EUROPEAN FOOD SAFETY AUTHORITY

Frequently asked questions on the Call for expressions of interest targeting SME–Novel Food potential applicants interested in receiving EFSA's advice

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Introduction

The European Food Safety Authority (EFSA) has launched a call for expressions of interest targeting small and medium-sized enterprises (SMEs) working in the area of novel foods. The call is open to novel food potential applicants interested in receiving advice on the contents and requirements for an application to obtain the authorization to put their product on the European Union market. This call aims to facilitate access to EFSA's General Pre-Submission Advice (GPSA) service and help potential applicant qualifying as SMEs to navigate the application process easier and to reduce the length of the assessment of their applications. The call will remain open until 31 October 2024.

This Frequently Asked Questions (FAQ) document answers to common questions about the call, the GPSA service, and the call process.

You can find additional information at the following links

- Call webpage,
- Detailed Call text and
- Pre-recorded Info Session.

Should you have any questions on the call that are not replied in this document, please send them via the Ask a Question service including in the subject "Novel food – Call for expressions of interest".

Frequently asked questions

The Call. GPSA service: Early advice and Pre-submission meetings

1. What is the purpose of this call?

The purpose of this call is to support SMEs working in the area of novel foods. They will have opportunity to meet EFSA and receive advice on the contents and requirements for an application to obtain authorization to put their novel food on the EU market.

2. Who is eligible ?

Potential applicants qualifying as SME and working in the area of novel foods, with limited or no experience in submitting novel food applications are eligible to participate in this call.

3. What is the definition of an SME?

For the purposes of this call, an SME is defined as in Title 1 of the EU Recommendation 2003/361.

4. What is the General Pre-Submission Advice (GPSA) service?

The GPSA service is a pre-submission activity that provides the potential applicants with information on the rules applicable to and the content required for an application. Through this service, EFSA replies to applicants' questions before they submit their application for the authorization to put their food regulated product on the EU market. It is non-mandatory but highly recommended to solve questions before submitting an application.

5. How is the advice provided in the context of this call different from the regular GPSA?

EFSA in all cases will address with the GPSA the set of questions submitted by the potential applicant. However, depending on the stage of preparation of their applications, potential applicants via this call can qualify for receiving a GPSA in the form of:

• **Early briefing meeting**, if they are at the very early stage of the development of the novel food, even before starting the studies that will be included in the application; or

• **Pre-submission meeting**, if they are at the latest stages of the preparation of the application, when most of the information that will be included in the application is already available to the SME.

Questions 6 and 7 explain the additional insights provided during these meetings.

6. What is the purpose of an Early Briefing Meeting?

The purpose of an Early Briefing Meeting is to provide advice on the content and rules applicable to the novel food application by replying the questions the potential applicant might have, and to advice on issues such as:

- the role of risk managers and the role of EFSA as a risk assessor
- where to find and consult the sectorial regulation
- the availability and importance of the administrative and scientific guidance documents and checklists
- the obligation to notify certain studies before their starting date
- the use of the relevant IT platforms (Connect.EFSA, ESFC and Open EFSA)
- EFSA's services available to support applicants through the lifecycle of an application.

7. What is the purpose of a Pre-Submission Meeting?

The purpose of a Pre-Submission Meeting is to provide advice on the content and rules applicable to the novel food application by replying the questions the potential applicant might have, and to advice on issues such as:

- the shortcomings frequently identified during the suitability check of novel foods applications, and how to avoid them.
- the updated guidance documents for novel foods and for traditional foods from third countries: what is to take into account if the application will be submitted to the European Commission as of 1 February 2025.

8. What are the benefits expected from this call?

The expected benefit of this call is to facilitate the access of novel foods SMEs to the GPSA service, and to speed up the intake phase of the novel food applications.

For the SMEs that are potential applicants, the main benefit is that they will receive additional information (please see the reply to the questions 6 and 7) that is relevant depending on the stage of the development of their novel food product and application, in addition to the replies to the specific questions they submitted in the GPSA.

The communication activities supporting this Call (social media, mailings, newsletters, pre-recorded info session) run by EFSA, the registered stakeholders relevant in the area of novel foods, the EFSA focal points, the European Innovation Council and other institutions and organisations, contribute to increase the awareness of SME applicants on the GPSA service, reaching some potential applicants that might not be aware of the availability of this service.

9. How specific can the advice provided by EFSA be?

The advice provided by EFSA should be general and abstractly transposable to all potential applicants who intend to submit an application for the same regulated product under the same regulated product area. During the pre-submission meeting EFSA will not perform any informal check nor provide any pre-assessment of the application in preparation, as those activities are out of the scope of the GPSA service.

10. Can other companies or the public in general have access to the questions submitted and the advice provided by EFSA?

No. The only information that EFSA will disclose is a succinct summary of the advice. The summary will not contain any personal, confidential or sensitive information. As foreseen by the legislation, the summary is made publicly available together with the non-confidential version of the application dossier once it is submitted by the applicant and declared valid by the European Commission.

11. How can potential applicants get help on this Call for EOIs?

By contacting EFSA via the Ask a Question service, including in the subject "Novel food – Call for expressions of interest".

Submission of Expressions of Interest (EOI)

12. What information is required to be provided in the EOI?

Potential applicants need to provide brief but clear information about the potential applicant, the novel food, when the application may be submitted, the type of meeting requested (Early advice or Pre-submission meeting) and their preferred timeframe to set the meeting.

13. How is the EOI submitted?

The EOI is to be filled in and submitted in EU-SURVEY. A short demo is available in this video (as of minute 7:40).

14. What is the deadline to submit the Expressions of Interest (EOI)?

The deadline to submit the EOI is 31 October 2024, 23:59 CET.

15. Who can submit the EOI?

The EOI may be submitted by a contact person working in the novel food SME, or by a third party acting on behalf of the novel food SME (consultant, industry association, business incubator centre, etc).

16. What are the requirements that the EOI has to accomplish to be eligible for the meeting with EFSA?

- on the **potential applicant**: qualifies as an SME, is aiming to submit a novel food application, and has no or limited experience in submitting novel food applications.
- on the **questions** submitted: they must be in the scope of the GPSA service [1].
- Specific requirements for **Early advice** meetings: the novel food is still under development, and the application is unlikely to be submitted in the next 12 months.
- Specific requirements for **Pre-submission** meetings: the novel food application is almost ready, and it is likely to be submitted in the next 12 months.

[1] as defined by Article 6 of EFSA's Practical arrangements on Pre-submission phase and public consultations. In this context, it should be noted that the GPSA is limited to the rules applicable to, and the content required for, an application. Aspects going beyond the information available in the rules and guidance documents or guidelines applicable to applications are out of the scope. Questions related to design of studies, unless the advice concerns guidance documents developed by EFSA in which study design is addressed, and questions related to hypotheses to be tested or risk management are out of the scope.

For the sake of clarity, you can find some examples of questions in the scope of the GPSA:

- *Do I need to notify EFSA in advance of all the studies that will be included in my novel food application?*
- *Which food categories should I indicate in my application?*
- *Which information is needed for the specifications of a novel food?*
- *What are the requirements for the analyses and tests supporting my application regarding laboratory accreditation/certification? Should I conduct studies following GLPs?*
- *My novel food is produced with a microorganism. Which data/information should I provide on the production strain?*

Also, some examples of questions out of the scope of the GPSA:

- *The protocol of my study is ready, and I would have it validated by EFSA before starting. Can you review it and send us your comments?*
- *The study results to demonstrate the stability of my novel food are ready. Can you confirm that they are acceptable for EFSA?*
- *I am having problems interpreting certain aspects of Regulation 2015/2283 on novel foods. Can you help me with that?*

17. Any recommendations to follow when preparing the EOI?

Potential applicants should take into account the following points:

- Ensure that all the eligibility criteria are met.
- Provide a short but clear description of your novel food and its conditions of use.
- Include a list of questions as detailed as possible. Avoid broad, very open questions.
- Select the type of meeting that fits your needs:
    - working on the development of the novel food or in the initial stages of the application: Early advice meeting.
    - application almost ready: Pre-submission meeting.

18. How can potential applicants get help to prepare and submit an EOI?

Contact EFSA via the Ask a Question service including in the subject "Novel food – Call for expressions of interest".

Appraisal of Expressions of Interest (EOI)

19. How will the appraisal of the EOI be performed?

The appraisal will be performed on the information made available by the potential applicants in the EOIs. EFSA may also consult relevant information in other sources, if deemed necessary. All the eligibility requirements must be met, otherwise the EOI will be declared non-eligible.

20. Can EFSA request additional information on the EOI during the appraisal?

Yes, EFSA will contact the potential applicant via email in case any additional information relevant for the appraisal is needed (i.e. on the novel food and its conditions of use, on the questions submitted, on the SME status, etc.).

21. Why is EFSA sending an invitation to create an Applicant account in Connect.EFSA?

An active Connect.EFSA account is a prerequisite to perform any pre-submission activities, such as sending a request for General pre-submission advice. It takes a few days to have it activated, so the potential applicant may be invited to create the account after submitting the EOI to avoid any delays afterwards in case the EOI is positively appraised. Even if the EOI is considered non-eligible, the potential applicant will find their account useful in the future when working on their Novel food application, i.e. to notify studies.

22. If some questions in the EOI do not fall in the scope of the GPSA service, will EFSA discard only these questions, or the EOI will be considered non-eligible?

The fact that some of the questions are out of the scope of the GPSA service does not mean that the EOI is non-eligible. If at least one of the questions submitted is within the scope, this eligibility requirement is fulfilled. On the contrary, the requirement is not fulfilled in case all the questions submitted are out of the scope, leading to the conclusion that the EOI is non-eligible.

23. In case the EOI is submitted by a third party (i.e. a consultant, an industry association, a business incubator center, etc.), how is the SME status assessed? On the potential applicant or on the third party submitting the EOI?

According to the eligibility requirements, the potential applicant must qualify as an SME. Consultancy firms, industry associations and other stakeholders are welcome to collaborate in the dissemination of the call amongst novel food SMEs, and also to support the submission of their Expressions of interest by fulfilling the EU-Survey form on their behalf. Nevertheless, the appraisal of the SME status is done only on the potential applicant.

24. The potential applicant is working on a novel food, but the company does not qualify as an SME. Is the EOI eligible?

No, according to the eligibility requirements, the potential applicant must qualify as an SME, according to the definitions in the EU Recommendation 2003/361. Non-SME applicants can submit their requests for regular GPSA any time via Connect.EFSA before submitting the application.

25. The potential applicants is working in a food regulated product different from novel food (i.e. Food improvement products, GMO, Feed additives, etc.) and qualifies as an SME. Is the EOI eligible?

No, according to the eligibility requirements, the potential applicant is aiming to submit to EC an application for pre-market authorisation of a novel food. Potential applicants working in other food domains can submit their requests for regular GPSA any time via Connect.EFSA before submitting the application.

26. The potential applicants has already submitted the application for the authorisation of the novel food, but they have some doubts during the risk assessment process. Is the EOI eligible?

No, the GPSA can be requested only before the application is submitted. In case of doubts during the assessment of an already submitted application, contact the relevant EFSA Unit or send a query via the Ask a Question service.

27. How long does the appraisal of the EOIs take to EFSA?

Depending on the volume and complexity of the EOI, the duration of the appraisal process might vary, but it is expected to last about two weeks on average.

28. What happens next if the EOI is eligible?

If the EOI is eligible, the potential applicant will be provided with details on how and when to submit the request for GPSA via Connect.EFSA so the meeting can be properly organized.

29. What happens next if the EOI is not eligible?

If the EOI is not eligible, the potential applicant will be notified accordingly and will be provided with information on other EFSA services that may fit their needs, or indications to contact the risk managers (EC, Member States), if applicable.

Early Advice and Pre-submission meetings

30. When will the meeting take place?

EFSA will get in touch with the potential applicant to agree on a timeslot that is convenient for all the attendants, preferably in the period indicated in the EOI.

31. Will the meetings be held online or offline?

For logistical and financial reasons, the meetings will be held preferably online.

32. What are the next steps after receiving the positive appraisal (EOI is eligible)?

The potential applicant will receive detailed indications on how to proceed with the notification of the result of the appraisal. Basically, they will be invited to log in Connect.EFSA with their account, create a pre-application ID for the novel food and submit a request for General pre-submission advice (GPSA) two weeks before the agreed date of the meeting.

33. Can potential applicants include new questions in the request for GPSA that were not included before in the EOI?

Yes, new questions can be added and will be assessed to check if they fall in the scope of the GPSA service. If that is the case, they will be also replied in the meeting.

34. Who should attend the meeting from the SME side?

It is recommended that a total of two to four people attend, especially those in charge of the development of the novel food and the preparation of the application at the SME. A third party representing the applicant (e.g. consultant) can also participate in the meeting.

35. Who will attend the meeting from the EFSA side?

Front-Desk & Workforce Planning (FDP) is the unit in charge of the GPSA service. Staff in other units can participate in the preparation of the advice depending on the questions received[2].

[2] According to Article 32a of the General Food Law, EFSA staff providing the GPSA will not be involved in any preparatory scientific or technical work that is directly or indirectly relevant to the application that is the subject of the advice.

36. What should potential applicants expect from an Early Briefing Meeting?

During the Early Briefing Meeting, EFSA staff will reply to the questions submitted that are in the scope of the GPSA service. In addition, potential applicants will be advised on:

- the role of risk managers and the role of EFSA as a risk assessor
- where to find and consult the sectorial regulation
- the availability and importance of the administrative and scientific guidance documents and checklists
- the obligation to notify certain studies before their starting date
- the use of the relevant IT platforms (Connect.EFSA, ESFC and Open EFSA)
- EFSA's services available to support applicants through the lifecycle of an application.

37. What should potential applicants expect from a Pre-Submission Meeting?

During the Pre-Submission Meeting EFSA staff will reply to the questions submitted that are in the scope of the GPSA service. In addition, potential applicants will be advised on:

- the shortcomings frequently identified during the suitability check of novel foods applications and to advise on how to avoid them.
- the updated guidance documents for novel foods and for traditional foods from third countries: what is to take into account if the application will be submitted to the European Commission as of 1 February 2025.

38. What not to expect from an Early advice or a Pre-submission meeting?

This service has some limitations and EFSA cannot:

- Take new questions during the meeting that were not included in the request for GPSA.
- Reply questions beyond the scope of the GPSA (see question "What are the requirements that the EOI have to accomplish to be eligible").
- Pre-assess or check the validity of the application, or parts of it.
- Provide scientific advice beyond the information available in the corresponding guidance documents.

39. Can the meeting be recorded, or a transcript made?

No, the tele-meetings cannot be recorded in any way.

40. Will EFSA prepare and share the minutes of the meeting?

No. Only a succinct summary of the advice is drawn up and stored by EFSA. It is also sent to the potential applicant for information purposes. The summary of the advice will not contain any confidential or sensitive information and is the only information that EFSA will publish about the request for advice submitted by the potential applicant. As foreseen by the legislation[3] , it is made public together with the non-confidential version of the application dossier once the application is declared valid.

41. If new questions arise in the future during the preparation of the novel food application, can the potential applicant request a new GPSA?

Yes, in case of new questions arise in the future, potential applicants can submit another request for GPSA[4] for the same application. EFSA has a specific service in place (Fast-tracked GPSA for SMEs[5]) so the GPSAs submitted by SMEs are replied in a shortened timeframe and preferably in a tele-meeting.

42. How can potential applicants get help to prepare and submit a request for GPSA?

Contact EFSA via the Ask a Question service including in the subject "Novel food – Call for expressions of interest".

43. How can potential applicants share with EFSA their feedback on the call and on the advice provided?

After the meeting, the potential applicant will be invited to fulfil and submit an anonymous survey to provide EFSA with their feedback on the Call for EOI and on the advice received. This feedback is very important for EFSA to develop and improve the services to support applicants, in particular SMEs.

[3] General Food Law Article 32a and EFSA Practical arrangements on pre-submission phase and public consultations
[4] as per Article 7 of the EFSA's Practical arrangements on pre-submission phase and public consultations, and also indicated in the Catalogue of support initiatives during the life cycle of applications for regulated products
[5] As per section 2.1.2 of EFSA's Catalogue of services during the lifecycle of applications for regulated products

List of acronyms

EFSA: European Food Safety Authority

EOI: Expression of Interest

ESFC: e-submission food chain platform

EU: European Union

GPSA: General pre-submission advice

SME: small and medium-sized enterprise