**Precision Breeding Summary (September 2023)**

**What is Precision Breeding?**

- A range of genetic techniques that can alter the DNA of plants and animals in a more precise way.
- These genetic techniques are often referred to as new breeding techniques and include gene editing.

**How Does Precision Breeding Differ from Traditional Breeding Methods?**

- Both methods produce genetic modifications to a plant or foodstuff, but traditional breeding methods introduce several genes to the plant or foodstuff.
- These genes may include genes responsible for desired characteristics, as well as genes responsible for unwanted characteristics.
- Genetic engineering enables the introduction into the plant of the specific genes responsible for the characteristics of interest, thus being a more targeted method.

**So, Isn’t Precision Breeding (E.g., Gene Editing) the Same as Genetic Modification (I.e., GMOs)?**

- No. As illustrated below, GMOs introduce novel gene configurations into the DNA, whereas in Precision Bred Organisms (PBOs), existing genes are cut, and the DNA is modified.
So, What Are the Benefits of Precision Breeding?

- As Precision Breeding is a more targeted method, it could be used for specific needs such as for disease resistance.
- Therefore, there are environmental benefits such as a reduced use of pesticides and fertilisers.
- There is also potential to produce more nutritious foods, increase food production, increase resilience to climate change and much more.

Why Has England Decided to Introduce New Legislation for Precision Breeding/Precision Bred Organisms (PBOs)?

- Genetic modification and the regulation of GMOs (Genetically Modified Organisms) was written many years ago and does not reflect the latest developments of new genetic technologies like gene editing.
- Following Brexit, there is a chance to review retained EU law, which would currently regulate Precision Breeding/PBOs as GMOs.
- New legislation will allow latest breeding techniques/organisms to be included in a system that is up to date and takes in to account the UK’s developments in innovation and science-based research.
- Countries such as Argentina, Brazil and Japan have already concluded that PBOs should not be regulated as GMOs.

Current Legislative Stage & Next Steps for Secondary Legislation:

- The FSA and DEFRA are working on a package of secondary legislation, which will initially be for plants, and then animals (in 2025).
- Information gathered in the FSA’s workshops in January, April and June 2023, as well as the statements from the Advisory Committee on Novel Foods and Processes (ACNFP) was used to gather information for September’s FSA board paper for the meeting on 20th September. In summary, the paper proposes a 2-tier system where tier 1 PBOs are similar to traditional bred organisms where the risks are more well known, and tier 2 is where the risks are not fully understood, and more assessment is needed. It is recommended that industry is to take responsibility on the triage process on whether a PBO falls under tier 1 or tier 2. A copy of the paper is here. Genetic Technology (Precision Breeding) | Food Standards Agency
- Following the board meeting, the proposed Regulation will then be subject to public consultation in Autumn 2023, which will inform the final design of the regulatory approach.
- Secondary legislation is expected to be laid in summer 2024 and to come into force by the end of 2024.
- The FSA has been working in partnership with DEFRA and is responsible for Part 3 of the Act (see more below).
- Annex 3 of the paper above sets out the enforcement responsibilities between the FSA and DEFRA.
Overview of the New Legislation Under the Precision Breeding Act:

- The Genetic Technology (Precision Breeding) Act 2023 (England only) is a different regulatory process for modern precision breeding techniques.
- The scope of the Act is for precision bred plants and animals.
- The 4 key policy changes in the Act are:
  1. Remove plants and animals produced through precision breeding technologies from regulatory requirements applicable to the environment release and marketing of GMOs.
  2. Establish a new science-based authorisation process for food and feed products developed using precision bred organisms.
  3. Introduce two notification systems; one for precision bred organisms used for research purposes and the other for marketing purposes. The information collected will be published on a public register on GOV.UK.
  4. Establish a proportionate regulatory system for precision bred animals to ensure animal welfare is safeguarded.

Information about DEFRA’s Precision Breeding Working Group

- At the Farm to Fork Summit on the 16th of May 2023, it was announced that DEFRA is to establish a working group with breeders, growers, manufacturers and retailers to initiate dialogue on precision bred products and facilitate routes to market.
- The working group will provide the forum to identify implementation challenges, potential opportunities and to develop collective approaches that would enable initial products to reach shelves.
- The BRC has been successful in gaining a place on the working group and the first meeting was on the 12th of September 2023. It has been agreed that the group will meet regularly in person and the next meeting will be in November 2023 (date tbc).
- We are awaiting a briefing note that can be shared with members and will be in touch regarding next steps and whether there is interest to set up a small precision breeding working group in the BRC, so we can discuss key developments.

The ACNFPs Statements:

- The UK Advisory Committee on Novel Foods and Processes (ACNFP) advises the FSA on matters relating to the safety of products, including PBOs.
- On the 7th of September, the ACNFP statement was updated here: Executive Summary July 2023 | Advisory Committee on Novel Foods and Processes
- The statement covers the criteria defining the tiers and includes:
• A triage process covering novelty, composition of the PBO and other safety concerns.
• Different models for the two-tiered assessment process as a decision tree.

What About Wales, Scotland and Northern Ireland?

- The Act applies to England only; however, in the working group on the 12th of September 2023, the FSA shared that discussions have been with all the devolved nations.
- Implications of the Windsor Framework have been considered and information has been shared in section 5 of the board paper here Genetic Technology (Precision Breeding) | Food Standards Agency.
- In summary, precision bred food and feed legally on the market in Great Britain will be able to move from Great Britain into Northern Ireland via the Retail Movement Scheme’s green lane – which ensures that consumers in Northern Ireland will have access to the same goods as the rest of the UK.
- Prepacked retail goods moving from Great Britain into Northern Ireland, which are destined to move onwards into the EU single market, will need to enter via the red lane and continue to meet EU rules.
- In the FSA workshops, it was said that the UKIMA (UK Internal Market Act) does not apply to processing after sale. Therefore, any PBO’s sold in Wales and Scotland under UKIM market principles would, if further processed there, be subject to legislation under GMOs. So, for example a PBO flour if sold in Wales / Scotland and then used in a bakery item, would only be able to be placed on the local market if it is authorised as a GMO.

What About the EU?

- The EU has been completing their own review of new genomic techniques, and the conclusion was that there are limitations to the legislation keeping up with scientific developments. New genomic techniques (europa.eu)
- The EU had a consultation last summer: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en
- On 5th July 2023, the European Commission adopted a proposal for a new Regulation on plants produced by certain new genomic techniques: gmo_biotech_ngt_proposal.pdf (europa.eu)
- The proposal is for 2 categories of NGTs covering organisms produced using modern, more targeted gene-editing tools (including PB techniques).
- Category 1, where organisms could have been achieved through conventional breeding, requires no labelling (only at seed level), authorisation, risk assessment or traceability, just a notification of category 1 to Member States.
- Category 2 includes organisms that could not have been achieved through conventional methods and will be regulated as GMOs with GM traceability and labelling requirements applied.
- The FSA continue to monitor the EU’s actions including the publication of their impact assessment/policy proposal and better understand how the EU intends to regulate these technologies in food and feed use going forward.

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