council of 25 October 2012, as amended by Regulation (EU, EURATOM) 1929/2015⁷ of the European Parliament and of the Council of 28 October 2015 and by Commission Delegated Regulation C(2012)7507⁸ on the rules of application of Regulation (EU) 966/2012, as amended by Commission Delegated Regulation (EU) No 2015/2462⁹ of 30 October 2015, on the financial rules applicable to the general budget of the Union.

The present Call is based on the Final work programme for grants and operational procurements 2017 as presented in Annex IX of the EFSA Programming Document 2017 – 2019, available on the EFSA's website¹⁰.

1.2 BACKGROUND, MAIN OBJECTIVE AND RESULTING GRANT AGREEMENT

BACKGROUND

Novel foods (NF) are foods and food ingredients that have not been used for human consumption to a significant degree in the EU before 15 May 1997.

Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods¹¹, repealing Regulation (EC) No 258/97, introduces a centralised assessment and authorisation procedure, as of January 2018. All applications for the authorisation of novel foods (pursuant to Article 10) shall be submitted to the European Commission (EC) who may then request a safety assessment by EFSA.

Regulation (EU) 2015/2283 also introduces a special procedure for safety assessment for traditional foods from third countries (TF), based on a history of safe food use. In this case, a notification for the placing on the market of a traditional food from a third country (pursuant to Article 14) is sent to the EC who forwards it to all the Member States (MSs) and EFSA. Within four months from receipt of a valid notification, a MS or EFSA may submit duly reasoned safety objections on the placing on the market of the notified TF. In this latter case, the applicant may transform the notification into an application (pursuant to Article 16), for which a safety assessment will be requested from EFSA.

⁶ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:298:0001:0096:EN:PDF>

⁷ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R1929&from=EN>

⁸ http://ec.europa.eu/budget/library/biblio/documents/regulations/c_2012_7507_en.pdf

⁹ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R2462&from=EN>

¹⁰ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/amp1719.pdf

¹¹ Regulation (EU) 2015/2283 of the European Parliament and of the Council 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 (2013/0435 (COD). OJ L 327, 11.12.2015, p. 1–22.

- Data requirements for NF applications pursuant to Article 10 are outlined in [EFSA Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation \(EU\) 2015/2283](#) (EFSA-Q-2014-00216)¹²,
- Data requirements for TF notifications (pursuant to Article 14) and applications (pursuant to Article 16) are outlined in EFSA [Guidance on the preparation and presentation of the notification and application for authorisation of traditional foods from third countries in the context of Regulation \(EU\) 2015/2283](#) (EFSA-Q-2015-00108)¹³.

As laid down in Regulation (EU) 2015/2283, EFSA shall adopt its opinion within 9 months from the date of receipt of a valid NF application pursuant to Article 10, and within 6 months from the date of receipt of a valid TF application pursuant to Article 16.

The final output provided by EFSA on the safety of the concerned NF serves as the scientific basis for EU Decisions on authorisation of the NF on the EU market.

MAIN OBJECTIVE

The aim of this call is to conclude Framework Partnership Agreements (FPA's) in cascade in order to identifying organisations to which preparatory work for the safety assessment of Novel Foods and Traditional Foods from third countries can be entrusted by EFSA.

It is not possible to predict the total number and type of applications/notifications which EFSA may receive, as this depends on the applicants that submit the applications to EC. Notwithstanding this uncertainty, a "high peak" in terms of applications/notifications is foreseen from 2018 onwards. In order to effectively and timely deal with the requested mandates and to ensure compliance with the above-mentioned legal deadlines for the delivery of its scientific output, this call for proposal aims to set up FPA's, through which preparatory work in this field can be entrusted by EFSA.

RESULTING GRANT AGREEMENT

Framework Partnership Agreement:

An FPA is a long-term cooperation, of up to 4 years, between the Authority and one or several partners. It sets out the framework conditions and is subsequently implemented through Specific Agreements.

Proposals submitted for the FPA will be evaluated by EFSA according to the award criteria indicated in section 2.5. A FPA will be awarded by EFSA to each organisation which passes the minimum quality thresholds set out in the award criteria, up to a maximum of 5 organisations.

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

In case the first ranked beneficiary does not accept the proposed Specific Agreement, the beneficiary ranked second will be consulted in accordance with the timescales mentioned in section 1.7. In case the second ranked beneficiary does not accept the proposed Specific Agreement, the beneficiary ranked third will be consulted etc.

12 <https://www.efsa.europa.eu/en/efsajournal/pub/4594>

13 <https://www.efsa.europa.eu/en/efsajournal/pub/4590>

Specific Agreements:

Specific Agreements will be awarded to an FPA beneficiary on the basis of cascade mechanism described above. Each Specific Agreement will set out the specific conditions for performing the respective assignment.

1.3 SPECIFIC OBJECTIVES OF THE CALL

Organisations awarded an FPA may be entrusted with preparatory work with respect to:

- NF applications submitted pursuant to Article 10 of Regulation (EU) 2015/2283;
- TF notifications submitted pursuant to Article 14 of Regulation (EU) 2015/2283;
- TF applications submitted pursuant to Article 16 of Regulation (EU) 2015/2283.

To this end, for each mandate received from the EC related to the above, for which EFSA requires preparatory work, the beneficiary awarded the Specific Agreement will be requested, as a minimum, to carry out the following tasks within the timeframe specified in the Specific Agreement:

For each assigned technical dossier:

- (i) carry out critical review and checking of data against EFSA guidance; and
- (ii) search for scientific literature;
- (iii) concisely summarise the data and findings;
- (iv) the written outcomes resulting from (i), (ii) and (iii), should be prepared in line with the format and structure of EFSA/NDA Panel outputs;
- (v) Upon request of NUTRITION Unit, the beneficiary shall attend meetings (physically or via teleconference) of the working group on Novel Foods (WG NF) or working group on traditional foods (WG TF) and/or the NDA Panel plenary, where relevant, to present the outcomes and answer questions related to the data in the technical dossier;
- (vi) In addition, the beneficiary will be requested to assist with tasks such as incorporating feed-back/comments from NUTRI Unit/ WG NF/WG TF/NDA Panel into EFSA/NDA Panel outputs, and finalising the outputs.

Further detail and precise timescales will be set out in each Specific Agreement.

1.4 ELIGIBLE ORGANISATIONS

To be eligible, to submit a proposal under this call, the applicant must be on **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.

1.5. ROLES AND RESPONSIBILITIES

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

- **The Applicant** submits the proposal to EFSA.

As soon as the Framework Partnership Agreement is signed, the applicant becomes **the beneficiary**. The beneficiary is liable for the technical implementation of the entrusted tasks as described in the Specific agreement.

Regarding **the beneficiary**, please note also the following important roles:

- Communicate with EFSA;
- Receive and answer all claims EFSA might have in relation to the implementation of the entrusted tasks;
- Request and review any documents or information required by EFSA and verify their completeness and correctness before passing them on to EFSA;
- Inform EFSA of any event that is likely to substantially affect the implementation of the entrusted tasks;
- Submit the deliverables and reports to EFSA;
- Request and receive payments from EFSA.

1.6. POSSIBILITY OF SUBCONTRACTING

Subcontracting is not permitted.

1.7 IMPLEMENTATION OF ENTRUSTED TASKS VIA SPECIFIC AGREEMENTS

Specific Agreements:

When in EFSA the need to entrust tasks arises, a request will be sent to the beneficiary ranked first in the cascade. The request will describe in detail the tasks to be entrusted and will also include a description of the expertise required to perform those tasks.

The beneficiary should reply to the request within 10 working days confirming their interest and should submit one or more CVs of staff members fulfilling the expertise requirements. Within 5 working days EFSA should confirm which person has been chosen and within another 5 working days EFSA should send the Specific Agreement to the beneficiary for signature.

Although some basic information on the preparatory work is set out in section 1.3, the precise scope of the tasks to be entrusted and the required profile/s of the staff that will perform them will be described in the Specific Agreement. The Specific Agreement will further specify on an *ad-hoc* basis:

- The precise conditions for the performance of the entrusted tasks;
- The criteria to ensure that tasks are performed to high scientific and technical standards;
- The rules and procedures for ensuring that tasks are carried out with independence, integrity and respect for confidentiality.

The duration of each Specific Agreement will be typically from 6 -12 months duration. More than one Specific Agreement may be signed with a beneficiary organisation during the period of implementation of the FPA.

Performance of entrusted tasks:

The tasks entrusted through the Specific agreements (requests) will be conducted by one or more staff members of the organisations awarded an FPA. The staff members will perform these tasks in the EFSA premises in Parma, Italy, or in the premises of the beneficiary if this is agreed by EFSA and detailed in each specific agreement.

The tasks will be performed in accordance with the EFSA policies applicable for the respective outputs and, where relevant, in compliance with the specific procedural provision of the relevant legislation.

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 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** will the beneficiary be allowed to use the outputs resulting from the entrusted tasks.

The staff having conducted the task will be mentioned in any authorship list and their affiliation to the beneficiary organisation will be acknowledged in any EFSA outputs.

Working conditions of employees from the selected organisations:

The employees of the organisation awarded a Specific Agreement to perform the entrusted task (hereafter referred to as 'employees') will be working closely with the EFSA NUTRITION (NUTRI) Unit, considering that only specific tasks, not full outputs, will be entrusted to the organisations and that a full coherence among EFSA outputs of similar nature is essential. They will work according to the plan and timeline of the NUTRI Unit coordination team, in close collaboration with scientific officers of the NUTRI Unit working on the same or similar outputs, regularly attend team meetings and will report to the EFSA Process Manager of the scientific area related to the specific action.

The working conditions (including remuneration, working hours, leaves, social security) applicable to the 'employees' will remain those established by their employer. Leaves should however be agreed in advance with EFSA before the formal approval by the employee's line manager in their home organisation. The 'employee' should provide EFSA with a monthly timesheet, to be approved by the EFSA Process Manager (Annex 9).

During the performance of the entrusted tasks, the 'employee':

- 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. They shall carry out the duties assigned to them objectively and impartially.
- Shall be fully subject to the EFSA Policy on Declarations of Interests¹⁴. They will submit a Declaration of Interest which will be screened taking into consideration the rules applicable to the external experts contributing to the EFSA's work (Article 8) and the rules applicable to screening of Declarations of Interest in the context of procurement and grant awarding procedures (Articles 21-23).
- Will not review their own work nor any output produced by an organisation of their country of origin.
- Shall be subject to the EFSA's rules on prior authorisation for officials when they wish to engage in an outside activity, whether paid or unpaid, or to carry out any assignment outside EFSA.

¹⁴ http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independencerules2014.pdf

- 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 *employee* access to the confidential versions of the technical dossiers (i.e. NF applications, TF notifications, TF applications) in order to perform the tasks. The *employee* will therefore be required to sign a confidentiality agreement before commencing the performance of tasks. (Annex 10)

The *employees* may be sent on mission if this is related to the tasks defined by the Specific Agreement, as part of a delegation led by an EFSA official or temporary staff member, or on his own on the basis of a specific mandate given by the EFSA Executive Director.

The *employees* shall be entitled to attend training courses organised by EFSA if the interest of EFSA warrant it.

Any mission and training expenses should be estimated in the estimated budget template for each Specific Agreement. The interest of the *employee*, in particular with a view to their reinstatement into their original administration after the completion of the Specific Agreement may also be considered when a decision is taken on whether to allow them to attend a training course.

The working language for performance of tasks will be English.

Budget for the Specific Agreements:

The budget for each specific agreement must be established in line with Annex 1 – Rules on eligibility of costs. To highlight some of the most important elements of Annex 1:

1. The staff assigned to the project have to be classified between these 3 categories according to the International Standard Classification of Occupations (ISCO-88 (COM)), in function of their role in the project:
 - Manager
 - Researcher / Teacher / Trainer
 - Technical-Administrative
2. The **UNIT COSTS** per day for staff indicated in the table below **must** be used when establishing the estimated budget for each specific agreement and when declaring the incurred costs.

The rate of the country in which the partner organisation is established should be applied and not the rate of EFSA, Italy.

UNIT COST PER DAY IN EUROS

Country	Manager	Researcher Teacher Trainer	Technical	Administrative
Austria	449	302	244	194
Belgium	460	360	240	214
Bulgaria	67	60	46	31
Croatia	213	192	154	97
Cyprus	316	235	146	99
Czech Republic	134	110	80	58
Denmark	398	340	277	217

Estonia	102	75	59	42
Finland	368	255	196	163
France	435	351	257	193
Germany	419	310	221	203
Greece	279	218	157	122
Hungary	107	86	65	44
Ireland	309	328	239	178
Italy	454	298	200	174
Latvia	81	66	52	38
Lithuania	75	62	47	34
Luxembourg	496	349	282	220
Malta	119	99	77	58
Netherlands	310	271	215	170
Poland	109	86	66	49
Portugal	258	181	122	77
Romania	124	95	74	47
Slovakia	121	98	86	70
Slovenia	240	182	146	92
Spain	321	212	163	117
Sweden	360	303	250	192
United Kingdom	355	334	231	158

3. **THE NUMBER OF DAYS** spent on the project (considering that one day is composed by 8 working hours according to working day duration at EFSA) is to be indicated when establishing the estimated budget and when declaring the incurred costs. The staff budget of the project shall be obtained by multiplying the number of days proposed with the daily staff rates.

In addition to the salary cost, and only in case of the beneficiary's employee is working in EFSA's premises, the specific agreement will also recognise a **REINSTALLATION COST** of 1500 EUR per month, to cover the additional cost for the individual's life in Parma and travels to and from their country of origin.

4. In case the selected person will be travelling a distance of less than 300 km to Parma, the monthly REINSTALLATION COSTS will be recognised at the level of 900 EUR. No allowance is foreseen in case of travel from a distance of less than 50 km.
5. The specific agreements may also foresee missions in the estimated budget, in line with Annex 1 - Rules on eligibility of costs.

The above indicated costs are co-financed by EFSA at a rate of 90%, see below in section 1.9 for further information on the co-financing principle.

1.8 PAYMENTS

Payments to the grant beneficiary will be made in accordance with the terms of the draft FPA published with this call and will be reconciled with the number of days declared in

the timesheet which must be approved by EFSA. Only days actually worked for EFSA should be declared (holidays, bank holidays and days of illness should not be declared).

Importantly, **each specific agreement may foresee a pre-financing of up to 60% of the EFSA initial grant value.**

1.9 GRANT PRINCIPLES

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

- **Co-financing:** co-financing from a source other than the Union budget is required. The costs not covered by the EFSA grant must be financed from the applicant. The applicant must therefore contribute financially to the project. Additionally, there may be also a financial contribution from another entity, but such an entity may be only a public body. Contributions from the private sector are not permitted.
- **No-profit:** A grant shall not have the purpose or effect of producing a profit within the framework of the entrusted task for the applicant. Profit is defined as a surplus of the receipts over the eligible costs incurred by the beneficiaries, at the time of request for payment of the balance. The receipts shall be limited to income generated by the project/entrusted task (likely to be zero in this case), as well as financial contributions specifically assigned by donors to the financing of the eligible costs. Where a profit is made, EFSA shall be entitled to recover a part of it in line with procedure foreseen in the Framework partnership agreement and the specific agreement. The verification of the non-profit rule does not apply to grants </= 60.000 €.
- **Non-retroactivity:** A grant may be awarded for a project/entrusted task which has already begun provided that the applicant can demonstrate the need for starting the entrusted task prior to signature of the grant agreement. In such cases, costs eligible for financing shall not have been incurred prior to the date of submission of the grant application under this call. No grant may be awarded retrospectively for a project already completed.
- **Non-cumulative:** A project / entrusted task may only receive one grant from the EU budget. In no circumstances shall the same costs be financed twice by the Union budget. To ensure this, the applicant shall indicate the sources and amounts of Union funding received or applied for the same project or part of the project or for its functioning during the same financial year as well as any other funding received or applied for the same project.

1.10 EFSA GRANT CONTRIBUTION

EFSA reserves the right to award specific agreements under this FPA to a maximum of 400.000 euro per year. Each year, for the four year duration of the FPA, this maximum annual amount is subject to review based on EFSA budget availability. EFSA further reserves the right not to award Specific Agreements under the FPA and to cancel the whole grant procedure at any time before the signature of the Specific Agreements without any compensation to be paid to the applicants.

The form of Specific Agreements signed under the FPA will be based on EU Financial Regulation, Article 123 (1)(e), including also the reimbursement of a specified proportion of the total eligible project costs actually incurred.

The costs under Specific Agreements are co-financed by EFSA at a maximum of 90% of the total eligible costs.

The total amount of estimated eligible costs, as presented by the applicant in the estimated budget for a Specific Agreement (Annex 3) (see also section 1.11 below), and which serves as a basis for calculation of the initial EFSA specific grant, will be verified by EFSA before signature of the Specific Agreement. EFSA reserves the right to implement the necessary adaptations to the estimated eligible costs in the case **the Rules on eligibility of costs** (Annex 1) were not correctly applied by the applicant.

1.11 ESTIMATED BUDGET AND ELIGIBLE COSTS

For the submission of a proposal under this Call, leading to the signature of the FPA, an **estimated budget is not required**.

The estimated budget will be necessary only before the signature of the Specific Agreement. It must be established in line with **Annex 1 - the Rules on eligibility of costs**. The estimated budget must show all the costs and income which the applicant considers necessary to carry out the tasks entrusted. The Estimated budget will be in practice prepared in close cooperation with EFSA NUTRI Unit and EFSA Finance Unit.

The estimated budget must be:

- sufficiently detailed to permit identification, monitoring and checking of the costs;
- balanced, i.e. total income and total costs must equal;
- consistent with the work plan;
- expressed in Euro.

Estimated budget – cost side:

- Eligible direct costs:
 1. Costs of personnel, including reinstallation costs (see section 1.7 above) and a grant agreement coordination cost recognised up to 10% of other staff costs;
 2. Mission travel costs and related subsistence allowances for missions made at EFSA's request;

The above categories represent an exhaustive list of the possible eligible direct costs under this particular FPA.

- Eligible indirect costs are applicable under this FPA only in case of beneficiary's employee working on their own premises.

Estimated budget – income side:

- Mandatory incomes:
 1. Grant requested from EFSA;
 2. Applicant's financial contribution;
- Optional incomes:
 3. Financial contributions from other public bodies;

1.12 PUBLICITY

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

According to Article 35 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.

1.13 PROTECTION OF PERSONAL DATA IN RELATION TO GRANT PROCEDURES

Processing your application in the context of this grant procedure, will involve the recording and processing of personal data (i.e. the name, any CV and contact details and/or financial details of individuals contained in your application) pursuant to Regulation (EC) N° 45/2001.

Unless indicated otherwise, the questions and any personal data requested are required to evaluate the application in accordance with the specifications of the Call and the data will be processed solely for that purpose.

Detailed information on the processing of personal data in the context of grant award procedures of EFSA is given in the privacy statement available on the EFSA website. This on-line privacy statement details the following:

- the legal basis, purpose and controller of the personal data processing;
- what personal information EFSA is collecting and/or further processing;
- to whom personal data is disclosed;
- what technical means are applied for data processing and way in which EFSA secures the information;
- how data subjects can access, modify and delete their information;
- how long EFSA keeps the personal data;
- the contact details for data subjects to exercise their rights;
- the right of recourse to the European Data Protection Supervisor.

Personal data may be registered in the Early Detection and Exclusion System (EDES) if you are in one of the situations mentioned in Article 106 of the Financial Regulation. For more information see the Privacy Statement on:

http://ec.europa.eu/budget/explained/management/protecting/protect_en.cfm).

In case the implementation of activities under an awarded grant entails the processing of personal data, the beneficiary shall comply with the relevant rules in the Framework Partnership Agreement and specific agreement (Annex 2) as a data processor of EFSA.

1.14 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.

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 (see 2.1)
2. eligibility criteria (see 2.2)
3. exclusion criteria (see 2.3)
4. selection criteria (see 2.4)
5. award criteria (see 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:

- The proposal was submitted within the deadline for submission of proposals.
- The proposal is submitted on the EFSA application form (Annex 4).
- The proposal is duly signed by the authorised representative of the applicant.
- The proposal is complete and includes all the supporting documents.

2.2 ELIGIBILITY CRITERIA

The following will be verified:

- The applicant is 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. This list is regularly updated by EFSA Management Board.
- The applicant is to be involved in the execution of the entrusted task with its own staff and with no sub-contracting foreseen.

Documents to be provided:

- **LEGAL ENTITY FORM** (Annex 5) ([download template here](#)) to be completed and signed by the applicant. For a public body this 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 6) ([download template here](#)) to be completed only by the applicant.

Please note 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.

For British applicants: Please be aware that eligibility criteria must be complied with for the entire duration of the grant. If the United Kingdom withdraws from the EU during the grant period without concluding an agreement with the EU ensuring in particular that British applicants continue to be eligible, you will cease to receive EU funding (while continuing, where possible, to participate) or be required to leave the project on the basis of II.17.2.2 (a) of the grant agreement.

2.3 EXCLUSION CRITERIA

Applicant must sign a declaration on their honour certifying that they are not in one of the exclusion situations referred to in the Articles 106 of the EU Financial Regulation.

Documents to be provided:

- **THE DECLARATION ON HONOUR** (Annex 7) to be completed/signed by the applicant.

2.4 SELECTION CRITERIA

Purpose of the selection criteria is to verify the operational capacity of the applicant.

Operational capacity:

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

Requirement for the organisation:

- a) The applicant must have extensive and demonstrable experience in the safety assessment of food and food ingredients;

Requirements for individuals assigned to perform the tasks:

- b) A level of education which corresponds to completed university studies of at least four (4) years attested by a diploma in Life Sciences or related areas; **OR**

A level of education which corresponds to completed university studies of three (3) years attested by a diploma in Life Sciences or related areas, plus appropriate professional experience of at least one (1) year;

- c) In addition to requirement b), the individual must have at least 7 years professional experience in at least one of the relevant scientific areas detailed below:

- Food chemistry and technology;
- Food consumption and exposure assessment
- (mammalian) Toxicology;
- Toxicokinetics / Absorption, distribution, metabolism and excretion (ADME);
- Genotoxicity;
- Human nutrition / human studies;
- Allergology (in particular Food allergy and intolerance);
- Clinical pharmacology;

- Microbiology
- d) Extensive and demonstrable experience in the safety assessment of food / food ingredients evidenced by:
 - Experience in evaluating dossiers in the field of foods / food ingredients; *and*
 - Proven ability to analyse complex information and technical dossiers, often from a wide range of scientific disciplines and sources; *and*
 - Evidence of experience in identifying pertinent studies, using databases and/or Endnotes; *and*
 - Evidence of awareness of quality, regulatory and scientific requirements relevant to the field of food / food ingredients (e.g. EFSA guidance documents, OECD, GMP, GLP)
- e) An excellent ability to communicate clearly and effectively in both spoken and written English. This should be evidenced by either:
 - a certificate demonstrating at least level B.2 of the Common European Framework of References for Languages; or
 - evidence of having worked for at least 2 years in a working environment where the day-to-day working language for meetings, communications is English; or
 - having written at least 3 reports or publications in English

Documents to be provided by the applicant:

- **Generic evidence (if applicable):** Additional document for private bodies only: to be submitted only if the grant requested from EFSA is > 60.000 €: **SIMPLIFIED FINANCIAL STATEMENT** (Annex 8) completed for at least last 2 closed financial years.
- **Generic evidence (if applicable): LETTER OF COMMITMENT:** applicable only in when another public body financially contributes to the project (body other than EFSA or the applicant); 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.
- **Evidence requested for the organisation (requirement a):** evidence of the preparation and drafting of at least 2 risk assessment reports on foods / food ingredients, carried out in the last 5 years;
- **Institutional Declarations of Interest** should be provided for each applicant institution. The template is available [here](#).
- **Evidence requested for the individuals, (requirements b – e): THE CURRICULUM VITAE** of the staff proposed to be assigned in the event of Specific Agreement award.
- **Individual Declarations of Interest** for the staff proposed to be assigned in the event of Specific Agreement award will only be requested prior to Specific Agreement signature. The template is available [here](#).

2.5 AWARD CRITERIA

The award criteria serve to assess the quality of the proposals in relation to the objectives of the Call.

The applying organisation will provide one¹⁵ risk assessment report in the field of foods / food ingredients that it considers to be representative of its capacity to perform the entrusted tasks described in these specifications under a Specific Agreement.

The risk assessment report (or where relevant, the part of the output of relevance) will be assessed by EFSA in light of the applicable Regulations and Guidance for the safety assessment of the food / food ingredients which are the subject of the safety assessment, in particular points will be awarded for:

1. Clearly describing the objective and scope (**Max 10 points**);
2. Providing a presentation of the four elements of risk assessment (hazard identification, hazard characterisation, exposure and risk characterisation) (**Max 30 points**);
3. Adequately addressing the source, nature and quality of the data, describing the assessment methods, assumptions, limitations and uncertainties (**Max 30 points**);
4. Presenting conclusions that are coherent with the main content (**Max 20 points**);
5. Risk assessment reports which have as their focus **novel foods** will automatically receive 10 points. (**10 points**)

In order for an application to be awarded an FPA, the proposal must **score a minimum of 70 points** out of maximum possible 100 points;

Proposals which have satisfied this quality threshold will be ranked according to the points obtained for the award criteria in order to form the cascade of beneficiaries to whom an FPA will be awarded.

2.6 PROCESS FOLLOWING THE ASSESSMENT AGAINST AWARD CRITERIA

The applicant(s) will be notified, once the evaluation has been finalized, whether they are eligible for a framework partnership agreement with EFSA. The Framework Partnership Agreement will specify the ranking obtained in the cascade by the organisation.

¹⁵ Two risk assessment reports are to be provided under the selection criteria but the applicant should specify for the award criteria which ONE individual risk assessment report is to be used for the evaluation against the award criteria.

3. SUBMITTING PROPOSALS

Only one proposal should be submitted per applicant.

3.1 APPLICATION FORM

The proposal must be submitted using the **EFSA APPLICATION FORM** (Annex 4). The application form is published together with this call and must be:

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

Please note that, by submitting the proposal, the applicant accepts the procedures and conditions as described in this Call and in the documents referred to therein.

In addition to a full paper version of the application the applicant shall submit the application also on a CD/USB data storage format. 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 in support of the proposal. These supporting documents are an integral part of the proposal. For more information on the relevant supporting documents to be submitted with the proposal, 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 EXPECTED DURATION OF PROCEDURE

Information on the expected duration of procedure – time to grant:

- Applicants will be informed of the decision regarding their application at the latest 6 months from the deadline for submission of proposals;
- Signature of the FPA will take place at the latest 3 months from the date on which the successful applicant has been informed of the decision on their application.

3.4 HOW TO SUBMIT A PROPOSAL

Details explaining how to submit your proposal are set out on page 2 of this Call.