Application details

Guidance for applicants requiring a food and/or feed marketing authorisation for a Precision Bred Organism (PBO). Please note that this is draft guidance. You can contact precisionbreeding@food.gov.uk with any questions or if you wish to discuss this draft guidance. This page is part of the Regulated products application guidance.

Before you apply

Before applying, applicants should have completed the “Tier 1 safety assessment” process using the FSA’s technical guidance on PBOs. Applicants must have determined the correct regulatory route for which they should apply through and have the necessary information to evidence their conclusions.

Application process

To apply for an authorisation of a PBO for use in food and feed in England:

1. Use our regulated products application service to complete the application. This is where you will be asked to provide information on your PBO to support your application.
2. You should adhere to the mandatory information requirements in Schedule 4 of the Genetic Technology (Precision Breeding) Regulations 2025 and supporting technical guidance provided by the FSA.
3. For all applications, you will need to submit the relevant marketing notice provided to the Secretary of State (and supporting documents) as well as the relevant precision bred confirmation issued by the Secretary of State.
4. If you are submitting a Regulation 20 application, you will be required to provide explanatory statements to demonstrate how you have reached your conclusions from the Tier 1 safety assessment process that there are no safety concerns relating to all of the criteria. You will not need to provide a data package to support your application.
5. If you are submitting a Regulation 22 application, you will be required to submit complete, unredacted copies of the evidence you used to make the explanatory statements for each safety concern that has arisen following the Tier 1 safety assessment process under one or more of the food/feed safety criteria. This may include, but is not limited to, test results, scientific analyses, data studies, surveys or scientific records. This will enable FSA officials to review the evidence and conduct a Tier 2 safety assessment. The outcomes of this assessment will be used to determine whether the PBO can be recommended for authorisation.

Application requirements

The mandatory information requirements are listed in Schedule 4 of the Genetic Technology (Precision Breeding) Regulations 2025. All applicants are expected to provide the following:

- name, organisation and contact details of the applicant

- complete, unredacted copies of the relevant marketing notice provided to Defra and supporting documents
- the relevant precision bred confirmation issued by the Secretary of State
- where the confirmation covers more than one PBO, a full list of all PBOs and the genetic change(s) in each PBO
- information on the organism and the genetic change(s), including a description of how the edible part of the PBO is affected
- statements in relation to each criterion (novelty, nutritional quality, toxicity, allergenicity and other safety concerns)
- any request for confidentiality of any information provided (including justification for the request)

During the application process you will be asked to complete the following sections in our regulated products application service:

1. Type of application – Whether you are applying under Regulation 20 or Regulation 22
2. Applicant and organisation details – If your PBO is granted authorisation for use in food and feed, the authorisation holder's name (or organisation) and address will be published on the public register.
3. Application summary – A brief summary of the application.
4. PBO details and safety information – This is where you will need to upload any relevant confirmation documents and enter information including:

- the confirmed Defra reference number (as issued by Defra at confirmation and listed on the Defra public register)
- identity of the PBO (genus and species)
- the intended use of the PBO (whether for food use, feed use, or both)
- a description of the genetic change and how this change affects the edible part of the organism
- a description of the purpose of the genetic change (e.g., to confer drought or disease resistance)
- for each criterion in Regulation 20(1)(b) and (c), you will need to declare the outcome from your Tier 1 safety assessment and provide a descriptive statement detailing your conclusions
- you will be asked to upload supporting evidence and corresponding explanatory statements for any of the criteria under which safety concerns have been identified or for which the conclusion is one of uncertainty

5. You will also be asked to complete a statement outlining any requests for confidentiality of information provided as part of your application and a statement of truth declaring the information you have provided to be accurate.

How long will my application take?

The length of the approval process will vary depending on the regulatory route and the complexity of the application. In most cases, we expect to submit recommendations to the Secretary of State for approval of a PBO for use in food and feed up to 60 days from receipt of a Regulation 20 application.

Applications made under Regulation 22 will take longer than this to allow for a bespoke safety assessment based on the conclusions provided in the application.

The quality of the application, and the information provided, will significantly affect the time needed for assessment and authorisation. For all applications (under Regulations 20 and 22), we encourage applicants to follow the guidance and provide as much information as possible to

ensure we can process your request as efficiently as possible.

Regulation 20 applications

Verification

Following receipt of a Regulation 20 application, FSA officials will undertake a verification process. This will involve checking that the required information has been provided to make a report to the Secretary of State, and that the required information has been provided for publication on the public register of PBOs authorised for use in food and feed.

If you have requested confidentiality of any information provided in your application, this will be decided as part of the verification process.

The Genetic Technology (Precision Breeding) Regulations 2025 require applications made under this regulation to be sufficiently detailed to allow the FSA to assess the application, having regard to the nature and scale of the application. The FSA may, at their discretion, request further information, including evidence, in support of the application as part of the verification process.

Regulation 22 applications

Verification

Following receipt of a Regulation 22 application, FSA officials will undertake a verification process. This will involve checking that the required information has been provided to enable a bespoke safety assessment to be conducted by FSA officials, and that the required information has been provided for publication on the public register of PBOs authorised for use in food and feed.

If you have requested confidentiality of any information provided in your application, this will be decided as part of the verification process.

Tier 2 Safety Assessment

Once the FSA has verified the application, the FSA will assess the supplementary scientific evidence provided by the applicant for each of the criteria associated with a potential safety concern. The technical guidance provides applicants with information on the type and amount of scientific data that should be submitted to the FSA for each of the criteria and applicants can submit any other scientific evidence they feel is relevant to their application. Given that each PBO may have a different combination of potential safety concerns, applications will be assessed on a case-by-case basis. There may be circumstances where additional specific information is required from the applicant and where this arises, the FSA will explain to the applicant why the additional information is needed.

Following the tier 2 safety assessment, and in line with the FSA/Food Standards Scotland's risk analysis process, the FSA will conduct risk management based on the outcomes of the safety assessment, consideration of any other legitimate factors associated with the application, and of any new information obtained through any public consultation, before a recommendation is made to the Secretary of State.

What happens next?

PBOs that have been authorised for use in food and feed and placed on the public register are free to be placed on the market (in England) as long as they are compliant with any conditions or

limitations set out in the authorisation.

PBOs placed on the market in England will be subject to the same standards as their traditionally bred equivalents and food and feed business operators handling PBOs are expected to meet their statutory obligations in relation to food and feed safety as is the case with any food or feed.

“Qualifying Progeny” of PBOs authorised for use in food and feed

The Genetic Technology (Precision Breeding) Regulations 2025 establish the qualifying progeny of authorised PBOs as within scope of the regulatory framework. New applications are not required for the qualifying progeny (as defined by Section 24 of the Genetic Technology (Precision Breeding) Act 2023), but businesses are prohibited from marketing food and feed containing varieties with precision bred features without prior authorisation for the precision bred element of those varieties. This means that breeders and developers are able to use authorised PBOs in traditional breeding cycles without seeking a new authorisation for food and feed uses, however any conditions and limitations attached to the PBO authorisation must be complied with when considering further breeding cycles.

Precision breeding and other regulated products

Some PBOs may be subject to further regulation depending on their intended use. For example, some regulated products could be developed using PBOs. Before using an authorised PBO in the development of a new regulated product (for example, a food enzyme or flavouring), guidance should be sought on the regulatory requirements for the new product.

Assimilated Regulations in other areas of regulated products have been amended by the Genetic Technology (Precision Breeding) Regulations 2025 to reflect these requirements. In the case of Assimilated Regulation (EC) 2015/2283 on novel foods (“Novel Food Law”), an amendment has been made to remove precision bred plants from the scope of Novel Food Law (in England). Similar amendments have also been made to Assimilated Regulations (EC) 1829/2003 and 1830/2003 to explicitly remove precision bred plants from the scope of GMO Food and Feed regulation (in England). These amendments mean that precision bred plants will not require assessment under either the GMO or novel foods regulatory frameworks.