

Precision Breeding Summary (March 2024)

What is Precision Breeding?

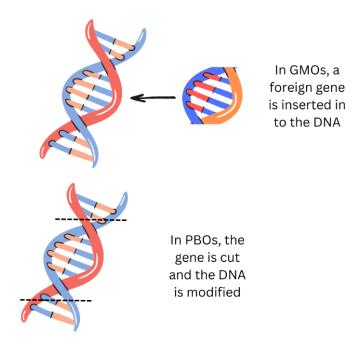
- A range of genetic techniques that can alter the DNA of plants and animals in a more precise way.
- These genetic techniques are often referred to as new breeding techniques and include gene editing.

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:

- On the 23^{rd of} March 2023, The Genetic Technology (Precision Breeding) Act 2023 passed law. The new Act can be seen here: https://www.legislation.gov.uk/ukpga/2023/6/enacted
- The FSA and DEFRA are working on a package of secondary legislation, which will initially be for plants, and then animals (in 2025).
- The FSA launched a consultation 'Proposals for a new framework in England for the regulation of precision bred organisms used for food and animal feed', which closed on the 8^{th of} January 2023. Consultation on proposals for a new framework in England for the regulation of precision bred organisms used for food and animal feed | Food Standards Agency. The BRC responded to the consultation see response here.
- The FSA 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.
- In the Defra working group on 8^{th of} March 2024, the FSA shared that they received over 400 responses; two-thirds respondents were consumers and whilst there was apposition, this could be from specific groups. The FSA said they are looking into pre-application support but otherwise, there is nothing to suggest a fundamental change to the proposed tier 1 and 2 process. They shared that consumer education is important and that precision breeding should be viewed as a traditional food, just with a new technique.



- Secondary legislation is expected to be laid in summer 2024 and to come into force by the end of 2024/early 2025.
- The FSA has been working in partnership with DEFRA and is responsible for Part 3 of the Act (see more below).

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

- DEFRA established a working group with breeders, growers, manufacturers, and retailers to initiate dialogue on precision bred products and facilitate routes to market.
- The working group provides the forum to identify implementation challenges, potential opportunities and to develop collective approaches that would enable initial products to reach shelves.
- The BRC is part of the working group and attended meetings in September 2023, December 2023 and March 2024.
- In the latest meeting on 8^{th of} March 2024, we were updated on a presentation by a US company who wish to bring strawberries to the UK market and would like to run trials next year, which would include taste and storage testing with retailers. The benefits of gene edited strawberries include a 3-month production instead of 1-month, with up to 5 times the amount of berries.
- Two subgroups have been formed for consumer research and trade + market readiness.
- Key developments will be shared to the Emerging risks and Labelling & Legislation groups. The next meeting will be 22^{nd of} July 2024, before regulations go into parliament.

What About Wales, Scotland and Northern Ireland?



- The Act applies to England only; however, 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 <u>Genetic Technology</u> (<u>Precision Breeding</u>) | <u>Food Standards Agency</u>.
- In summary, precision bred food and feed legally on the market in Great Britian 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 Britian 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?

- On 5th July 2023, the European Commission adopted a proposal for a new Regulation on plants produced by certain New Genomic Techniques (NGTs): gmo biotech ngt proposal.pdf (europa.eu)
- On the 29th January 2024 the Committee on the Environment, Public Health and Food Safety (ENVI) adopted the following report: <u>REPORT on the</u> proposal for a regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 | A9-0014/2024 | European Parliament (europa.eu)
- A plenary vote took place on the 7^{th of} February 2024, which voted in favour of the proposal: New Genomic Techniques: MEPs back rules to support green transition of farmers | News | European Parliament (europa.eu).
- The proposal is for 2 categories of NGTs and 2 sets of rules for NGTs plants.
 - NGT 1 plants: NGT plants considered equivalent to conventional ones will be exempted from the requirements of the GMO legislation. They also agreed on NGT seeds to be labelled accordingly and to set up a public online list of all NGT 1 plants.
 - NGT 2 plants: A GMO framework should apply to those plants, including mandatory labelling of products. In order to incentivise their uptake, MEPs also agree to an accelerated procedure for risk assessment, taking into account their potential to contribute to a more sustainable agri-food system, but underline that the precautionary principle must be respected.
- Next steps: Parliament is now ready to start negotiations with EU member states on the final law.
- The FSA continue to monitor the EU's actions. We are aware that FSS is also waiting for the EU.





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