Cell-cultivated products Business Support Service

This service is designed to support companies wishing to submit applications for cell-cultivated products to the GB market authorisation service. It supports the applicant throughout the life of the application, offering both pre- and post-submission support.

The Business Support Service (BSS) is a new pilot service offered by the Food Standards Agency, in partnership with Food Standards Scotland (FSS). This service is designed to support companies wishing to submit applications for cell-cultivated products to the UK market authorisation service. It supports the applicant throughout the life of the application, offering both pre- and post-submission support.

We are planning to extend the pilot service to companies producing precision fermentation foods in the future.

Current eligibility

This pilot service is available for cell-cultivated product producers who are planning to apply for authorisation of their product for the UK market.

Benefits to prospective applicants

The service is designed to:

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

How we will use the information gained through the BSS

Through the service, the FSA/FSS will gain insights from prospective applicants about the new technologies, processes and ingredients being used to develop cell-cultivated products for human consumption. This improved understanding will lead to a more efficient risk assessment process and better anticipation of when applications will be submitted for market authorisation

Contacting the team

Should you have any questions about whether you are eligible for this service, or need assistance in applying for support, please contact the cell-cultivated products Sandbox team via email at CCPSandbox@food.gov.uk.

Service Details

Business support service functions

Pre- and post-submission support will be available for cell-cultivated product applicants.

Pre-submission support:

Prospective applicants can engage with the FSA/FSS before submitting a dossier to gain clarity on essential requirements such as data collection, hazard identification, and overall safety standards. Based on their product's development stage and estimated timeline for dossier submission, companies are assigned to one of three tiers.

Post-submission support:

During the processing of the application, if the FSA/FSS identify any gaps in the dossier, a Request for Information (RFI) will be issued to the applicant. Businesses responding to RFIs can access additional guidance through the BSS to help them understand and address any missing information identified in their dossiers.

Advice provided by the FSA/FSS as part of this service will be general in nature and provided without prejudice. It will not form part of the formal statutory process and should not be viewed as an authoritative or binding statement as to the likely outcome of an application or constitute approval in-principle.

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.

If prospective applicants require further support to develop their dossiers to the standard required for submission, beyond the level of support that is able to be provided by the BSS, they should consult an independent regulatory specialist.

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

The following are not included as part of the BSS'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's 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 cell-cultivated product for human consumption on the UK market, and
- submit a pre-submission enquiry form (PSEF1) following the process outlined in the section titled 'Engaging with the Pre-submission support'.

Engaging with the Pre-submission support service

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

Upon submission of the PSEF1, you will receive an automated message advising of the form's receipt and the next steps to be taken by the FSA/FSS.

The FSA/FSS will also receive an email notification of the form's submission. Within ten (10) business days of the email notification, the FSA/FSS will:

1. verify the applicant's eligibility and the questions raised in the PSEF1 are within scope of the pre- submission support service and, if applicable, triage the incoming request according to the product's development stage and estimated date of dossier submission, following the process outlined in the section titled 'Tiers of pre- submission support available'
2. notify you as to whether their request has been:

- accepted, outlining any next steps in terms of engagement; or
- declined, providing a justification for the decision (for example, the questions raised were not in scope of the pre-submission support service).

Under the BSS, prospective applicants will be able to request pre-submission support from the FSA/FSS at any time prior to application.

To ensure the timely provision of advice, it is recommended prospective applicants engage with the service at least six (6) months prior to their application's envisaged submission date.

Whilst engaging with the BSS prior to application submission is not mandatory, it is strongly encouraged.?

If a prospective applicant seeks to make changes to their dossier after engaging with the service, they should ensure all changes are captured in the final documentation submitted.

Tiers of pre-submission support available

Pre-submission support offered by the FSA/FSS will vary based on the FSA/FSS's assessment on each product's 'Tier', ranging from:

- **Tier 1:** For products in their final stage of development, with dossiers expected to be submitted for approval in <12 months.
- **Tier 2:** For products that are well progressed in their development, with dossiers expected to be submitted for approval in >12 and < 24 months.
- **Tier 3:** For products in their early stage of development, with dossiers expected to be submitted for approval in >24 months.

Tier 1

Support provided will include offering prospective applicants up to two (2) one-to-one meetings 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; and
- The prospective applicant to enhance their knowledge of the regulatory process and receive further clarity in respect to any technical questions.

Tier 2

Prospective applicants that are well progressed with their product's development and expected to submit a dossier to FSA/FSS for approval within the next twelve (12) to twenty-four (24) months will receive enhanced support from the FSA/FSS 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 to do so. The applicant must also have expressed compelling reasons in their PSEF1 as to why their request should be prioritised. Please note that this will be judged at the FSA/FSS' discretion. Compelling reasons could include, but are not limited to:

- the product being non-routine or highly innovative relative to other cell-cultivated products, 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

Prospective applicants that are in the early stages of product development and are not expected to submit a dossier for approval in the next two years will receive light touch support from the FSA/FSS in the form of written guidance and public facing webinars.

In alignment with the Tier 2 process, and the FSA/FSS's Service Standards, the FSA/FSS will have twenty (20) business days from the date of the applicant's PSEF1 submission to provide a written response.

One-to-one meetings with Tier 3 applicants will only be offered in exceptional circumstances, following a review of the compelling factors outlined above.

In addition to providing written responses, the FSA/FSS will also communicate the learning from the sandbox programme to prospective applicants. These communications will:

- provide an overview of the FSA/FSS's role and the market authorisation process,
- provide a high-level overview of cell-cultivated products and their regulatory requirements,
- discuss the role of the Sandbox and progress made to date
- provide prospective applicants the opportunity to ask tailored questions about their product, ensuring any information shared is not confidential

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's post-submission support function, the applicants must meet all the below three (3) criteria:

- have applied for market authorisation to place a cell-cultivated product for human consumption on the UK market prior to the establishment of the BSS, unless otherwise agreed by the FSA/FSS,
- have been issued a Request for Information (RFI) 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
- submitted a post-submission enquiry form (PSEF2) following the process outlined in the section titled 'How do I engage with the post-submission Support?'.

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 cell-cultivated product for human consumption on the UK market prior to the BSS launch,
- did not have a meeting before submitting their dossier, and
- have subsequently been issued a request for information (RFI) by the FSA/FSS.

Applicants falling into this latter 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).

Upon submission of the PSEF2 form, the applicant will receive an automated message advising of the form's receipt and the next steps to be taken by the FSA/FSS. The FSA/FSS will also receive an email notification of the form's submission. Within ten (10) business days of the email notification, the FSA/FSS will:?

- verify the applicant's eligibility and if the questions raised in the PSEF2 are in scope of the service. Information provided in the PSEF2 will be used by the FSA/FSS to decide the company's eligibility.
- notify the applicant as to whether their request has been:?
- accepted, outlining any next steps in terms of engagement; or??
- declined, providing a justification for the decision (for example the applicant was not eligible, or the questions raised were not in scope of service) and a mechanism for raising complaints if not satisfied with the service.

If a prospective applicant seeks to make changes to their dossier after engaging with the BSS, they should ensure all changes are captured in the final documentation submitted.

Signing up with the service

Please refer to the relevant section depending on your application submission stage.

Should you have any questions about whether you are eligible for this or need assistance in applying for the service, please contact the cell-cultivated product Sandbox team via email at CCPSandbox@food.gov.uk .

Expanding the offer to precision fermentation companies

The FSA and FSS aims to provide this service to companies producing precision-fermented foods in the near future. We will update this webpage when the service is expanded to incorporate these products.