

Precision breeding business support service (BSS)

Guidance for organisations intending to apply to the Food Standards Agency (FSA) for market authorisation of a precision bred organism (PBO).

Important

Please consider the following supporting documents before submitting a request:

- [PB Applicant guidance](#)
- [PB Technical guidance and its Annex A](#)
- [PB Applicants FAQ](#)

In some instances, useful information can also be found in other guidance:

- [Novel food](#) - The novel food consultation process (also known as an Article 4 consultation request) is available to businesses who are unsure of the novel food status of their product(s) and have evidence of a significant history of consumption of the food in the UK or European Union (EU) prior to May 1997. This may be used when unsure whether the species a PBO from has a relevant History of safe food use (Section 11).

Organisations intending to apply to the Food Standards Agency (FSA) for market authorisation of a precision bred organism (PBO) can request support through the FSA's [Precision Breeding Business Support Service \(BSS\)](#) before submitting their application. Please review the guidance provided and complete the accompanying enquiry form.

Who is eligible for BSS

To be eligible to engage with the BSS, prospective applicants must:

- Be a registered company in one or more jurisdictions, or an organisation which will be represented by such a company for their application.
- Intend to submit an application for market authorisation of a precision bred organism(s) to the Food Standards Agency, and
- Submit a fully completed [pre-submission enquiry form](#) following the process outlined in the section titled 'Engaging with the BSS'. Requests submitted through any other channel, including the Regulated Products Inbox, will not be processed.

Items falling within the scope of the BSS

General advice on rules, guidelines, and content requirements for applications seeking authorisation to place a PBO on the food or feed market in England, as set out in the relevant legislation and guidance, including:

- High-level advice on the market authorisation process.

- Guidance on conducting a Tier 1 safety assessment.
- Information or evidence to be submitted as part of an application under Regulation 20 (Tier 1) or Regulation 22 (Tier 2).

What is not covered by the BSS function

- Information that goes beyond that which is available in the legislation or technical guidance.
- Formal review or consultation on draft dossiers (or parts of).

Engaging with the BSS

To engage with the service, prospective applicants must submit a [pre-submission enquiry form](#). The FSA will acknowledge receipt of the enquiry form within 20 days.