



Department
for Environment
Food & Rural Affairs

Genetic Technology (Precision Breeding) Bill

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Environment
Agency



Forestry Commission



NATURAL
ENGLAND

Rationale



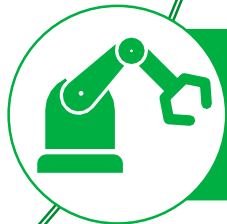
Enabling innovation in genetic technologies could help deliver key agricultural and environmental objectives including addressing food security challenges, climate change and biodiversity loss.



The UK is at the leading edge of genetics and genomics research, and we want UK researchers and commercial breeders to be at the forefront of exploring what this technology has to offer.



Leaving the EU has provided the UK with the opportunity to adopt a more science-based and proportionate approach to the regulation of precision bred organisms.



Current GMO legislation is more than 30 years old and has not kept pace with advances in technology and scientific development.

The Genetic Technology (Precision Breeding) Bill



- The Precision Breeding Bill will introduce a new, simpler regulatory regime in England for precision bred plants and animals to enable these organisms and derived human food and animal feed products to be authorised and brought to market.
- We will be starting with plants first, followed by animals.
- The four key policy changes are:



Removing precision bred plants and animals from regulatory requirements applicable to GMOs (excluding those relating to microbes, organics and contained use).

Introducing two notification systems for research and marketing purposes where breeders and researchers will need to notify Defra of precision bred organisms. The information collected will be published on a public register.

Establish a proportionate regulatory system for precision bred animals to ensure animal welfare is safeguarded. We will not be introducing changes to the regulations for animals until this system is in place.

Establish a new science-based authorisation process for food and feed products developed using precision bred organisms.



Notification of a Precision Bred Organism

- Before a prospective PBO can be marketed, developers must submit a notification to Defra, outlining the genetic changes made.
- This will be assessed by Advisory Committee on Releases to the Environment (ACRE), who will provide advice to Defra's Secretary of State. The Secretary of State will base a decision on whether to confirm PBO status based on this advice.
- Organisms designated as precision bred must only have genetic changes that could have occurred naturally or by traditional processes.
- Once a PB status confirmation is received for plants, they can be marketed (subject to meeting other regulatory requirements not specific to PBOs)
- For PB animals, there is an additional step for welfare considerations.



The process of applying for a precision bred animal marketing authorisation (including imports)



Step 1: Confirm that the organism is a Precision Bred Organism (PBO)



Step 2: Submit an application containing an Animal Welfare Declaration and supporting evidence to confirm that the trait does not have adverse effects on the welfare of the animals



Step 3: Animal Welfare Advisory Body assess the declaration and may choose to request additional information from the developer (the notifier)



Step 4: The Animal Welfare Advisory Body submit a report on the application to the Secretary of State for Defra



Step 5: If the Secretary of State is satisfied with the application, then a marketing authorisation may be granted, and the animal (and qualifying progeny) can be marketed



Step 6: Post-market monitoring of precision bred animals and their qualifying progeny for adverse health and welfare effects



Implementation

- The Act will be brought into force by commencement regulations.



The intention is that provisions relating to plants will be brought into force first.



The provisions relating to animals will be brought into force at a later stage, once we have put in place measures to safeguard animal welfare.



Powers for a new proportionate, and science-based food and feed authorisation process to be introduced, with a pre-market risk assessment for food and feed products developed using precision bred organisms.

- Developing a more proportionate and science-based approach will align us with many other countries that have considered or are in the process of considering whether to regulate PBOs differently from GMOs.

Legislative Impacts



- **Labelling**

- Due to the scientific advice that precision bred organisms pose no greater risks than their traditionally bred counterparts, and that food and feed will be authorised as being safe by the FSA, labelling will be restricted to known health issues such as presence of allergens or significant nutritional or compositional changes.

- **Public Register**

- **Monitoring and Inspection**

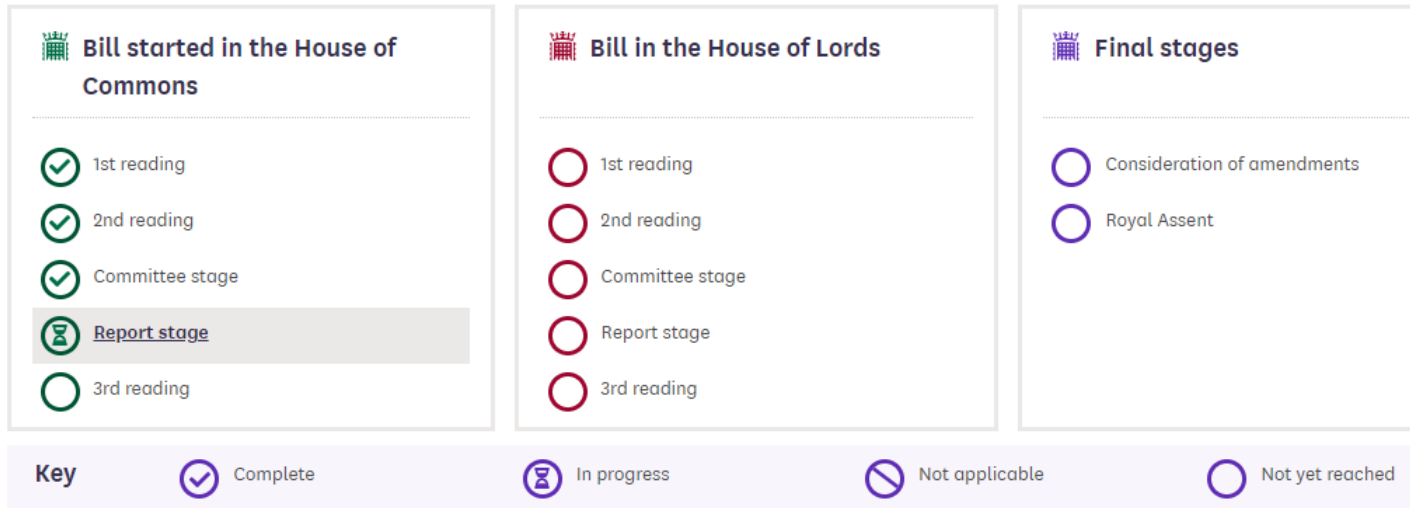
- **Enforcement**

- **Fees**

Next Steps



Bill passage



Ongoing engagement with stakeholders and expert advisory bodies

Commission research to help us develop a welfare assessment framework for precision bred animals