

CALL FOR PROPOSALS

AND GUIDE FOR APPLICANTS

Call reference: EUBA/EFSA/2024/FEEDCO/01

Call title: Role of nitrate/nitrite and of processing and storage in the *N*-nitrosamine formation in certain

foods

Restricted to **the list of competent organisations** established by the Authority's Management Board in application of article 2 the Commission Regulation (EC) No 2230/2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organisations operating in the fields within the Authority's remit.

Brief description of the call objectives: *N*-nitrosamines are genotoxic and carcinogenic compounds occurring in food. Their formation has been linked to the presence of nitrates and nitrites in food, mainly in processed food products. The EFSA's evaluations on nitrates and nitrites as food additives and on *N*-nitrosamines in food indicated the need for further studies, with known ingoing amounts of nitrates/nitrites added, on the levels of N-nitrosamines formed in different processed meat products and in foods other than processed meat as well as in all products when cooked in different ways (CONTAM Panel, 2023). The present call seeks to address these recommendations by asking interested parties to analyse nitrates, nitrites and *N*-nitrosamines at least in processed and unprocessed meat, fish, cheese and leafy vegetable food model products under different cooking type and storage conditions. The objective of this call is to investigate possible correlations between nitrates/nitrites and nitrosamines, and the role of cooking and storage on nitrosamine formation.



INDICATIVE PROCEDURE TIMETABLE

Milestone	Date ¹	Comments
Launch date	04/07/2024	Date of call publication on EFSA's website.
Deadline for applicants to raise clarification questions to EFSA	21/11/2024	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	23/11/2024	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	28/11/2024 At 17:00 (CEST)	Applicants can submit proposals by following the instructions in section 3.1 of this call for proposals. All applications must be submitted through the EU Funding and Tenders portal, following the instructions provided. Hard copy paper applications will not be accepted.
Notification of the evaluation results	February 2025	Estimated Attention: outcome of the present call will be communicated to all applicants to the e-mail address indicated in their proposal. Accordingly, applicants who have submitted proposals under the present call are strongly invited to check regularly the inbox in question.
Grant agreement signature	March 2025	Estimated

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 $^{^{\}mbox{\scriptsize 1}}$ All times are in the time zone of the country of the EFSA.



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ANNEXES

Annex 1: Draft grant agreement

<u>Documents to be submitted with proposals (to be downloaded from the EU Funding and Tender portal Submission Service, see section 2 'Selecting proposal')</u>:

Annex 2: Administrative Declaration

Annex 3: Declaration on honour on exclusion criteria

Annex 4: Declaration on honour on selection criteria

Annex 5: Selection criteria template

Annex 6: Award criteria template



1. GRANT OPPORTUNITY AND CONDITIONS²

1.1 LEGAL FRAMEWORK

Article 36 (1) of the Regulation (EC) 178/2002³ of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, 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 by the coordination of activities, the exchange of information, the development and implementation of joint projects⁴, as well as the exchange of expertise and best practices in the fields within the Authority's mission. The list of competent organisations designated by the Member States, which may assist EFSA with its mission, is approved and regularly updated by EFSA's Management Board. The full list of Article 36 organisations can be found here.

EFSA's founding regulation was amended by Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain.

The Commission Regulation (EC) 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of the European Parliament and Council Regulation (EC) 178/2002 with regard to the network of organisations operating in the fields within the EFSA's mission specifies in Article 4 that tasks may be entrusted by the Authority to organisations on the list of competent organisations.

The present call specifically focuses on the below tasks defined in Article 4(3):

- Collecting and analysing data with a view to facilitating risk assessment by the Authority, including
 assessment tasks in the field of human nutrition in relation to Community legislation, especially
 the compiling and/or processing of scientific data on any substance, treatment, food or feed,
 preparation, organism or contaminant which may be linked with a health risk, and the collection
 and/or analysis of data on the exposure of Member States' populations to a health risk associated
 with food or feed;
- 2. Producing scientific data or works contributing to the risk assessment tasks, including assessment tasks in the field of human nutrition in relation to Community legislation, for which the Authority is responsible; this type of task must correspond to precise problems identified in the course of the work of the Authority, and in particular that of its Committee and permanent Scientific Panels, and must not duplicate Community research projects or data or contributions which it is the industry's duty to provide, especially in the context of authorisation procedures.

Article 5(2) of the Commission Regulation (EC) 2230/2004⁵ of 23 December 2004 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 proposals and guide for applicants (hereinafter referred to as "the Call") is procedurally governed by Title VIII of Regulation (EU, Euratom) 2018/1046 of the European

² The applicant is reminded that this Call and guide for applicants contains a selection of the most important conditions for the grant implementation. For the full set of conditions, the applicant is invited to consult the draft grant agreement in Annex 1 of this Call.

³ http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF

⁴ Project is frequently referred to in this Call as "action", in line with EU Financial Regulation terminology.

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



Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union.

This call is based on EFSA Founding regulation⁶ and EFSA's 2024 Work Programme for grants and operational procurements as presented in Annex XII of the Programming Document 2024-2026, available on the EFSA's website⁷.

1.2 BACKGROUND AND OBJECTIVES OF THE CALL

BACKGROUND

N-nitrosamines are genotoxic and carcinogenic compounds occurring in food. Their formation has been linked to the presence of nitrates and nitrites in processed food, particularly in meat products. However, N-nitrosamines might also be formed in processed leafy vegetables characterized by high levels of nitrite [1-3], especially if stored under acidic conditions; in processed fish, especially those with added nitrate as a food preservative (up to 500 mg/kg) [4-5] and those characterized by high concentration of free secondary amines; in ripened cheese, especially cheese with added nitrate as a food preservative and long period of ripening. Moreover, some authors [6-10] reported that particular types of cooking such as frying and grilling, seem to cause an increase of N-nitrosamines levels, even in food with no added nitrite/nitrate.

The European Food Safety Authority (EFSA) Panel on Food Additives and Nutrient Sources added to Food (ANS Panel), in 2017, has re-evaluated potassium nitrite (E 249) and sodium nitrite (E 250) and sodium nitrate (E 251) and potassium nitrate (E 252) [11-12] for their use as food additives. The opinions recommended the need for further studies on the levels of nitroso-compounds formed in different meat products with known ingoing amounts of nitrates /nitrites, with appropriate controls and with specified levels of detection (LOD) and levels of quantification (LOQ) for potentially formed nitroso-compounds, focusing in particular on *N*-nitrosamines.

The EFSA Panel on Contaminants in the Food Chain (CONTAM Panel), in 2023, assessed the risk to public health of the presence of N-nitrosamines in food and identified the need for data collection on N-nitrosamines in processed meat and in other foods than processed meat and of products cooked in different ways, with and without the addition of nitrate and nitrite [13].

Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives⁸ and the Commission Regulation (EU) 2023/2108 of 6 October 2023 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards food additives nitrites (E 249-250) and nitrates

⁶ Regulation (EC) 178/2002 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, as amended by Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain.

https://www.efsa.europa.eu/sites/default/files/2024-01/programming-document-2024-2026.pdf

 $^{^8}$ Regulation (EC) 178/2002 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, as amended by Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain.



(E 251-252) 9 sets maximum amounts of nitrites and nitrates that may be added as food additives to certain foods. The aim is to minimize the risk of nitrosamine formation due to the presence of these additives in food, while also maintaining their effectiveness in preventing bacterial growth. However, data gaps hinder the understanding of the correlation between the levels of nitrates/nitrites and N-nitrosamines present in food as well as the effects of processing and storage on the formation of N-nitrosamines.

The FEEDCO Unit of EFSA is therefore launching the present call for the generation of data in the interest of reducing the identified data gaps.

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 9 Commission Regulation (EU) 2023/2108 of 6 October 2023 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards food additives nitrites (E 249-250) and nitrates (E 251-252)C/2023/6632OJ L, 2023/2108, 09.10.2023,



Lambrè C, Leblanc J-C, Lindtner O, Moldeus P, Mosesso P, Oskarsson A, Parent-Massin D, Stankovic I, Waalkens-Berendsen I, Woutersen RA, Wright M, van den Brandt P, Fortes C, Merino L, Toldrà F, Arcella D, Christodoulidou A, Cortinas Abrahantes J, Barrucci F, Garcia A, Pizzo F, Battacchi Dand Younes M. (2017). Scientific Opinion on the re-evaluation of potassium nitrite (E 249) and sodium nitrite (E 250) as food additives. EFSA Journal 2017;15(6):4786, 157 pp. https://doi.org/10.2903/j.efsa.2017.4786

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OBJECTIVES OF THE CALL

This call for proposals seeks to address the EFSA Panels' recommendations [11-13]. The beneficiary will be required to analyse nitrates, nitrites and N-nitrosamines in processed and unprocessed food model products under different cooking types and storage conditions. The objective of this call is to analyse the obtained results to investigate possible correlations between nitrates/nitrites and N-nitrosamines, and the role of cooking and storage on N-nitrosamine formation.

1.3 TASKS, DELIVERABLES, TIMELINES, MEETINGS AND PAYMENTS

Role of nitrate/nitrite and of processing and storage in the N-nitrosamine formation in certain foods			
Work Package	Tasks	Deliverables	Deadlin e
WP 1	Task 1: Defining food model products and a detailed project plan to assess the relationship/correlation of nitrite/nitrate use, product formulation, cooking, processing and storage conditions on the formation of N- nitrosamines Subtask 1a.	Deliverable 1: Provide a single report containing relevant information for each sub- task: Deliverable 1a: A proposed list of model products of interest to be analysed for the presence of nitrates/nitrites and nitrosamines before and after treatments and storage. Relevant and widely consumed products in the EU should be selected based on	2 months from kick-off meeting



Identify and suggest model products including:

- 1) products falling within food categories permitted to contain nitrates/nitrites. This should include products with and without the addition of nitrates/nitrites, covering:
- meat (including but not limited to sausage, bacon, ham and cooked ham);
- fish (pickled herring and sprat); and
- cheese (hard, semi-hard and semisoft ripened products).

Select a range of known amounts of nitrates/nitrites to be added, including levels similar to the most recent limits set in the Commission Regulation (EU) 2023/2108.

- 2) products falling under the categories of:
- fresh meat, fish of different species and treated with formulations, with special focus on the use of spices. No nitrite and nitrate are anticipated to be added in these products;
- Leafy vegetable products, with special focus on "fresh-cut" and frozen products.

Propose cooking types and standard heat-treatment conditions to be applied during cooking for the suggested model products.

Propose standard product storage conditions for the suggested model products.

Subtask 1b. Provide a detailed project plan for Tasks 2-4, including information on sampling, the analytical methods to be used, the number and type of *N*-nitrosamines to be tested and relevant timelines.

experience and on data provided in the EFSA Comprehensive European Food Consumption Database.

The conditions of treatment (e.g. nitrate/nitrite addition, heat, storage) should be defined based on most widespread practices in Europe and the literature.

Deliverable 1b: Provide detailed information on the project plan for performing Tasks 2-4, including information on:

- the sampling plan and the statistical design implemented in the analysis of the samples;
- the analytical methods, their validation and the equipment to be used;
- the number and type of Nnitrosamines to be tested including at least

N-nitrosodimethylamine and N-nitrosodiethylamine and N-nitrosopyrrolidine and as many as



	Task 2: Development of model products and sampling Prepare the model products and obtain the samples for the analysis as proposed above.	possible from the 10 carcinogenic <i>N</i> -nitrosamines found in food [13] • a Gantt chart on the relevant timelines Deliverable 2: Provide the protocols for the model products preparation, the sampling plan, and the sampling storage conditions.	8 months from kick-off meeting
WP 2	Task 3: Selection, optimisation and verification of the analytical methods for the measurement of nitrates/nitrites/N-nitrosamines. Select, optimise and verify extraction and analytical methods with the highest achievable sensitivity (lower best feasible LOQ) and provide evidence of analytical performances, in particular for the detection of N-nitrosamines, with limits of detection, expressed as concentration in matrix appropriate for the matrices similar to the model products to be analysed. Regarding nitrite and nitrate determination, analytical techniques able to simultaneously detect nitrite and nitrate, directly, will be preferable.	Deliverable 3: Provide an interim report with the results of the performance parameters and the data collected until this point and an updated timeline for the completion of the data analysis.	16 months from kick-off meeting
WP 3	Task 4: Sample processing and analytical measurements Extract and analyse nitrates/nitrites and N-nitrosamines from the samples proposed.	Deliverable 4: Provide the protocols for sample processing and for chemical analysis. Provide also the parameters measured for analytical performances and methods used for quality assessment.	25 months from kick off meeting
WP 4	Task 5: Data analysis and reporting Compile and present the data on appropriate data analysis tools. Characterise the measurements and results and the uncertainty of the measurements and provide appropriate statistical data analysis.	Deliverable 5a: Provide a draft final report with the following information and annexes containing the relevant information for each sub-task. The report should address the comments and suggestions made by EFSA during the previous tasks. The changes to the draft final report proposed by the beneficiary to address EFSA's comments are to be discussed in the final meeting. Following the final meeting, the beneficiary has 1 month to submit the final version of the report. The report to be provided as Word document should contain the following elements:	28 months from kick off meeting



- Presentation of the data in a clear and organised manner. This should include tables, graphs and figures.
- The method performances and related statistical parameters.
- Descriptive statistics (mean, standard deviation, etc.) to summarise the data.
- Annexed Excel spreadsheets with the raw and clean data used for analysis. Submission of the data should be provided in a structured data model agreed with EFSA and based as much as possible on EFSA's SSD2 (Standard Sample Description version 2) and EFSA's standard controlled terminologies (for more information
 - https://www.efsa.europa.eu/en/e fsajournal/pub/3424
 - https://zenodo.org/record/75902 16#.Y NCWXbMKUk
- Discussion of the obtained results and related uncertainties focusing on the relationship between nitrates/nitrites and N-nitrosamines and the effect that processing and storage may have on the levels of the individual compounds and their relationship.
- Proposal for eventual models to predict correlations between the parameters measured.

Deliverable 5b: Provide the final report taking into consideration the EFSA comments together with a detailed presentation that covers all aspects of the project.

30 months from kick off meeting

Subcontracting is allowed for non-core tasks only. Core tasks for this project are: Task 1 - 5. Please also refer to section 1.7 'Possibility of implementing contracts and subcontracting'.



No.	Meetings	Deadline for finalisation
1	Kick-off meeting 1: half day / physical meeting in Parma The kick-off meeting is regarded as the start of the project and must take place no later than 1 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, deliverables and timeframe will be clarified. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary. The presence at the kick-off meeting of a beneficiary's staff member responsible for administrative/finance issues of the project is advised as this will facilitate understanding by the beneficiary of the grant principles, related financial reporting requirements and significantly ease the financial management of the grant agreement, both for EFSA and the beneficiary.	1 month from signature of the grant agreement
2	Interim meeting 2: half day / teleconference The purpose of this meeting is to discuss Deliverable 1 as well as any problems or difficulties encountered during the conduct of the project. The beneficiary should provide a presentation of the project addressing the Deliverable 1 (the objectives, the methodology, the model products etc.) Minutes of the meeting shall be taken and provided to EFSA by the beneficiary maximum two weeks after the meeting.	3 months from kick-off meeting
3	Interim meeting 3: half day / teleconference The purpose of this meeting is to discuss Deliverable 2 as well as any problems or difficulties encountered during the conduct of the project. The beneficiary should provide a presentation addressing the Deliverable 2. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary maximum two weeks after the meeting.	9 months from kick-off meeting
4	Interim meeting 4: half day / teleconference The purpose of this meeting is to discuss Deliverable 3 as well as any problems or difficulties encountered during the conduct of the project. The beneficiary should provide a presentation addressing the Deliverable 3. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary maximum two weeks after the meeting.	17 months from kick-off meeting
5	Interim meeting 5: half day / teleconference The purpose of this meeting is to discuss the status of the work on the data collection, any preliminary results of deliverable 4 as well as any problems or difficulties encountered during the conduct of the project. The beneficiary should provide a presentation addressing the Deliverable 4. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary maximum two weeks after the meeting.	21 months from kick-off meeting
6	Interim meeting 6: half day / teleconference The purpose of this meeting is to discuss Deliverable 4 as well as any problems or difficulties encountered during the conduct of the project. The beneficiary should provide an updated presentation addressing the Deliverable 4. Minutes of the meeting shall be taken and provided to EFSA by the beneficiary maximum two weeks after the meeting.	26 months from kick-off meeting
7	Final meeting 7: half day / physical meeting To discuss draft final report as required in Deliverable 5a. The beneficiary should provide an updated presentation addressing the Deliverable 5a. Comments to Deliverable 5a proposed by EFSA are to be applied to the final version of Deliverable 5b.	29 months from kick-off meeting
No.	Payments	Linked to EFSA approval of deliverable No.
1	Pre-Financing payment of 30% as specified in articles I.4.1 and I.5.2 of the draft grant agreement (Annex 1 of the call for Proposals).	NA
2	Interim payment , of 20% as specified in articles I.4.3 and I.5.3 of the draft grant agreement (Annex 1 of the call for Proposals).	3



3	Payment of the balance as specified in article I.4.4 and I.5.4 of the draft	5h
3	grant agreement (Annex 1 of the call for Proposals).	30

Deliverables must be drafted in English and may be subject to publication at EFSA's discretion.

Please note that all reporting, minutes, outcome of the discussions could be shared at EFSA's discretion to EFSA's Scientific Panels and Working Group members. The final report will be published as might be other grant deliverables, subject to the terms and conditions set out in the draft grant agreement (Annex 1 of the call for proposals).

1.4 INFORMATION ON THE GRANT AGREEMENT

Applicants should note that the draft grant agreement is published with the call for proposals. If any applicant should have specific comments on the provisions of the draft grant agreement, these must be raised in a clarification, prior to the deadline for receipt of proposals so that a clear and transparent reply may be published for the benefit and information of all applicants.

The total amount EFSA has available to award grants under this call for proposals is € 750.000. Applicants should note that in the Funding and Tender opportunities portal submission service under Administrative Form (Part A) there is an obligatory field regarding the budget (section 3). Applicants must insert the total budget in the 'Requested grant amount' field.

1.4.1 Direct Agreement

This Call for proposals aims to conclude a Direct Agreement for the performance of the tasks described in these specifications for a fixed duration. The Agreement can be signed between the Authority and one or several partners.

The maximum duration of this Direct Agreement is 30 months from the kick-off meeting.

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 reserves the right not to award any grant and/or 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.

1.5 ELIGIBLE ORGANISATIONS

To be eligible, applicants 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 regularly updated by EFSA Management Board and is available for consultation using this link https://efsa.force.com/competentorganisations/s/.

In order to achieve the main objective of the call, proposals 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 (consortium leader) is responsible for identifying consortium partners.

1.6 ROLES AND RESPONSIBILITIES

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

Proposals submitted by a sole applicant:



• **The Applicant** submits the proposal to EFSA. There can be only one applicant in the proposal.

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 becomes Annex 1 of the grant agreement.

The beneficiary:

- Communicates with 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 to EFSA;
- Informs EFSA 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.

Proposals submitted by consortium:

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

Once the grant is awarded, the grant agreement is signed between EFSA and the applicant (leading entity of the consortium).

Partners do not sign the grant agreement directly but instead sign a mandate (template provided by EFSA) authorising the applicant to sign the grant agreement and any future amendments on their behalf.

As soon as the grant agreement is signed, the applicant becomes the Coordinator and partner/s become co-beneficiary/ies. The coordinator and co-beneficiary/ies are 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 becomes Annex 1 of the grant agreement. If a beneficiary fails to implement its part of the project, the other beneficiaries become responsible for implementing that part.

The coordinator has the following important roles:

- Takes part in implementing the project;
- Monitors the action is implemented properly;
- Act as intermediary for communication between the consortium and EFSA;
- Receives and answers all claims EFSA might have in relation to implementation of the project;
- Requests and reviews any documents or information required by EFSA and verifies their completeness and correctness before passing them to EFSA;
- Informs EFSA and the partner/s of any event that is likely to substantially affect 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.

The other beneficiary/ies:

- · Take part in implementing the project;
- Forward to the coordinator the data needed to draw up 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.

1.7 IMPLEMENTING CONTRACTS AND SUBCONTRACTING

Implementation contracts:

Where the implementation of the project requires the award of procurement contracts (implementation contracts), e.g. purchase of services and/or goods or equipment necessary for the implementation of the action, the beneficiary must award the contract to the entity offering the best value for money or the lowest price (as appropriate), avoiding conflicts of interests. The beneficiary is expected to clearly document the tendering procedure and retain the documentation for the event of an audit.

Entities acting in their capacity as contracting authorities within the meaning of Directive 2014/24/EU¹⁰ must comply with the applicable national public procurement rules.

Sub-contracting:

Sub-contractors are not consortium partners and are not party to the grant agreement. They do not have any contractual relationship with EFSA. Subcontractors are entities contracted by the beneficiary to carry out some specific tasks or activities. Subcontracting is allowed under these conditions:

- Core tasks must not be subcontracted. Only ancillary and assistance tasks can be subcontracted.
- Subcontracts must be awarded to the entity offering best value for money or the lowest price (as appropriate), avoiding conflicts of interests;
- Subcontracting must only cover the implementation of a limited part of the action;
- Recourse to subcontracting must be justified having regard to the nature of the project and what is necessary for its implementation;
- Tasks to be subcontracted must be identified in the proposal and be approved by EFSA before the signature of the grant agreement;
- Recourse to subcontracting during project implementation, if not envisaged from the outset in the proposal, is subject to prior authorisation in writing by EFSA, and must be formalised via an amendment to the grant agreement. Approval may be granted as long as it does not entail a change to the grant agreement which would call into question the decision awarding the grant or be contrary to the equal treatment of applicants;
- The conditions applicable to the beneficiaries under Articles II.6 (*Confidentiality*), II.7 (*Processing of Personal Data*), II.8 (*Visibility of Union Funding*) of the grant agreement are also applicable to the subcontractor.

-

Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, p. 65-242)



1.8 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:

The form of grant awarded under this Call is based on financing not linked to the costs of the relevant operations in accordance with Article 125 (1)(a) of the EU Financial Regulation. Grants financed in this way require the fulfilment of conditions set out in sector specific rules of Commission decisions or the achievement of results measured by reference to previously set milestones or through performance indicators.

The present call for proposals comes with an innovative and simplified grant management, where the grant amounts paid to the partner are based on the pre-defined sums which are not linked to the actual costs of the action. This means there is no need for co-financing from the partner, and no need for completion of estimated budgets or timesheets to record the work. The agreed sums are set at a level designed to stimulate the mutually convenient partnership creation. The payment of agreed sums from EFSA will be carried out based on the acceptance by EFSA of the delivered work. If you have questions on this grant form, during the application period, please raise any clarification questions to EFSAProcurement@efsa.europa.eu.

The financial support 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 certain grant principles established in the EU Financial Regulation, specifically:

• **Non-retroactivity**: A grant may be awarded for a project which has already begun only where the applicant can demonstrate in the grant application the need to start the action before the grant agreement is signed. In accordance with Article 193 of the Financial Regulation. The tasks entrusted by EFSA should not be performed before the signature of the grant Agreement.

Article 180(3) of the EU Financial Regulation specifically states that **the following grant principles are NOT applicable** where the grant takes the form of financing not linked to the costs pursuant to article 125(1)(a):

- **Co-financing**: In accordance with Article 190 of the Financial Regulation, grants shall involve co-financing.
- **No-profit**: In accordance with Article 192(3)(d) of the Financial Regulation, grants shall not have the purpose or effect of producing a profit within the framework of the project for the applicant or partner.
- **Non-cumulative**: In accordance with Article 191(3) of the Financial Regulation, in no circumstances shall the same costs be financed twice from the EU budget.

1.9 ESTIMATED BUDGET AND ELIGIBLE COSTS

Not applicable.

1.10 PUBLICITY

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



According to Article 38 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

1.11 PROTECTION OF PERSONAL DATA IN RELATION TO GRANT PROCEDURES

Processing of personal data by EFSA

Information on the processing of personal data by EFSA in the context of this grant procedure is available in the <u>Privacy Statement</u> on the EFSA website as well as in Article II.7 of the draft grant agreement. Any personal data included in the Agreement must be processed by EFSA in accordance with Regulation (EU) No 2018/1725.¹¹

Applicants should note that personal data as applicant or selected beneficiary may be registered in the Early Detection and Exclusion System (EDES) if you are in one of the situations mentioned in Article 136 of the Financial Regulation. For more information see the Privacy Statement on: http://ec.europa.eu/budget/explained/management/protecting/protect_en.cfm#BDCE).

Processing of personal data by the beneficiary

In case the implementation of activities under the grant agreement resulting from this call entails the processing of personal data, the beneficiary shall comply with the relevant rules in Article II.7.2 of the Grant Agreement (Annex 1) as a data processor of EFSA.

1.12 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.

1.13 OPEN ACCESS

EFSA is committed to the publication of grant output as External Scientific Reports and, if applicable in the Knowledge Junction, in order to improve transparency, reproducibility and evidence reuse. The Knowledge Junction runs on the EU-funded Zenodo research-sharing platform where uploaded items receive a unique Digital Object Identifier to make them citable. Any part of the output resulting from the action under this grant may be published (at EFSA's discretion) on the Knowledge Junction with attribution to the beneficiary.

The publication by the beneficiary of the output resulting from the action under this grant in scientific journals is also encouraged, following prior consultation and agreement with EFSA.

Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC



1.14 HUNGARIAN PUBLIC INTEREST TRUSTS ESTABLISHED UNDER HUNGARIAN ACT IX OF 2021

Following the Council Implementing Decision (EU) 2022/2506, as of 16th December 2022, no legal commitments (including the grant agreement itself as well as subcontracts, purchase contracts, financial support to third parties etc.) can be signed with Hungarian public interest trusts established under Hungarian Act IX of 2021 or any entity they maintain.

Affected entities may continue to apply to calls for proposals. However, in case the Council measures are not lifted, such entities are not eligible to participate in any funded role (beneficiaries, affiliated entities, subcontractors, recipients of financial support to third parties).



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 (2.1)
- 2. Eligibility criteria (2.2)
- 3. Exclusion criteria (2.3)
- 4. Selection criteria (2.4)
- 5. Award criteria (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:

- proposal was submitted within the deadline for submission of proposals;
- administrative data for grant application form is duly signed by the authorised representative of the applicant;
- proposal is complete and includes all the supporting documents.

2.2 ELIGIBILITY CRITERIA

Criterion No. 2.2	Requirements and requested evidence	
1	Eligibility criteria	
	The following requirements will be verified:	
	 At the day of deadline for submission of proposals, 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; 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. 	
	Requested evidence:	
	ADMINISTRATIVE DECLARATION Annex 2 of this Call for Proposals, available to download in the Funding and Tenders Portal under Part B Templates. The applicant and partner(s) (if applicable) must complete and sign the form. The applicant must upload the signed form in the relevant field under Part B and Annexes of the Funding and Tenders Portal.	



2.3 EXCLUSION CRITERIA

Criterion No. 2.3	Requirements and requested evidence	
2	Exclusion criteria	
	The following requirements will be verified:	
	The applicant and partner/s must sign a declaration on their honour certifying they are not in one of the exclusion situations referred to in the Articles 136-140 of EU Financial Regulation.	
	Requested evidence:	
	THE DECLARATION ON HONOUR ON EXCLUSION CRITERIA Annex 3 of this Call for Proposals, available to download in the Funding and Tenders Portal under Part B Templates. The applicant and the partner(s) (if applicable) must complete and sign separate forms. The applicant must upload the form in the relevant field under Part B and Annexes of the Funding and Tenders Portal. If applying in consortium, the consortium leader must convert all declarations on honour on exclusion for all partners into one single pdf and upload the single document in the relevant field under Part B and Annexes of the Funding and Tenders Portal.	

2.4 SELECTION CRITERIA

A) Financial capacity

Criterion No. 2.4A	Requirements and requested evidence
1	Financial capacity
	The purpose of the selection criteria is to verify the financial capacity of the applicant and in case of consortium also of its partner/s.
	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 If the Authority considers that financial capacity is weak, it may:
	 request further information; decide not to give pre-financing; decide to give pre-financing paid in instalments; decide to give pre-financing covered by a bank guarantee; where applicable, require the joint and several financial liability of all the cobeneficiaries.
	If EFSA considers that the financial capacity is insufficient, the application may be rejected.
	Requested evidence:
	Documents to be provided by the applicant:



DECLARATION ON HONOUR ON SELECTION CRITERIA

Annex 4 of this Call for Proposals, available to download in the Funding and Tenders Portal. Only the applicant (or consortium leader if applicable) is required to complete and sign the form. The applicant must upload the form in the relevant field under Part B and Annexes of the Funding and Tenders Portal.

• **SIMPLIFIED FINANCIAL STATEMENT** available here
only required for private bodies if the grant requested from EFSA is >60.000 €. The template published with the Call should be completed for at least the last two closed financial years.

AUDIT REPORT

only required for private bodies if the grant requested from EFSA is >750.000 \in . In the event of an application grouping several applicants (consortium), the threshold applies to each applicant. If the audit report is not available AND a statutory report is not required by law, a self-declaration signed by the applicant's authorised representative certifying the validity of its accounts for the last 2 years available must be provided.

The audit report should be produced by an approved external auditor certifying the accounts for the last two years available, where such an audit report is available or whenever a statutory report is required by law.

The authorising officer responsible may, depending on a risk assessment, waive the obligation of providing an audit report for education and training establishments, and in the case of agreements with several beneficiaries, for applicants who do not bear any financial responsibility or who have accepted joint and several liabilities.

• LETTER OF COMMITMENT:

applicable only when another 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.

The applicant must convert the **Declaration on honour on selection criteria, the Simplified Financial statement (if applicable) and the letter of commitment** (if applicable) into one single pdf and upload the single document in the relevant field under Part B and Annexes of the Funding and Tenders Portal.

B) Professional and operational capacity

Criterion No. 2.4.B	Requirements and requested evidence
1	Professional and operational capacity:
	Requirements:
	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: 1. Requirements for the organisation: The applicant should provide evidence of expertise of the organisation in the field of the analysis of chemicals, preferably contaminants and food additives, in food, and publication in peer-reviewed journals of the research outputs.
	2. Requirements for the team of experts:



Experts involved in the tasks should include:

- a. At least one senior researcher with at least 7 years of experience in the field of chemical analysis, preferably contaminants and food additives, and with experience in managing European research projects. The senior researcher will have the responsibility of ensuring high scientific standards of the methods used in the quality of the project outputs in due time.
- b. At least one post-doctoral researcher, with a at least 3 years of experience in a relevant field (e.g. chemical analysis, preferably *N*-nitrosamines) which will support the senior researcher in the scientific supervision of the project, who can closely supervise the researchers in charge of the data production, and that may lead/supervise the data analysis activities.
- c. At least one project manager, which will oversee the practical and administrative aspects of the work and to ensure timely implementation of the activities, with experience in implementation of similar projects (e.g. international EU-funded projects)
- d. A sufficient number (at least 3) of researchers (e.g. PhD students, research assistants, or post-doctoral researchers) with experience in chemical analysis and food technology to undertake the sample production and chemical analysis activities. A larger number may be suggested depending on the extent of the products to be analysed.
- e. The Team coordinator and the Work Package Leaders should have a very good level of spoken and written English. For non-native speakers, this should be demonstrated by an official certificate proofing at least level B.2 of the Common European Framework of References for Languages; or at least 2 years of work/study in an English-speaking environment where English is used for meetings, communications and producing written reports and scientific publications OR at least 3 years of experience working in international projects where English is the working language.

3. Requirements for operational capacity:

Expertise, equipment and infrastructure required to carry out analyses or tests and sufficient number of suitably qualified, trained and experienced staff in chemical analysis and food processing, Standard Operational Procedures, ISO certification.

4. Environmental management (the answers to this section are for information purposes and will not be considered under any criteria, neither selection nor award criteria):

Environmental protection is an integral part of EFSA's governance. EFSA has established, implemented and maintains a certified environmental management system in accordance with the international standard ISO 14001 and the European EMAS regulation. Environmental impacts of EFSA's activities are identified, managed and monitored in order to improve environmental performance. This commitment to environmental sustainability requires us to consider a life-cycle perspective when purchasing our services.

For this reason, we are asking you some information on the environmental management of your activities, to be provided filling in **Annex 5 of the Call for Proposals** (Selection criteria - Information on environmental management).

Requested evidence:



• EVIDENCE REQUESTED FOR REQUIREMENT 1:

A list of 5 relevant peer-reviewed publications, published in the last 10 years, on chemical analysis should be provided. References related to the chemical analysis of nitrates/nitrites and in particular *N*-nitrosamines are considered more relevant for the purposes of this project.

• EVIDENCE REQUESTED FOR REQUIREMENT 2:

CURRICULUM VITAE of the experts and other staff to be involved in the project, including a brief description of the expertise and a list of publications relevant to the project for each person proposed. If individual team members are not yet assigned for the proposed project, applicants should provide details of the staff profiles necessary for the project.

LIST OF PROJECT TEAM MEMBERS NAMES AND ROLES – In addition to the CV's of each team member, the applicant should also summarise on one page, the names of the individual project team members and the expected role of the team member in the project.

EVIDENCE REQUESTED FOR REQUIREMENT 3:

A combination of documentation, records, and certifications to provide evidence of expertise, staff qualifications, equipment, infrastructure, SOP adherence, and ISO certification.

• EVIDENCE REQUESTED FOR REQUIREMENT 4:

Annex 5 - Selection criteria, Information on environmental management

For requirements 1-4 a template (Annex 5) is available to download in the Funding and Tenders Portal. The applicant must upload the completed template (a single pdf document of all requirements including CVs), in the relevant field under Part B and Annexes of the Funding and Tenders Portal.

INDIVIDUAL DECLARATION OF INTERESTS

Template available here. EFSA may request Individuals DoIs for members of the project team having influence and/or control over scientific outputs, prior to and as a condition of grant agreement signature. The requirement to submit Individual DoIs will be specified in the award letter and will have to be provided and validated by the EFSA Authorising Officer before and as a condition of grant agreement signature. here to EFSA's policy on independence and the Decision of the Executive Director on Competing Interest Management for more detailed information.

2.5 AWARD CRITERIA

Criterion No. 2.5

For the award criteria a template (Annex 6) is available to download in the Funding and Tenders Portal. The applicant must upload the completed template (a single pdf document of all criteria) in the relevant field under Part B and Annexes of the Funding and Tenders Portal.

The award criteria serve to assess the quality of the proposals in relation to the objectives of the Call. The applicant is requested to provide a document with the proposed workplan explaining in detail how each task will be addressed. The plan (including scientific approach, logistics and estimated timelines) should cover all Tasks. The plan should be realistic, scientifically sound and provide an overview of the timelines and logistics for



	proposed implementation of work. The proposal will be assessed in relation to the following award criteria:	
1	Work plan quality (MAX 40 POINTS): Overall quality of the workplan to undertake each task (recommended max 30 pages excluding annexes). The workplan should be scientifically sound, clear, feasible and include sufficient detail. It should include project phases, timelines, milestones, deliverables and GANTT chart as well as logistic details for project implementation. Risks and barriers foreseen in each task and respective proposed contingency plan in case of deviations should also be briefly described.	
2	 Scientific quality of the proposal (MAX 40 POINTS): The proposal needs to clarify how: Its operational capacity will be used to achieve the required deliverables with high scientific quality standards. Specify how personnel, equipment, and infrastructure will be allocated to different tasks within the project. (MAX 10 POINTS) Outline the quality assurance measures that will be implemented to ensure that all deliverables meet high scientific quality standards. (MAX 10 POINTS) Explain how the project's progress and performance will be monitored and evaluated throughout its duration. (MAX 10 POINTS) Highlight any plans for continuous improvement or refinement of operational processes based on lessons learned and feedback received during the project. (MAX 10 POINTS) 	
3	Project management and quality of the outputs: (MAX 20 POINTS) a. Project management and communication— overview how the project will be managed (if the project has multiple partners, how will be the project coordinated, task breakdown among partners) and which steps are taken to ensure timely delivery of outputs and smooth communication with EFSA (MAX 10 POINTS) b. Quality of communication, internal within the team (and in case of joint offers & subcontractors also the communication between joint offers partners and subcontractors) and external with EFSA; (MAX 5 points) c. Quality of risk management identification/mitigation and measures for quality assurance proposed for this particular project (including role of team leader / leading partner in quality assurance); (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.

Proposals which satisfy the quality threshold will be ranked in a reserve list. The reserve list will be valid for six months form the signature of the feedback letter.

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 on the reserve list or not.

EFSA reserves the right to invite the 1st ranked applicant on the reserve list, to adapt its proposal based on the evaluators' comments in accordance with article 200(5) EU Financial Regulation.

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 $1^{\rm st}$ ranked applicant fails to adapt its proposal, EFSA reserves the right to reject the proposal. 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 SUBMISSION MODALITIES

You must submit your proposal electronically via the <u>EU Funding & Tenders Portal</u> before the time limit for receipt of proposals (indicated on page 2 of this call). A webinar showing step-by-step the use of the EU funding and Tender Portal for Grant submission on a pilot EFSA call is available at <u>this link</u> (from minute 15:39 to minute 45:55).

Registration in the Participant Register

Applicants submitting a proposal must be registered in the Participant Register - an online register of organisations and natural persons participating in European Commission's calls for tenders or proposals.

On registering, each participant obtains a Participant Identification Code (PIC, 9 - digit number) which acts as its unique identifier in the Participant Register. A participant needs to register only once – the information provided can be further updated or re-used by the participant in other European Commission's calls for tenders or calls for proposals.

At any moment during the grant procedure the Research Executive Agency Validation Services (hereafter the EU Validation Services) may contact the participant and ask for supporting documents on legal existence and status.

The requests will be made through the register's messaging system to the e-mail address of the participant's contact person indicated in the register. It is the responsibility of the participant to provide a valid e-mail address and to check it regularly.

The documents that may be requested by the EU Validation Services are listed in the <u>EU Grants and Tenders Rules on Legal Entity Validation, LEAR appointment and Financial Capacity assessment</u>. Please note that a request for supporting documents by the EU Validation Services in no way implies that the grant application has been successful.

Submitting your proposal

The EU Funding & Tenders Portal allows applicants to respond to calls for proposals by preparing applications electronically in a structured and secured way and submitting proposals electronically.

To find more information on submitting your proposal, please read carefully the information on the page <u>Submit a proposal – electronic submission system</u>. On the same page useful links to the <u>User guide of the submission system</u> and an <u>FAQ on proposal submission</u> are provided.

Make sure you submit your application on time: you are advised to start completing your application early. To avoid any complications with regard to late receipt/non-receipt of applications within the deadline, please ensure that you submit your application several hours before the deadline. It is not possible to submit an application after the deadline.



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 (e.g. CVs) are required. These supporting documents are an integral part of the proposal. If these supporting documents are in a language other than English, to facilitate and speed up the evaluation, it would be appreciated if a reliable translation of the relevant parts of the documents into English is provided with the proposal.

3.3 EXPECTED DURATION OF PROCEDURE

In accordance with Article 194(2) of the Financial Regulation, the maximum time-limits for the procedure are as follows:

- All applicants will be informed of the decision regarding their application within 6 months of the deadline for submission of proposals.
- Signature of the grant agreement will take place within 3 months from the date the successful applicant/s has/have been informed of the decision on their application.