

Notice of call for expressions of interest

**Scientific and Technical Support in the areas
of Novel Foods & Nutrient Sources**

1. INTRODUCTION TO EFSA AS CONTRACTING AUTHORITY

CONTRACTING AUTHORITY:

European Food Safety Authority (EFSA)
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More information about EFSA can be found here: <http://www.efsa.europa.eu/>

2. LIST OF INDIVIDUALS FOR SCIENTIFIC AND TECHNICAL SUPPORT SCHEME

2.1 OBJECTIVE OF THE CALL

The objective of this call for expressions of interest is to establish a list of **individuals (natural persons) with scientific expertise** to assist EFSA in carrying out the preparatory work in the areas of **Novel Foods and Nutrient Sources** to deliver scientific outputs to risk managers.

Background Information

The safety assessment of **novel foods (NF)** (defined by EU legislation as “foods or ingredients that have not been used for human consumption to a significant degree in the EU before 15 May 1997”) and **nutrient sources (NS)** (e.g. sources of vitamins and minerals) is carried out by EFSA, particularly the Panel on Nutrition, Novel Foods and Food Allergens (NDA Panel) and its Working Group on Novel Foods, on the basis of the following regulatory framework:

- [Regulation \(EU\) 2015/2283](#) introduces a centralised assessment and authorisation procedure for novel foods. All applications for the authorisation of NFs shall be submitted to the European Commission (EC) who may then request EFSA to carry out a safety assessment.
- In the framework of [Directive 2002/46/EC](#) on food supplements, [Regulation \(EC\) No 1925/2006](#) on fortification of foods or [Regulation \(EC\) No 609/2013](#) on foods for specific groups, the EC may also request EFSA to carry out the safety assessment of the nutrient sources proposed for use in food supplements, fortified foods or foods for specific groups.

EFSA will adopt its opinion in 9 months¹ from the date of receipt of a valid application from the EC. The final output provided by EFSA on the safety of the concerned NF/NS serves as the scientific basis for the EC to take EU authorisation decision for the placing of the NF on the EU market, or for the use of the NS.

Data requirements for applications (technical dossiers) are outlined in EFSA Guidance:

- [Guidance on the preparation and presentation of an application for authorisation of a novel food in the context of Regulation \(EU\) 2015/2283.](#)
- [Guidance on safety evaluation of sources of nutrients and bioavailability of nutrient from the sources.](#)

¹ Excluding stop-the-clock times needed for requesting supplementary information to applicants.

2.2 FIELDS OF EXPERTISE SOUGHT & REQUIRED TASKS

Individuals are required to have **scientific expertise** for undertaking the following tasks **in the areas of Novel Foods and Nutrient Sources**, in particular:

The preparation of structured summary reports on **critical data** extracted from an application (dossier).

- (A) Check compliance of the application with EFSA/applicable guidance.
- (B) Critically analyse and review the data (studies) submitted in the application.
- (C) Extract critical data from the application, and from literature search where applicable. The data extracted should be factual, concisely summarising the overall data and key findings/study observations, indicating the relevance of critical data, highlighting uncertainties and inconsistencies identified and missing information. **The critical data extracted should be presented in a structured summary** according to EFSA Template (to be provided in the awarded contract).
- (D) On some occasions following the evaluation of the initially submitted application, there may be requests to applicants for submission of additional data/studies. In these cases, the individual(s) may be requested to carry out within the specified timeline the above-mentioned tasks for the additional data submitted.

The critical information should focus on **TOXICOLOGICAL data** that are relevant for the safety assessment of the NF/NS.

These data are submitted in the application, or are identified from additional literature search where applicable. They could relate to:

- Absorption, distribution, metabolism, and excretion (ADME studies)
- Bioavailability studies
- Genotoxicity studies
 - *In vitro* tests
 - *In vivo* tests
- General toxicity studies
 - Preliminary/Dose Range Finding studies
 - Subchronic toxicity - 90-day oral study
 - Chronic toxicity/Carcinogenicity studies
 - Reproductive/Developmental toxicity studies
- Other studies
 - Neurotoxicity
 - Immunotoxicity
 - Allergenicity
 - Other experimental and/or human studies (investigating safety parameters)

2.3 PROCEDURAL ASPECTS OF THE LIST

HOW THE LIST IS ESTABLISHED AND MAINTAINED

- The procedure has its legal basis in Art 237 of the EU Financial Regulation.
- Individuals submit an expression of interest in accordance with the rules set out in this notice.
- The contracting authority will draw up a list of individuals who meet the criteria set out at point 3.
- Individuals listed in the list do not act or speak on behalf of EFSA and EFSA cannot be held responsible for their actions and expressions.

LIST DURATION

The list resulting from this call for expression of interests is valid for maximum 5 years from publication of the notice. The list is intended to cover the period of activity of the EFSA mandate in the areas of NF/NS. It may be closed as a result of a period of inactivity.

The list resulting from this call for expression of interests will be used exclusively for execution of the tasks described at point 2.2 above.

Inclusion on the list entails no obligation on the part of EFSA to award a contract.

LIMITATION TO VOLUME PER INDIVIDUAL

Maximum amount that can be paid to an individual during the whole duration of the list is **144.000 €**, including both remunerations and possible reimbursements.

HOW INDIVIDUALS ARE SELECTED FOR PARTICULAR ASSIGNMENTS

Where a particular task relating to the field described at point 2.2 is to be performed by an individual, the contracting authority will assign individuals to the task on the basis of the skills, experience and knowledge necessary and in accordance with the principles of non-discrimination, equal treatment and absence of conflict of interests.

DECLARATION OF INTEREST (DoI)

EFSA will request an Individual DoI to be submitted prior to the signature of the contract. The requirement to submit an Individual DoI will be specified in the award letter. **Individual DoI will be assessed by EFSA before and as a condition of the contract signature.** Please refer to EFSA's policy on independence and [the Decision of the Executive Director on Competing Interest Management](#) for more detailed information.

The Individual DoI form is available [here](#) and as annex III of this Notice of call for expressions of interest.

2.4 CONDITIONS OF APPOINTMENT FOR A PARTICULAR ASSIGNMENT

REMUNERATION

Individuals shall be remunerated at **a fixed fee of 350 euros per day worked.**

The individuals commit themselves to respect applicable national legislation, including taxation, social security and labour law with regard to any payment received from EFSA.

EXPENSES REIMBURSEMENT

Where applicable, the travel and subsistence expenses will be reimbursed under the conditions set out in the contract according to the conditions stipulated in Annex I.

PLACE OF WORK

Tasks will be carried out in most of the cases remotely and delivered using electronic communication tools. In certain cases EFSA may request that specific tasks are carried out in EFSA premises or other sites that will be mentioned in the contract specifications.

2.5 EX POST TRANSPARENCY

A list of individuals who have concluded with EFSA a contract of more than 15.000€ following the procedure set out at point 2.3 shall be published on EFSA website, no later than 30 June of the year following the year in which the contract was awarded. Information published includes name of individual, locality (region of origin), amount, and subject of the contract. The information shall be removed two years after the year of the contract award.

3. REQUIREMENTS

3.1 ELIGIBILITY CRITERIA

Applicant must be citizenship of a Member State of the European Union (EU), or of a country of the European Free Trade Association (EFTA) or of an EU Candidate country. Experts from third countries may also apply, and will be considered, if the required level of expertise may not be found among nationals of EU, EFTA or EU Candidate countries.

3.2 EXCLUSION CRITERIA

Individuals shall be excluded from participation in the award where they are in one or more of the following exclusion situations:

- (a) the person or entity is bankrupt, subject to insolvency or winding-up procedures, its assets are being administered by a liquidator or by a court, it is in an arrangement with creditors, its business activities are suspended, or it is in any analogous situation arising from a similar procedure provided for under Union or national law;
- (b) it has been established by a final judgment or a final administrative decision that the person or entity is in breach of its obligations relating to the payment of taxes or social security contributions in accordance with the applicable law;
- (c) it has been established by a final judgment or a final administrative decision that the person or entity is guilty of grave professional misconduct by having violated applicable laws or regulations or ethical standards of the profession to which the person or entity belongs, or by having engaged in any wrongful conduct which has an impact on its professional credibility where such conduct denotes wrongful intent or gross negligence, including, in particular, any of the following:
 - (i) fraudulently or negligently misrepresenting information required for the verification of the absence of grounds for exclusion or the fulfilment of eligibility or selection criteria or in the implementation of the legal commitment;
 - (ii) entering into agreement with other persons or entities with the aim of distorting competition;
 - (iii) violating intellectual property rights;
 - (iv) attempting to influence the decision-making of the authorising officer responsible during the award procedure;
 - (v) attempting to obtain confidential information that may confer upon it undue advantages in the award procedure;
- (d) it has been established by a final judgment that the person or entity is guilty of any of the following:
 - (i) fraud, within the meaning of Article 3 of Directive (EU) 2017/1371 of the European Parliament and of the Council (1) and Article 1 of the Convention on the protection of the European Communities' financial interests, drawn up by the Council Act of 26 July 1995 (2);
 - (ii) corruption, as defined in Article 4(2) of Directive (EU) 2017/1371 or a active corruption within the meaning of Article 3 of the Convention on the fight against corruption involving officials of the European Communities or officials of Member States of the European Union, drawn up by the Council Act of 26 May 1997 (3), or conduct referred to in Article 2(1) of Council Framework Decision 2003/568/JHA (4), or corruption as defined in other applicable laws;
 - (iii) conduct related to a criminal organisation as referred to in Article 2 of Council Framework Decision 2008/841/JHA (5);
 - (iv) money laundering or terrorist financing within the meaning of Article 1(3), (4) and (5) of Directive (EU) 2015/849 of the European Parliament and of the Council (1);

(v) terrorist offences or offences linked to terrorist activities, as defined in Articles 1 and 3 of Council Framework Decision 2002/475/JHA (2), respectively, or inciting, aiding, abetting or attempting to commit such offences, as referred to in Article 4 of that Decision;
(vi) child labour or other offences concerning trafficking in human beings as referred to in Article 2 of Directive 2011/36/EU of the European Parliament and of the Council (3);

- (e) the person or entity has shown significant deficiencies in complying with main obligations in the implementation of a legal commitment financed by the budget which has:
- (i) led to the early termination of a legal commitment;
 - (ii) led to the application of liquidated damages or other contractual penalties; or
 - (iii) been discovered by an authorising officer, OLAF or the Court of Auditors following checks, audits or investigations;
- (f) it has been established by a final judgment or final administrative decision that the person or entity has committed an irregularity within the meaning of Article 1(2) of Council Regulation (EC, Euratom) No 2988/95 (4);
- (g) it has been established by a final judgment or final administrative decision that the person or entity has created an entity in a different jurisdiction with the intent to circumvent fiscal, social or any other legal obligations in the jurisdiction of its registered office, central administration or principal place of business;
- (h) it has been established by a final judgment or final administrative decision that an entity has been created with the intent referred to in point (g).

SUPPORTING EVIDENCE REQUESTED:

The declaration of honour on exclusion criteria is available [here](#) and as an annex II of this Notice of call for expressions of interest.

In question 7 of the application form, applicants are requested to declare that they are in none of the situations listed in section I "SITUATION OF EXCLUSION CONCERNING THE PERSON" and section IV "GROUNDS FOR REJECTION FROM THIS PROCEDURE". EFSA reserves the right to ask for further supporting evidence of non-exclusion.

In case applicants are in one or more of the situations of exclusion/ grounds for rejection, they must download, complete and send the declaration of honour on exclusion criteria and relevant documentation to EFSAProcurement@efsa.europa.eu.

3.3 SELECTION CRITERIA

Applicants to be placed on the list shall be selected on the basis of their professional and technical capacity to perform the tasks described in point 2.2. In particular, the applicants must meet these selection criteria to evidence their capacity:

(i) **Education**

A level of **education** which corresponds to completed university studies of **at least three (3) years** attested by a diploma in one of the following fields:

- Toxicology (e.g. general, genetic toxicology),
- Clinical pharmacology,
- Immunology / Allergology (in particular Food allergy and intolerance),
- Veterinary toxicology,
- Pathology,

- Chemistry/biochemistry,
- Human or veterinary medicine,
- Toxicological risk assessment,
- or related areas.

(ii) Professional experience

In addition to the above:

- **at least 3 years of proven professional experience** in at least one of the above fields in which the above qualifications (i) were obtained; **and**
- **demonstrable experience in the safety assessment of food/food ingredients or other chemical substances, as evidenced by:**
 - The preparation and drafting of at least 2 safety assessment reports on foods/food ingredients or other chemical substances, carried out in the last 5 years before the application date; **and**
- **An excellent ability to communicate clearly and effectively in both spoken and written English**, evidenced by either:
 - having written at least 3 reports or publications in English; *or*
 - a certificate demonstrating at least level B.2 of the Common European Framework of References for Languages; *or*
 - having worked for at least 2 years in a working environment where the day-to-day working language for meetings, communications is English.

SUPPORTING EVIDENCE REQUESTED:

- CV evidencing the above requirements.
- Before any contract of appointment, EFSA reserves the right to request **the selected applicant to provide supporting documents relating to their education and professional experience (i.e. copy of university degree, and certificates of working experience, etc.) to demonstrate fulfilment of the selection criteria.**

4. HOW TO APPLY

4.1 GENERAL INFORMATION

The call for expression of interests shall be read in conjunction with its annexes which contain essential additional information.

Submission of an application implies the acceptance of the terms and conditions laid down in this CEI and all the relevant annexes.

Expenditure on preparing and submitting expressions of interest will not be reimbursed by EFSA.

Applications should be submitted in one of the official languages of the European Union.

Applications may be submitted at any time during the period of validity of the call for expression of interest, with the exception of the last three months of that period. However, we advise you to apply as early as possible, as assignments can arise at any point in time during the validity of the list.

Individuals may withdraw their application at any moment by written notice to EFSA.

Incoming applications received in response to this call will be evaluated at least on a quarterly basis. Individuals will be notified of the outcome of their application as soon as possible after the evaluation is finished.

4.2 APPLICATION PROCESS

The application shall be submitted online on the EFSA careers page. Fill in and sign electronically the application form (the Declaration for non-exclusion criteria is embedded in the application form)

4.3 PERSONAL DATA PROTECTION

As an EU Agency, EFSA is subject to Regulation (EU) 2018/17251, forming the primary legal basis for measuring the lawfulness of personal data processing. The applicability of this Regulation in the context of this call has the following implications:

- As data Controller, EFSA shall ensure that personal data contained in your application (e.g. names of individuals, CVs, contact details, financial details of individuals, declarations of interest) is processed in compliance with the Regulation. More detailed information on the processing of personal data in the context of procurement procedures of EFSA is available in the Privacy Statement on our website;
- The selected individual acts as a processor of EFSA with regard to personal data handled under the contract in the sense of Article 29 of the Regulation. In accordance with this provision, the individual:
 - shall only process personal data on documented instructions of EFSA as the data Controller,
 - ensures that persons processing personal data have committed themselves to confidentiality,
 - undertakes appropriate technical and organisational measures to ensure the confidential and secure processing of personal data needed for the implementation of the Contract,
 - deletes or returns to EFSA all personal data after the end of the provision of services,
 - makes available to EFSA all information necessary to demonstrate compliance with the obligations pursuant to the Regulation and allows for or contributes to audits and inspections by or on behalf of EFSA,
 - notifies personal data breaches to EFSA.

Annex I - TRAVEL COSTS AND SUBSISTENCE ALLOWANCES

Travel costs

These lump sums must be applied for travel costs:

Distance in road Km	Travel cost
up to 100	no allowance
between 100 - 400	200 €
Above 400	400 €

Daily subsistence allowances (DSA)

The DSA of 200 € applies if the distance between the place of residence of the individual and the agreed place of work is more than 50 km. Such DSA covers accommodation, meals, local transport to reach airport/train station etc. For each started day of a presence in the agreed place of work one DSA is granted.

Annex II – DECLARATION ON HONOUR FOR EXCLUSION CRITERIA

<http://www.efsa.europa.eu/sites/default/files/DeclarationofHonourexclusioncriteria.docx>

Annex III – INDIVIDUAL DECLARATION OF INTEREST FORM

http://www.efsa.europa.eu/sites/default/files/engage/Procurement/IndividualDOI_grant_procedures.doc