

FAQs

Novel food SMEs call 2026

Frequently asked questions on the
third call for expressions of interest
for SME–Novel Food potential
applicants interested in receiving
EFSA's advice
2026

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Introduction

The European Food Safety Authority (EFSA) is launching a third call for expressions of interest targeting small and medium-sized enterprises (SMEs) business operators 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 pre-market authorisation to put their novel food on the European Union market.

EFSA launched two dedicated calls in 2024 and 2025 aimed at supporting novel food SMEs. Both initiatives were highly successful, attracting 110 expressions of interest, primarily from companies in the early stages of product development and with limited or no prior experience in preparing applications or engaging with EFSA and the European Commission. Feedback from participants was very positive: potential applicants considered EFSA's support to be clear, comprehensive, and extremely valuable. Based on the experience gained through those calls, EFSA is launching a new call targeting novel food SMEs to guide them in the preparation of their applications in line with the requirements of the guidance documents.

The call will remain open until 18 November 2026 at 13:00 CET.

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

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 SMEs 2026".

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/traditional foods. They will have the opportunity to meet EFSA and receive advice on the contents and requirements for an application to obtain pre-market authorisation to put their novel food on the EU market. The call focuses on two specific stages of the application process: the very early stage of development of the novel food, and the latest stages of preparation of the application, when most of the information that will be included in the application is already available to the SME.

2. Who is eligible?

Potential applicants qualifying as SMEs and working in the area of novel foods/traditional foods, with limited or no experience in submitting novel food applications, are eligible to participate in this call. SMEs that have previously received advice through previous editions are also welcome to apply, provided that their request concerns a different novel food.

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 are Novel foods (and Traditional foods)?

Under EU regulations¹, any food that was not consumed “significantly” prior to May 1997 is considered to be a novel food. The category covers new foods, food from new sources, new substances used in food as well as new ways and technologies for producing food. Examples include oil rich in omega-3 fatty acids from krill as a new source of food, edible insects, or plant sterols as a new substance or nanotechnology as a new way of producing food.

Traditional food is a subset of novel food and refers to food that is traditionally consumed anywhere outside Europe.

¹ [Regulation 2015/2283 on novel foods](#)

5. 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.

6. 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 Advice 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.

Based on the information available, EFSA will decide on the service that better fits the needs of the potential applicant.

7. What is the purpose of an Early Advice Meeting?

The purpose of an Early Advice 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
- aspects related to confidentiality of applications
- 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.

8. 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, covering administrative, scientific and confidentiality aspects 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 after their implementation.

9. What are the benefits expected from this call?

The expected benefit of this call is to facilitate access for novel foods SMEs to the GPSA service, guide them in the preparation of their applications in line with the requirements of the guidance documents, and speed up the intake phase of 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 questions 6 and 7) that is relevant depending on the stage of 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, together with the experience gained through the previous editions, contribute to increasing awareness of the GPSA service among SME applicants and to reaching potential applicants that may not be aware of the availability of this service.

10. 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.

11. 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.

12. *Is this call a competition between potential applicants?*

No. The call is not a competition. All expressions of interest that fulfil the eligibility requirements will be declared eligible and the potential applicant will be entitled to receive EFSA's advice.

13. *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 SMEs 2026".

Submission of Expressions of Interest (EOI)

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

Potential applicants need to provide brief but clear information about the potential applicant, including the company name, country, two email addresses, contact person and self-declaration on SME status; about the novel food, including its source and, if already known, the conditions of use and the EU country where it will be placed on the market for the first time; about when the future application is planned to be submitted; whether the novel food status has already been confirmed via the consultation process; whether the potential applicant is aware of EFSA's Administrative and Scientific Guidance documents on Novel Foods; the non-exhaustive list of questions they have about their novel food application; and their preferred timeframe to set the meeting. If the EOI is submitted by another organisation on behalf of the potential applicant, information on that organisation and a declaration that the potential applicant agrees with the submission of the EOI are also required.

15. *How should the expression of interest be submitted*

The expression of interest must be filled in and submitted via [MS Forms](#). If submitted by other means (i.e. email, Ask a Question), the requester will be invited to submit it via Forms.

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

The deadline to submit the EOI is 18 November 2026, 13:00 CET.

17. Who can submit the EOI?

The EOI may be submitted by a contact person working in the novel food SME business operator, or by a third party acting on behalf of the novel food SME (consultant, industry association, business incubator centre, etc). In any case, at least two different contact emails are needed, one of them necessarily from a contact person working in the novel food SME. When the EOI is submitted by another organisation on behalf of the potential applicant, a declaration that the potential applicant agrees with the submission of the EOI is also required.

18. 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 a business operator aiming to submit to EC an application for pre-market authorisation of a novel food/traditional food in the near future, 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 ².

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?*
- *Can EFSA share a list of laboratories to commission the studies / a list of consultancy firms to help us prepare the application / an estimate of the costs of preparing an application?*
- *Is my product a novel food according to EU regulations? Is it a traditional food?*

² 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.

19. 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, its source and its conditions of use.
- Include a list of questions as detailed as possible. Avoid broad, very open questions.
- Indicate whether the novel food status has already been confirmed via the consultation process.
- Review the relevant EFSA Administrative and Scientific Guidance documents on Novel Foods before submitting the EOI.
- Provide a realistic, non-committal indication of when the future application is planned to be submitted.

20. How to proceed in case of a mistake or typo is spotted in the EOI after its submission?

It is not possible to amend the EOI once it is submitted. Contact EFSA via the Ask a Question service including in the subject "Novel Food – call SMEs 2026", and indicate what information is wrong and how it should be updated.

21. Does the planned submission date of the future application create an obligation for the potential applicant?

No. The call text states that the information about when the potential application is planned to be submitted is non-committal for any later decision by the potential applicant regarding the submission date of the future application.

22. 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 SMEs 2026".

Appraisal of Expressions of Interest (EOI)

23. 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 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. All the eligibility requirements must be met, otherwise the EOI will be declared non-eligible.

24. What happens if EFSA needs clarification during the appraisal?

If clarification on the content of the EOI or on SME status is needed, EFSA may request additional information from the potential applicant by email before finalising the appraisal.

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26. 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.

27. 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.

28. 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 and to support the submission of EOIs on behalf of novel food SMEs. Consultants will be entitled to receive EFSA's advice provided that they are working on behalf of SME business operators preparing such applications. Nevertheless, the appraisal of the SME status is done only on the potential applicant.

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

No, as indicated in 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.

30. 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.

31. 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](#).

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

The appraisal will start as soon as the EOI is received. The appraisals are expected to end on 18 December 2026.

33. 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.

34. 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

35. 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. Meetings will be organised on a rolling basis once the result of the appraisal is notified and after submission of the corresponding GPSA request via the Connect.EFSA portal. Meetings are expected from 19 October 2026, and meetings with applicants submitting EOIs in September may start before the deadline to submit EOIs.

36. Will the meetings be held online or in person?

For logistical and financial reasons, the meetings will be held preferably online. If EFSA staff use a presentation during the meeting to guide the discussions, it may be shared with the applicant afterwards.

37. 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) three weeks before the agreed date of the meeting.

38. *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.

39. *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 or helping in the preparation of the application (e.g. consultant) can also participate in the meeting.

40. *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 received³.

41. *What should potential applicants expect from an Early Advice Meeting?*

During the Early Advice 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
- aspects related to confidentiality of applications
- 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.

42. *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:

³ 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.

- the shortcomings frequently identified during the suitability check of novel foods applications covering administrative, scientific and confidentiality aspects, and 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.

43. *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.

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

No, the tele-meetings cannot be recorded in any way. If EFSA staff use a presentation during the meeting to guide the discussions, it may be shared with the applicant afterwards.

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

46. *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 GPSA⁵ for the same application. EFSA has a specific service in place (Fast-tracked GPSA for SMEs⁶) so the GPSAs submitted by SMEs are replied in a shortened timeframe and preferably in a tele-meeting.

⁴ General Food Law Article 32a and EFSA Practical arrangements on pre-submission phase and public consultations

⁵ 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

⁶ As per section 2.1.2 of EFSA's Catalogue of services during the lifecycle of applications for regulated products

47. *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 SMEs 2026”.

48. *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.

List of acronyms

CET: Central European Time

EC: European Commission

EFSA: European Food Safety Authority

EOI: Expression of Interest

ESFC: e-submission food chain platform

EU: European Union

FAQ: Frequently Asked Question

FDP: Front-Desk & Workforce Planning

GLP: Good Laboratory Practice

GMO: genetically modified organism

GPSA: General pre-submission advice

IT: Information Technology

SME: small and medium-sized enterprise