Data collection to characterise the impact of canine leishmaniosis and modelling of the role of animals in spreading *Leishmania infantum* within the European Union.

Call for proposals CFP/EFSA/AHAW/2011/02 and guide for applicants

Restricted to the list adopted by EFSA Management Board according to article 36 of European Parliament and Council Regulation (EC) No 178/2002
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1. INFORMATION ABOUT THE 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 20th 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 was updated on 18th December 2008 by the 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 the 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.


1.2 CONTEXT AND SCIENTIFIC BACKGROUND OF THE CALL

Canine leishmaniosis was listed in the 2011 EFSA Management Plan as a topic to be considered by the AHAW Panel. Leishmaniosis is a non-food-borne zoonosis with sandflies (Phlebotomus spp.) as vector. Only two transmission cycles are known to be endemic in the European Union (EU): i) cutaneous leishmaniosis caused by L. tropica, which is usually regarded as an anthropornosis, although the parasite was isolated also from rodents and dogs and which occurs sporadically in Greece and ii) zoonotic, cutaneous and visceral leishmaniosis caused by L. infantum which occurs throughout the Mediterranean region with domestic dogs as main reservoir hosts. Recently high prevalences of L. infantum infection in apparently healthy wild carnivores were found in southern Spain, suggesting also the existence of a sylvatic cycle independent of dogs. Factors that may trigger changes in the distribution of the disease include climate and environment changes, changes in vector capacity and competence, importation or dispersal of vectors and reservoir hosts and travelling dogs with their own owners. Currently, two questions need to be addressed that are: the impact of the disease and the role of animals in spreading L. infantum.

Canine leishmaniosis (CanL) has become more apparent in northern latitudes where sandfly vectors are either absent or present in very low densities (Ready, 2010). For example, in the last decade, several publications have reported cases of L. infantum in Germany (Harms et al., 2003; Naucke and Schmitt, 2004 and Mettler et al., 2005 and Menn, 2010). Most of these L. infantum infections might be explained by dog importation from, or travel to and back from, endemic regions, potentially followed by vertical transmission from bitch to pup or horizontal transmission by biting hounds.

Canine leishmaniosis has a high prevalence of infection in endemic areas, involving as much as 63%–80% of the population (Berrahal et al., 1996; Solano-Gallego et al., 2001b) even if it is accompanied by a lower rate of apparent clinical disease. When present, clinical signs in dogs may manifest with variable degrees of severity. Substantial research published recently on the pathogenesis of CanL and immune responses during infection has contributed considerably to the current understanding of this complex zoonosis and its epidemiology (Quinnell et al., 2001; Solano-Gallego et al., 2001a; Oliva et al., 2006). These aspects were recently reviewed by a Scientific Report submitted to EFSA (EFSA, in press).

Current studies have revealed new facts about the prevalence and spread of infection (e.g. data made available by EU-funded projects such as EDEN, EDENext, VBORNET, LeishRisk or public and veterinary surveillance programmes) and established novel concepts on its evolution and dynamics (Ferroglio et al., 2005; Werneck et al., 2006; Solano-Gallego et al., 2001a and b; Leontides et al., 2002; Oliva et al., 2006). These new insights may help in modelling the spread of the disease and to assess its impact and evaluate efforts to prevent and control the disease and its spread into human populations.
References


1.3 OBJECTIVES OF THE CALL FOR PROPOSALS

In order to carry out preparatory work in anticipation of a mandate on leishmaniosis from the European Commission, EFSA requests the successful applicant under this grant to:

1. Carry out a systematic review, investigating the efficacy of different control measures of canine leishmaniosis, including vaccines, diagnosis, treatment, vector control, culling of reservoir hosts. The review shall be followed by a meta-analysis by the successful applicant, if applicable.

2. Assess the role of animals in the spread of L. infantum within the European Union and evaluate potential mitigation measures including the following:
   a. review and evaluate models that could be used or adapted, taking into account the data availability and accessibility;
   b. collect the necessary data for the most appropriate model; and
   c. implement the model that best fit the purpose, using the collected data.

3. Evaluate the impact of canine leishmaniosis in those areas where the disease is endemic by collecting the necessary data to characterise the impact of CanL following the guidance of the manual created by PHYLUM for OIE and the EC1 and consequently enable the AHAW Panel to characterise the impact of CanL according to the above mentioned methodology.

1.4 STRUCTURE AND ESSENTIAL REQUIREMENTS OF THE PROPOSAL

The proposal should describe the methodological approaches for each of the objectives 1-3:

1. The proposal should precise the objectives and outcomes of primary interest of the systematic review (SR), the search strategy, data sources, a flow chart with the different phases of the review, the inclusion criteria, methods to avoid bias and methods to extract and summarise (quantitative) data. The guiding principles for the application of the systematic review (SR) methodology in the context of food safety can

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be found in the [EFSA guidance for systematic reviews](http://www.efsa.europa.eu/en/efsajournal/pub/4386.pdf) (EFSA, 2010). The EFSA’s Data Collection Framework (DCF) should be used to receive datasets.

2. The proposal shall precise the mechanisms that will be used to search for existing models and the different potential data sources. Each model should be explained with sufficient scientific detail to allow an appraisal of its scientific soundness. For each model an inventory for the data needs has to be provided. the advantages and disadvantages of each model have to be elaborated in view of the data availability and the minimum time frame that needs to be allocated. EFSA’s DCF should be used to receive datasets.

3. The methodology for the impact assessment shall be based on the manual created by PHYLUM by the OIE and EC. An inventory of potential data sources needs to be provided. EFSA’s DCF should be used to receive datasets.

Further, the proposal should address how collaboration between the public health and veterinary health sector will be guaranteed to facilitate a disciplinary approach.

### 1.5 MEETING AND REPORTING REQUIREMENTS

The below mentioned meetings with EFSA are foreseen:

**A first workshop** should be organised latest by 31 January 2012 to present the review of the different models, to present an inventory of possible data sources and to discuss the appropriate data model, (i.e. the types of data, controlled terminology, description of the fields and choice of mandatory data) for the data collection. During this workshop the protocol for the SR need to be presented and discussed. The successful applicant shall prepare the notes of the kick-off meeting.

**A second workshop**, involving the AHAW Panel, should be held by 31 March 2012 at the latest. After reviewing the potentials of the respective models, a decision on the most suitable spread model(s) should be made during this workshop. The workshop will also update on the state of play of the SR and the data collection for the characterisation of the impact of CanL. The successful applicant shall prepare the notes of the interim meeting.

**Final meeting**: The final meeting should be held in September 2012. The purpose is to present the results of the spread model, the data collection for the impact of CanL and the SR.

Below mentioned reports must be drafted in the English language and may be subject to publication at EFSA’s discretion.

**Interim report N.1**: After 2 months from the start date of the project and latest 10 days before the second meeting, a first written interim report must be submitted to EFSA. The written interim report must describe the progress of the project and the results already achieved. The interim report must also be regarded as an opportunity to draw attention to any technical or financial difficulties encountered in implementing the project. The report shall include:

**Objective 1:**
- A detailed protocol for the SR on control measures of CanL. The protocol for the SR should clearly indicate the objectives and outcomes of primary interest, search strategy, data sources, a flow chart with the different phases of the review, the inclusion criteria, methods of to avoid bias and methods to extract and summarise (quantitative) data.

**Objective 2:**
- A narrative review of existing spread models in general that could be used/adapted to estimate the role that dogs play in the spread of *L. infantum* in the European Union and to evaluate the efficacy of different control measures.
- An inventory of ideally needed data and available data to estimate the parameters for the different models (most common models in this area, and particularly developed to deal with this specific situation).

**Objective 3:**
- A data collection model for the data collection necessary for the characterisation of the impact of *L. infantum* in those areas where the disease is endemic, based on the manual created by PHYLUM by the OIE and EC, considering that the EFSA is DCF should used to receive datasets.

**Interim report N.2**: After 7 months the start date of the project second written interim report must describe the progress of the project and the results already achieved. The interim report must also be regarded as an opportunity to draw attention to any technical or financial difficulties encountered in implementing the project. Specifically, it shall describe:
Objective 1:
- An overview of the SR, carried out using the software Distiller SR, including the outcomes of the first steps of the SR (search strategy, relevance screening, eligibility screening and data extraction).
- The Distiller SR® and the project should be available at all stages of the review. The DCF should be used to receive datasets.
- List of retrieved papers preferably saved in reference management software such as endnote with their pdfs.

Objective 2:
- Database with collected data necessary to estimate the parameters for the chosen model as well as those most commonly used in the field. The DCF should be used to receive datasets.

Objective 3:
- State of play of database with data necessary for the characterisation of the impact of *L. infantum* in those areas where the disease is endemic, based on the manual created by PHYLUM by the OIE and EC. The DCF should be used to receive datasets.

**The draft final report:** after 8 months from the start date of the project a draft final report must be submitted to EFSA. It shall contain:

Objective 1:
- A detailed description of the SR using the PRISMA statement\(^2\) as a guideline for reporting.

Objective 2:
- Report providing the rationale for model(s) used, and details of the data sources that were used to estimate the key parameters. The report will also include the results obtained from implementing selected model(s).
- Application/interface integrating the chosen model, including also the possibility to use other competitive models in this area, to evaluate and assess the appropriateness of the model when comparing to other existing approaches. The user interface should be developed in one of the programming languages that are supported by EFSA, and a list of supported programming languages could be found in EFSA website. Models should be developed in the following packages SAS, R, Winbugs/Openbugs or @Risk. Models developed using other software packages will not be accepted. The report should also identify gaps in knowledge and recommendations for further research.

Objective 3:
- Database with data necessary for the characterisation of the impact of *L. infantum* in those areas where the disease is endemic, based on the manual created by PHYLUM by the OIE and EC. The DCF should be used to receive datasets.

Please note that all reporting, minutes, outcome of the discussions could be submitted at EFSA’s discretion to EFSA’s Panel and WG members.

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<td>Signed Grant Agreement</td>
<td>Workshop 1</td>
<td>Interim Report 1</td>
<td>Workshop 2</td>
<td>End of data collection for spread model</td>
<td>Interim Report 2</td>
<td>Draft Final report Final report Final meeting</td>
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### 1.6 AMOUNT AVAILABLE FOR FINANCIAL SUPPORT BY EFSA

The EFSA grant will equal up to 90% of the total eligible project costs (the applicant can ask for a lower EFSA grant percentage) provided that EFSA grant doesn’t exceed 200,000.00 € which is the maximum which might be received from EFSA for this project. EFSA grant will not be awarded for more than the amount requested.

The total amount of estimated eligible costs, which serves as a basis for calculation of the EFSA grant, will be verified by EFSA who might exclude some cost items as ineligible according to the Rules on eligibility of costs (see annex 1 of this Call) if these rules were not properly applied by the applicant when establishing the Estimated budget.

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\(^2\) [http://www.annals.org/content/151/4/W-65.full.pdf+html](http://www.annals.org/content/151/4/W-65.full.pdf+html)
2. PROCEDURAL RULES APPLICABLE TO THE CALL

2.1 APPLICATION FORM

The proposal must be submitted using the EFSA Standard Application Form (hereinafter referred to as “Application form”) annexed to the present Call. It may be downloaded from the EFSA website http://www.efsa.europa.eu. 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 be appreciated and strongly recommended as this would significantly facilitate and 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 the 30/09/2011.

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 (ahaw@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
AHAW
CFP/EFSA/AHAW/2011/02
Largo Natale Palli 5/a
I – 43121 Parma

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 reference number of the Call (CFP/EFSA/AHAW/2011/02);
- the title of the Call (“Data collection to characterise the impact of canine leishmaniosis and modelling of the role of animals in spreading L. infantum within the European Union.”);
- the name of the applicant;
• the indication: “Proposal - Not to be opened by EFSA reception – to be passed without opening to the AHAW unit”;
• the address for submission of proposal (see above);
• the posting date (if applicable) should be legible on the outer envelope.

Proposal must be complete and must include:
The completed Application form (including all annexes) 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.

2.5 FURTHER INFORMATION

Any questions regarding the present Call may be posed by e-mail indicating clearly the reference of the Call CFP/EFSA/AHAW/2011/02 no later than on the 09/09/2011. These questions may only be addressed to the following e-mail address ahaw@efsa.europa.eu.

Replies will be given no later than on the 20/09/2011. Questions together with the answers will be published on the EFSA website.

3. EVALUATION AND SELECTION OF PROPOSAL

Introduction:
After having verified the compliance with all the submission requirements (see 3.1), EFSA selects the admissible proposals through a procedure that involves 3 types of evaluation criteria in this order:
1. eligibility and exclusion criteria (see 3.2),
2. selection criteria (see 3.3),
3. award criteria (see 3.4).

If the submission requirements are not met, the proposal is rejected without looking at the eligibility, selection or award criteria. If the eligibility and exclusion criteria are not met, the proposal is rejected without looking at the selection or award criteria. If the selection criteria are not met the proposal is rejected without looking at the award criteria. It is therefore essential to complete the proposal in full and provide all the supporting documents requested.

An Evaluation Committee will be established in accordance with article 116 of the Financial Regulation and article 178 of its Implementing Rules in order to evaluate the submitted proposals. EFSA intends to finalise the evaluation of proposals within 6 months since the final deadline for submission of proposals. In compliance with article 116 (3) of the Financial Regulation, the applicant will be informed in writing of the decision on their 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.

General principles:
In compliance with the Financial Regulation and its Implementing Rules, the proposals must comply with the following principles:
• Co-financing rule: external co-financing from a source other than EU budget is required as indicated in part 1.6;
• Non-profit rule: the grant may not have the purpose or effect of producing a profit for the applicant or partner;
• Non-retroactivity rule: the costs eligible for financing must be incurred after the entry into force of the Grant agreement;
• Non-cumulative rule: only a single EU grant may be awarded for a specific project carried out by a given beneficiary in one financial year.

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 on 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 AND EXCLUSION CRITERIA

#### 3.2.1 ELIGIBILITY OF THE APPLICANT AND ITS PARTNERS

Applicant must apply in a consortium with partners established for the purpose of the project implementation and it is up to him to identify the partners.


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<th>Documents to be provided on support of eligibility of the applicant and the partners</th>
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<td><strong>LEGAL ENTITY FORM</strong> to be completed and signed separately by the applicant and by each of its partners. This legal entity form should be returned together with a copy of the public legal act establishing the entity in question or failing that, any other official document attesting to the establishment of the entity, clearly indicating it pursues public interest objectives. EFSA provides a template to be used – Annex 1 of the Application form.</td>
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Both applicant and the partners must participate in the project both financially and technically/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 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 his 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 in point 3.2.1 above, the partners must satisfy the same eligibility criteria as the applicant organisation.

The Grant agreement will be signed between EFSA, the applicant and the partners. In the case of selection of its proposal, the applicant will become the Coordinator-Beneficiary (hereinafter referred to as “the Coordinator”) and its 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 a **partnership statement** defining the technical/intellectual and financial involvement of each of them. Each organisation (applicant and all partners) must sign this partnership statement.
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.

### Documents to be provided in support of the eligibility of the consortium of the applicant and its partners

- **PARTNERSHIP STATEMENT** defining the technical/intellectual and financial involvement of each member of the consortium (applicant and partners) signed individually by each member of consortium (see Annex 7 of the Application form).

### Subcontracting:

The applicant and its partners are expected to have the resources necessary to carry out the work required by the project. In certain circumstances though, it could be more economic or efficient to subcontract some aspects of the work. In any case in which the applicant and its partners are willing to subcontract certain aspects of the work under the conditions hereinafter, prior written authorisation from EFSA shall be requested. In any case, where implementation of the project requires the award of subcontracts, they shall be awarded by applying public procurement procedure to the tender offering **best value for money**. The beneficiary has to be able to demonstrate that he has chosen the sub-contractor/tenderer offering the best value for money, that is to say, to the one offering the best price/quality ratio, in compliance with the principles of transparency and equal treatment for potential contractors, care being taken to avoid any conflict of interests.

Sub-contracts of this type may be awarded only subject to 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 estimated costs must be set out in the Estimated budget and approved by EFSA before the signature of the Grant agreement;
- 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;
- The Coordinator and the Co-beneficiaries retain sole responsibility for implementing the project and complying with the provision of the Grant agreement;
- The Coordinator and the 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 partners. Subcontractors are organisations formally contracted by the applicant or its partners to carry out specific tasks. Cost of subcontracting is borne by the applicant and/or the partners and the subcontractor doesn’t contribute financially to the project.

Please note that sub-contracts of external expertise provided by scientific experts not employed by the applicant or his partners are not allowed. External expertise can be provided only under the following conditions:

- external experts should be recruited, at least 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 receives a monthly salary for his work).

### 3.2.2 EXCLUSION CRITERIA

Article 114(2) of the Financial Regulation states that “Grants may not be awarded to applicants who are, at the time of a grant award procedure, in one of the situations referred to in Articles 93 and 94”. Accordingly, applicant and partners must certify that they are not in one of the following exclusion situations:

- they are in a state of or subject to proceedings for bankruptcy or liquidation, are having their affairs administered by the courts, have entered into an arrangement with creditors, have suspended business activities or are in any analogous situation arising from a similar procedure provided for in national legislation or regulations;
- they have been convicted of an offence concerning their professional conduct by a judgment which has the force of res judicata;
- they have been guilty of serious professional misconduct proven by any means which the contracting EFSA can justify;
• they have not fulfilled their obligations relating to the payment of social security contributions or taxes in accordance with the statutory provisions of the country in which they are established, the country of the awarding EFSA or the country where the contract is to be performed;
• they have been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the financial interests of the Union;
• following another procurement procedure or grant award procedure financed by the Union budget, they have been declared to be in serious breach of contract for failure to comply with their contractual obligations.

In addition, grants may not be awarded to applicants who, at the time of the selection procedure:
• are subject to a conflict of interest;
• have been guilty of misrepresentation in supplying the information required by EFSA as a condition for participation in the award procedure or in failing to supply this information.

Please note that, according to article 175 of the Implementing Rules, administrative and financial penalties may be imposed in the event of false declarations.

Documents to be provided on support of eligibility of the applicant and the partners
- THE DECLARATION OF HONOUR to be completed and signed separately by the applicant and by each of its partners. EFSA provides a template to be used – Annex 2 of the Application form.

3.3 SELECTION CRITERIA

Only proposals which have satisfied the requirements of the eligibility criteria will be evaluated against the selection criteria. The selection criteria are used to evaluate the applicant's (and its partners') financial and operational capacity.

3.3.1 FINANCIAL CAPACITY OF APPLICANTS AND PARTNERS

The applicant and its 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;

The applicant must prove that it has available, throughout the duration of the project, own financial resources and he can count on the financial contributions from his partners (mandatory in case of consortium) and/or from other public sector bodies.

Documents to be provided by the applicant and partners:
- LETTER OF COMMITMENT signed by the public sector body (see point 4.1.1.2, third point); the letter must express a confirmation of commitment of the public sector body to financially contribute to the project (see Annex 8 of the Application form)

3.3.2 OPERATIONAL CAPACITY OF APPLICANTS AND PARTNERS

The applicant and its partners must have the management capacity, professional competencies and qualifications required to successfully complete the proposed project. To prove their operational capacity, the applicant and the partners must provide the following information:

Documents to be provided by the applicant and partners:
- THE LATEST AVAILABLE ANNUAL ACTIVITY REPORT in order to prove that the applicant (partner) is active in the specific field and is aware of the type of activities with which this Call is involved (see Annex 3 of the Application form)
- THE CURRICULUM VITAE of the project manager/s and scientific staff to be involved in the project, (see Annex 6 of the Application form).
- DETAILED DESCRIPTION OF AT LEAST TWO SIMILAR ACTIONS/PROJECTS carried out during the last 5 years, indicating the subject, partners and budget amount used (see Annex 4 of the Application form).
- ANY REFERENCES concerning participation in grant agreements or contracts concluded for EU funded activities or with other international organisations and Member States (see Annex 5 of the Application form).
3.4 AWARD CRITERIA

Only proposals which have satisfied the requirements of the eligibility and selection criteria will be evaluated against the award criteria. The award criteria are used to assess the quality of the proposals submitted and enable the identification of proposal for which EFSA can be confident that it will comply with EFSA objectives and priorities. There are the following 3 main award criteria in this Call:

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>WEIGHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. QUALITY OF THE PROPOSAL</td>
<td>50 points</td>
</tr>
<tr>
<td>1. The extent to which the proposal achieves the objectives of the Call, guarantees an excellent level of science output and demonstrates its capacity to provide significant and sustainable impact and added value to the existing knowledge</td>
<td>30 points</td>
</tr>
<tr>
<td>2. The extent to which the project is described in detail, as well as the proposed methodology is well described and of high quality, and the feasibility of the timetable</td>
<td>20 points</td>
</tr>
<tr>
<td>2. QUALITY OF THE MANAGEMENT (INCLUDING CONSORTIUM)</td>
<td>40 points</td>
</tr>
<tr>
<td>1. The extent to which the project management and the internal project communication is described and is demonstrably of high quality</td>
<td>30 points</td>
</tr>
<tr>
<td>2. The extent to which the implementation of the project by the experts involved and their real participation have been clearly described and appear to be suitable to the tasks/objectives targeted</td>
<td>10 points</td>
</tr>
<tr>
<td>3. COST EFFECTIVENESS</td>
<td>10 points</td>
</tr>
<tr>
<td>1. The extent to which the Estimated budget is cost-effective (comparison between the costs and the anticipated achievement of the objectives and results obtained)</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>100</td>
</tr>
</tbody>
</table>

In order to be considered for funding, the proposal must:
- score a minimum of 80 points in total out of possible 100 points and
- for each sub-criterion (1.1, 1.2, 2.1, 2.2, 3.1), score at least half of the points attributed to that criterion.

Proposals which have satisfied these thresholds will be ranked. Depending on budget availability, the highest ranked proposal will be awarded a grant from EFSA.

4. GRANT AGREEMENT AND PAYMENTS

According to article 116 (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 (EFSA signature). Costs incurred prior to the date of the signature of the Grant agreement will not be considered as eligible.

4.1 CALCULATING THE EFSA GRANT

4.1.1 ON THE BASIS OF THE ESTIMATED BUDGET - BEFORE IMPLEMENTATION OF THE PROJECT

Following the financial analysis of the Estimated budget (see point 4.1.1.1.), the evaluation committee will decide the exact amount of EFSA grant which will be expressed: 1. as an amount in Euros and 2. as a percentage of the total eligible project cost (EFSA participation percentage).

4.1.1.1 ESTIMATED BUDGET AND ITS COST SIDE

All proposals must be supported by Estimated budget. It must be submitted as Annex 9 of the Application form showing all the costs and income which the applicant considers necessary to carry out the project. 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 from countries where the Euros is not national currency are asked to use the official ECB exchange rate published on: 

The Estimated budget shall have the following headings on the side of costs:

Eligible direct costs:
1. Costs of permanent or temporary staff;
2. Travel and subsistence costs;
3. Equipment;
4. Consumables and supplies;
5. Subcontracting;
6. Miscellaneous costs directly linked to the project. These are costs arising directly from requirements imposed by the Grant agreement;

!!!ATTENTION!!!

The figures of staff costs (item A1) shall be documented (it is sufficient to submit them in electronic format, such as PDF, together with proposal, as Annex 10 of the Application Form) by the 12 last available salary slips of the staff members proposed to work within the project. For the part of the salary cost not mentioned on the salary slips (as is sometimes the case with employer's contribution to the national social security), other accounting documents should be provided (e.g. extracts from the ledger or IT accounting system showing the individual accounting entries for the concerned staff members). Centralised or global overviews not enabling EFSA to isolate the concerned costs are unacceptable.

If the concerned staff member was not employed during the full last 12 months, all available salary slips should be provided and the fictional annual salary should be calculated on the basis of these documents.

If the provided documents are not drawn in English, it would be much appreciated to provide an informal translation or explain the terms on these documents as it would significantly accelerate the evaluation procedure of the calls.

Unilateral declarations regarding staff costs by the applicant himself, extracts from legal acts or general internal guiding documents are insufficient.

Starting from the provided documents, a full reconciliation should be possible with the yearly salary mentioned by the applicant in the estimated budget submitted with the proposal. If the in the estimated budget mentioned yearly salary differs significantly from the one calculated on basis of the submitted documents, this should be explained and documented as well and it will be subject to a detail analysis by EFSA Finance Unit.

If the staff costs contain salary estimations for staff members to be recruited (for the purpose of the project) an explanation has to be given how the yearly salary cost was calculated referring to grade, seniority and the normal basic salaries applicable to that category of personnel.

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.

4.1.1.2. INCOME SIDE OF ESTIMATED BUDGET

1. Applicant’s and partners’ direct financial contribution to the project - MANDATORY;
2. Grant requested from the EFSA;
3. OPTIONAL - Possible external financial contributions to the project, but only from the public sector bodies; these other contributions are possible contributions from any other public sector bodies other than EFSA, applicant and partners. Each such public sector body must sign a letter of commitment to the project. Financial contribution to the project budget from a private sector body is NOT allowed.
Interest generated on EFSA pre-financing:
The interest generated on EFSA pre-financing cannot be treated as an income for the project, therefore it may not be entered on the income side of the Estimated budget. The EFSA will recover this interest in accordance with terms of the Grant agreement.

4.1.1.3 FINANCIAL ANALYSIS OF ESTIMATED BUDGET

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

a) assess whether it is consistent with the proposed project and decide whether the Estimated budget is sufficiently detailed to consider funding of the project;
b) assess whether the Estimated budget matches the specific objectives/expected results of the project;
c) eliminate any item of costs which cannot be accepted according to the Rules on eligibility of costs;
d) 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.

!!!ATTENTION!!!

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 covered by the call. An over- or underestimation of costs will have a negative impact on the evaluation score under the award criteria named “Cost effectiveness”.

This analysis is made in accordance with the Rules on eligibility of costs (see annex 1 of this Call). It is EFSA who takes the final decision as regards the nature and amount of the costs to be considered eligible. Either at this stage – when analysing proposals in order to agree the Approved Estimated Budget, or later – when examining financial statements of costs actually incurred in order to determine the final amount of the grant (see point 4.1.2).

4.1.1.4 APPROVED BUDGET

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, EFSA suggests some modifications to the Estimated budget, it will present those modifications to the applicant. After the proposed modifications are accepted by the applicant and EFSA, the Estimated budget as modified will become the Approved Estimated Budget for the project. For further details regarding eligibility of costs please refer to the Rules on the eligibility of costs.

4.1.2 ON THE BASIS OF THE FINAL ACCOUNTS – AFTER IMPLEMENTATION OF THE PROJECT

The EFSA grant will be recalculated after completion of the project, presentation of the final report and the related supporting documents. This recalculation will consist in applying the EFSA participation percentage (agreed in the Grant agreement) to the total actual eligible costs (EFSA grant as expressed in the Grant agreement was calculated on the basis of total estimated eligible costs). Please note that EFSA has the right to audit all costs and income for the project.

1. If, at the end of the project, the total actual eligible costs are lower than was estimated in the Estimated budget, the EFSA grant will equal the amount obtained by applying the EFSA participation percentage to the total actual eligible costs as approved by EFSA.
2. If the actual eligible costs are higher than was estimated in the Estimated budget, EFSA grant cannot under any circumstances exceed the amount stated in Euros in the Grant agreement.

The EFSA grant shall be limited to the amount necessary to balance the project income and costs and it may not in any circumstances produce a profit for the Coordinator and the Co-beneficiaries. Profit shall mean any surplus of total actual income attributable to the project over the total actual costs of the project. The actual income to be taken into account shall be that which has been established (irrespective whether already
received or not) on the date on which the request for payment of the balance is drawn up to which shall be added the amount of EFSA grant determined as mentioned above. Any surplus determined in this way shall result in a corresponding reduction in the amount of EFSA grant. As regards the actual costs, it is important that the costs are incurred during the lifetime of the project, which doesn’t necessarily mean that the cost has in fact has to be paid in that lifetime.

4.2. SUBMISSION OF REPORTS AND PAYMENT ARRANGEMENTS

Within 45 days from the date of the signature of the Grant agreement by EFSA, a pre-financing payment equaling to 40% of EFSA’s grant will be made to the bank account indicated in the Grant agreement.

The payment of the balance will be made according to the Grant agreement and will be linked to the final report (see 1.5).

4.3 ACCOUNTING RECORDS OF THE PROJECT AND AUDIT

Accounting records:
The Coordinator and the Co-beneficiaries must keep accurate and regular accounting records as well as separate and transparent accounts of the implementation of the project. The Coordinator and the Co-beneficiaries 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 Co-beneficiaries 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. The Coordinator and the Co-beneficiaries 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 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) No 45/2001. Unless indicated differently, any personal data contained in your application are required to evaluate your application in accordance with the Call for proposals and will be processed solely for that purpose. Individuals acting or presented on behalf of applicants, are entitled to obtain access to their personal data on request and to rectify any such data that is inaccurate or incomplete until the deadline for submission of proposals indicated in part 2.3.

Recipients of personal data at EFSA are all staff members involved by virtue of EFSA’s Financial Regulation in the grants preparation process, including: the members of the opening and evaluation committees, the staff of the unit/directorate acting as authorising officer for the related grant agreement, the Finance and Legal Units as well as the Accounting Officer regarding the financial and legal verification, the grant agreement preparation and financial and grant management.

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4 Applicants are also informed that for the purposes of safeguarding the financial interest of the EU, personal data may be transferred to internal audit services, to the Court of Auditors, to the Financial Irregularities Panel and/or to the European Anti-Fraud Office
If you have any queries concerning the processing of personal data in the context of this grant procedure, you may address them to the unit/directorate acting as authorising officer for the grant and signing the Call for proposals. Such queries may be followed up further with the Head of EFSA Finance Unit, identified as controller for personal data processing in the context of grant management at EFSA. You have the right of recourse at any time to the European Data Protection Supervisor for matters relating to the processing of personal data.

5.2 PUBLIC ACCESS TO DOCUMENTS


Name of the
Authorising Officer: Dr Hubert Deluyker

Signature of the
Authorising officer: [signed]

Date: 28/07/2011

(OLAF). Data of economic operators which are in one of the exclusion situations referred to in Articles 93, 94, 96(1) and 96(2)(a) of the general Financial Regulation may be included in a central database and communicated to the designated persons of the European Commission, other institutions, agencies, authorities and bodies mentioned in Article 95(1) and (2) of the general Financial Regulation. This refers as well to the persons with powers of representation, decision making or control over the said economic operators. Any party entered into the database has the right to be informed of the data concerning it upon request to EFSA. EFSA will obtain the requested information for the accounting officer of the European Commission.
LIST OF ANNEXES

ANNEX 1: RULES ON ELIGIBILITY OF COSTS