Precision bred organisms: application guidance

What are precision bred organisms?

Precision bred organisms (PBOs) are plants or animals where the genetic makeup of the organism has been altered using techniques of modern biotechnology (such as gene editing) in a precise way.
This page is part of the Regulated products application guidance.

Precision bred organisms (PBOs) are plants or animals where the genetic makeup of the organism has been altered using techniques of modern biotechnology (such as gene editing) in a precise way. To qualify as a PBO, the changes to the organism must be those that could have also been achieved through traditional breeding methods.

Precision breeding does not include organisms that contain DNA that isn't present in the non-modified organism or in sexually compatible species. These organisms remain classified as genetically modified organisms (GMOs) and regulated as such. You can find guidance on applying for a food and feed marketing authorisation of a GMO on our website.

Before a PBO can be used in food or feed and placed on the market in England, it must first be authorised.

Important
Whilst the Genetic Technology (Precision Breeding) Act 2023 makes provision for precision bred animals, further secondary legislation is required before any gene edited animal can be granted precision bred status. It is therefore not possible to apply for the authorisation of the use of precision bred animals in food and feed.

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 Please note that this is draft guidance. You can contact precisionbreeding@food.gov.uk with any questions or if you wish to discuss this draft guidance.
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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.

Important

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.

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.

Change in circumstances affecting a market authorisation

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.

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Following authorisation, it is the duty of the authorisation holder and any businesses placing on the market authorised food or feed produced from the PBO to ensure that the PBO is being used in line with the authorisation, including any conditions or limitations that have been imposed.

The FSA's technical guidance provides advice to applicants on how to consider potential uses of their PBO in food and feed, and how this may have an impact on the overall safety of the end product; however, we appreciate that not all intended uses of the PBO in food and feed will be known at the time of application.

If the authorisation holder or any business placing (or intending to place) on the market food and feed produced from the PBO becomes aware of any changes in circumstances that may affect the safe use of the PBO, they must advise the FSA immediately.

In many cases, it is likely that any change in circumstance may be sufficiently covered by existing food and feed legislation. In these instances, the FSA will be able to provide advice on how to manage any potential safety risks. In some cases, the FSA may need to conduct further assessment of the PBO in order to consider whether any variations need to be made to the authorisation in the context of the change in question. For example, if the PBO is intended to be processed in a way post-harvest that would otherwise be considered a novel process under Novel Food Law (and this process has not been assessed previously under the relevant framework) the FSA may need to conduct further assessment of the novel process before the PBO can be used in such a way.

Should the FSA be made aware of any information or evidence that justifies further assessment of the PBO, the authorisation holder or business using the PBO may be asked to provide additional information to support the assessment.

Should any variation to the authorisation or new conditions or limitations be required, these changes will be reflected on the public register .

Revocation of a market authorisation

Under Regulation 33 of the Genetic Technology (Precision Breeding) Regulations 2025, the Secretary of State may revoke a food and feed marketing authorisation should new evidence come to light that calls into question the safety of the PBO as it is used in food and/or feed. In the event of any such evidence being made available, the authorisation holder will be given the opportunity to respond before an authorisation is revoked.

Under Regulation 7 of the Genetic Technology (Precision Breeding) Regulations 2025, the Secretary of State may revoke a precision bred confirmation relating to a PBO if they are no longer satisfied that the PBO is precision bred. Since precision bred confirmation is a prerequisite for the lawful marketing of food and feed produced from a precision bred organism, a revocation of this manner will automatically lead to a revocation of the subsequent food and feed market authorisation.

UK internal market

The Genetic Technology (Precision Breeding) Regulations 2025 apply only in England. However, under the market access principles of The United Kingdom Internal Market Act 2020 (UKIMA), food and feed produced from authorised PBOs in England can be sold into Wales and Scotland.

The UKIMA market access principles do not, however, extend to the further processing of such goods moved into Wales and Scotland. Any precision bred food/feed which is subject to further processing in Wales or Scotland before being placed on the market would be subject to legislation regulating the use of Genetically Modified Organisms (GMOs) in food and feed.

In Northern Ireland, only food and feed which meets the criteria of the Northern Ireland Retail Movement Scheme can be moved into and placed on the market in Northern Ireland.

Getting help

If you have any questions about the authorisation procedure or application requirements, you can contact us at regulatedproducts@food.gov.uk

Apply for a marketing authorisation

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.

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Getting help

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Please also refer to the technical guidance when making your application.

England, Northern Ireland and Wales

PDF
View DRAFT Technical guidance to applicants for the authorisation of Precision Bred Organisms for food and feed as PDF(Open in a new window) (1.55 MB)

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Revision log

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- **28 February 2025** added 'Change in circumstances affecting a market authorisation' page
- **27 February 2025** removed 'Change in circumstances affecting a market authorisation' (25556) from this guide for time being

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