

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Please note that this is draft guidance.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with any questions or if you wish to discuss this draft guidance.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

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](mailto:regulatedproducts@food.gov.uk)