INFO SESSION: CALL FOR EOI
TARGETING NOVEL FOOD - SMES
Team Advice, FDP Unit
16 July 2024
WHAT’S ON THE MENU

1. Call for expression of interest
2. Early briefing & pre-submission meetings
3. Submission & Appraisal of EOIs
4. Provision of advice & feedback on the service
5. Q&A
INTRODUCTION

REGULATION ON NOVEL FOODS (EU) 2015/2283 OF 25 NOVEMBER 2025
CALL FOR EXPRESSIONS OF INTEREST - WORKFLOW

1. Submission of expression of Interest
2. Appraisal
3. Invitation to submit a GPSA
4. Advice provided in a meeting
CALL FOR EXPRESSIONS OF INTEREST - TIMELINES

- **Call launched**: 26/06
- **Submission of EOI**: 15/07
- **Appraisal of EOI (15 days)**
- **Meetings**
- **Call closes!**: 31/10
- **First meetings**: 15/07
- **The last meeting**: 12/12
EARLY BRIEFING AND PRE-SUBMISSION MEETINGS
# General Pre-submission Advice

## WITHIN THE SCOPE

- **Explaining the requirements contained in rules, guidances documents and guidelines**
- **Study design: general explanations if addressed in the guidance documents**

## OUT OF SCOPE

- **Questions to be addressed to the Risk Managers (EC)**
- **Pre-assessment of results or wrongly submitted requests**
- **How to develop or manage a study, hypothesis to be tested and validation of protocols**

*examples will be provided during the Q&A session*
Early advice meetings

- Risk managers vs risk assessors and sectoral regulation
- Admin and Scientific Guidance & checklist,
- **Obligation to notify studies**
- IT Platforms and support services

Pre-submission meetings

- Common shortcomings identified during suitability check
- Advice on how to overcome frequent mistakes

Risk managers vs risk assessors and sectoral regulation
Admin and Scientific Guidance & checklist,
Obligation to notify studies
IT Platforms and support services
Eligibility Requirements (common)

- Working on Novel Food
- Potential applicant
- SME with limited or no experience
- Questions within the scope of GPSA
Early Advice meeting

- Novel food under development
- Few/no studies performed
- Submission > 12 months
Pre-submission meeting

Application almost complete

Submission < 12 months
SUBMISSION AND APPRAISAL OF EOIs
SUBMISSION OF EXPRESSIONS OF INTEREST

by 31 October
Call for expressions of interest targeting SME–Novel Food applicants interested in receiving EFSA’s advice

Introduction

EFSA is launching a Call for expressions of interest 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 product in the European Union market.

This call aims to raise awareness and facilitate access for SMEs to the General Pre-submission Advice (GPSA) service, and to speed up the validation process of the Novel Food applications. In practice, applicants whose expressions of interest accomplish the selection criteria qualify to receive the advice in the form of an Early Briefing Meeting (potential applicants working in the early stages of the development of the novel food) or a Pre-submission meeting (potential applicants working in applications close to be submitted). This service is provided in form of tele-meetings, ensuring confidentiality.

The expressions of interest can be submitted from 25 June to 31 October 2024 and the meetings will take place from 15 July to 12 December 2024.

For further details, please consult the call text, available in the Background documents section on the right side, and the Call webpage. If you have any questions on this call, contact us via the Ask a Question service. Don’t forget to include “Novel Food –
PROVISION OF ADVICE & FEEDBACK TO EFSA
MEETINGS, SUMMARY OF ADVICE AND USER FEEDBACK
TAKE HOME MESSAGES

1. Support to SMEs in Novel Foods
   Confidentiality ensured

2. Advice in a GPSA meeting:
   - Early briefing meetings
   - Pre-submission meetings

3. Important dates:
   - Call opened 25/06 - 31/10
   - Meetings 15/07 - 12/12

4. If non-eligible you may be redirected to other services
QUESTIONS & ANSWERS
Q1 – EXAMPLES OF QUESTIONS WITHIN THE SCOPE OF 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?
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?

I am just requesting general support to prepare my application
- If **at least one** question is within the scope, this eligibility requirement is fulfilled.

- EOI is **non-eligible if all** the questions are out of the scope.
If applicable:
- redirected consult to risk managers
- invited to request other EFSA Services
No, only a succinct summary is published:

- lacking any personal, confidential or sensitive information

- together with the non-confidential version of your application after it is submitted to EC and validated.
USEFUL TO KNOW!

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