



Department
for Environment
Food & Rural Affairs

The Regulation of GM and Precision-bred animals in the UK

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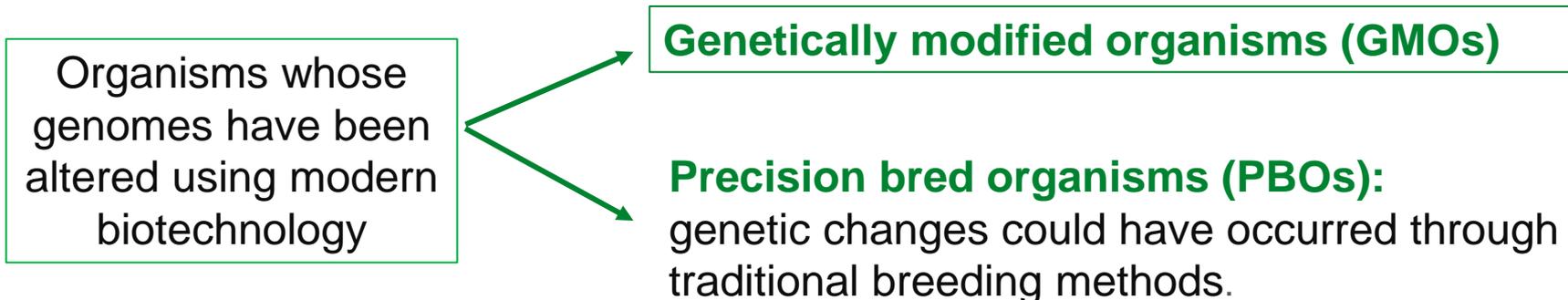
Background

- The UK has GMO-specific legislation. GMO policy and regulation is 'devolved'.
- Recombinant nucleic acid techniques used to introduce genetic changes in the organism trigger GMO regulations
- UK intervened in the 2018 European Court of Justice Case (ref: C-528/16) arguing that the definition of a GMO has a 'product-based' element (aligning it to the Cartagena Protocol on Biosafety)
- But the Court clarified that all genome edited organisms are GMOs irrespective of whether a 'novel combination of genetic material is introduced' and cannot be excluded unless they have a history of safe use.
- On EU exit, England brought in new primary legislation enabling us to introduce a 'product-based' element to the definition.
- But this has not been implemented through secondary legislation, so existing GMO requirements still apply. No GM animals have been authorised for marketing in UK.

The Genetic Technology (**Precision Breeding**) Act, 2023

Provides for (1) the removal of precision bred animals and plants from regulatory requirements applicable to GMOs (including food/ feed) and (2) for an alternative framework of regulations.

Organisms whose genomes have been altered using modern biotechnology



Genetically modified organisms (GMOs)

Precision bred organisms (PBOs):
genetic changes could have occurred through traditional breeding methods.

- Applies to England only
- Does not apply to the contained use of Precision Bred Organisms.

Requirements for Precision Bred Organisms in the Act (not implemented)

Introduction of two notification systems:

- Before research trials can take place, developers will need to notify their Precision Bred Organisms to Defra.
- Before marketing, developers will need to notify Defra and receive a confirmation that the organism is a Precision Bred Organism.
- Transparency: public register.

Authorisation for precision bred vertebrate animals prior to marketing

- An animal welfare declaration....
- ..supported by an assessment of risks to health and welfare that could be 'reasonably expected' to result from a precision bred trait
- Provision for post-market reporting

Authorisation process and register for food and feed products developed from precision bred organisms.



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Thank you and any questions?

