



Department  
for Environment  
Food & Rural Affairs

# Government Chemist Conference

## Genetic Technology (Precision Breeding) Act

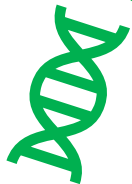
### 2023



# Rationale for Regulation Change



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.



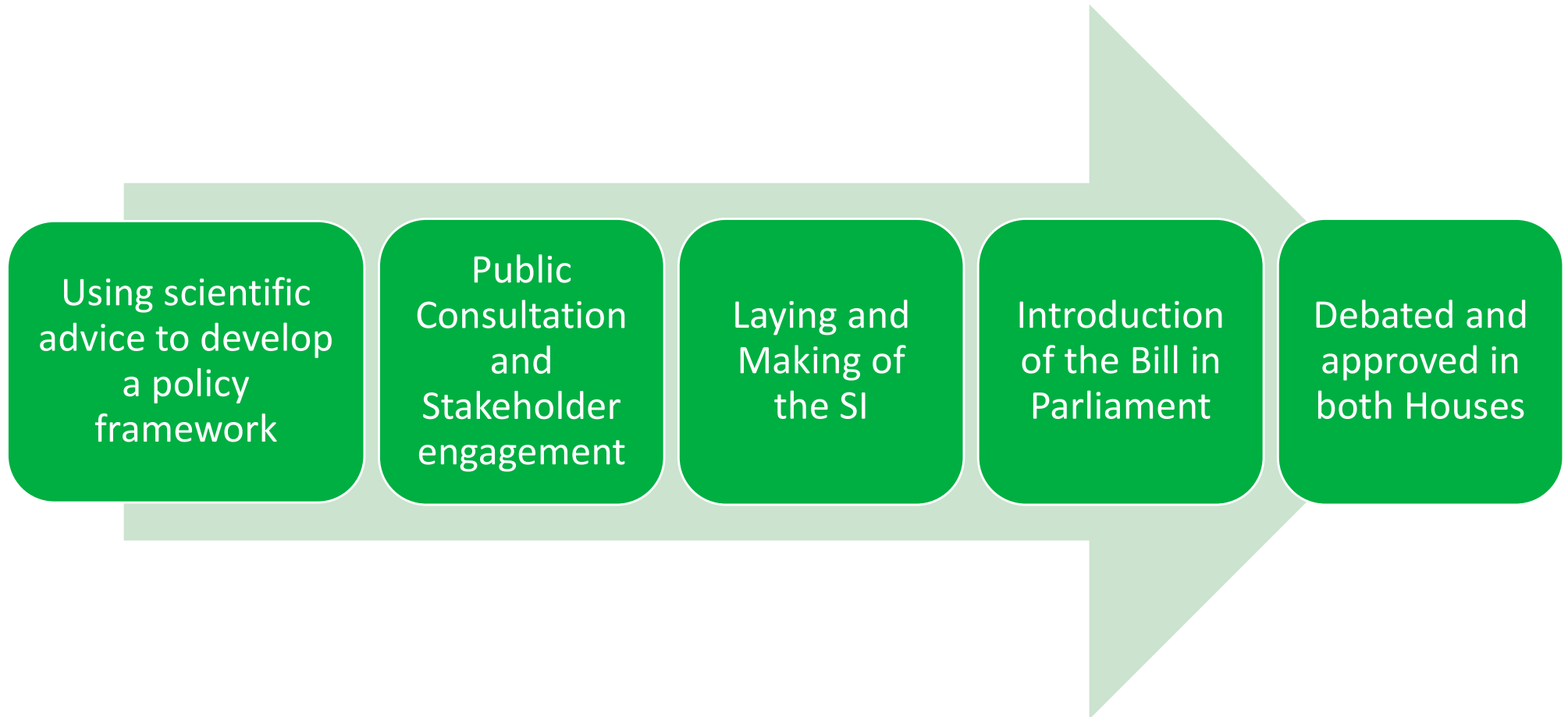
Leaving the EU has provided the UK with the opportunity to adopt a more science-based and proportionate approach to the regulation of precision bred organisms.



Moving to a more progressive, scientifically based approach to governing the use of gene edited products and products generated using other genetic technologies could create significant economic opportunities for the UK.

# From policy proposal to an Act...

**The Advisory Committee on Releases to the Environment (ACRE) advised that it is the final characteristics of an organism that determine risk, rather than the method used to produce it.**

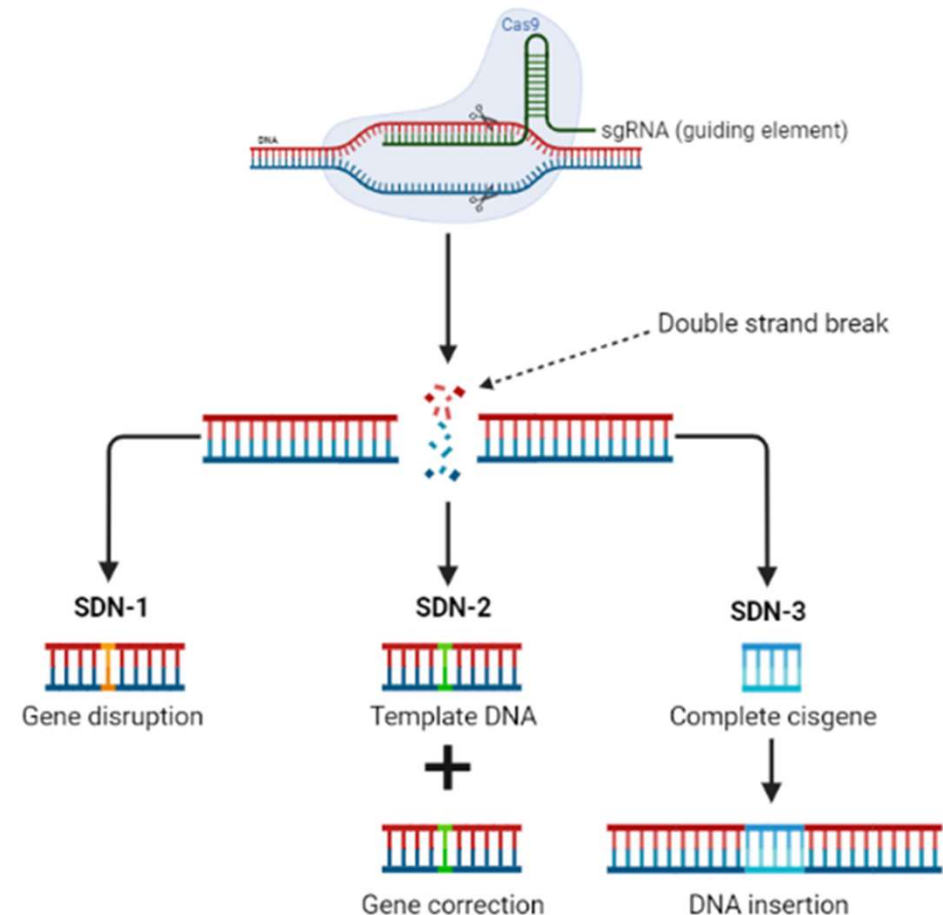


**The Genetic Technology (Precision Breeding) Bill received Royal Assent from the King on Thursday 23rd March 2023, becoming an Act.**

# What is Precision Breeding?


- Precision breeding (PB) refers to the use of modern biotechnology to produce a plant or animal with genetic changes that could also have arisen through traditional processes.

- In practice, this means that precision bred organisms may contain genetic changes arising through SDN1, SDN2 or SDN3, so long as these changes could have arisen within the existing gene pool. This means some cisgenic applications may be considered precision breeding.



# Key policy changes

The Act will bring about the following policy changes:



Removal of precision bred plants and animals from regulatory requirements applicable to the deliberate release of GMOs and introduce simpler regulatory measures to enable these products to be authorised and brought to market more easily.  
(the Act does not apply to microbes and contained use. Organics legislation will not be amended by this Act).

**Organisms whose genomes have been altered using modern biotechnology**

**Genetically modified organisms (GMOs):**

produces organisms containing genes from a sexually incompatible species and that could not occur through traditional breeding.

**Precision bred organisms (PBOs):**

where the genetic changes could have occurred naturally or through traditional breeding methods.

# Key policy changes

The implementation of the associated delegated powers will deliver a proportionate and science based regulatory system:



Introduction of two notification systems:

- For research purposes, developers will need to notify precision bred organisms to Defra before trials can take place.
- For marketing, developers will need to notify Defra and receive a confirmation from Defra SoS on the status of the organism. Defra SoS is required to seek advice from ACRE.
- The information collected will be published on a public register.

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

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

# Animal welfare safeguards in the Act

Marketing  
authorisation

Animal  
welfare  
declaration

Welfare  
advisory body

Post-market  
monitoring

- The system will require a developer to seek a marketing authorisation from Defra before any precision bred animals can be marketed in England.
- When applying, the developer must confirm that the health and welfare of the animal (and its qualifying progeny) is not expected to be adversely affected by any trait resulting from precision breeding.
- The application must be reviewed by a welfare advisory body which must provide a report to the Secretary of State. The Secretary of State will then decide whether to grant a marketing authorisation.
- If granted, there will be post-market monitoring requirements to identify health and welfare problems in precision bred animals.

# Territorial Scope

## **The territorial scope is England only.**

- The regulation of the GMOs and PBOs, is devolved.
- Currently, both the Scottish and Welsh Governments want PBOs to continue to be regulated as GMOs in their territories.
- Northern Ireland (NI) could not join due to the Northern Ireland Protocol at the time.

**We will continue to engage with the Devolved Administrations as we move forward to introduce our legislative programme**





# Next steps in the legislative programme

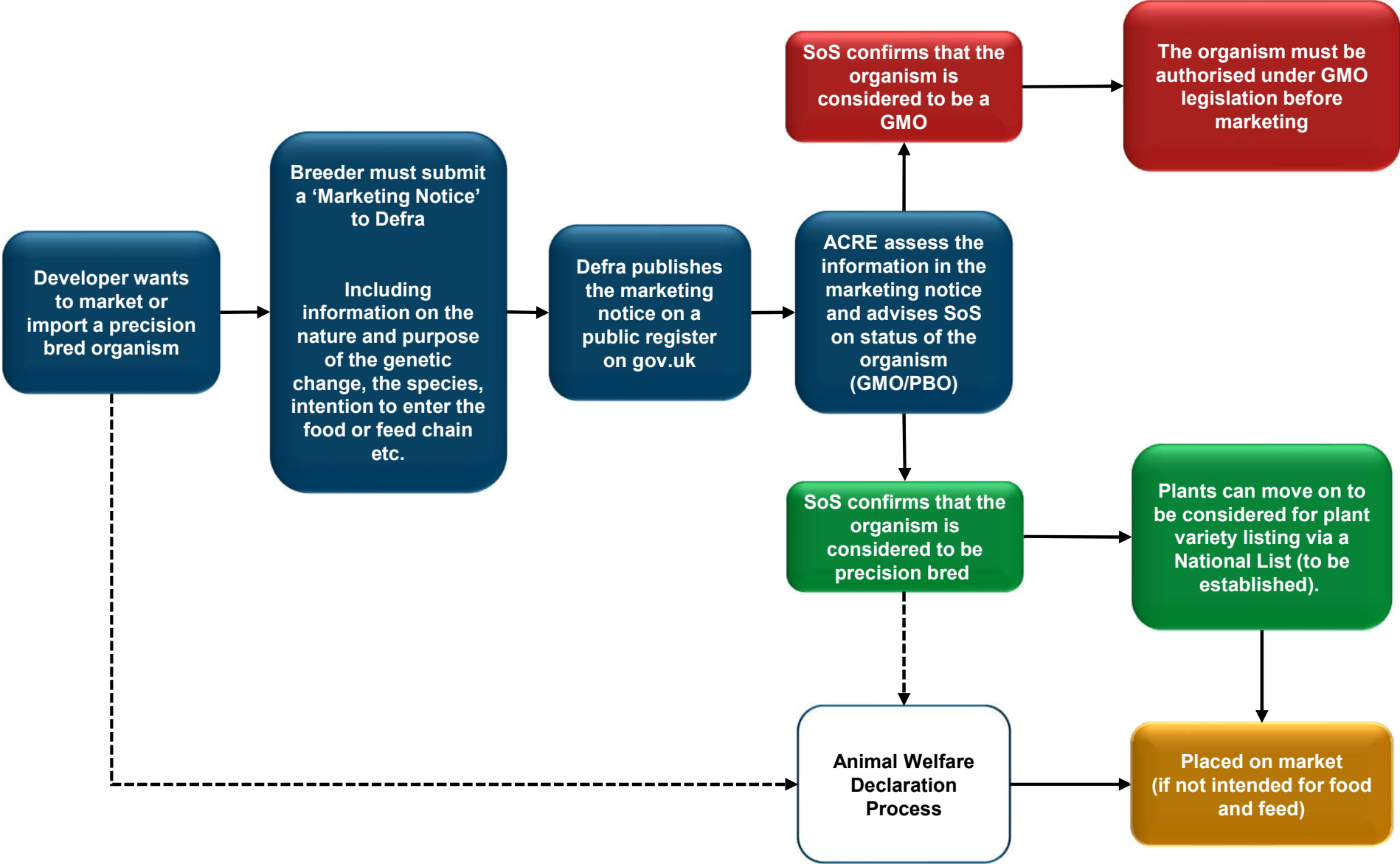
Secondary legislation is needed to implement the Act.

Defra are working on SIs for commencement, enforcement and notification regulations for plants

Legislation for animals will be brought in once animal welfare measures are developed. Animals will be brought into force through a phased approach

Plant varieties and seeds legislation will be amended to ensure PB varieties can be registered on a national list

# Notification Process





Department  
for Environment  
Food & Rural Affairs

# Thanks for listening



Environment  
Agency



Forestry Commission



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