

Call for expressions of interest targeting
SME–Novel Food potential applicants
interested in receiving EFSA’s advice



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1. Call for expressions of interest

Objective

The European Food Safety Authority (EFSA) is launching a call for expressions of interest (EOI) to identify small and medium-sized enterprises (SMEs) working in the area of novel foods that are interested in receiving EFSA’s advice on the contents and requirements for an application to obtain the authorisation to put their novel food in the European Union market (hereinafter referred as “the call”).

This call aims to raise awareness and facilitate access for SMEs to the general pre-submission advice (GPSA) service. Despite this service can be requested at any moment before the submission of an application, this call focuses on **two specific stages** of the application process that can be of special interest for SMEs with no or limited experience in submitting a novel food application, namely:

- on the **very early stage of the development of the novel food**, even before starting the studies that will be included in the application
- on 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.

This call is by no means a competition and all the expressions of interest fulfilling the requirements will be declared eligible. Accordingly, the SMEs will be entitled to receive EFSA’s advice. In the context of this call, SMEs working on the preparation of an application in the area of Novel Foods are referred to as potential applicants.

The expected benefit of this call in the long term is to speed up the intake phase of the novel food applications, and as a consequence, to reduce the length of the assessment of those applications.

Confidentiality

As the advice is provided in the context of the GPSA service, the information submitted to EFSA to answer the call, to request the advice and in the meetings will be treated as confidential.

The only information that EFSA will make publicly available is a succinct summary of the advice, only if and when the future application for the authorisation to put the novel food in the EU market that is the subject of the advice is declared valid, and together with the non-confidential version of the application dossier, as mandated by Article 9(3) of EFSA’s [Practical arrangements on pre-submission phase and public consultations](#).

Calendar

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|--------------------------------|------------------------------------|
| • Opening of the call: | 25 June 2024 |
| • Info session: | 16 July 2024 |
| • Deadline to submit the EOIs: | 31 October 2024 |
| • Appraisal of the EOIs: | immediately after their submission |
| • Meetings: | from 15 July to 12 December 2024 |

2. The GPSA service in the context of novel food application procedure and the SMEs.

An applicant who intends to place on the EU market a novel food should submit an application to the European Commission (EC). After having verified its validity, EC makes it available to the Member States and mandates EFSA for a scientific assessment. EFSA does not authorise marketing of novel foods. Its role is to provide, upon request of the EC, independent scientific advice on the safety of the novel food before it can be placed on the EU market. Further details on the [application procedure for novel foods](#) and the [role of EFSA](#) can be consulted on EFSA’s website.

Potential applicants may request [general pre-submission advice](#) at any point before the submission of the application. The advice is given by EFSA staff and aims at providing information on the rules applicable to and the content required for the application. The GPSA is a non-mandatory but highly recommended pre-submission activity, in particular for SMEs with no or limited experience in the preparation and submission of applications.

SMEs are defined in the [EU recommendation 2003/361](#). SMEs are very active EFSA stakeholders, and in particular, most of the applicants in the area of novel foods qualify as SMEs. This call is supported by Article 7(5) of EFSA’s [Practical arrangements on pre-submission phase and public consultations](#), which calls for measures to facilitate the access to GPSA for SMEs.

3. Early briefing meetings and Pre-submission meetings

In a nutshell, potential applicants will receive EFSA’s advice in a meeting. This advice will consist of the **replies to the questions** submitted in advance about the content and the rules applicable to their novel food application.

Depending on the stage of preparation of their applications, potential applicants 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;
- **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.

In **Early briefing meetings**, in addition to receiving answers to their questions, potential applicants will be also 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.

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In **Pre-submission meetings**, in addition to receiving answers to their questions, potential applicants will be presented with the shortcomings frequently identified during the suitability check of novel foods applications and advised on how to avoid them. During the pre-submission meeting EFSA will not perform any informal check nor provide any pre-assessment of the application in preparation.

4. Eligibility requirements and prioritization criteria

Common eligibility requirements (each must be met)

- The potential applicant is aiming to submit to EC an application for pre-market authorisation of a novel food in the incoming months or years.
- The potential applicant qualifies as an SME, according to the definitions in the EU Recommendation 2003/361.
- The potential applicant has no or limited experience in submitting novel food applications to EC.
- The questions submitted by the potential applicant are in the scope of the GPSA service 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.

Specific requirements for each of the services

- **Early briefing meetings:** the potential applicant is still working on the development of the product, and few or no studies supporting the future application have already been performed. The submission of the application is not foreseen in the next 12 months.
- **Pre-submission meetings:** the application is almost complete, and the potential applicant is planning to have it submitted in the next 12 months.

Prioritization criteria regarding the timeframe of the meetings

In case several potential applicants were requesting to meet in the same timeframe and exceeding EFSA’s availability of resources that allows to organize up to six meetings in the same month, the following criteria shall apply:

- Potential applicants that have never submitted an application to EFSA will be prioritized versus those that already submitted any application.
- First come, first served basis will be considered if additional prioritisation criteria are needed.

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5. Structure, submission and appraisal of the EOIS

Submission of the expression of interest

- The EOI is to be filled in and submitted in [EU-SURVEY](#) ¹.
- The **deadline** to submit the EOI is **31 October 2024 23:59 CET**.

Structure and content of the Expressions of Interest

- Information about the **potential applicant**: name of the company, country, two email addresses, contact person (name and surname), self-declaration on the SME status.
- In case the EOI is submitted by **another organisation** on behalf of the potential applicant: email address, contact person, declaration that potential applicant agrees with the submission of the EOI.
- Information about the **novel food**: brief description of the novel food subject of the future application and, if already known, the conditions of use and the EU country where the novel food will be placed on the market for the first time.
- Information about when the potential application is **planned to be submitted**².
- **Type of GPSA service** requested: Early briefing meeting or Pre-submission meeting.
- Non-exhaustive **list of questions**, allowing EFSA to understand whether they are in the scope of the GPSA service.
- Preferred **timeframe** to set the meeting with EFSA.

For any questions regarding the submission of the EOI, please send inquiries via the [Ask a Question service](#) ³ including in the subject “Novel Food – call for expressions of interest”.

Appraisal process

Given that the call is not a competition and in benefit of potential applicants that may have an urgency in receiving EFSA’s advice, the appraisal will start as soon as the EOI is received. The latest appraisals are expected to end on 15 November 2024 at the latest.

The appraisals will be performed on the information made available by the potential applicants in the EOIs. EFSA can also consult information about the potential applicant and the intended application in other sources such as the Connect.EFSA and Open.EFSA portals, the ESFC submission portal and the EFSA Journal.

EFSA may also collect information about the potential applicant’s approved annual accounts that are already publicly available to verify their SME status.

Every EOI will be appraised against the eligibility requirements indicated in section 4. If any clarifications on the content of the EOIs or the SME status were needed, EFSA may request additional information to potential applicants via email.

The appraisal of each EOI will conclude whether the potential applicant is entitled or not to receive EFSA’s advice in an Early briefing meeting or in a Pre-submission meeting.

¹ <https://ec.europa.eu/eusurvey/runner/EOI-NF-SMEs-24>

² this information is non-committal for any subsequent decision taken by the potential applicant with regard to the submission date of their future application

³ <https://connect.efsa.europa.eu/RM/s/new-ask-efsa-request>

6. Notification of results

The results of the appraisals will be notified to the potential applicants via email as soon as they are available.

- **Eligible EOI**, meaning that it fulfils all the eligibility requirements. The potential applicant will be provided with details on how and when submit the request for GPSA in Connect.EFSA so the meeting (Early briefing meeting or Pre-submission meeting) can be properly organized.
- **Non-eligible EOI**, meaning that it is not fulfilling at least one of the eligibility requirements. The potential applicant will be notified accordingly and will be provided with information on other EFSA services that may fit their needs to have their questions solved, or indications to contact the risk managers (EC, Member States), if applicable.

7. Meetings, summary of the advice and feedback to EFSA

The Early briefing meetings and the Pre-submission meetings will be organised between 15 July and 12 December 2024, following the submission of the corresponding requests via the Connect.EFSA portal. In the sake of efficiency, meetings will be held preferably online. In duly justified cases, the meeting may be organized after 12 December 2024.

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 legislation⁴, it is made public together with the non-confidential version of the application dossier once the application is declared valid.

After the meeting, potential applicants 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.

⁴ [General Food Law](#) Article 32a and [EFSA Practical arrangements on pre-submission phase and public consultations](#)