CALL FOR PROPOSALS
and guide for applicants

Call reference: GP/EFSA/AFSCO/2016/01

Call title: Methodology development in risk assessment

The call is divided into three different lots:

Lot 1: Methods and systems for the identification of emerging food risks

Lot 2: Integrated methodologies for the risk assessment of mycotoxin mixtures in food and feed

Lot 3: Output-based methods for the assessment of the freedom of animal disease/infection

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

Indicative procedure timetable:

Milestone	Date	Comments
Launch date	31/03/2016	Date of call publication on EFSA's website
Intermediate submission (informal) Step 1: Informing EFSA on consortium composition (Deadline)	11/07/2016	This step has the sole purpose of confirming that the indicated (potential) consortium partners are on the Article 36 List. If you would like to confirm the applicants'/partners' eligibility i.e. confirmed Art.36 list inclusion, you should contact EFSA at procurement&grants@efsa.europa.eu. Please provide the specific information as indicated in the Application Form – part 1 (Annex 4). Please note that such communication is not binding either for submitting a proposal or for fixing the consortium composition. In particular, the applicants are free to modify further the consortium composition. **NOTE:** This informal step is introduced by EFSA for assisting the Art.36 organisations (eligible entities) in applying in consortia of eligible partners. This intermediate submission step is not obligatory: a consortium can submit an application under the present call even if this step was not followed.
Intermediate (informal) Step 2: EFSA confirming the consortium eligibility (Deadline)	29/07/2016	EFSA, via e-mail, will confirm whether the indicated organisations are on the Article 36 List, if requested by applicants under Step 1.
Deadline for applicants to raise clarification questions to EFSA	15/09/2016	If, after having read this Call for proposals and guide for applicants, you have any questions you may address them to EFSAProcurement@efsa.europa.eu by indicating the Call reference
Deadline for EFSA to reply to clarification questions	22/09/2016	Replies will be provided on EFSA's webpage where this Call is published and which the applicants are requested to consult regularly.
Deadline for submission of proposals Any proposal posted after the final deadline will automatically be rejected.	06/10/2016	You can submit your proposal: - either by post (registered mail) or by courier not later than 06/10/2016, in which case the evidence of the date of dispatch shall be constituted by the postmark or the date of the deposit slip, to the address indicated below. The consortium submitting an proposal by post or by courier is requested to send an informative e-mail to EFSAProcurement@efsa.europa.eu - or delivered by hand not later than 17.00 hours (Italy time) on 06/10/2016 to the address indicated below. In this case, a receipt must be requested from EFSA as proof of submission, signed and dated by the staff member in EFSA Post Office who took over the delivery. The EFSA Post Office is open from 8.30 to 13.00 and from 14.00 to 18.00 Monday to Friday. It is closed on Saturdays, Sundays and EFSA holidays. Submission by post, courier or hand to this address: *European Food Safety Authority - EFSA* *For the attention of – Finance Unit (Procurement Team) Ms. Joanna Swarcewicz Unit* *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 FOR PROPOSALS GP/EFSA/AFSCO/2016/01 – NOT TO BE OPENED BY THE INTERNAL MAIL DEPARTMENT".* - name of the applicant - the posting date should be legible on the outer envelope - indication of the lot you are applying for.
Notification of the evaluation results	November 2016	Estimated. *Attention: outcome of the present call will be communicated to all applicants to the e-mail address indicated in their proposal. Accordingly, the applicants who have submitted proposals under the present call are strongly invited to check regularly the inbox in question.*
Grant agreement(s) signature	December 2016/January 2017	Estimated

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.

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1. GRANT OPPORTUNITY AND CONDITIONS[1]

1.1 LEGAL FRAMEWORK

Article 36 of the Regulation (EC) 178/2002[2] 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. Article 36 (1) stipulates that the aim of such networking is, in particular, to facilitate a scientific cooperation framework, the development and implementation of joint projects[3], the exchange of expertise and best practices in the fields within the Authority`s mission.

On the 19 December 2006 the Management Board, drew up a list of competent organisations designated by the Member States which may assist EFSA with its mission. This list is regularly updated by EFSA's Management Board and the updates are published on EFSA's website.

Article 5 of the Commission Regulation (EC) 2230/2004[4] 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:

- Part 1, Title 6 of Council Regulation (EU, EURATOM) No 966/2012 of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002, as amended by REGULATION (EU, EURATOM) 1929/2015 of the European Parliament and of the Council of 28 October 2015;
- Part 1, Title 6 of Commission Delegated Regulation (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union, as amended by Commission Delegated Regulation (EU) No 2015/2462 of 30 October 2015.

The present Call for proposal is based on EFSA's 2016 Work Programme for grants and operational procurements in science – Financing Decision as presented in Annex II of the Programming document 2016 - 2018, available on the EFSA's website[5].

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://www.efsa.europa.eu/sites/default/files/programmingdocument2016_2018.pdf#page=97

1.2 MAIN OBJECTIVE OF THE CALL

The development, validation, implementation and harmonisation of methodologies and approaches for the assessment of health risks for humans, animals, plants and the environment is one of the key strategic objectives of EFSA. EFSA's risk assessment methodologies have been described in the form of guidance documents of the Scientific Committee, Panels and Units. The implementation of these guidance documents is regularly reviewed and priorities are set for revision of existing and development of new risk assessment methods in various fields with potentially high impact on human, animal and plant health. To bring forward risk assessment in areas that are still under elaboration, new methods and tools need to be developed and validated in cooperation across EU Member States, reaching for commonly approved methods. Areas which EFSA considers as challenges for the future include the assessment of chemical mixtures, assessment of freedom of animal disease/infection, and the identification of emerging risks.
One of EFSA's key areas is to support scientific cooperation in Europe and beyond, building on the scientific expertise of Member States, ensure that the scientific work carried out at national level is not duplicated at EU level, and stimulating Member States to contribute to consolidating the EU risk assessment community.
In the context of this call, the main objective is for projects to:

- boost scientific cooperation between EFSA and among Member States through the formation of consortia of national agencies from different EU countries with diverse technical capabilities and expertise,
- be of innovative nature, taking efforts of EFSA and other organisations (e.g. ECHA, EMA, EEA, FAO, WHO, OECD, EPPO, IPPC, ECVAM) into consideration, and
- ensure that the results of the project are transferable and their dissemination is sustainable, with the aim of further enhancing knowledge and competence sharing.

In particular, the action co-financed by this EFSA grant, to be awarded following the present call for proposals, shall develop and validate new methods/tools, making the best use of the scientific data available or generate new data, to be applied in a structured and transparent way for identifying emerging food risks, assessing the risk of mycotoxin mixtures in food and feed, and assessing the freedom of animal disease/infection.

The call for "methodology development in risk assessment" is divided into three different lots:

Lot 1: Methods and systems for the identification of emerging food risks
Lot 2: Integrated methodologies for the risk assessment of mycotoxin mixtures in food and feed
Lot 3: Output-based methods for the assessment of the freedom of animal disease/infection

1.3 OBJECTIVES OF EACH LOT

Lot 1: Methods and systems for the identification of emerging food risks

Background
Researchers, governments, agencies, food producers and the civil society are increasingly concerned about 'emerging food risks'. It is recognised that the successful identification of emerging risks is at the heart of protecting public health and the environment, and that this requires worldwide cooperation between all parties involved in the food supply chain.
Identification of emerging risks in the food chain is essential for EFSA to anticipate future needs in risk assessment both on data and methods as well as to support risk managers in anticipating potential risks and taking effective and timely measures to protect consumers. The general food law requires EFSA to establish monitoring procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging risks in the fields within its mission. Over the past years, EFSA has been implementing an approach to identify emerging risks. This consists of an operational definition of emerging risks and an overall strategy for the collection, analysis and evaluation of the relevant data and information[6,7,8,9,10,11,12,13].

[6] EFSA (European Food Safety Authority), 2006. Opinion of the Scientific Committee on a request from EFSA related to the early detection of emerging risks. EFSA Journal, 375, 14 pp.

[7] EFSA (European Food Safety Authority), 2007. Definition and description of "emerging risks" within the EFSA's mandate. http://www.efsa.europa.eu/en/scdocs/doc/escoemriskdefinition.pdf

It is recognised that resources for addressing future risks are limited. Therefore, it is of paramount importance that there is coordination of resources, expertise and data across Europe and internationally. To facilitate such wide ranging networking, new methodologies and tools are required to help manage the sharing of complex and rapidly updated data.

MAIN OBJECTIVE

The overall objective of Lot 1 is the establishment of a collaborative platform to support the current EFSA procedure for emerging risks identification[10]. The platform should allow EU Member State authorities and EFSA to share knowledge, data and methods for the identification of emerging food-related risks in a rapid and effective manner. The project should ensure the interoperability of the information generated by the platform with the EFSA data repository currently under development.

The proponents should present their proposal to achieve the main objective, elaborating on the methodology proposed to create, structure and manage the platform; on the tools to sustain the activities of the platform; and on the coordination of existing knowledge and integration of additional competences, where relevant. The proposal should aim at establishing and testing the platform and methods proposed, and also consider its sustainability after the end of the project.

SPECIFIC OBJECTIVES

1. **Development of new tools for automatic data retrieval and validation from multiple sources for emerging risks identification**

This would build on experience gained in text mining, webcrawling, media monitoring approaches, but would also include the development of tools for data mining, particularly of "big data". Proposals should take into consideration work already existing in EU and non-EU organisations which are putting significant resources in developing and validating methods and tools for identifying emerging risks.

2. **Integration of data and methodologies from social sciences into the emerging risk identification process on a farm to fork approach**

Further elaboration of methods developed for expert elicitation[14] into the emerging risks identification process, but also the use of crowd sourcing and social media. EFSA is also interested in aspects concerning the integration of behavioural science into understanding human behaviour as a driver of the emergence of new risks, and economic indicators and methodologies to assess system vulnerabilities.

3. **Set up of a collaborative emerging risk platform to further strengthen EU emerging risks capacity**

Propose and implement a methodology to structure, manage and maintain a collaborative platform in the area of emerging food risks. Such platform should enable national food agencies and EFSA to rapidly and effectively share knowledge on e.g. specific emerging risks, methodologies and relevant data sources. In addition, the development of structures and mechanisms for maintenance of such platform, beyond the duration of the grant, would be necessary. The proposal should also demonstrate how the project effectively contributes to the transfer of knowledge and capacity between countries and organizations, involved in emerging risks identification, having different technical expertise and resource availability.

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8 EFSA (European Food Safety Authority), 2011a. EFSA's 15th Scientific Colloquium on emerging risks in food: from identification to communication. http://www.efsa.europa.eu/en/supporting/pub/114e.htm

9 EFSA (European Food Safety Authority), 2011b. Data collection for the identification of emerging risks related to food and feed. EFSA Journal 2011; 9(8):EN-185. [52 pp.] doi:10.2903/j.efsa.2011.EN-185

10 EFSA (European Food Safety Authority), 2012. Piloting a process for Emerging Risk Identification: Lessons learnt and next steps. EFSA supporting publications 2012, EN-310, 39 pp.

11 EFSA (European Food Safety Authority), 2015. Identification of emerging risks: an appraisal of the procedure trialled by EFSA and the way forward. EFSA supporting publication 2015:EN-824. 30 pp.

12 Robinson T, Altieri A, Chiusolo A, Dorne J-L, Goumperis T, Rortais A, Deluyker H, Silano V, Liem D, 2012. EFSA's approach to identifying emerging risks in food and feed: taking stock and looking forward. EFSA Journal 2012;10(10):s1015, 8 pp. doi:10.2903/j.efsa.2012.s1015

13 Food and Consumer Product Safety Authority (VWA) with BfR, BVL, FAO, FAVV-AFSCA, FSA, CSL, OIE, RIKILT and RIVM, 2006. Forming a Global System for Identifying Food-related Emerging Risks, EMRISK. Available online at: http://www.efsa.europa.eu/en/search/doc/224r.pdf

14 EFSA (European Food Safety Authority), 2014. Guidance on Expert Knowledge Elicitation in Food and Feed Safety Risk Assessment. EFSA Journal 2014;12(6):3734, doi:10.2903/j.efsa.2014.3734

Lot 2: Integrated methodologies for the risk assessment of mycotoxin mixtures in food and feed

Background

Mycotoxins as mixtures are produced mainly by fungi of the genera Aspergillus, Penicillium and Fusarium. They include many food commodities including cereals, fruit and vegetables. Their ubiquitous presence represents a challenge to the health of humans, animals and the environment. Over the last decade, EFSA has been very active in the area of risk assessment of mycotoxins food and feed:

- Scientific opinions dealing with risk assessment of mycotoxins in food and feed. These have included well characterised mycotoxins (e.g. aflatoxins, T-2 and HT-2 toxins, zearalenone, etc.) and emerging mycotoxins (e.g. alternaria toxins, beauvericin, enniatins, etc.) [15,16,17,18,19].
- A grant investigating "modelling, predicting and mapping the emergence of aflatoxins in cereals in the EU due to climate change"[20].

In addition, EFSA has initiated a series of projects dealing with the risk assessment of chemical mixtures in food and feed: review of the frameworks available for the human risk assessment of chemical mixtures, review of modern methods, including toxicokinetics (TK), OMICs and *in silico* tools, data collection activities, and an EFSA colloquium on the harmonisation of methods for human and ecological risk assessment of mixtures [21,22,23].

From these activities and from the consultation with EFSA Panels and staff dealing with chemical risk assessment and with other experts from international bodies (ECHA, OECD, WHO, etc.), EFSA has formulated several recommendations to further develop methods for the risk assessment for mixtures. These include the refinement of:

1. The detection and reporting of realistic mixtures in food and feed samples for exposure assessment, and
2. The scientific basis to set cumulative assessment groups/assessment groups for chemicals based on their elimination patterns in a number of organisms (TK) and their combined toxicity profiles (dose addition, response addition, or interaction (i.e. synergistic effects/ antagonism) for further refinement of hazard characterization).
3. Combining the refinements of 1 and 2 for risk characterisation and uncertainty analysis based on realistic mixtures in food and feed [21,22,23].

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15 EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2007. Opinion of the scientific panel on contaminants in the food chain [CONTAM] related to the potential increase of consumer health risk by a possible increase of the existing maximum levels for aflatoxins in almonds, hazelnuts and pistachios and derived products. doi:10.2903/j.efsa.2007.446

16 EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2011a. Scientific Opinion on the risks for animal and public health related to the presence of T-2 and HT-2 toxin in food and feed. EFSA Journal 2011;9(12):2481, 187 pp. doi:10.2903/j.efsa.2011.2481

17 EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2011b. Scientific Opinion on the risks for public health related to the presence of zearalenone in food. EFSA Journal 2011;9(6):2197, 124 pp. doi:10.2903/j.efsa.2011.2197

18 EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2011c. Scientific Opinion on the risks for animal and public health related to the presence of Alternaria toxins in feed and food. EFSA Journal 2011;9(10):2407, 97 pp. doi:10.2903/j.efsa.2011.2407

19 EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2014a. Scientific Opinion on the risks to human and animal health related to the presence of beauvericin and enniatins in food and feed. EFSA Journal 2014;12(8):3802, 174 pp. doi:10.2903/j.efsa.2014.3802

20 Battilani P, Rossi V, Giorni P, A. P, Gualla A, H.J. vdF-K, Booij CJH, Moretti A, Logrieco A, Miglietta F, Toscano P, Miraglia M, De Santis B and Brera C, 2012. Scientific report submitted to EFSA. Modelling, predicting and mapping the emergence of aflatoxins in cereals in the EU due to climate change. Available from: http://www.efsa.europa.eu/en/supporting/doc/223e.pdf

21 EFSA (European Food Safety Authority), 2013. International Framework Dealing with Human Risk Assessment of Combined Exposure to Multiple Chemicals. EFSA Journal 2013;11(7):3313. [69 pp.] doi:10.2903/j.efsa.2013.3313

22 EFSA (European Food Safety Authority), 2014b. Modern methodologies and tools for human hazard assessment of chemicals. EFSA Journal 2014;12(4):3638, 87 pp. doi:10.2903/j.efsa.2014.3638

23 EFSA (European Food Safety Authority), 2015. Harmonisation of human and ecological risk assessment of combined exposure to multiple chemicals. EFSA supporting publication 2015:EN- 784. 39 pp.

These recommendations are directly applicable to the refinement of methodologies for risk assessment of mycotoxin mixtures. In practice, mycotoxin data for specific realistic co-occurrence of free and masked/modified mycotoxins are combined with food consumption patterns for exposure assessment, which are then further combined with TK/toxicity profiles for risk characterisation [24,25,26,27,28].

A major challenge is the understanding of the actual production of mycotoxin mixtures and consequently their realistic occurrence in plants and fruit [29]. In order to address this challenge, the investigation of complex taxonomic, biochemical, genetic and environmental variables and conditions that would influence the biosynthesis and occurrence of mycotoxin mixtures in plants is needed. These variables include biosynthetic pathways, species/strain specificity on host species, climate change, temperature, resistance of the individual strains to fungicides and associated mechanisms, availability of nutrients and mycotoxin precursors etc. to name but a few [30]; Medina., 2013;[31,32].

MAIN OBJECTIVE

The main objective of Lot 2 is to develop integrated innovative methods for the risk assessment of mixtures, using mycotoxins as a case study for the development of a holistic approach, from synthesis in primary production to effects on human health, animal health and environment. It is foreseen that these methods will be applied in the future by risk assessors dealing with mycotoxin mixtures for the food and feed area.

SPECIFIC OBJECTIVES

1. **Extensive literature searches and structured data collection on biochemical, genetic and environmental variables and their impact on mycotoxin production**

   These extensive literature searches (ELS) should review key environmental conditions and variables, that would influence the biosynthesis and occurrence of mycotoxin mixtures in plants of relevance to food and feed safety, including biosynthetic pathways, species or strain specificity of mycotoxin(s) production on host specie(s), resistance to fungicides and their mechanisms, influence of climate change, temperature, season, nutrient availability (e.g. amino acid etc.), other stressors, etc. The ELS should consider all available reviews, available Member States' data and individual primary research studies of relevance such as laboratory studies, field studies, molecular, OMIC studies, occurrence data of free and masked/modified mycotoxins on plants and fruit, and available *in silico* computer models. The summary statistics from each individual study should be computed in a structured database that will be designed by the beneficiary in collaboration with EFSA.

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24 De Mattsson JL, 2007. Mixtures in the real world: the importance of plant self-defense toxicants, mycotoxins, and the human diet. Toxicol Appl Pharmacol. 223(2):125-132.

25 Steinmetz WE, Rodarte CB, Lin A, 2009. 3D QSAR study of the toxicity of trichothecene mycotoxins. Eur J Med Chem. 44(11):4485-4489.

26 Vettorazzi A, van Delft J, López de Cerain A, 2013. A review on ochratoxin A transcriptomic studies. Food Chem Toxicol. 59:766-83. doi: 10.1016/j.fct.2013.05.043.

27 Zhang J, Pan Z, Moloney S, Sheppard A, 2014. RNA-Seq analysis implicates detoxification pathways in ovine mycotoxin resistance. PLoS One. 17; 9(6):e99975. doi: 10.1371/journal.pone.0099975.

28 De Boevre M, Graniczkowska K, De Saeger S, 2015. Metabolism of modified mycotoxins studied through in vitro and in vivo models: An overview Toxicology Letters 233, 24-28.

29 Streit E, Schatzmayr G, Tassis P, Tzika E, Marin D, Taranu I, Tabuc C, Nicolau A, Aprodu I, Puel O, Oswald IP, 2012. Current situation of mycotoxin contamination and co-occurrence in animal feed--focus on Europe. Toxins (Basel). 4(10):788-809.

30 Abou Ammar G, Tryono R, Döll K, Karlovsky P, Deising HB, Wirsel SG, 2013. Identification of ABC transporter genes of Fusarium graminearum with roles in azole tolerance and/or virulence. PLoS One. 11;8(11):e79042.

31 Kabak B, Dobson AD, 2015. Mycotoxins in Spices and Herbs: An Update. Crit Rev Food Sci Nutr. Nov online.

32 Blandino M, Scarpino V, Vanara F, Sulyok M, Krska R, Reyneri A, 2015. Role of the European corn borer (Ostrinia nubilalis) on contamination of maize with 13 Fusarium mycotoxins. Food Addit Contam Part A Chem Anal Control Expo Risk Assess. 32:533-543.

2. **Extensive literature searches and structured data collection on realistic occurrence of mycotoxin mixtures, toxicokinetics and combined toxicity in animals and humans**

These ELS should review TK and toxicity data for single and combined mycotoxins in livestock, fish and humans. The ELS should consider all available reviews, available Member States' data and individual primary research studies of relevance including laboratory studies, OMIC studies, blood, plasma and urine concentrations of parent/metabolite(s) free and masked/modified mycotoxins as single compound (s)/realistic mixtures, and available *in silico* computer models (e.g. TK, physiologically-based-TK, PB-TK-toxicodynamic). Summary statistics from each individual study should be computed in a structured database including TK and toxicity endpoints for each species (e.g. absorption, distribution, metabolism, excretion, half-life, clearance, acute, sub-chronic and chronic toxicity using lethal and sub-lethal endpoints etc.). Data describing and quantifying the metabolic or the toxicological basis for species tolerance to mycotoxins should also be collected. The structured database should follow the data model from EFSA's chemical hazards database that will be provided by EFSA at the kick-off meeting.

3. **An integrated approach to the risk assessment of mycotoxin mixtures using modelling**

The data from A and B should be integrated using modelling techniques (e.g. Monte Carlo modelling using frequentist/Bayesian methods) to develop an integrated method for the risk assessment of mycotoxin mixtures in humans and animals. The modelling should aim to combine the environmental variables with the TK and toxicity data to support risk assessment using a whole food chain approach (from the environment to the internal dose including carry over in farm animals and toxicity) and a comparative approach to mycotoxin toxicity in vertebrates. At least five realistic case studies should be developed for mycotoxin mixtures and illustrated for the risk characterisation of such mixtures in animal species and humans. Uncertainties and data gaps should be described and discussed.

Lot 3: Output-based methods to assess the freedom of animal disease/infection

BACKGROUND

Each year, the EU provides financial support to eradicate, control and prevent various animal diseases. A report from the Commission to the European Parliament and the Council on the outcome of the EU co-financed programmes over the period of 2005-2011[33] shows that, in most cases, the benefit of these activities is evidenced by the continuous expansion of disease-free zones in the EU[34]. For those diseases, the EU legislation defines and sets all the necessary standards for the Member States to carry over the relevant countermeasures.

However, not all animal diseases are regulated by relevant EU legislation and for these diseases Member States can adopt countermeasures on a voluntary basis. This means also that the choice of the type of intervention, and the way of implementing it, are left to the Member States. As a consequence, for the same disease, different types of interventions can be adopted with very different standards, making any comparison of the available information originating from those activities very difficult. Because of different regions and countries operating differently designed control programs, an assessment of the risk of introduction of infection arising from movements of susceptible species between regions or countries is difficult.

33 EC, 2014a. Report from the Commission to the European Parliament and the Council on the outcome of the EU co-financed programmes for the eradication, control and monitoring of animal diseases and zoonosis over the period of 2005-2011. http://ec.europa.eu/food/animal/diseases/docs/11377r5_en.pdf

34 EC, 2014b. "Funding of Animal Health Measures". http://ec.europa.eu/dgs/health_food-safety/funding/cff/animal_health/index_en.htm

Output-based surveillance techniques (e.g. estimation of the surveillance system sensitivity, freedom from disease probability, etc.) provide a valid support to achieve harmonised and comparable surveillance activities while allowing flexible approaches that are adapted to the different populations under surveillance[35].

However, despite the theoretical background for demonstrating 'Freedom from Disease/Infection' being well known and broadly accepted, the practical implementation in the field represents a challenging task. In recent works issued by EFSA, where the 'Freedom from Disease/Infection' methodology was adopted, gaps regarding the reporting tools and the certainty around the parameters needed to implement the 'Freedom from Disease/Infection' methodology (e.g. the target population size, the diagnostic test sensitivity, etc.) were identified.

MAIN OBJECTIVE

Considering all these aspects, the main objective of Lot 3 is to develop a framework that could enable to evaluate, standardise and compare the outcomes of different control programmes for non-regulated diseases, with particular emphasis on the confidence of freedom at different level of aggregation (animal, herd, area, country, etc.)[36]. The framework should allow estimating if a given entity is truly free from infection with a given non-regulated disease considering the control or eradication program applied[37]. Such a framework will also be useful in the context of the new Animal Health Law, which foresees the implementation of voluntary surveillance activities for non-regulated diseases by the Member States. Furthermore, the development and implementation of such a harmonised methodology would strengthen the European risk assessment capacity in the area of animal disease control.

SPECIFIC OBJECTIVES

1. **Development of a method for the comparison of the outcomes of different control programmes for non-regulated diseases**, with a view to confidence of freedom, for different epidemiological units. The method should allow heterogeneous data inputs, but generate comparable outputs. The uncertainty related to the latter, should be thoroughly assessed and described.
2. **Development of a framework describing the non-regulated disease control activities implemented in the different EU Member States**. The framework should include a database populated with the relevant parameters of the developed method (e.g. test performance, type and purpose of the sampling activity, etc.), in line with, but not necessarily restricted to, the existing EFSA standards[38], and of a descriptive summary of the available information.
3. **Implementation of the framework in a case study on a specific disease for validation**. It is expected that the outcome of this exercise will lead to the identification of the most problematic aspects in the harmonisation process, providing feedback to improve the developed framework. The case study could also be a good opportunity to explore the concept of "expected cost of error", which combines probability and consequences of

35 Cameron AR, 2012. "The consequences of risk-based surveillance: Developing output-based standards for surveillance to demonstrate freedom from disease"; Prev Vet Med. 2012 Aug 1;105(4):280-6. doi: 10.1016/j.prevetmed.2012.01.009. Epub 2012 Feb 3.

36 EFSA (European Food Safety Authority), 2013. Modelling the impact of a change in MI sensitivity on the surveillance of bTB at the country level. Supporting Publications 2013:EN-450. [40 pp.].

37 EFSA (European Food Safety Authority), 2014. Assessment of Echinococcus multilocularis surveillance reports submitted in 2014 in the context of Commission Regulation (EU) No 1152/2011. EFSA Journal 2014;12(10):3875, 44 pp. doi:10.2903/j.efsa.2014.3875

38 EFSA (European Food Safety Authority), 2012. A framework to substantiate absence of disease: the risk based estimate of system sensitivity tool (RiBESS) using data collated according to the EFSA Standard Sample Description - An example on Echinococcus multilocularis. Supporting Publications 2012:EN-366. [44 pp.].

surveillance failure: this parameter is of primary importance for the design of the surveillance activities, to set consistent design prevalence.

A plan for communicating the developed methodology and results with the aim of transferring the acquired knowledge to stakeholders and risk managers, with a special emphasis on the advantages that such a methodology could bring at all levels, from the farm, through trade, to the consumer.

Applicable to all lots:
Duration of the project - The Call for Proposals does not specify the duration and any details on the end date of the proposed projects. It is up to the applicant consortium to decide the duration of the project proposed.

1.4 ELIGIBLE ORGANISATIONS

In order to achieve the main objective of the call, the proposal must be submitted in a consortium of **at least two eligible organisations,** from **(at least) two different EU countries, Norway or Iceland.** One of the partners must be identified in the proposal as the consortium leader (= applicant). The applicant is responsible for identifying consortium partners.
The applicant may submit an application for one or more lots but each proposal should indicate clearly for which lot you apply. In the case you decide to apply for more than one lot, a separate proposal must be provided for each lot. For the material composition of the proposal, please consult the checklist in the Application Form (Annex 4).
To be eligible, the applicant and 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. This list is regularly updated by EFSA Management Board and the latest update is published on EFSA's website.
Searching for consortium partner(s) among Article 36 organisations can be supported by contact persons of the Article 36 organisations accessing the Article 36 Search Tool[39], or your EFSA national Focal Point[40] for support.

1.5. ROLE AND RESPONSIBILITY OF BENEFICIARIES

For proper understanding of this call, it is also important to have clarity of the used terminology related to 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 appplicant, if they agree so, a power of attorney/mandate, 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 its following important roles:

- Takes part in implementing the project and incurs related costs;
- Monitors that the action is implemented properly;

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[39] https://art36.efsa.europa.eu/art36-web/;jsessionid=BD3817EF3A3B6C4618D20B5A8C5ECB32?wicket:interface=:1::::

[40] http://www.efsa.europa.eu/en/people/fpmembers

- Acts as the intermediary for any communication between the consortium and EFSA;
- Receives and answers all claims EFSA might have in relation to the implementation of the project;
- Requests and reviews any documents or information required by EFSA and verifies their completeness and correctness before passing them on to EFSA;
- Informs EFSA and the partner/s of any event that is likely to substantially affect the implementation of the project;
- Submits the deliverables and reports to EFSA;
- Requests and receives payments from EFSA and distributes 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 its/their following important roles:

- Take part in implementing the project and incur related costs;
- 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.

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 beneficiaries 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 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 MINIMUM MEETING & REPORTING REQUIREMENTS

The Applicant must indicate in the project proposal all the foreseen meetings and reporting. Such meeting and reporting schedule must include, but is not necessarily limited to:

Meetings:

- **Kick off meeting**: It is regarded as the start of the project from which the project duration indicated in the proposal is counted. In any case, the costs will be eligible as from the entry into force of the Grant agreement. Kick off meeting takes place as a physical meeting not later than three months after the entry into force of the grant agreement at EFSA premises (Parma-Italy). The details and objectives of the project will be discussed at this meeting, as well as the project outcomes, timeframe and communication with EFSA. The presence of a beneficiary's staff member responsible for administrative/finance issues of the project at kick-off meeting is compulsory. This is because the understanding 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. In addition the parties will agree on the impact assessment to be provided to EFSA as part of the final report, and on a section of the final report to be published on EFSA's website as an External Report.
- **Interim meeting**: to discuss the progress of the project, any encountered difficulties, risks and proposed mitigating measures.
- **Final meeting**: will be held at the end of the project as a physical meeting at EFSA premises (Parma-Italy). The purpose of this meeting is to present to EFSA the final outcome/deliverable.

Reporting:

- **Interim report** on the progress of the project, to be submitted in the middle of the project and to be discussed at the interim meeting. In addition, it is expected that at the middle of the project some deliverables (in addition to the interim report) will be presented to EFSA.
- **Final report**, to be submitted after the execution of the project and to be discussed at the final meeting. The Final report will include a part on the impact assessment of the project, and a section which will be published on EFSA's website as an External Report. Templates for these sections will be provided by EFSA.

1.8 PAYMENTS

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

- **pre-financing payment**, upon grant agreement entry into force, without need for a request for payment, of 35% 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;
- **interim payment**, in the middle of the project, based on the request for interim payment, up to 35% of the maximum grant amount set out in the grant agreement or 50% of actually incurred costs declared for the reporting period, whichever is lower; interim payment is subject to the approval by EFSA of the interim report with the corresponding deliverables and approval of the statement of actual costs incurred by the beneficiaries;
- **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 and interim payments already made; if the total amount of earlier payments 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 payments 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.

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 consortium resources. The consortium 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.
  Clarifications on application of co-financing principle:
  - It is acceptable that in an applicant consortium there are partners that will participate in the action but which will not receive any portion of the EFSA grant. It shall be noted that such partners, as they participate in the action will incur costs but they will not ask for these costs to be reimbursed. This situation shall be reflected in the description of the action and in the estimated budget in the Grant agreement.
  - The 50% co-funding will be calculated overall for all consortium partners. Not all partners need to equally contribute to the 50% co-funding.
- **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**: Costs will be eligible as from the entry into force of the Grant agreement (signature of the grant agreement). 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 grants awarded under this Call are grants based on EU Financial Regulation, Article 123 (1e).

EFSA's co-financing rate: Given the complementary and motivational nature of EFSA grants, the projects to be supported under this Call are co-financed by EFSA at maximum 50% of the total eligible project costs. In addition, the maximum possible amount of EFSA grant for an individual project is 375.000 €. In other words, each grant has double ceiling: the maximum amount and the reimbursement rate applied on the total eligible project cost.

EFSA's maximum grant amount per project: *Overall, EFSA has currently available under this Call 1.125.000 Euro. EFSA intends to fund more proposals following this Call. The currently available amount of 1.125.000 Euro shall be sufficient to co-finance at least one successful project per lot. 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 i.e. if the submitted proposals do not meet the set award criteria thresholds (2.5 Award Criteria). In such case EFSA reserves the right to re-distribute funds from one lot to another lot that has more than one successful proposal (i.e. proposals which have satisfied the quality thresholds and are ranked in a reserve list). If more than one proposal is proposed for award under a given lot, the evaluation committee should assess and confirm that there is no duplication of scope.*
- *to award more grants in cumulative value above 1.125.000 Euro in case additional funds will be made available in 2016 EFSA budget. In such case EFSA reserves the right to distribute the additional funds to the lot(s) that has/have more than one successful proposal(s) (i.e. proposals which have satisfied the award criteria thresholds and are ranked in a reserve list). In case more than one lot has more than one successful proposal then the highest ranked proposal(s) across all lots will be proposed for award. If more than one proposal is proposed for award under a given lot, the evaluation committee should assess and confirm that there is no duplication of scope.*

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

All proposals 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. Workshops, seminar, conferences;
    6. Subcontracting;
    7. Eligible VAT;
    8. Miscellaneous costs are costs arising directly from the requirements imposed by the grant agreement.

    The above 8 categories represent an exhaustive list of possible eligible direct costs. **However, if, for example, the project doesn't foresee costs for workshops/seminars/conferences, then this category of costs can be left empty in the estimated budget.**
- 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 criteria 9 and 10.

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 50% 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 beneficiaries 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.

Your personal data may be registered in the Early Detection and Exclusion System (EDES) if you are in one of the situations mentioned in Article 106 of the Financial Regulation. For more information see the Privacy Statement on http://ec.europa.eu/budget/explained/management/protecting/protect_en.cfm#BDCE).

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.

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 applies in a consortium with partner/s.
- The applicant and 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 partner/s participate in the project financially.
- Applicant and 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 by partner/s.
- **FINANCIAL IDENTIFICATION FORM** (Annex 6) (download template here) to be completed only by the applicant.

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;
- EFSA reserves the right during the evaluation procedure to request the following supporting documents regarding the Legal Entity Form: for a public body a copy of the resolution or decision establishing the public body, or other official document establishing that public body. For a private body an extract from the official journal, copy of articles of association, extract of trade or association register, certificate of liability to VAT (if, as in certain countries, the trade register number and VAT number are identical only one of these documents will be required).

- **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. The partnership statement can also be a bilateral document between the applicant and a partner. Please note that no original copy is required in the application.

2.3 EXCLUSION CRITERIA

Applicant and 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 of EU Financial Regulation as listed therein.

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 its partner/s.

Financial capacity:
The applicant and partner/s must have stable and sufficient financial resources to:

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

Operational capacity:
The consortium as a whole must have the professional resources, competencies and qualifications necessary to complete the proposed project.

Documents to be provided:

- **THE DECLARATION ON HONOUR ON SELECTION CRITERIA** (Annex 8).
- 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.
- **THE CURRICULUM VITAE** of the experts and other staff involved in the project, or, if the individual members not yet assigned for the proposed project, at least staff profiles necessary for the project. There is no minimum number of CVs required. Each applicant can choose the CV format, however the information to be included in each CV should be complete. Please note that for the identified individual team members listed in the Estimated Budget under the spreadsheet/A1. Personnel Costs, the CVs should also be provided. If only staff profiles are available then a description of the staff profile should be provided.
- **LETTER OF COMMITMENT:** applicable only in the case when other public body financially contributes to the project (body other than EFSA, applicant or 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 (applicable to all lots)

The award criteria serve to assess the quality of the proposals in relation to the objectives of the Call for each lot. The following award criteria are applicable:

1. The extent to which the proposal **a)** falls **within the scope** of the indicated lot **(MAX 5 POINTS)**; **b) clarity of project objective and description (MAX 5 POINTS); c) feasibility** of project and likelihood of project delivering output that will be useful **(MAX 10 POINTS)**: total **MAX 20 POINTS**.
2. **Innovative nature** of the proposed action: it should be innovative and avoid duplication with other existing actions at EU level, i.e. the applicant must clearly identify the progress the project intends to make within a given field in relation to the state of the art and demonstrate that as far as it is aware there will not be inappropriate duplication, whether partial or total, between projects and activities already carried out at EU and international level: **MAX 10 POINTS**.
3. The extent to which the proposal is likely to **boost scientific cooperation** between EFSA and MS, and at EU level, in particular (total **MAX 20 POINTS**):
    a. consortium size: for any additional consortium member beyond the mandatory 2 members, 3 additional points, up to a maximum of 15 additional points: **MAX 15 POINTS**; and;

b. consortium geographical coverage - applicants must ensure that the geographical coverage of the project is commensurate with its objectives, and as well explain the reasons for choosing their partners, including their role (e.g. if knowledge transfer is foreseen by including less experienced partners in the project): **MAX 5 POINTS**.

4. **Project planning**, including project phases, timeline, milestones, output and deliverables, providing a Gantt chart: **MAX 10 POINTS**.
5. **Task distribution** among consortium partners and individual team members; also communication both internally (i.e. within the consortium/team) and externally (with EFSA and stakeholders): **MAX 10 POINTS**.
6. Adequacy of the **dissemination strategy (**illustrating the envisaged dissemination tools, including what, how, when, to whom and why to be disseminated, and methodology to ensure transferability of results and sustainability of dissemination) and impact on **target groups** (in particular, the long term effect/s and **potential multiplier effect/s,** such as replicable, transferable and sustainable activities): **MAX 10 POINTS**.
7. Description of **identified risks** and proposed **mitigating actions**, if any: **MAX 5 POINTS**.
8. Description of **specific quality assurance measures** proposed for the project to guarantee high quality of output/deliverables: **MAX 5 POINTS**.
9. **Cost effectiveness**: proper justification demonstrating that the expected added value of the project can be achieved efficiently within the proposed cost of the project: **MAX 5 POINTS.**
10. **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, compliance with EFSA's rules on eligibility of costs: **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 criteria (1, 2, ~~3~~, 4 and 5), score at least half of the points attributed to each criterion.

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

2.6 PROCESS FOLLOWING THE ASSESSMENT AGAINST AWARD CRITERIA

EFSA reserves the right to invite applicants on the reserve list per lot, following their ranking on the reserve list, to adapt their proposal based on the evaluators' comments only if such adjustments imply a non-substantial change to the application. In the case some applicants fail to adapt the proposal, EFSA reserves the right to reject the co-funding of that project.

Overall, EFSA has currently available under this Call 1.125.000 Euro. EFSA intends to fund more proposals following this Call. The currently available amount of 1.125.000 Euro shall be sufficient to co-finance at least one successful project per lot. 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 i.e. if the submitted proposals do not meet the set award criteria thresholds (2.5 Award Criteria). In such case EFSA reserves the right to re-distribute funds from one lot to another lot that has more than one successful proposal (i.e. proposals which have satisfied the quality thresholds and are ranked in a reserve list). If more than one proposal is proposed for award under a given lot, the evaluation committee should assess and confirm that there is no duplication of scope.*
- *to award more grants in cumulative value above 1.125.000 Euro in case additional funds will be made available in 2016 EFSA budget. In such case EFSA reserves the right to distribute the additional funds to the lot(s) that has/have more than one successful proposal(s) (i.e. proposals which have satisfied the award criteria thresholds and are ranked in a reserve list). In case more than one lot has more than one successful proposal then the highest ranked proposal(s) across all lots will be proposed for award. If more than one proposal is proposed for award under a given lot, the evaluation committee should assess and confirm that there is no duplication of scope.*

Award decision: If more than one proposal is proposed for award under a given lot, the evaluation committee should assess and confirm that there is no duplication of scope and this should be reflected in the award decision. Following the successful conclusion of the adaptation phase, the award decision will be taken by EFSA.

The applicants will be notified, once the evaluation has been finalized, whether they are proposed for grant award or not.

Subsequently, the grant agreement will be prepared based on the draft grant agreement in the Annex II.

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.

If an applicant wishes to apply for more than one lot, a separate proposal should be submitted for each lot.

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 partner/s accepts 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 SUBMISSION MODALITIES

Proposals can be submitted as indicated in the second page of this document in the Indicative procedure timetable (Call for Proposals and guide for Applicants).

3.4 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

Applicants should note that in the event that their proposal is successful, the resulting grant agreement will be based on the model annexed to this call for proposals. EFSA reserves the right to modify the draft grant agreement prior to signature in order to incorporate updated terms & conditions.

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