

CALL FOR PROPOSALS AND GUIDE FOR APPLICANTS

Call reference: GP/EFSA/NUTRI/2014/01

Call title: Scientific substantiation of health claims made on food: collection, collation and critical analysis of information in relation to claimed effects, outcome variables and methods of measurement

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

Provide EFSA with feedback:

If, as an economic operator, you considered applying to this call for proposals but finally decided not to do so, your feedback and reasoning for such a decision would be very much appreciated. You should address your feedback to the EFSA contact point indicated in this document. EFSA will process your feedback so as to improve the quality of its future grant calls.

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1. ABOUT THIS CALL FOR PROPOSALS

1.1 LEGAL FRAMEWORK AND APPLICABLE TEXTS

Article 36 of the European Parliament and Council Regulation (EC) No 178/2002 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 a networking of organisations operating in the fields within the EFSA'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 Management Board.

Article 5 of 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 EFSA's mission specifies that the financial support to the networking organisations shall take the form of grants awarded in accordance with the EFSA's financial regulation and implementing rules.

The present Call for proposal and guide for applicants (hereinafter referred to as "the Call") is governed by the Regulation No 966/2012 of the European Parliament and of the Council of 25 October 2012 (OJ L 298, 26.10.2012, p.1) (hereinafter referred to as "EU Financial Regulation") and Commission Delegated Regulation C(2012)7507 on the rules of application of Regulation (EU) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union, adopted on 29 October 2012 (hereinafter referred to as "Rules of Application of EU Financial Regulation").

This call is launched following the 2014 EFSA annual work programme for grants adopted on 24 October 2013 and it is published at EFSA webpage: <http://www.efsa.europa.eu/en/art36grants/docs/art36grants2014.pdf>

1.2 CONTEXT AND SCIENTIFIC BACKGROUND OF THE CALL

Regulation (EC) No 1924/2006¹ harmonises the provisions that relate to nutrition and health claims and establishes rules governing the Community authorisation of health claims made on foods. According to the Regulation, health claims should only be authorised for use in the Community after a scientific assessment of the highest possible standard has been carried out by EFSA. The Nutrition Unit, within the Department of Scientific Evaluation of Regulated Products, provides scientific and administrative assistance to the Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) in view of delivering independent scientific advice on behalf of EFSA on questions related to the scientific substantiation of health claims, among others.

In addition to scientific and technical guidance to assist applicants in the preparation and presentation of applications for authorisation of health claims made on foods following a request of the European Commission, the NDA Panel has issued a general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims, and specific guidance documents on the scientific requirements for health claims in the areas of post-prandial blood glucose responses/blood glucose control, weight management, energy intake and satiety; protection against oxidative damage and cardiovascular health; bone, joints, oral and skin health; neurological and psychological functions; and physical performance; and gut and immune function upon EFSA's request. These guidance documents represent the views of the NDA Panel based on the experience gained to date with the evaluation of health claims under Articles 13.1, 13.5 and 14 of Regulation (EC) No 1924/2006 and have been launched for public consultation before adoption by the NDA Panel. Guidance documents and reports of public consultations addressing the comments received by stakeholders during the consultation period are available at EFSA's website².

¹ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30.12.2006, p. 9–25.

² <http://www.efsa.europa.eu/en/nda/ndaguidelines.htm>

The present call aims to gather information in relation to claimed effects, outcome variables and methods of measurement in the context of scientific substantiation of health claims. The information collected will serve as basis for further guidance to applicants in the preparation of applications for authorisation of health claims made on food.

1.3 OBJECTIVES OF THE CALL FOR PROPOSALS

This call for proposals aims at collecting, collating and critically analysing existing information in relation to claimed effects, outcome variables and methods of measurement in the context of scientific substantiation of health claims. The collection, collation and critical analysis of such information should be documented in a scientific report.

The report should provide information on claimed effects proposed by applicants with respect to whether they have been considered as beneficial physiological effects by the NDA Panel, to the outcome variables proposed for their evaluation, and to the methods of measurement available for such outcomes.

Objectives:

The **general objective** of the call for proposals is to **collect, collate and critically analyse existing information in relation to all claimed effects proposed by applicants** in the context of:

- a) Applications for authorisation of health claims under Articles 13.5 and 14 for which a Scientific Opinion has been published up to the date of publication of this call (around 230 such Opinions have been published up to June 2014);
- b) Guidance documents on the scientific requirements for health claims in the areas of gut and immune function; post-prandial blood glucose responses/blood glucose control, weight management, energy intake and satiety; protection against oxidative damage and cardiovascular health; bone, joints, oral and skin health; neurological and psychological functions; and physical performance;
- c) Comments received during public consultations related to the specific guidance documents on scientific requirements for health claims.

All documents (i.e. scientific opinions, guidance documents and comments received during public consultation) are published on the EFSA website³ and the beneficiary is expected to retrieve them via the website.

The **specific objectives** are to provide

1) details on whether the **claimed effect** (e.g. lowering blood pressure) **has been sufficiently defined** for a scientific evaluation.

2) details on whether the **claimed effect** has been considered as **a beneficial physiological effect** by the NDA Panel (only for those claimed effects considered to be sufficiently defined – see specific objective 1)

3) details on **the outcome variables** proposed by applicants for the scientific assessment of the claimed effect and/or used in key studies submitted for the scientific substantiation of the claim (e.g. measurement of brachial blood pressure to assess changes in blood pressure) (only for those claimed effects considered to be beneficial physiological effects – see specific objective 2):

3.1) For outcome variables (e.g. brachial blood pressure) considered appropriate by the NDA Panel for the scientific assessment of the claimed effect the following items should be addressed in detail in the report. The considerations made in the report should be supported by adequate justification and scientific references:

- Methods of measurement available which are generally accepted in the field (e.g. guidelines published by scientific societies based on rigorous methodological approaches) to measure the outcome variable (e.g. office blood pressure, 24-h ambulatory blood pressure, home blood pressure, etc), and parameters used for efficacy (e.g. systolic blood pressure, diastolic blood pressure, mean blood pressure, etc). Whether such methods of measurement have been developed for particular sub-groups of the population (i.e. are population-specific) should be considered.
- Methods which are generally NOT accepted in the field to measure the outcome variable
- Methods of measurement under development and/or validation

³ <http://www.efsa.europa.eu/en/publications.htm>

3. 2) For outcome variables NOT considered appropriate by the NDA Panel for the scientific assessment of the claimed effect:

- A compilation of outcome variables which were NOT considered appropriate to assess a claimed effect regardless of the method of measurement used (e.g. the outcome measure macular pigment optical density (MPOD) is NOT appropriate for the scientific assessment of the claimed effect visual function, regardless of how MPOD is measured). The reasons why the outcome variable could not be considered as appropriate to assess the claimed effect should be elaborated on together with scientific references.
- If the reasons for NOT considering the outcome variable appropriate were fully or partially related to the method of measurement (e.g. changes in body fat assessed using skinfold thickness), a compilation of other methods available which could be used to measure the outcome variable in a precise and reliable manner (e.g. neutron activation analysis, DEXA) should be provided, together with justifications and supporting scientific references.

In carrying out the tasks the general guidance for stakeholders on the evaluation of Article 13.1, 13.5 and 14 health claims, of guidance documents on the scientific requirements for health claims in the specific areas, on the technical reports addressing the comments received by stakeholders during the public consultations, and of the published Scientific Opinions related to the scientific evaluation of health claims under Articles 13.5 and 14 of Regulation (EC) No 1924/2006 issued by the NDA Panel have to be taken as a basis.

1.4 MEETINGS, REPORTING AND PAYMENTS

Below mentioned meetings with EFSA are foreseen:

1. **Kick off meeting (one-day physical meeting, held at EFSA premises):** This is regarded as the start of the project. It takes place not later than one month after the entry into force of the grant agreement. At this meeting, details of the project will be discussed and the objectives, the interim and final reports structure and timeframe will be clarified. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.

The presence at the kick-off meeting of a beneficiary's staff member responsible for administrative/finance issues of the project is advised. This is because the understanding by the beneficiary of the grant principles and related financial reporting requirements (declaration and documentation of incurred costs) will significantly ease and speed up the financial management of the grant agreement, both for EFSA and the beneficiary.

2. **Interim one-day physical meeting (held at EFSA premises) will be held at the latest one month after the submission of the protocol in conjunction with a meeting of the Working Group Claims of the Panel on Dietetic Products, Nutrition and Allergies (NDA):** The purpose of this meeting is to discuss the proposed protocol together with the experts involved in the assessment of health claims at EFSA. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.
3. **Interim tele-meeting N.1 will be held 2 weeks after the submission of the interim report 1:** The purpose of this meeting is to discuss the first interim report as well as any problems or difficulties (**technical**) encountered during the project. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.
4. **Interim tele-meeting N.2 will be held 2 weeks after the submission of the interim report 2.** The purpose of this meeting is to discuss the second interim report as well as any problems or difficulties (**technical or financial**) encountered during the project. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.
5. **Interim tele-meeting N.3 will be held 2 weeks after the submission of the interim report 3.** The purpose of this meeting is to discuss the third interim report as well as any problems or difficulties (**technical**) encountered during the project. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.
6. **Final physical meeting (one-day physical meeting, held at EFSA premises) will be held one month before the end of the project. The purpose of this meeting is to discuss the draft final report as well as any problems or difficulties (technical or financial) encountered during the project.**

Below mentioned reports must be drafted in English UK Standard language. The final report will be published on the EFSA website. The reports will include a full description of the protocol, a clear and full description of the results and the conclusions drawn.

1. **Protocol: Three months after the start date of the project (the kick off meeting)** a protocol must be submitted to EFSA. The protocol should build on the draft protocol submitted as part of the Grant Application and shall clearly outline the methodology used to retrieve the data and for the critical appraisal of the data.
2. **Interim report N.1: Nine months after the start date of the project (the kick off meeting) a written interim report N.1** must be submitted to EFSA. The written interim report 1 must describe the progress of the project and results of the work which addresses claims that are related to the guidance documents of the NDA Panel on i) protection against oxidative damage and cardiovascular health and ii) post-prandial blood glucose responses/blood glucose control, weight management. This should cover any claimed effects addressed in the before-mentioned guidance documents as well as any claimed effects addressed in Opinions of the Panel not (yet) included in the respective guidance documents but related to the subject matter of the guidance.
3. **Interim report N.2: Fifteen months after the start of the project (the kick off meeting) a written report must be submitted to EFSA.** The written interim report 2 must describe the progress of the project and the results of the work which addresses claims that are related to the guidance documents of the NDA Panel on i) bone, joints, oral and skin health and ii) neurological and psychological functions. This should cover any claimed effects addressed in the before-mentioned guidance documents as well as any claimed effects addressed in Opinions of the Panel not (yet) included in the respective guidance documents but related to the subject matter of the guidance.
4. **Interim report N.3: Twenty-one months after the start of the project (the kick off meeting) a written report must be submitted to EFSA.** The written interim report 3 must describe the progress of the project and the results on the work which addresses claims that are related to the guidance documents of the NDA Panel on i) gut and immune function and ii) physical performance. This should cover any claimed effects addressed in the before-mentioned guidance documents as well as any claimed effects addressed in Opinions of the Panel but not (yet) included in the respective guidance documents but related to the subject matter of the guidance.
5. **The draft final report: Twenty-three months after** the start date of the project **a draft final report** must be submitted to EFSA. The final report will comprise the integration of the interim reports N.1, 2 and 3, and an overall summary and conclusions and discussion for the whole project.
6. **The final report: Twenty-four months after** the start date of the project **a final report** must be submitted to EFSA. The final report will comprise the integration of the interim reports N.1, 2 and 3, and an overall summary and conclusions and discussion for the whole project.

Please note that all reporting, minutes, outcome of the discussions could be shared with EFSA Panel and WG members at EFSA's discretion.

The report (interim N.1 & N.2&N.3 draft final and final) shall be written in English UK Standard and will follow the template structure and format provided by EFSA and EFSA citation standards⁴ and shall be submitted in electronic format (Word file).

	Month 0 - Grant agreement signature	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9
Deliverables				Protocol						Interim Report 1
Meetings		Kick-off meeting (physical)			Interim physical meeting					Interim meeting 1
Payments	Pre-financing									

⁴ To be provided by EFSA after the signature of the agreement

	Month 10	Month 11	Month 12	Month 13	Month 14	Month 15	Month 16	Month 17	Month 18
Deliverables						Interim Report 2			
Meetings						Interim meeting 2			
Payments						Interim payment			

	Month 19	Month 20	Month 21	Month 22	Month 23	Month 24	Month 25	Month 26	Month 27
Deliverables			Interim Report 3		Draft Final report	Final Report			
Meetings			Interim meeting 3		Final physical meeting				
Payments						End of project			Final payment

The maximum duration of the project from the kick-off meeting is 24 months.

1.5 STRUCTURE OF THE PROPOSAL

The applicant shall provide, in the proposal, **using the EFSA STANDARD APPLICATION FORM (in part 2.1)**, beside other requested information, a description of **the methodology** it proposes to achieve the objectives of the call and to deliver the expected deliverables and to execute successfully the project. In the proposal, the applicant shall also describe **the involvement of various partners in case of consortia, and the task division between the proposed team members**, and also indicate a detailed and realistic **project timeline**, which must be in any case in line with the meeting and reporting requirements of this call.

In particular, the applicant must describe in detail the proposed approach including the following information:

- 1) A detailed description of the methodology proposed for collecting, collating, critically analysing and presenting existing information relative to the objectives of the call, and in particular regarding:
 - a. The strategy to retrieve, select and handle all scientific publications which could be pertinent to the specific objectives of the call as outlined in Section 1.3. This includes but is not limited to the suitability of: the proposed information sources to be used, the proposed search strategies to retrieve pertinent publications, the proposed eligibility criteria for selection of publications, in particular for scientific publications relative to the methods available for the measurement of outcome variables and the method for assessing the methodological quality of the included publications.
 - b. The approach towards critically analysing the suitability of outcome variables proposed for the scientific assessment of the claimed effects, and the methods of measurement available for each outcome variable with respect to their validity, accuracy, precision, measurement conditions, etc.
 - c. Description of how the information collected, collated and critically analysed will be presented in order to fulfil the objectives of the project.

To this end, the applicant to this call for proposals is requested to submit a **draft protocol** addressing the above mentioned points.

This information will be used for the assessment of the award criterion 1

- 2) Description of specific quality control mechanisms to be put in place to guarantee high quality of deliverables.
This information will be used for the assessment of the award criterion 2.1
- 3) Description of the specific measures put in place in order to assure a sound project management, including the way the various tasks are distributed within the team; internal communication inside the project team, and communication with EFSA;
This information will be used for the assessment of the award criterion 2.2
- 4) A clear indication of the timelines for the completion of the project's tasks providing detailed milestones for each task (e.g. via a project Gantt chart) as well as a description of the risks that might be foreseen per each individual task, and a description of the specific measures put in place to assure that the deadlines for providing deliverables are met. In addition, a contingency plan in case deviations from the project programme is required.
This information will be used for the assessment of the award criterion 2.3

Regarding other documents to be submitted together with the Application please refer to the checklist attached to the Application form

1.6 AMOUNT AVAILABLE FOR EFSA GRANT AND MAIN GRANT PRINCIPLES

The EFSA grant co-financing rate will equal up to **90 %** of the total eligible project costs, provided that EFSA grant does not exceed **200.000 €** which is the maximum grant which might be received from EFSA for this project. The applicant is free to ask for an EFSA grant co-financing rate lower than 90%. The EFSA grant will not be awarded for more than the amount requested. **EFSA intends to fund one proposal**. EFSA reserves the right not to award all the funds available.

The total amount of estimated eligible costs, which serves as a basis for calculation of the EFSA grant, will be verified by EFSA during the evaluation of the received proposals. If **RULES ON ELIGIBILITY OF COSTS** (annex 1 of this Call) were not correctly applied by the applicant, when establishing the estimated budget, EFSA reserves the right to impose the necessary corrections.

Main grant principles:

In compliance with the Financial Regulation and its Implementing Rules, the proposals must comply with the following principles:

- **Co-financing:** co-financing from a source other than EU budget is required. The project costs not covered by EFSA grant must be financed from the applicant or partners` resources. In addition to these resources, only financial contributions from other public bodies are allowed. Contributions from private sector are not permitted.
- **Non-profit:** The EFSA grant may not have the purpose or effect of producing a profit for the applicant or partner organisation. Profit is defined as a surplus of the receipts over the eligible costs incurred by the beneficiary, when the request for payment of the balance is made. Where a profit is made, EFSA shall be entitled to recover the percentage of the profit corresponding to the Union contribution to the eligible costs actually incurred by the beneficiary to carry out the project. The verification of the non-profit rule does not apply to low value grants, i.e. grants \leq 60.000 €.
- **Non-retroactivity:** the costs eligible for financing must be incurred after the entry into force of the Grant agreement.
- **Non-cumulative:** A project 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, applicants 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.

1.7 FURTHER INFORMATION

Any questions regarding the Call may be sent to REPRO.Grants.and.Procurements@efsa.europa.eu no later than by 05/09/2014, clearly indicating the Call reference. Replies will be given no later than by 12/09/2014. Questions together with the answers will be published on the EFSA website and therefore the applicants are requested to consult it regularly..

2. SUBMITTING PROPOSALS

2.1 APPLICATION FORM

The proposal must be submitted using the **EFSA STANDARD APPLICATION FORM** (hereinafter referred to as “Application form”) together with all the requested annexes correctly completed. The application form may be downloaded from the EFSA website <http://www.efsa.europa.eu>, where this Call for Proposals is published. The applicant organisation (hereinafter referred to as “applicant”) must complete and submit the application form together with all indicated annexes.

The applicant should keep strictly to the format of the application form and fill in the paragraphs and the pages in order. A duly authorised representative of the applicant must sign the application form. The application form must be completed carefully and clearly so that it can be properly assessed. The applicant should be precise and provide enough detail to ensure the application form is clear and complete. Any major inconsistency with the submission requirements (see point 3.1) may lead to the immediate rejection of the proposal.

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

2.2 LANGUAGE OF THE PROPOSAL AND THE SUPPORTING DOCUMENTS

Proposals may be submitted in any official language of the European Union. Please note that EFSA working language is English and accordingly the submission of proposals in English will speed up the evaluation process.

Please note that a number of supporting documents is 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 3 of this Call. Where 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.

The EFSA may ask for further clarification in the course of the evaluation.

2.3 FINAL DEADLINE AND ADDRESS FOR SUBMISSION OF PROPOSALS

The final deadline for submission of proposals is **19/09/2014**.

You can submit your proposal:

- either by registered mail or by courier service to the below address (the post office stamp or the date of the deposit slip from the courier service will be considered as proof of the date of submission). In this case, you are requested to send a message to EFSA’s dedicated e-mail address (REPRO.Grants.and.Procurements@efsa.europa.eu) shortly stating that you have sent a proposal. Any proposal posted after the final deadline will automatically be rejected.
- or by hand to the below address, not later than 17.00 hours (Italy time). Any proposal hand delivered after the final deadline will automatically be rejected.

The proposal must be sent to the following postal address:

European Food Safety Authority - EFSA
REPRO Planning and Monitoring Team
GP/EFSA/NUTRI/2014/01
Via Carlo Magno 1/A
I – 43126 Parma

Information of expected duration of procedure – time to grant:

- Applicants will be informed on the decision regarding their application at the latest six months after the deadline for submission of proposals.

- The signature of the grant agreement will take place at the latest three months after the successful/unsuccessful applicant(s) have been informed about the decision on their application.

For more details please refer to the indicative timetable below:

Milestone	Date	Comments
Launch date	11/07/2014	Date of publication on EFSA' s website
Deadline for sending a request for clarification to EFSA	05/09/2014	
Deadline for submission of proposals	19/09/2014	See section 2.4 for details
Notification of the evaluation results	October 2014	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/application form. Accordingly, the applicants who have submitted a proposal under the present call are strongly invited to check regularly the inbox in question.</i>
Grant agreement signature	October-November 2014	Estimated

2.4 HOW TO SEND THE PROPOSALS

Your proposal 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:

- the Call reference: **GP/EFSA/NUTRI/2014/01**
- the title of the Call: **Scientific substantiation of health claims made on food: collection, collation and critical analysis of information in relation to claimed effects, outcome variables and methods of measurement;**
- the name of the applicant;
- the indication: **“Proposal - Not to be opened by EFSA reception – to be passed without opening to the REPRO – Planning and Monitoring Team”;**
- the address for submission of proposal (see above);
- the posting date (if applicable) should be legible on the outer envelope.

Proposal must include: The completed Application form (including all documents as indicated in Part 2 of the Application Form under the Checklist) in 1 original paper version and 1 CD containing the complete set of documents as submitted on paper. This electronic version must be identical to the paper version. In case of any discrepancies between the electronic and original paper version, the latter will prevail. All documents presented by the applicant become the property of EFSA and are deemed confidential.

3. SELECTING PROPOSALS

No modification to the application is allowed once the deadline for submission of proposals has elapsed. However, if there is a need to clarify certain aspects or for the correction of clerical mistakes, EFSA may contact the applicant for this purpose during the evaluation process.

An Evaluation Committee will be established in accordance with article 133 of the Financial Regulation and article 204 of its Implementing Rules in order to evaluate the submitted proposals. EFSA intends to finalise the evaluation of proposals within six months after the final deadline for submission of proposals. In compliance with article 133 (3) of the Financial Regulation, the applicant will be informed in writing about the decision on the applicant's proposal. Please note that EFSA has the right not to award a grant and to cancel the procedure at any time before the signature of the Grant agreement without any compensation to be paid to the applicant.

Evaluation will proceed in 5 steps:

1. verification of compliance with all submission requirements (see 3.1)
2. eligibility criteria (see 3.2)
3. exclusion criteria (see 3.3)
4. selection criteria (see 3.4)
5. award criteria (see 3.5)

If the proposal fails at any step it is automatically excluded from further evaluation.

3.1 VERIFICATION OF SUBMISSION REQUIREMENTS

The following will be assessed:

- The final deadline for submission of proposals: If this deadline has not been respected the proposal will automatically be rejected.
- The proposal is submitted using the Application form and is duly signed by the authorised representative of the applicant. If the applicant did not submit the proposal using the Application form or if this form is not signed then the proposal may be rejected on that sole basis.
- The proposal is complete, including all supporting documents. If any of the requested information/documents is missing or is not complete the proposal may be rejected on that sole basis.

The proposal which meets all the submission requirements will be considered admissible and will pass to the next stage of evaluation process – verification of eligibility criteria.

3.2 ELIGIBILITY CRITERIA

Eligible applicants:

Applicant is offered the possibility to apply individually, or in a consortium with partners established for the purpose of the project implementation. The applicant is responsible for identifying possible consortium partners.

Both applicant and possible partner(s) must comply with the essential condition of being on the list of competent organisations designated by the Member States in accordance with Article 36 of Regulation (EC) No 178/2002 and Commission Regulation (EC) No 2230/2004. This list is regularly updated by EFSA Management Board. You may consult the list of competent organisation at this link: <http://www.efsa.europa.eu/en/networks/art36.htm>.

The applicant may not submit more than one proposal under this Call.

Documents to be provided on support of eligibility:

- **LEGAL ENTITY FORM** ([download template here](#)) to be completed and signed by the applicant, and by partner(s) in case of a proposal made by a consortium. In case of public bodies this legal entity form should be provided together with a copy of the resolution or decision establishing the public company/body, or other official document establishing the public law entity. In case of private bodies 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** ([download template here](#)) to be completed and signed by the applicant.

Please note that you do not have to submit legal entity form and/or the financial identification form if it/they has/have already been submitted to EFSA under another procurement or grant procedure and provided that this/these document(s) is/are still valid. In this case, please clearly indicate in the application the reference of the call under which the document(s) was/were submitted to EFSA.

In case of a consortium:

In case the applicant applies in a consortium with partners, both applicant and the partners must participate in the project both financially and intellectually.

Regarding the applicant, please note the following:

- There may be only one applicant per project;
- The applicant must submit the proposal on behalf of a consortium to EFSA;
- The applicant must act as the intermediary for any communications between the partners and EFSA;
- The applicant shall be liable vis-à-vis EFSA for the correct and timely fulfilment of the obligations of the partners, and receive and answer all claims EFSA might have in relation to the performance of the action;
- The applicant shall inform EFSA and the partners of any event they are aware of that is liable to substantially affect the implementation of the project;
- The applicant participates in the project, for which its costs are borne;
- The applicant shall request and receive all payments made by EFSA, and shall be responsible for distributing them among the partners.

Regarding the partner organisations, please note the following:

- Partners participate in the project, for which their costs are borne;
- Partners shall forward to the applicant the data needed to draw up the reports, financial statements and other documents provided for in the Grant agreement;
- Partners shall immediately inform the applicant of any event liable to substantially affect or delay the implementation of the project.

As mentioned above, the partners must satisfy the same eligibility criteria as the applicant organisation.

In the case of a consortium, the Grant agreement will be signed between EFSA, the applicant and the partners. In the case of selection of the applicant's proposal, the applicant will become the Coordinator-Beneficiary (hereinafter referred to as "the Coordinator") and its possible partners will become the Co-beneficiaries within the framework of the Grant agreement. For the purposes of the proposal, it is required that the applicant and his partners provide EFSA with **PARTNERSHIP STATEMENTS** defining the technical/intellectual and financial involvement of each of them. Each organisation (applicant and all partners) must sign this partnership statements.

Should a member of a consortium already be either directly or indirectly financially supported by the EU budget, its costs, direct or indirect, are not eligible under the present project, unless adequate proof is provided to EFSA that there is no double financing of costs.

In case of a consortium: additional documents to be provided:

- **PARTNERSHIP STATEMENTS** defining the intellectual and financial involvement of each member of the consortium (applicant and partners) signed by each member of consortium (to be provided for each consortium partner). **No template is provided by EFSA.**

Eligibility of implementation contracts/subcontracting:

Where the implementation of the project requires the award of procurement contracts (implementation contracts), the beneficiary must award the contract to the bid offering best value for money or the lowest price (as appropriate), avoiding conflicts of interests and retain the documentation for the event of an audit.

Entities acting in their capacity of contracting authorities in the meaning of Directive 2004/18/EC⁵ or contracting entities in the meaning of Directive 2004/17/EC⁶ shall abide by the applicable national public procurement rules.

⁵ Directive 2004/18/EC on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts.

⁶ Directive 2004/17/EC coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors.

Sub-contracting, i.e. the externalisation of specific tasks or activities which form part of the project as described in the proposal must satisfy the conditions applicable to any implementation contract (as specified above) and in addition to them the following conditions:

- Recourse to the award of sub-contracts must be justified with regard to the nature of the project and what is necessary for its implementation;
- Project management, organisation or any core tasks cannot be subcontracted;
- Subcontracting may only be used to subcontract ancillary and assistance related tasks.
- The tasks intended to be subcontracted and the corresponding to the estimated costs must be set out in the Estimated Budget and approved by EFSA before the signature of the Grant agreement;
- In case subcontracting needs are identified after the Grant Agreement signature: Any recourse to the award of sub-contracts while the project is in progress, if not envisaged from the outset in the proposal, is subject to prior authorisation in writing by the EFSA through an amendment.
- The Coordinator and the possible Co-beneficiaries retain sole responsibility for implementing the project and complying with the provision of the Grant agreement;
- The Coordinator and the possible Co-beneficiaries undertake to ensure that the conditions applicable to them as regards responsibility, conflict of interests, ownership and use of results, confidentiality, publicity, transfer of claims, and controls and audits also apply to the sub-contractor.

Please note that sub-contractors are not consortium partners. Subcontractors are organisations formally contracted by the applicant or its possible partners to carry out specific tasks. Cost of subcontracting is borne by the applicant and/or the possible partners and the subcontractor does not contribute financially to the project.

External expertise to the project can be provided only under the following conditions:

- External experts should be recruited, also temporarily, based on an employment contract and the payment for expert should be based on a monthly salary slip as contrary to the invoice (i.e.: the expert does not issue invoices for carrying out the tasks foreseen, but is recruited by the applicant/partner and he/she receives a monthly salary for his/her work);
- Subcontracting - may be used only for ancillary and assistance related tasks.

Eligibility of actions:

As defined in part 1 of this Call. The application may not envisage provision of financial support to third parties.

Eligibility implementation period:

Activities may not start before the grant agreement signature by both parties and must be executed in the deadlines stipulated in part 1 of this Call.

Eligibility of costs:

Please refer to Annex 1 of this Call – Rules on eligibility of the costs. Budget must be balanced. Total costs must equal total revenue.

3.3 EXCLUSION CRITERIA

Exclusion from participation:

Applicants will be excluded from participating in the call for proposals procedure if they are in any of the following situations:

- they are bankrupt or being wound up, are having their affairs administered by the courts, have entered into an arrangement with creditors, have suspended business activities, are the subject of proceedings concerning those matters, or are in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
- they or persons having powers of representation, decision making or control over them have been convicted of an offence concerning their professional conduct by a judgment of a competent authority of a Member State which has the force of res judicata;
- they have been guilty of grave professional misconduct proven by any means which the contracting authority can justify including by decisions of the European Investment Bank (EIB) and international organisations;
- they are not in compliance with their obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which they are established or those of the country where the grant agreement is to be performed;

- they or persons having powers of representation, decision making or control over them have been the subject of a judgement which has the force of res judicata for fraud, corruption, involvement in a criminal organisation, money laundering or any other illegal activity, where such an illegal activity is detrimental to the Union's financial interests;
- they are currently subject to an administrative penalty referred to in Article 109(1) of EU Financial Regulation⁷.

Exclusion from award:

Applicants will not be granted financial assistance if, in the course of the grant award procedure, they:

- are subject to a conflict of interest;
- are guilty of misrepresentation in supplying the information required by EFSA as a condition of participation in the grant award procedure or fail to supply this information;
- find themselves in one of the situations of exclusion, referred above.

Applicants must sign a declaration on their honour certifying that they are not in one of the exclusion situations referred to in the Articles 106(1) and 107 to 109 of EU Financial Regulation.

Please note that, according to Article 200 of the Rules of Application of EU Financial Regulation, financial or administrative penalties, or both, may be imposed on applicants who have made false declarations or substantial errors, or committed irregularities or fraud, in accordance with the conditions laid down in Article 145 of Rules of Application of EU Financial Regulation. Such financial or administrative penalties, or both, may also be imposed on beneficiaries who have been found in serious breach of their contractual obligations.

Documents to be provided by the applicant:

- **THE DECLARATION ON HONOUR (template available at EFSA's website as published together with this Call for Proposals)** to be completed and signed separately by the applicant and by each of its possible partners. This declaration covers both exclusion criteria and financial and operational capacity selection criteria.
- In order to demonstrate that the team members are not subject to a conflict of interest for which they might potentially be excluded, they should complete an **Individual Declaration of Interest (download template here)** for each member of the proposed project team. Further information on the DoI policy of EFSA can be found in the [Decision of the Executive Director implementing EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests](#)

3.4 SELECTION CRITERIA

The selection criteria are used to evaluate **the financial and operational capacity** of the applicant(s), and its partners in case of consortia.

Financial capacity of applicants and possible partners:

The applicant and its possible partners must have stable and sufficient financial resources to:

1. maintain their activity throughout the period during which the project is being carried out, and
2. participate in its funding.

Documents to be provided by the applicant:

- **THE DECLARATION ON HONOUR** (this declaration is covered in the document requested under point 3.3 above). This declaration covers both exclusion criteria and financial and operational capacity selection criteria.
- **Additional document for private bodies in case of grant > 60.000 €: SIMPLIFIED FINANCIAL STATEMENT (template available at EFSA's website as published together with this Call for Proposals)** completed for last three closed financial years.
- **Additional document in case other public bodies financially contribute to project, bodies other than EFSA, the applicant or partners: LETTER OF COMMITMENT** signed by the public body confirming the commitment of this public body to financially contribute to the project. **No template is provided by EFSA.**

⁷ In particular s subject to an administrative penalty for being guilty of misrepresenting the information required as a condition of participation in a procurement procedure or another grant award procedure or failing to supply this information, or having been declared to be in serious breach of its obligations under contracts or agreements covered by the Union's budget.

Operational capacity of applicants and possible partners:

The applicant, or in case of consortium the consortium as a whole, must have the professional competencies as well as appropriate qualifications necessary to complete the proposed project.

Documents to be provided by the applicant:

- **THE DECLARATION ON HONOUR** (this declaration is covered in the document requested under point 3.3 above). This declaration covers both exclusion criteria and financial and operational capacity selection criteria
- **THE CURRICULUM VITAE** of the project manager/s and scientific staff to be involved in the project, ***including for each member a brief description of the expertise and a list of publications relevant to the project.***
- **A concise description** of the applicant activities in the fields relevant to the subject matter of the Call. In case of a consortium, this description should be provided also for each partner.

3.5 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 to this Call:

AWARD CRITERIA	WEIGHT
<p>1. QUALITY OF THE PROPOSAL addressing the related requirements as outlined in Section 1.5.</p> <p>1. The extent to which the proposal achieves <u>the objectives of the Call</u> guarantees an <u>excellent level of science output</u>. In particular, 1) the <u>appropriateness of the proposed strategy</u> to retrieve, select and handle all scientific publications which could be pertinent to the objectives of the call (this includes but is not limited to the suitability of: the proposed information sources to be used, the proposed search strategies to retrieve pertinent publications, the proposed eligibility criteria for selection of publications, in particular for scientific publications relative to the methods available for the measurement of outcome variables and the method for assessing the methodological quality of the included publications, 2) the <u>proposed methodology to critically analyse the information</u> retrieved (in particular with respect to the suitability of outcome variables proposed for the scientific assessment of the claimed effects, and with respect to the validity, accuracy, precision and measurement conditions methods of measures available for each outcome variable) and 3) the approach towards <u>reporting and presenting</u> the retrieved information in the interim reports and in final report, as presented in the draft protocol to be submitted as part of the Application, will be used as a basis for the evaluation. Attention will also be paid to the detail in which the project is described.</p>	max 60 points
<p>2. QUALITY CONTROL AND PROJECT MANAGEMENT addressing the related requirements as outlined in Section 1.5. (INCLUDING CONSORTIUM, if applicable)</p> <p>1. The extent to which the specific quality control mechanisms to be put in place will guarantee high quality of deliverables.</p> <p>2. The extent to which the specific measures put in place in order to assure a <u>sound project management</u>, including the <u>way the various tasks are distributed within the team; internal communication</u> inside the project team, and <u>communication with EFSA</u> have been <u>clearly described</u> and appear to be <u>suitable</u>.</p> <p>3. The extent to which a clear indication of the <u>timelines</u> for the completion of the project's tasks with <u>detailed milestones</u> for each task (e.g. via a project Gantt chart) as well as a description of the <u>risks that might be foreseen per each individual task</u>, a description of the <u>measures put in place to assure that the deadlines for providing deliverables are met</u> have been clearly described. In addition, the <u>suitability of the proposed contingency plan</u> in case deviations from the project programme will be assessed</p>	max 30 points max 10 points max 10 points max 10 points
<p>3. FINANCIAL COHERENCE AND COST EFFECTIVENESS</p> <ul style="list-style-type: none">• The extent to which the estimated budget is <u>cost-effective</u> (comparison between the costs and the anticipated achievement of the objectives and results obtained) and the <u>consistency between proposed budget and technical part of proposal</u>.	max 10 points
TOTAL	100

In order to be considered for funding, the proposal must:

- **score a minimum of 70 points in total out of possible 100 points and**
- **for each criterion (1, 2, 3), score at least 50% of the points attributed to that criterion.**

Proposals which have satisfied these quality thresholds will be ranked according to the points they have achieved. Depending on budget availability the highest ranked proposal will be awarded a grant from EFSA.

4. GRANT AGREEMENT, IMPLEMENTATION AND PAYMENTS

According to article 133 (3) of the Financial regulation, applicants will be informed in writing of the decision on their proposal. If the grant requested is not awarded, EFSA will give the reasons for the rejection of the application. Following the decision to award a grant, a Grant agreement will be proposed to the successful applicant. The project may begin at the earliest on the day the Grant agreement has been signed by the last of the parties (usually EFSA signature). Costs incurred prior to the date of the signature of the Grant agreement will not be considered as eligible.

4.1 ESTIMATED BUDGET

All proposals must be supported by an **ESTIMATED BUDGET (template available at EFSA's website as published together with this Call for Proposals)** which must be compiled in line with the **RULES ON ELIGIBILITY OF COSTS (template available at EFSA's website as published together with this Call for Proposals)**. The estimated budget must show all the costs and income which the applicant considers necessary to carry out the project. The estimated budget must:

- Be sufficiently detailed to permit identification, monitoring and checking of the proposed costs;
- Be balanced, i.e. total income and costs must equal;
- Be consistent with the work plan;
- Be expressed in Euros. This requirement is due to the fact that EFSA grant will be expressed in Euros only. Applicants which foresee that costs will not be incurred in Euros are invited to use the exchange rate published at: <http://www.ecb.int/stats/exchange/eurofxref/html/index.en.html>.

Estimated budget - costs:

- Eligible direct costs:
 1. Costs of permanent or temporary staff
 2. Travel and subsistence costs
 3. Equipment
 4. Consumables and supplies
 5. Subcontracting of ancillary and assistance tasks
 6. Miscellaneous costs directly linked to the project. These are costs arising directly from requirements imposed by the Grant agreement.
- Eligible indirect costs:
 7. The indirect costs incurred in carrying out the project may be eligible for a flat-rate funding fixed at not more than 10 % of the total eligible direct costs.

Estimated budget – incomes:

- Applicant's financial contribution
- In case of consortium: partners' financial contributions
- Grant requested from EFSA
- OPTIONAL - financial contributions from **public bodies** other than EFSA, applicant and consortia partners. Applicant must attach to the application a letter signed by such a public body confirming that the public body is committed to contributing the indicated amount to the project.

4.2 APPROVED ESTIMATED BUDGET

The estimated budget as presented by the applicant with the proposal is analysed by EFSA in order to:

- assess whether it is consistent with the proposed project and decide whether the estimated budget is sufficiently detailed to consider funding of the project;
- assess whether the estimated budget matches the specific objectives/expected results of the project;
- eliminate any item of costs which cannot be accepted according to the Rules on eligibility of costs;
- if necessary, propose a downward revision of the estimated budget in relation to some items of costs considered as being excessive compared to the nature of the project and/or to the volume of work that has to be implemented in order to achieve the planned results.

The proposal should enable EFSA to evaluate the estimated budget, i.e. it should contain the detailed justification of the necessity of the proposed expenditure for performance of the project. An over- or underestimation of costs will have a negative impact on the evaluation score under the award criteria named "Cost effectiveness".

The analysis of the estimated budget is made in accordance with the Rules on eligibility of costs. It is EFSA who takes the final decision as regards the nature and amount of the costs to be considered eligible.

If, following the financial analysis, EFSA regards the estimated budget as realistic, established in accordance with the Rules on eligibility of costs and no modification is needed, it will become the **APPROVED ESTIMATED BUDGET** and the EFSA grant may correspond to the applicant's request. In some cases, however, the analysis of the estimated budget could result in suggestions for reductions as a consequence of, e.g. the correct application of the Rules on eligibility of costs. Accordingly, if following the financial analysis of the estimated budget, EFSA suggests some modifications to it, EFSA will present the proposed modifications to the applicant. After the proposed modifications are agreed by the applicant and EFSA, the estimated budget, as modified, will become the Approved Estimated Budget for the project. Following the financial analysis of the estimated budget and having agreed to the Approved Estimated Budget, the evaluation committee will decide the exact amount of the EFSA grant which will be expressed as an amount in € and as a percentage of the total eligible project cost (EFSA co-financing rate).

4.3 DETERMINATION OF FINAL EFSA GRANT

THE FINAL EFSA GRANT will be determined after completion of the project based on the actually incurred costs and after approval by EFSA of the final report. Please remember that the EFSA grant as expressed in the Grant agreement is calculated on the basis of the **estimated eligible costs**. The final EFSA grant determination process can be summarised as follows:

- EFSA will analyse the final statement of actually incurred costs and receipts submitted according to the Grant agreement by the beneficiary to EFSA and will establish the amount of actually incurred eligible costs.
- If the total actually incurred eligible costs are lower than the total eligible costs as estimated in the estimated budget, EFSA will consider as ceiling for the final EFSA grant 90 % (EFSA co-financing rate) of the total actually incurred eligible costs. If there is no profit identified during analysis of the actually incurred costs/receipts, this ceiling will also correspond to the final EFSA grant. If there is profit identified EFSA will deduct 90 % of such profit in order to establish the final EFSA grant.
- If the total actually incurred eligible costs are higher than the total eligible costs as estimated in the estimated budget, EFSA will consider as ceiling the amount of the EFSA grant stipulated in the Grant agreement. If there is no profit identified during analysis of actually incurred costs/receipts, this ceiling will also correspond to the final EFSA grant. If there is a profit identified EFSA will deduct 90 % of such profit in order to establish the final EFSA grant.
- If the total of earlier payments is higher than the final EFSA grant, the beneficiary will be required to reimburse the amount paid in excess by EFSA through a recovery order.

The verification of the non-profit rule does not apply to grants \leq 60.000 €.

4.4 REPORTS AND PAYMENTS

Within 30 days from the date of the signature of the Grant agreement by EFSA, a **pre-financing payment** between 10 % and 40 % of the EFSA grant will be made to the bank account indicated in the Grant agreement. Please note that the exact amount of pre-financing will be determined at the time of awarding grant.

The interim payment between 10 % and 40 % of the EFSA grant or of the actually incurred eligible costs declared in the interim statement of costs, whichever is lower, will be made according to the Grant agreement and will be linked to the approval by EFSA of the interim report N. 2 ([see part 1.4 of this Call](#)).

The payment of the balance will be made according to the Grant agreement and will be linked to approval by EFSA of the final deliverable/s ([see part 1.4 of this Call](#)).

4.5 PUBLICITY

By the beneficiaries:

Beneficiaries must clearly acknowledge the EU contribution in all publications or in conjunction with activities for which the grant is used. In this respect, beneficiaries are required to give prominence to the name and emblem of

EFSA on all their publications, posters, programmes and other products realised under the co-financed project. Those publications shall contain a disclaimer stating that EFSA is not responsible for the views displayed in the publications and/or in conjunction with the activities for which the grant is used. If this requirement is not fully complied with, the beneficiary grant may be reduced in accordance with the provisions of the grant agreement or grant decision.

By EFSA:

All information relating to grants awarded in the course of a financial year shall be published on an internet site of EFSA no later than the 30th June of the year following the financial year in which the grants were awarded. EFSA will publish the following information:

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

Upon a reasoned and duly substantiated request by the beneficiary, the publication shall be waived if such disclosure risks threatening the rights and freedoms of individuals concerned as protected by the Charter of Fundamental Rights of the European Union or harm the commercial interests of the beneficiaries.

4.6 ACCOUNTING RECORDS OF THE PROJECT AND AUDIT

Accounting records:

The coordinator, and the possible co-beneficiaries in case of consortium, must keep accurate and regular accounting records as well as separate and transparent accounts of the implementation of the project. They must keep all the accounting records and all the supporting documents underlying the accounting records regarding the project for the period of five years after the payment of the balance.

Audit:

The coordinator, and the possible co-beneficiaries in case of consortium, will have to provide any detailed information requested by EFSA or by any other outside body authorised by EFSA to check that the project and the provisions of the grant agreement are being properly implemented. They must agree that EFSA may have an audit of the use made of the grant carried out either directly by its own staff or by any other outside body authorised to do so on its behalf. Such audits may be carried out throughout the period of implementation of the grant agreement until five years from the date of payment of the balance.

Please note that by virtue of Council Regulation (Euratom, EC) No 2185/96 and Regulation (EC) No 1073/1999 of the European Parliament and the Council, the European Anti-Fraud Office (OLAF) may also carry out on-the-spot checks and inspections in accordance with the procedures laid down by Union law for the protection of the financial interests of the European Union against fraud and other irregularities.

Finally the European Court of Auditors shall have the same rights as EFSA, notably right of access, as regards checks and audits.

5. PROTECTION OF PERSONAL DATA AND PUBLIC ACCESS TO DOCUMENTS

5.1 PROTECTION OF PERSONAL DATA IN RELATION TO GRANT PROCEDURES

Processing your application in the context of this grants 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° 45/2001⁸.

Unless indicated otherwise, the questions and any personal data requested are required to evaluate the application in accordance with the specifications of the Call 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 the data processing and the 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 Central Exclusion Database (CED) by the Accounting Officer of the Commission, should the beneficiary be in one of the situations mentioned in:

- the Commission Regulation 2008/1302 of 17.12.2008 on the Central Exclusion Database (for more information see the Privacy Statement on: http://ec.europa.eu/budget/explained/management/protecting/protect_en.cfm).

5.2 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.

LIST OF ANNEXES

ANNEX 1: Rules on eligibility of costs

⁸ Regulation (EC) N° 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, Official Journal of the European Union, L8, 12.1.2001, pp.1-22