

## Legislative requirements

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 Please note that this is draft guidance.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[precisionbreeding@food.gov.uk](mailto:precisionbreeding@food.gov.uk) with any questions or if you wish to discuss this draft guidance.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](#).

### Obligations on food and feed businesses (“General Food Law” and other statutory requirements)

All food and feed businesses have a duty to ensure that the food and feed they market is compliant with existing food and feed safety legislation. Under [Assimilated Regulation \(EC\) 178/2002](#), food must not be marketed if it is injurious to health or is unfit for human consumption. Animal feed fed to food producing animals must not have an adverse effect on human or animal health, or make the food derived from the animal unsafe for human consumption.

Before considering their application, applicants should have regard to existing duties and requirements imposed by the [overarching regulations](#) that underpin food safety in the UK.

In addition to complying with the specific requirements for the authorisation of a PBO for use in food and feed, all food and feed businesses are expected to exercise appropriate due diligence in ensuring food and feed containing or consisting of PBOs is safe. [The FSA provides food businesses with guidance](#) to help make sure they understand their statutory obligations under food and feed law.

The FSA has published [technical guidance to support applicants throughout the application processes](#) outlined in Regulations 20 and 22 of The Genetic Technology (Precision Breeding) Regulations 2025. It explains the level of due diligence we would expect food and feed business operators to exercise to ensure that the food and feed that they are producing is as safe as is reasonably possible, as well as specific measures that should be taken into account when determining which regulatory route applies to their PBO. It is not intended to be a comprehensive guide on food or feed safety and applicants are expected to refer directly to food and feed safety legislation and guidance in addition to this.

As the food safety authority, the FSA has the statutory function of providing advice and information on matters related to food and feed safety or other consumer interests in relation to food and feed. [Our technical guidance](#) serves to support compliance with the statutory requirements in law. It establishes best practice on what the FSA considers the key considerations that must be made to ascertain the safety of a PBO.

The requirements are not exhaustive, and applicants should consult the FSA if there are any key factors not outlined in the guidance that they have identified through due diligence that may impact the safety of the PBO (or any food or feed produced from it).

The Genetic Technology (Precision Breeding) Regulations 2025 establish enforcement powers for Local Authorities in England to monitor compliance and take action on non-compliance with

the Regulations. Local Authorities also have existing powers in [The Food Safety Act \(1990\)](#) to take action on food and feed businesses where precision bred food or feed is found to be unsafe and to prosecute those responsible.

## **The Genetic Technology (Precision Breeding) Act and The Genetic Technology (Precision Breeding) Regulations 2025**

Before a PBO can be used in a food or feed product and placed on the market in England, it must be authorised under The Genetic Technology (Precision Breeding) Regulations 2025. The Regulations are made under powers established in [The Genetic Technology \(Precision Breeding\) Act 2023](#). The Regulations outline the statutory requirements on applicants to consider the safety of the use of their PBO in food and feed and submit an application under the correct regulatory route.

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### **Application for a precision bred confirmation**

Before you can apply for a food and feed marketing authorisation for a precision bred organism, you must first obtain a precision bred confirmation from the Secretary of State for Environment, Food and Rural Affairs. You must do this by submitting a marketing notice to Defra in line with the requirements in the Genetic Technology (Precision Breeding) Regulations 2025.

Defra has published [new draft guidance documents to support the understanding of the Genetic Technology \(Precision Breeding\) Regulations 2025](#), including the PBO confirmation process, on its website.

Under the requirements in The Genetic Technology (Precision Breeding) Act, The Advisory Committee on Releases to the Environment (ACRE) will provide a recommendation to the Secretary of State on the marketing notice before the Secretary of State determines whether to issue a precision bred confirmation. The statutory time limit for ACRE to consider the marketing notice is 90 days.

All confirmed PBOs will be published by Defra on its public register.

Applications to the FSA for a PBO food and feed marketing authorisation that do not include the precision bred confirmation issued by the Secretary of State will not be considered valid.

### **Application for a food and feed marketing authorisation**

There are two routes to authorisation for PBOs used in food and feed, set out Regulation 20 and Regulation 22 of the Genetic Technology (Precision Breeding) Regulations 2025:

1. Regulation 20: PBOs that are very similar to traditionally bred varieties, which consumers are familiar with and for which potential safety risks are understood. Applicant-led Tier 1 safety assessments are required but there is no requirement for a Tier 2 FSA safety assessment and there would be a simpler route to market.
2. Regulation 22: PBOs with traits where the risks are not fully understood. Specifically, this would include novelty or PBOs that have compositional changes which could affect nutritional quality, toxicity or allergenicity, or other safety concerns where potential food and feed safety risks need further consideration. There would be a bespoke Tier 2 safety assessment process, including a more detailed examination of the characteristics of the PBO.

Prior to applying for a food or feed marketing authorisation, applicants are expected to determine the correct regulatory route by assessing the PBO against the following criteria:

- **History of Safe Food Use** - whether the PBO belongs to a species that has a history of safe food use in that its safety as food has been confirmed with compositional data and from experience of continued food use in the customary diet of a significant number of people in the United Kingdom or the European Union beginning before 15 May 1997
- **Composition** - whether the application of modern biotechnology introduces genetic changes that are expected to:
  1. Significantly alter the nutritional quality of the organism as it is being consumed as food or feed at the date of the application in a way that is likely to be disadvantageous to the consumer
  2. Significantly elevate the toxicity of any food or feed produced from the precision bred organism
  3. Alter the allergenicity of any food or feed produced from the precision bred organism
- **Other safety concerns** - Whether the application of modern biotechnology introduces any additional features that may affect the safety of any food or feed produced from the precision bred organism

[The FSA's technical guidance](#) provides details on what is expected from applicants when conducting their safety assessment and making a determination on which regulatory route to apply through.

## Batching of PBOs

The Genetic Technology (Precision Breeding) Regulations 2025 allow applicants to include multiple PBOs in their application, provided that the requirements in Schedule 4(1)(3)(d) are met for all PBOs to which the application relates. The information provided in the application must be representative of all PBOs in the batch.

All PBOs included in the application to the FSA must be covered by the same marketing notice and subsequent precision bred confirmation issued by the Secretary of State. Multiple PBOs included in the same marketing notice provided to Secretary of State must meet the requirements in Regulation 5(4) of the Genetic Technology (Precision Breeding) Regulations 2025.

New PBOs cannot be retrospectively added to an existing precision bred confirmation. Should modern biotechnology be used to produce a new PBO which contains the same genetic changes as one which has previously been granted a precision bred confirmation, a new marketing notice must be submitted to the Secretary of State. Similarly, any PBOs intended to be used in food and feed and subject to a new marketing notice would require a new food and feed application to be submitted to the FSA.