



Department
for Environment,
Food & Rural Affairs

Precision Breeding Regulatory Overview

1st May 2025 – Dr Richard Kino



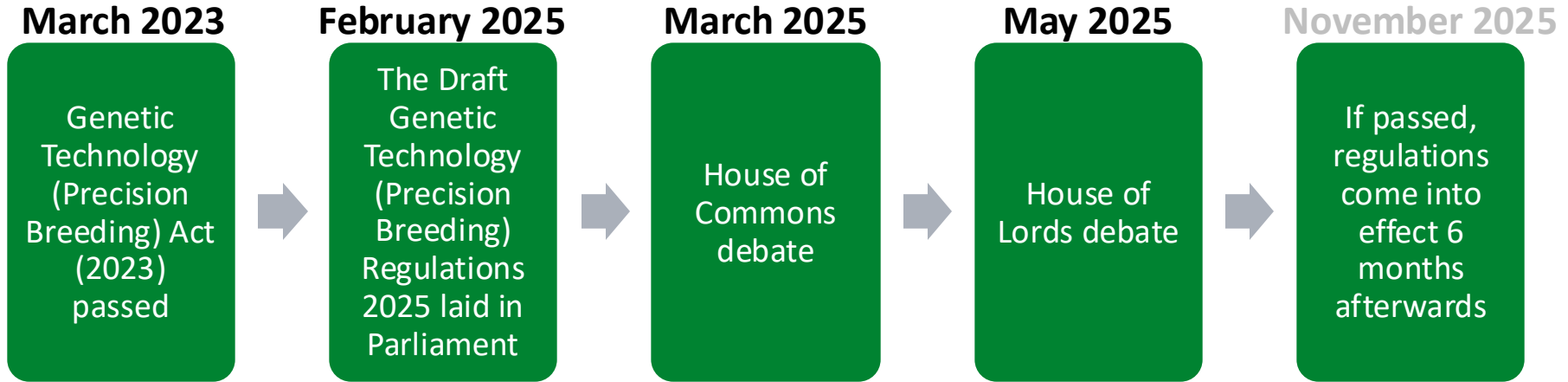
Precision Breeding Act & Regulations

- **The Act:** Genetic Technology (Precision Breeding) Act 2023
 - Sets out the regulatory framework – defines PBO, who regulates & enforces what
- **The Regulations:** The Genetic Technology (Precision Breeding) Regulations 2025
 - Operational implementation of The Act
 - Currently draft legislation: laid before parliament but not yet into law
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Timeline



The Draft Genetic Technology (Precision Breeding) Regulations 2025

Contents

- Release of precision bred organisms
- Marketing of precision bred organisms
- The precision breeding register
- Monitoring and inspection of release and marketing
- Food and Feed produced from precision bred organisms
- The food and feed register
- Monitoring and inspection of marketing
- Enforcement of relevant breaches

<i>Draft Regulations laid before Parliament under section 41(4) of the Genetic Technology (Precision Breeding) Act 2023, for approval by resolution of each House of Parliament.</i>	
DRAFT STATUTORY INSTRUMENTS	
2025 No.	
AGRICULTURE, ENGLAND	
ENVIRONMENTAL PROTECTION, ENGLAND	
FOOD, ENGLAND	
The Genetic Technology (Precision Breeding) Regulations 2025	
Made - - - - - ***	
Coming into force in accordance with regulation 1(1)	
CONTENTS	
Part 1	
Introduction	
1.	Citation, commencement, extent and application
2.	Interpretation
Part 2	
Release of precision bred organism	
3.	Notification requirement for release of precision bred organism in England
4.	Transitional provisions for release
Part 3	
Marketing of precision bred organism	
5.	Application for precision bred confirmation - marketing notice
6.	The advisory committee - reporting period etc.
7.	Revocation of precision bred confirmation
8.	Review of a precision bred confirmation or revocation decision
9.	Appeal to the First-tier Tribunal
Part 4	
The precision breeding register	
10.	Information to be included in the precision breeding register
11.	Keeping of the precision breeding register
Part 5	
Environmental risk assessment	
12.	Environmental risk assessment for precision bred organism in contained use

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Release of Precision Bred Organisms – Notification Requirement for Release

- A '**Release Notice**' must be submitted to Defra **20 days prior to release** (i.e. field trialling) of Precision Bred plants.
- The **information required** in 'Release Notices' is listed in the SI's Schedules
- **Different Precision Bred plant lines can be released** following submission of a single notice provided they are (i) of the same species and (ii) contain the types of genetic changes described in the 'General Description' section of the submitted release notice.
- One Release Notice may cover R&D trials at **multiple sites over multiple years and involve multiple organisations** – but there must be one notifier who takes responsibility.

Release Notice Information Requirements

1 & 2 – Name

3. A description of any **persons assisting in the release** of precision bred organisms

4. A **General Description** of the precision bred organism:

- (a) the genus and species
- (b) the intended alterations to characteristics of the organism
- (c) the types of genetic changes introduced to cause the alterations described in paragraph (b)
- (d) the techniques of modern biotechnology used to make the genetic changes described in paragraph (c)

5. **Confirmation** that the person named in paragraph 1:

- (a) Will take appropriate measures, as necessary, to prevent material from the precision bred organism being marketed
- (b) Has assessed that all organisms covered by the release notice **meet the criteria for a precision bred organism** as set out in the Act.

Marketing of Precision Bred Organisms – Notification Requirement for Marketing

- **Defra must confirm** that a plant is a precision bred organism before it can be marketed.
- This decision is based on information provided by developers in a '**Marketing Notice**'.
- The Advisory Committee on Releases to the Environment (ACRE), provides a **recommendation on regulatory status to Defra within 90 days**.
- ACRE **can request additional information** in an 'information notice' and notifiers must respond within 90 days.
- **Different Precision Bred Plants can receive confirmation under one Marketing Notice** when they are (i) from the same species, (ii) have been developed using the same precision breeding techniques, and (iii) have the same alterations to characteristics defined in the notification

Regulatory Process Summary – Precision Bred Organisms

	Release of Precision Bred Organisms (e.g. Field Trials)	Authorisation to Market	Can apply for Food and Feed authorisation
Release Notice	✓	✗	✗
Marketing Notice*	✓	✓	✓

Register of Precision Bred Organisms

- Regulations set out what information must be contained on the public register of Precision Bred Organisms. This includes information submitted in Release and Marketing Notices.
- Notifiers can ask for information in Marketing Notices to be considered commercially confidential. **However**, the '**General Description**' of Precision Bred Organisms, cannot be claimed as being commercially confidential information.
- Release Notices will be added within 20 days of receipt. Marketing Notices, and any enforcement notices associated with a Precision Bred Plant will be added as soon as practicable after a decision has been made or after a Marketing Notice has been withdrawn.

Useful links:

<https://www.legislation.gov.uk/ukdsi/2025/9780348269123> - **The Draft Regulations**

<https://www.legislation.gov.uk/ukpga/2023/6/contents> - **The Act (2023)**

<https://www.gov.uk/government/publications/acre-draft-guidance-on-release-and-marketing-of-precision-bred-organisms> - **Draft Technical Guidance produced by ACRE**

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