

# Precision Fermentation Business Support Service (BSS)

Guidance on the Precision Fermentation Business Support Service (BSS), including who is eligible and how to apply

The Business Support Service (BSS) Pilot was launched on 22 September 2025 as part of the Department for Science, Innovation and Technology funded Market Authorisation Innovation Research Programme (IRP) and will run until 15 June 2026.

It is designed to support companies wishing to submit applications for precision fermented products to the UK market authorisation service, and those with existing applications.

Also funded through IRP is a [business guidance hub](#) for innovative food products which provides more accessible support for businesses looking to navigate the novel foods process.

This pilot is available for companies who are planning to [apply for authorisation](#) of their precision fermentation product for the UK market, and those with existing applications.

## Precision fermentation definitions

**Precision fermentation product** means food or food ingredients containing components such as proteins, sugars, carbohydrates, vitamins and/or fats, produced by precision fermentation. Following fermentation, the desired product is separated from the fermentation broth and purified before being incorporated into food.

**Precision fermentation** is a specialised form of fermentation that uses single-celled prokaryotic or eukaryotic microorganisms grown in a controlled environment. It uses biotechnological methods to cultivate microorganisms (such as bacteria, yeast, or other microbes) to produce specific target molecules, including proteins, lipids, and vitamins.

Unlike traditional fermentation, which relies on natural microbial processes to generate broad metabolic products, precision fermentation is designed to produce high purity, well defined compounds. This is often achieved through the use of engineered microbial strains and advanced biotechnology.

After fermentation, the resulting ingredient is extracted and purified from the fermentation broth ensuring that no live production organisms remain in the final food product.

## Benefits to prospective applicants

The service is designed to:?

- provide clarification and guidance on applicable regulatory requirements?
- provide high-level advice on the UK market authorisation process??
- identify relevant information contained in existing guidance material?

# How we will use the information gained through the BSS Pilot

Through the service, the FSA/FSS will gain insights from prospective applicants about the new technologies, processes and ingredients being used to develop precision fermentation products. This improved understanding will lead to a more efficient risk assessment process. It will also help us anticipate when applications will be submitted for market authorisation and the type of technology used.

## Service details

### Business support service functions

The focus of the BSS is to provide pre-submission support for businesses who are planning to [apply for UK market authorisation](#), though the service is also open to those with existing applications.

### Pre-submission support

Prospective applicants can engage with the FSA/FSS before submitting a dossier to gain clarity on essential requirements and applicability of the guidance.

### Post-submission support

Businesses responding to a Request for Information can access additional support through the service to help them understand and address any missing information identified in their dossiers.

Advice provided as part of this service will be general in nature and provided without prejudice. It will not form part of the statutory process and should not be viewed as an authoritative or binding statement as to the likely outcome of an application.

Support provided will not extend to the writing, or refinement, of dossiers. It will not substitute the need for prospective applicants to do their own work to prepare an application that meets the requirements outlined in [assimilated Regulation \(EU\) 2015/2283](#).

### What is not covered by the pre-submission support function of BSS Pilot

The following are not included as part of the BSS Pilot's pre-submission support function:

- information that goes beyond that which is available in the legislation, rules, guidance documents or guidelines applicable to the application
- the design of the studies to be submitted and questions related to hypotheses to be tested, unless already covered in pre-existing guidance?
- formally reviewing prospective applicants' draft dossiers and providing written feedback?

### Who is eligible for pre-submission support

To be eligible to engage with the BSS Pilot pre-submission support, prospective applicants must:

- be a registered company in one or more jurisdictions ?

- intend to submit an application for authorisation to place a precision fermentation product on the UK market

## Engaging with the pre-submission support service

To engage with the service, prospective applicants must submit a [pre-submission enquiry form \(PSEF1\)](#).

Within ten business days of the PSEF1 form, the FSA/FSS will:

1. verify the applicant's eligibility and that the questions raised in the PSEF1 are within scope of the pre-submission support service
2. notify the applicant as to whether their request has been accepted or declined

## Tiers of pre-submission support available

Pre-submission support offered by the FSA/FSS will vary based on the FSA/FSS's assessment of each product's 'tier': ?

- Tier 1 is for products in their final stage of development, with dossiers expected to be submitted for approval within 12 months
- Tier 2 is for products that are well progressed in their development, with dossiers expected to be submitted for approval within the next 12 and 24 months
- Tier 3 is for products in their early stage of development, with dossiers expected to be submitted for approval in more than 24 months' time

### Tier 1?

Support provided in Tier 1 will include up to two one-to-one meetings with the applicant to discuss the specifics of their application and any technical questions that they might have. These meetings will provide an opportunity for:

The FSA/FSS to get a greater understanding of the proposed product and its associated hazards

The prospective applicant to enhance their knowledge of the regulatory process and receive further clarity in respect to any technical questions

### Tier 2

Applicants in Tier 2 will receive enhanced support in the form of written advice and, where possible, one-to-one meetings.

One-to-one meetings will only be offered to Tier 2 applicants if the FSA/FSS has sufficient resources, and there are compelling reasons to do so. Compelling reasons could include:

- the product being non-routine or highly innovative, for example a first of kind innovation
- the product is expected to be high profile and/or controversial?
- the provision of advice could significantly affect application timeframes or cost, for example the prospective applicant has expressed they are ready to submit their dossier but are questioning if they should undertake an additional study which would come at significant additional time and cost
- the product's development would stall unless further clarity is provided on the regulatory framework, and this clarity is unable to be sourced elsewhere, such as from an independent regulatory specialist

## Tier 3

Tier 3 support will include light-touch support from the FSA/FSS in the form of written guidance and public-facing webinars. ??

One-to-one meetings with Tier 3 applicants will only be offered in exceptional circumstances.

## Post-submission support

Post-submission support will mostly mirror the existing regulated products post submission service offering. This includes, where necessary, the provision of one-to-one meetings.

### What is not covered within post-submission support

The following are not included as part of the post-submission support service:??

- information that goes beyond the information available in the legislation, rules, guidance documents or guidelines applicable to the application
- formally reviewing applicants updated dossiers and providing written feedback?
- discussions with the applicant that the FSA/FSS does not perceive will deliver any benefit in respect to progressing the application?

### Who is eligible for post-submission support

To be eligible to engage with the BSS Pilot post-submission support function, applicants must meet all the below criteria: ?

- have applied for market authorisation to place a precision fermentation product on the UK market prior to the establishment of the BSS Pilot, unless otherwise agreed by the FSA/FSS, ??
- have been issued a Request for Information by the FSA/FSS about their application, for which the FSA/FSS is awaiting a response, or be seeking to raise a 'highly relevant' development in respect to their application with the FSA/FSS, and
- have submitted a post-submission enquiry form (PSEF2)?

In addition to the above general eligibility requirements, the FSA/FSS will also offer limited post-submission support to applicants that have:?

- applied for market authorisation to place a precision fermentation product on the UK market prior to the BSS Pilot launch
- not had a meeting before submitting their dossier ?
- subsequently been issued a request for information (RFI) by the FSA/FSS

Applicants falling into the last category should also submit a PSEF2 in order to access the service.

In deciding whether an applicant is eligible to use the service, the FSA/FSS will also consider if, in the context of the questions raised in the applicant's PSEF2, further discussion would help to progress the application.

### Engaging with the post-submission support service

To engage with the service, applicants must submit a [post-submission enquiry form \(PSEF2\)](#).

Within ten business days of submission of the PSEF2 form the FSA/FSS will:

- verify the applicant's eligibility and if the questions raised in the PSEF2 are in scope of the service
- notify the applicant as to whether their request has been accepted or declined

## **Northern Ireland guidance**

In Northern Ireland, novel foods and processes, including precision fermentation, must undergo a safety assessment and authorisation before being placed on the market. Businesses seeking to place their products on the NI market should follow EU rules and the European Commission's authorisation process. For guidance on starting this process, visit the [EFSA website](#).

Information on novel foods currently authorised for sale in the EU and Northern Ireland can be found in the [EU Union List of Novel Foods](#). The [EU Novel Food Status Catalogue](#) can also be used to search for the status of specific products.

Retail agri-food goods moving through the Northern Ireland (NI) Retail Movement Scheme will be able to meet Great Britain public health requirements as set out in legislation, including in relation to novel foods. NIRMS applies to pre-packed retail agri-food goods intended for final consumer sale. A novel food authorised in England, Wales or Scotland will therefore be able to move into Northern Ireland via NIRMS. A list of these can be found in the [register of novel foods](#).

## **Novel food taste trials**

If you conduct a taste trial in the UK, you should refer to the recently updated [novel food taste trial guidance](#) to ensure the trial does not amount to an unlawful placing on the market of an unauthorised novel food.

## **Contacting the team**

If you have any questions about the BSS pilot, please contact the Market Authorisation Innovation Programme team via e-mail at [InnovationResearch@food.gov.uk](mailto:InnovationResearch@food.gov.uk).