

Apply for a marketing authorisation

The Genetic Technology (Precision Breeding) Regulations 2025 have come into force on the 13th November 2025, which means businesses can apply for a Precision Bred Organism (PBO) food and feed marketing authorisation.

This page is part of the Regulated products application guidance.

The <u>Genetic Technology (Precision Breeding) Regulations 2025</u> have come into force. Applicants must first apply to <u>Defra for PBO confirmation and marketing authorisation</u>. Once this is granted, applicants can then apply to the FSA for a food and feed marketing authorisation.

Applicants should follow the instructions in the PBO technical guidance to conduct a safety assessment of their PBO and determine the correct application route. Further details of the application process can be found here.

Update on Technical Guidance for Precision Bred Organisms (PBOs)

In February 2025, the Food Standards Agency (FSA) published draft Technical Guidance for applicants seeking authorisation of Precision Bred Organisms (PBOs) for food and feed use. Since then, we have worked closely with stakeholders through workshops and surveys to ensure the guidance is clear, practical, and meets the needs of prospective applicants. Participants included small and medium enterprises, academia, seed breeders, and industry representatives such as the British Society of Plant Breeders (BSPB).

Feedback highlighted the need for clearer technical language, a concise explanation of Tier 1 and Tier 2 data requirements, guidance on selecting information sources, and a clearer distinction between PBO and GMO safety assessments. In response, the FSA has revised the guidance to improve clarity and usability. Updates include simplified text, additional figures and definitions, a benchmark references section, and formal instructions for conducting a hypothesis-led Tier 1 safety assessment. A shorter, streamlined version of the guidance will also be available.

These improvements were validated through follow-up workshops, which confirmed that the changes enable applicants to confidently undertake Tier 1 assessments and identify the correct regulatory route for their PBO. The revised guidance has also been reviewed by the Advisory Committee for Novel Foods and Processes (ACNFP) Subcommittee on Products of Genetic Technologies Destined for Food and Feed Purposes.

We would like to thank all stakeholders for their valuable input, which has strengthened the guidance and ensured it supports innovation while maintaining safety.

Next steps

The Precision Breeding Technical Guidance can be viewed below.

To receive further updates on market authorisations, please <u>sign up</u> to our market authorisations newsletter.

PDF

<u>View Precision Breeding Technical Guidance for Applicants as PDF(Open in a new window)</u> (1.59 MB)

PDF

<u>View Annex A: Precision Breeding Technical Guidance for Applicants as PDF(Open in a new window)</u> (407.9 KB)

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