

CALL FOR PROPOSALS

and guide for applicants

Call reference: GP/EFSA/BIOCONTAM/2015/02

Call title: In vivo toxicity and genotoxicity of beauvericin and enniatins

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

The deadline for submission of proposal:
18/09/2015

FURTHER INFORMATION:

If, after having read this Call for proposals and guide for applicants, you have any question you may address it to EFSAprocurement@efsa.europa.eu no later than by **11/09/2015**, indicating the Call reference. Replies will be provided no later than by **14/09/2015** at EFSA webpage where this Call is published and which the applicants are requested to consult regularly.

Provide EFSA with feedback:

If you considered applying to this call for proposals but finally decided not to do so, your feedback on reasoning for such a decision would be very much appreciated. Please address it to: EFSAprocurement@efsa.europa.eu. EFSA will process any feedback in order to improve the quality of its future grant calls.

TABLE OF CONTENT:

1.	GRANT OPPORTUNITY AND CONDITIONS.....	3
1.1	LEGAL FRAMEWORK	3
1.2	BACKGROUND AND MAIN OBJECTIVE OF THE CALL	3
1.3	SPECIFIC OBJECTIVES OF THE CALL.....	4
1.4	ELIGIBLE ORGANISATIONS	5
1.5.	ROLES AND RESPONSIBILITIES	6
1.6.	POSSIBILITY OF IMPLEMENTING CONTRACTS AND SUBCONTRACTING	7
1.7	MEETINGS AND REPORTING	8
1.8	PAYMENTS.....	9
1.9	GRANT PRINCIPLES.....	10
1.10	EFSA GRANT CONTRIBUTION	10
1.11	ESTIMATED BUDGET AND ELIGIBLE COSTS	11
1.12	APPROVED ESTIMATED BUDGET	11
1.13	INITIAL EFSA GRANT	12
1.14	FINAL EFSA GRANT	12
1.15	PUBLICITY.....	12
1.16	PROTECTION OF PERSONAL DATA IN RELATION TO GRANT PROCEDURES	12
1.17	PUBLIC ACCESS TO DOCUMENTS	13
1.18	FURTHER INFORMATION	13
2.	SELECTING PROPOSALS	13
2.1	VERIFICATION OF SUBMISSION REQUIREMENTS.....	14
2.2	ELIGIBILITY CRITERIA	14
2.3	EXCLUSION CRITERIA	14
2.4	SELECTION CRITERIA.....	15
2.5	AWARD CRITERIA	16
2.6	PROCESS FOLLOWING THE ASSESSMENT AGAINST AWARD CRITERIA.....	17
3.	SUBMITTING PROPOSALS	17
3.1	APPLICATION FORM.....	17
3.2	LANGUAGE OF THE PROPOSAL AND THE SUPPORTING DOCUMENTS	18
3.3	DEADLINE FOR SUBMISSION OF PROPOSAL.....	18
3.4	SUBMISSION MODALITIES	18
3.5	EXPECTED DURATION OF PROCEDURE	18

Annex 1: Rules on eligibility of costs

Annex 2: Draft grant agreement

Annex 3: Estimated budget template

Annex 4: Application form

Annex 5: Legal entity form ([download template here](#))

Annex 6: Financial identification form ([download template here](#))

Annex 7: Declaration on honour for exclusion criteria

Annex 8: Declaration on honour for selection criteria

Annex 9: Simplified financial statement

1. GRANT OPPORTUNITY AND CONDITIONS¹

1.1 LEGAL FRAMEWORK

Article 36 of the Regulation (EC) 178/2002² of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety foresees the possibility to financially support networking of organisations operating in the fields within the EFSA's mission.

In particular, Article 36 (1) stipulates that the Authority shall promote the European networking of organisations operating in the fields within the Authority's mission. The aim of such networking is, in particular, to facilitate a scientific cooperation framework, the development and implementation of joint projects³, the exchange of expertise and best practices in the fields within the Authority's mission.

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

Article 5 of the Commission Regulation (EC) 2230/2004⁴ of 23 December 2004 laying down detailed rules for the implementation of the European Parliament and Council Regulation (EC) 178/2002 with regard to the network of organisations operating in the fields within the EFSA's mission specifies that the financial support to the networking organisations shall take the form of subsidies (grants) awarded in accordance with the EFSA's financial regulation and implementing rules.

The present Call for proposal and guide for applicants (hereinafter referred to as "the Call") is procedurally governed by the Regulation 966/2012⁵ of the European Parliament and of the Council of 25 October 2012 (EU Financial Regulation) and Commission Delegated Regulation C(2012)7507⁶ on the rules of application of Regulation (EU) 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.

The present Call for proposal is based on EFSA's draft 2015 Work Programme for grants and procurement in science as presented in Annex F of the Draft Preliminary Annual Management Plan, Budget and Establishment Plan 2015, available on the EFSA's website⁷.

1.2 BACKGROUND AND MAIN OBJECTIVE OF THE CALL

BACKGROUND

1 The applicant is reminded that this Call and guide for applicants contains a selection of the most important conditions for the grant implementation. For the full set of conditions the applicant is invited to consult the draft grant agreement attached to this Call.

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

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

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

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

6 http://www.europarl.europa.eu/meetdocs/2009_2014/documents/cont/dv/c_2012_7507/_c_2012_7507_en.pdf

7 <http://www.efsa.europa.eu/en/mb140320/docs/mb140320-ax6.pdf>

The structurally related mycotoxins beauvericin and enniatins are produced by *Fusarium* fungi that invade and grow on crops, and may produce these toxins under moist and cool conditions. They are predominantly found in cereal grains and their products.

EFSA's Panel on contaminants in the food chain (CONTAM) has recently assessed the risk for public and animal health related to the presence of beauvericin and enniatins in food and feed⁸. Only limited information on the toxicity of beauvericin and enniatins were retrieved by EFSA's Panel on contaminants in the food chain (CONTAM Panel). Due to the overall lack of toxicity data, the CONTAM Panel could not establish an acute reference dose or a tolerable daily intake, and therefore could not draw firm conclusions on the risks to human health related to the dietary exposure to these mycotoxins.

Therefore, this call is for proposals to deliver a subchronic oral toxicity study in rodents. EFSA asks that beauvericin and one selected enniatin should be studied in an appropriate repeat dose regime; the most relevant enniatin should be chosen for study in agreement with EFSA (on the basis of published information). The study should assess the standard toxicological endpoints, with particular focus to those identified by the CONTAM Panel (nervous, immune and endocrine systems), and integrate screening of the reproductive and developmental functions. In addition, EFSA request that tailored *in vivo* genotoxicity assays shall be included within the subchronic study, or via the inclusion of satellite groups to the main study.

The study outcomes should result in supporting information to assist the CONTAM panel in a future assessment on the risks to human and animal health related to the presence of beauvericin and enniatins in food and feed.

1.3 SPECIFIC OBJECTIVES OF THE CALL

This call for proposals aims at obtaining data from a subchronic repeat dose oral toxicity study in rodents in accordance with internationally agreed methods for toxicological testing of chemicals; this study should be tailored to include appropriate *in vivo* genotoxicity tests. The beneficiary shall perform the following tasks, in order to achieve the objectives:

1. To elaborate a protocol for a subchronic oral toxicity study of beauvericin and one selected enniatin in rodents. This study should be designed to deliver information on the following;
 - a. Standard toxicological endpoints;
 - b. More comprehensive information upon nervous, immune and endocrine systems;
 - c. Screening of reproductive and developmental functions (to be conducted in accordance with, for example OECD GL422);
 - d. *in vivo* genotoxicity (by integration of subgroups within the subchronic study/inclusion of satellite groups to the main study)
2. To collate and analyse the results in an appropriate format;
3. To prepare an Interim and Final External Scientific Report and a database providing the detailed results from the studies. The Interim and Final External Scientific Reports as well as the databases will be prepared in line with the time schedule reported in 1.7 of the present call for proposal.

⁸ The Opinion of the CONTAM Panel can be found on the EFSA website available at : <http://www.efsa.europa.eu/en/efsajournal/pub/3802.htm>

The Interim Scientific Report shall be written in English and follow the template structure provided by EFSA and EFSA citation Standards⁹. The Interim Scientific Report shall contain the following information from the experimental study:

- Rationale behind the study design;
- Rationale for and justification of the choice of enniatin to be studied;
- Justification of the choice of species and doses of beauvericin and the selected enniatin used;
- Detailed information of the methods;
- Detailed description of the statistical analysis of the results and a discussion of their validity;
- Interpretation of the study outcomes;
- An evaluation of the reliability of the results from the experimental study and the related uncertainties;

A draft database of the results will be generated and delivered to EFSA written in English.

4. To prepare a Final External Scientific Report and a database providing the results of the study. The database as well as the Final External Scientific Reports will be prepared in line with the time schedule reported in 1.4 of the present call for proposals.

The Final External Scientific report shall be written in English and follow the template structure provided by EFSA and EFSA citation standards¹⁰. The Final External Scientific Report shall contain the following information:

- justification of the choice of animals, enniatin studied and doses;
- validation of the tests;
- description of the statistical analysis;
- results of the studies;
- a critical evaluation of the reliability of the submitted data and the related uncertainties

1.4 ELIGIBLE ORGANISATIONS

In order to achieve the main objective of the call, the proposal can be submitted by **one eligible organisation or by a consortium of eligible organisations**. In case of a consortium, one of the partners must be identified in the proposal as the consortium leader. The applicant is responsible for identifying consortium partners.

To be eligible, the applicant and in case of a consortium the partner/s must be on the list of competent organisations designated by the Member States in accordance with Article 36 of Regulation (EC) 178/2002 and Commission Regulation (EC) 2230/2004. This list is

⁹ To be provided by EFSA after the signature of the grant.

¹⁰ To be provided by EFSA after the signature of the contract.

regularly updated by EFSA Management Board. You may consult the list on EFSA's website at <http://www.efsa.europa.eu/en/networks/art36.htm>.

1.5. ROLES AND RESPONSIBILITIES

A) If the proposal is submitted by a consortium:

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

- **The Applicant** submits the project proposal/grant application to EFSA on behalf of the consortium. The applicant is the leading entity of the consortium. There can be only one applicant in project proposal/grant application.
- **The Partner** is the other entity in the consortium. There can be a minimum of one partner or preferably more partners.

Once the grant is awarded the grant agreement is signed between EFSA, the applicant and all partners. However the partners do not sign themselves the grant agreement. They give to the applicant, if they agree so, a mandate (template will be provided by EFSA), where they authorise the applicant to sign the grant agreement, and any possible amendments to it, also on their behalf. This facilitates the signature process where only two signatures need to be collected, one from EFSA and one from the applicant. As soon as the grant agreement is signed the applicant becomes **the Coordinator** and its partner/s become **the Co-Beneficiary/ies**. The coordinator and co-beneficiary/ies are together referred to as **the Beneficiaries**. The beneficiaries are jointly and severally liable for the technical implementation of the project as described in the proposal which will become annex 1 of the grant agreement. If a beneficiary fails to implement its part of the project, the other beneficiaries become responsible for implementing its part.

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

- Take part in implementing the project;
- Monitors that the action is implemented properly;
- Act as the intermediary for any communication between the consortium and EFSA;
- Receive and answers all claims EFSA might have in relation to the implementation of the project;
- Request and review any documents or information required by EFSA and verify their completeness and correctness before passing them on to EFSA;
- Inform EFSA and the partner/s of any event that is likely to substantially affect the implementation of the project;
- Submit the deliverables and reports to EFSA;
- Request and receive payments from EFSA and distribute the funds to partner/s without unjustified delays;

The coordinator may not delegate the above-mentioned tasks to the Co-Beneficiary/ies or subcontract them to any third party.

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

- Take part in implementing the project;
- Forward to the coordinator the data needed to draw up the reports, financial statements and other documents required under the grant agreement;
- Inform the coordinator of any event or circumstances likely to substantially affect or delay the implementation of the project.

B) If the proposal is submitted by a sole applicant:

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

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

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

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

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

1.6. POSSIBILITY OF IMPLEMENTING CONTRACTS AND SUBCONTRACTING

Implementation contracts:

Where the implementation of the project requires the award of procurement contracts (implementation contracts), e.g. purchase of an equipment, the beneficiary/ies must award the contract to the entity offering the 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 applicable public procurement directive shall abide by the applicable national public procurement rules.

Sub-contracting:

It is a subgroup of the implementation contracts, hence must satisfy the above conditions. Sub-contractors are not consortium partners. They are not part of the grant agreement. They don't have a contractual relationship with EFSA. Subcontractors are entities contracted by the applicant and/or its partner/s to carry out some specific tasks. Subcontracting is allowed under these conditions:

- Subcontracting only covers the implementation of a limited part of the action.
- Recourse to subcontracting is justified having regard to the nature of the project and what is necessary for its implementation;
- The tasks intended to be subcontracted and the corresponding estimated costs must be set out in the estimated budget (Annex 3) and approved by EFSA before the signature of the grant agreement;
- Any recourse to subcontracting while the project is in progress, if not envisaged from the outset in the proposal, is subject to prior authorisation in writing by EFSA, and shall be formalised via an amendment of the grant agreement.
- The conditions applicable to the beneficiaries under Article II.7 of the grant agreement are also applicable to the subcontractor.
- Core tasks cannot be subcontracted. Only ancillary and assistance tasks can be subcontracted.

1.7 MEETINGS AND REPORTING

Below mentioned meetings with EFSA are foreseen:

- 1. Kick off meeting (physical meeting, held at EFSA premises):** The kick-off meeting is regarded as the start of the project and takes place no later than **one month** after the signature of the grant agreement. At this meeting, details of the project will be discussed and the objectives, the final report structure and timeframe will be clarified. In particular, the beneficiary will explain their proposal. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.

The presence at 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 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 tele-meeting N.1 will be held one week 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 or financial**) encountered during the project. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary.
- 3. Interim tele-meeting N.2 will be held one week 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.
- 4. Final meeting (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 final report as well as any problems or difficulties (technical or financial) encountered during the project.**

Below mentioned reports must be drafted in United Kingdom Standard English language and **may be subject to** publication at EFSA's discretion.

Interim report N.1: Six months after the start date of the project (the kick off meeting) and one week before interim meeting N.1, a written interim report N.1 must be submitted to EFSA. The written interim report 1 must describe the progress of the project and all available interim results. The draft report shall be submitted in electronic format (Word file).

- 1. Interim report N.2: Twelve months after the start of the project (the kick off meeting) and one week before interim meeting N.2, a written report** must be submitted to EFSA. The written interim report 2 must describe the progress of the project and the analytical results already achieved. The draft report shall be submitted in electronic format (Word file).
- 2. Draft Final report and draft database: 17 months after the start of the project (the kick off meeting) and one week before the final meeting, a written draft final report must be submitted to EFSA.**
- 3. The final report and final database: 18 months after the start of the project (the kick off meeting), the final report shall be submitted to**

EFSA. The final report shall contain all the parts specified above in '1.3. Objectives of the call for proposals' and the modifications agreed for the interim reports N.1 and N. 2 and the draft final report during the previous interim meetings and final meeting. The scientific report shall follow the template structure provided by EFSA and EFSA citation standards¹⁰. The final report shall be submitted in electronic format (Word file). The final database shall be submitted not later than 18 months from the beginning of the start of the project. The final report and results database shall contain all the modifications agreed in the final meeting after submission of the draft report.

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

	Month 0	Month 1- project starts	Months 2-5	Month 6	Months 7-11	Month 12	Months 13-16	Month 17	Month 18 - project ends	Month 19-21
Deliverables		Selection of enniatin to be studied		Interim report N.1 ¹¹		Interim report N.2 ¹²		Draft final report+ draft database ¹³	Final Report + Final Database	
Meetings		Kick-off meeting		Interim tele meeting N.1		Interim tele meeting N.2		Final Meeting		
Payments	Pre-financing									Final payment

1.8 PAYMENTS

The following payment scheme will be applied to the signed grant agreement:

- **pre-financing payment**, upon grant agreement entry into force, without need for a request for payment, between 10% and 40% of the maximum grant amount set out in the grant agreement; the aim of the pre-financing is to provide the beneficiaries with a float; it remains the property of the EU until the payment of the balance. Please note the exact amount/% of pre-financing will be determined at the time of awarding the grant;
- **final payment (payment of the balance)**, after the final EFSA grant amount was determined in line with the grant agreement (Article II.25); the amount due as the balance payment is calculated by EFSA by deducting from the final EFSA grant amount the total amount of pre-financing already made; if the total amount of earlier payment is greater than the final EFSA grant amount, the payment of the balance takes the form of a recovery; if the total amount of earlier payment is lower than the final EFSA grant amount, EFSA will pay the balance; payment is subject to the approval of the final report by EFSA.

¹¹ to be submitted 1 week before interim meeting 1

¹² to be submitted 1 week before interim meeting 2

¹³ to be submitted one week before Final meeting

1.9 GRANT PRINCIPLES

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

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

1.10 EFSA GRANT CONTRIBUTION

The form of grant awarded under this Call is grant based on reimbursement of a specified proportion of the total eligible project costs actually incurred (EU Financial Regulation, Article 123 (1e)).

The project to be supported under this Call is co-financed by EFSA at maximum **90%** of the total eligible project costs. In addition, the maximum possible amount of EFSA grant for the project is **512.000 €**. In other words, the grant has double ceiling: the maximum amount and the reimbursement rate applied on the total eligible project cost.

EFSA intends to fund one proposal following this Call. However, EFSA reserves the right not to award all the funds available at any cost, e.g. if the quality of submitted proposals will not be satisfactory.

Please note that EFSA has also the right not to award any grant and to cancel the whole grant procedure at any time before the signature of the grant agreement without any compensation to be paid to the applicant.

The total amount of estimated eligible costs, as presented by the applicant in the estimated budget (annex 3) (see also part 1.11), and which serves as a basis for calculation of the initial EFSA grant, will be verified by EFSA during the evaluation of

proposals. EFSA reserves the right to implement the necessary adaptations to the estimated eligible costs in the case **the Rules on eligibility of costs** (Annex 1) were not correctly applied by the applicant.

If the amount granted is lower than the funding sought by the applicant, it is up to the latter to find supplementary financing or to cut down on the total cost of the project without diluting either the objectives or the content.

1.11 ESTIMATED BUDGET AND ELIGIBLE COSTS

The proposal must be accompanied by the estimated budget (Annex 3) which must be established in line with **the Rules on eligibility of costs** (Annex 1). The estimated budget must show 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 costs;
- balanced, i.e. total income and total project costs must equal;
- consistent with the work plan;
- expressed in Euro.

Estimated budget – cost side: for more details please refer to the Rules on eligibility of costs - Annex 1 of this Call:

- Eligible direct costs:
 1. Costs of personnel;
 2. Travel costs and subsistence allowances;
 3. Depreciation costs of equipment or other assets;
 4. Consumables and supplies;
 5. Subcontracting;
 6. Eligible VAT;
 7. Miscellaneous costs are costs arising directly from the requirements imposed by the grant agreement.The above 7 categories represent an exhaustive list of possible eligible direct costs.
- Eligible indirect costs incurred in carrying out the project are eligible for a flat-rate funding capped at not more than 10% of the total eligible direct costs. Should a member of consortium already receive an operational grant from the EU budget its indirect costs are not eligible under the present call.

Estimated budget – income side:

- Mandatory incomes:
 1. Grant requested from EFSA;
 2. Applicant's financial contribution;
 3. Partners financial contribution;
- Optional incomes:
 4. Financial contributions from other public bodies;
 5. Income generated by the project.

1.12 APPROVED ESTIMATED BUDGET

The estimated budget submitted with the proposal is analysed by EFSA, as part of evaluation process, in order to:

- assess whether it is realistic;
- assess whether it is consistent with the proposed project;

- assess whether the estimated budget is sufficiently detailed;
- assess whether the cost items are reasonably justified;
- eliminate cost items which cannot be accepted according to the Rules on eligibility of costs (Annex 1).

An overestimation or underestimation of costs, or missing justification of the costs, missing details, or detected inconsistency with the technical description of the project will all have a negative impact on the evaluation score under the award criterion 6.

If EFSA regards the estimated budget as realistic, consistent with the technical description of project, sufficiently detailed, well justified and established in accordance with the Rules on eligibility of costs (Annex 1) and hence 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, the analysis of the estimated budget could result in EFSA suggesting reductions, e.g. need to correct the costs in line with the Rules on eligibility of costs. 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.

1.13 INITIAL EFSA GRANT

Having agreed the approved estimated budget, and provided the proposal is selected for the grant award, EFSA will establish the amount of **the initial EFSA grant**, having regard to the limits set out in part 1.10 of this call. The initial EFSA grant will be expressed as an amount in Euro and also as a percentage (EFSA max. 90% co-financing rate) of the total eligible project cost. This amount will be indicated in the grant agreement as the maximum grant amount.

1.14 FINAL EFSA GRANT

Maximum grant amount set out in the grant agreement was calculated based on the estimated eligible costs. **The final EFSA grant** will naturally have to be determined based on actually incurred costs. The final EFSA grant is determined by EFSA in line with Article II.25 of the grant agreement.

1.15 PUBLICITY

The beneficiary/ies is/are expected to follow the rules on visibility of EFSA funding set out in Article II.7 of the grant agreement.

According to Article 35 of the EU Financial Regulation EFSA is bound to publish information on recipients of its grants at its website. Such publication shall take place no later than 30 June of the year following the financial year in which the grants were awarded and shall cover these data of the beneficiaries:

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

1.16 PROTECTION OF PERSONAL DATA IN RELATION TO GRANT PROCEDURES

Processing your application in the context of this grant procedure, will involve the recording and processing of personal data (i.e. the name, any CV and contact details

and/or financial details of individuals contained in your application) pursuant to Regulation (EC) N° 45/2001.

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

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

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

Personal data may be registered in the 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).

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

1.17 PUBLIC ACCESS TO DOCUMENTS

In the general implementation of its activities and for the processing of grant procedures in particular, EFSA observes Regulation (EC) N° 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

1.18 FURTHER INFORMATION

If, after having read this Call for proposals and guide for applicants, you have any question you may address it to EFSAprocurement@efsa.europa.eu no later than by **11/09/2015**, indicating the Call reference. Replies will be provided no later than by **14/09/2015** at EFSA webpage where this Call is published and which the applicants are requested to consult regularly.

2. SELECTING PROPOSALS

The Evaluation Committee established by EFSA specifically for this call will evaluate the submitted proposals in five steps:

1. verification of submission requirements (see 2.1)
2. eligibility criteria (see 2.2)
3. exclusion criteria (see 2.3)
4. selection criteria (see 2.4)

5. award criteria (see 2.5)

If the proposal fails at any step it is automatically excluded from further evaluation. EFSA may contact the applicant during the evaluation process if there is a need to clarify certain aspects or for the correction of clerical mistakes.

2.1 VERIFICATION OF SUBMISSION REQUIREMENTS

The following will be verified:

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

2.2 ELIGIBILITY CRITERIA

The following will be verified:

- The applicant and in case of consortium also its partner/s are on the list of competent organisations designated by the Member States in accordance with Art 36 of Regulation (EC) 178/2002 and Commission Regulation (EC) 2230/2004. This list is regularly updated by EFSA Management Board.
- Applicant and in case of consortium also its partner/s participate in the project financially.
- Applicant and in case of consortium also its partner/s are involved in the execution of the project.
- Subcontracting, if any, is justified in the proposal and indicated in the estimated budget.

Documents to be provided:

- **LEGAL ENTITY FORM** (Annex 5) ([download template here](#)) to be completed and signed by the applicant and in case of consortium also by its partner/s.
- **FINANCIAL IDENTIFICATION FORM** (Annex 6) ([download template here](#)) to be completed only by the applicant and in case of consortium only by the coordinator.

Please note that there is no need to submit these forms if they have already been submitted under another EFSA procurement or grant procedure and provided that these forms are still valid. In this case simply indicate in the application form the reference of the call under which the form/s were submitted to EFSA.

The following is applicable only if the applicant is a consortium:

- **PARTNERSHIP STATEMENT:** it is required that the applicant and partner/s provide EFSA with this statement in which they indicate their technical and financial involvement. The applicant and partner/s must sign this partnership statement. No template is provided by EFSA.

2.3 EXCLUSION CRITERIA

Exclusion from participation:

Organisations are excluded from participation in this call 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 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 with those of the country of the RAO 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 judgment 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 Regulation.

Exclusion from award:

Organisations cannot be awarded a grant 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.

Applicant and in case of consortium also its partner/s 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.¹⁴

Documents to be provided:

- **THE DECLARATION ON HONOUR** (Annex 7): template is published together with this Call; to be completed/signed individually by the applicant and by each of the partners.

2.4 SELECTION CRITERIA

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

Financial capacity:

The applicant and in case of consortium also its partner/s must have stable and sufficient financial resources to:

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

Operational capacity:

¹⁴ Please note that, according to Article 200 of the Commission Delegated Regulation C(2012)7507 on the rules of application of Regulation (EU) 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union, financial or administrative penalties, or both, may be imposed on applicants who have made false declarations or substantial errors, or committed irregularities or fraud. Such financial or administrative penalties, or both, may also be imposed on beneficiaries who have been found in serious breach of their contractual obligations.

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

Requirement 1:

Direct experience in the subject matter of this Call.

Documents to be provided by the applicant:

- **Generic evidence: THE DECLARATION ON HONOUR ON SELECTION CRITERIA** (Annex 8).
- **Generic evidence (if applicable):** Additional document for private bodies only: to be submitted only if the grant requested from EFSA is > 60.000 €: **SIMPLIFIED FINANCIAL STATEMENT** (Annex 9) (template available at EFSA's website, published together with this Call) completed for at least last 2 closed financial years.
- **Evidence requested for requirements 1: THE CURRICULUM VITAE** of the experts and other staff to be involved in the project, or, if the individual members not yet assigned for the proposed project, at least staff profiles necessary for the project, including for each member a brief description of the expertise and a list of publications relevant to the project.
- **Generic evidence (if applicable): LETTER OF COMMITMENT:** applicable only in the case when other public body financially contributes to the project (body other than EFSA, applicant or in case of consortium, its partners); to be signed by the contributing public body; it serves to confirm its commitment to financially contribute to the project; no template is provided by EFSA.

2.5 AWARD CRITERIA

The award criteria serve to assess the quality of the proposals in relation to the objectives of the Call. The following award criteria are applicable in this call:

1. The extent to which the project is described in detail, achieves the objectives of this call and is likely to deliver output that will be useful, as well as the proposed methodology is well described and of high quality with particular reference to the following **MAX 60 POINTS**:
 - a. A detailed description of the experiment approach (max. 50 points), including:
 - i. Justification of the choice of animals (species, strain and group size), enniatin chosen, dose regime, controls;
 - ii. Tests to be undertaken to examine the toxicity, reproductive and developmental functions and genotoxicity endpoints;
 - iii. Experience of performing the proposed tests;
 - iv. Proposed approach to statistical analysis;
 - b. Approach for reporting the results (max. 10 points).
2. **Project description clarity**, including phases, clear timelines for the project tasks completion, detailed milestones per task (e.g. via a project Gantt chart), expected outcomes and deliverables, measures to be put in place to guarantee that the deadlines for providing deliverables are met and a contingency plan in case of deviations from the project: **MAX 10 POINTS**.
3. **Task distribution** among consortium partners (if applicable) and individual team members, internal communication (i.e. within the consortium/team) and external communication (i.e. with EFSA): **MAX 10 POINTS**.
4. Description of **specific quality assurance measures** proposed for the project to guarantee high quality of deliverables: **MAX 10 POINTS**.

5. **Cost effectiveness:** comparison between the expected added value and the costs of the project: **MAX 5 POINTS.**
6. **Technical and financial consistency of the proposal:** consistency between the proposed project and its estimated budget, e.g. how it reflects the task distribution/role of partners: **MAX 5 POINTS.**

In order to be considered for a reserve list, the proposal must:

- **score a minimum of 70 points out of maximum possible 100 points; and, at the same time**
- **for the criterion 1, score at least 40 points out of 60 points attributed to that criterion.**

Proposals which have satisfied these quality thresholds will be ranked in a reserve list.

2.6 PROCESS FOLLOWING THE ASSESSMENT AGAINST AWARD CRITERIA

The applicant(s) will be notified, once the evaluation has been finalized, whether they are placed or not on the reserve list.

EFSA reserves the right to invite the 1st ranked applicant on the reserve list, to adapt its proposal based on the evaluators' comments.

Following the successful conclusion of the adaptation phase, the award decision will be taken by EFSA. Subsequently, the grant agreement will be prepared.

If the 1st ranked applicant fails to adapt its proposal, EFSA reserves the right to reject the co-funding. The budget made available in this way may be used for a project of the next ranked applicant on the reserve list.

3. SUBMITTING PROPOSALS

3.1 APPLICATION FORM

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

- The application form shall be duly completed in all its parts.
- The application form shall be supported with all the requested annexes.
- The application form must be signed by a duly authorised legal representative of the applicant.

The applicant should be precise and provide enough detail to ensure the proposal is well described in the application form.

Please note that, by submitting the proposal, the applicant and in case of consortium also its partner/s accept/s the procedures and conditions as described in this Call and in the documents referred to in it.

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

3.2 LANGUAGE OF THE PROPOSAL AND THE SUPPORTING DOCUMENTS

Proposals may be submitted in any official language of the European Union. However, as EFSA's working language is English, the submission of proposals in English would speed up the evaluation process.

Please note that some supporting documents are required in support of the proposal. These supporting documents are an integral part of the proposal. For more information on the relevant supporting documents to be submitted with the proposal, please refer to part 2 of this Call. If these supporting documents are in a language other than English, in order to facilitate and speed up the evaluation, it would be appreciated if a reliable translation of the relevant parts of the documents into English is provided with the proposal.

3.3 DEADLINE FOR SUBMISSION OF PROPOSAL

18/09/2015

3.4 SUBMISSION MODALITIES

Proposals can be submitted:

- either by registered mail or by courier service to the address below. 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 EFSAprocurement@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 address below, not later than 17.00 hours (Italy time). Any proposal hand delivered after the final deadline will automatically be rejected.

European Food Safety Authority - EFSA
FIN UNIT – DONATA NALDINI
GP/EFSA/BIOCONTAM/2015/02
Via Carlo Magno 1/A
I – 43126 Parma

Proposals must be submitted using the double envelope system. The outer envelope should be sealed with adhesive tape, signed across the seal and carry the following information:

- Call reference: GP/EFSA/BIOCONTAM/2015/02;
- title of the Call: In vivo toxicity and genotoxicity of beauvericin and enniatins
- name of the applicant
- the indication: "Proposal - Not to be opened by EFSA reception – to be passed without opening to the EFSA FIN UNIT – Donata Naldini";
- the address for submission of proposal (see above);
- the posting date (if applicable) should be legible on the outer envelope.

3.5 EXPECTED DURATION OF PROCEDURE

Information on expected duration of procedure – time to grant:

- Applicants will be informed on the decision regarding their application at the latest by 6 months since the deadline for submission of proposals.
- Signature of the grant agreement will take place at the latest by 3 months since the successful applicant/s has/have been informed on the decision on their application.

- Annex 1: Rules on eligibility of costs
- Annex 2: Draft grant agreement
- Annex 3: Estimated budget template
- Annex 4: Application form
- Annex 5: Legal entity form ([download template here](#))
- Annex 6: Financial identification form ([download template here](#))
- Annex 7: Declaration on honour for exclusion criteria
- Annex 8: Declaration on honour for selection criteria
- Annex 9: Simplified financial statement