

FSA 22-06-08 - The Genetic Technology (Precision Breeding) Bill

This paper gives an update on the Genetic Technology (Precision Breeding) Bill, announced in the Queen's Speech on 10 May 2022 and outlines the parliamentary process and timelines involved.

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1. Summary

1.1 The Genetic Technology (Precision Breeding) Bill (England only) was announced in the Queen's Speech on 10 May 2022. The aim of the Bill is to alter the definition of Genetically Modified Organisms (GMOs) to exclude certain organisms (plants, including algae) created by genetic technologies in ways which could have occurred naturally or been produced by traditional breeding.

1.2 Defra is the lead department, and the FSA has been ensuring that Defra takes account of our role as the competent authority in authorising any future precision bred food and feed. The Bill provides the enabling powers and scope for the FSA to fulfil our statutory function and ensure that a future regulatory approach for food and feed is proportionate. It is consistent with the principles to underpin the FSA's approach, agreed by the Board in September 2021: safety, transparency, proportionality, traceability and building consumer confidence.

1.3 The Board is asked to:

- discuss the new Genetic Technology (Precision Breeding) Bill
- note the parliamentary process and timelines

2. Introduction

2.1 [The Bill](#) includes sections on the objectives of the legislation, the current regime for marketing GMO products, other legislation controlling the use of GMOs, the proposed definition change, the notification system and a section on the FSA's approvals process for food and feed products covered by the scope of the definition change.

2.2 The four key policy changes in the Bill are to:

- DEFRA: Remove plants and animals produced through precision breeding technologies from regulatory requirements applicable to the environmental release and marketing of GMOs.
- FSA: Establish a new science-based authorisation process for food and feed products developed using precision bred organisms.
- DEFRA: 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.
- DEFRA: Establish a proportionate regulatory system for precision bred animals to ensure animal welfare is safeguarded.

2.3 The Bill was introduced into the House of Commons on 25 May. Second reading is on 14 June, and we expect the Bill to be in Committee stage by late June/early July.

3. Evidence and Discussion

3.1 Over the last two decades advancements in precision breeding have been rapid and led to the development of a range of beneficial outcomes (e.g., to improve health or environmental sustainability). However, the regulation has not kept pace with technological developments and is now seen by scientists and food producers as restrictive and outdated.?

3.2 ?The independent Advisory Committee on Novel Foods and Processes (ACNFP) which advises the FSA on the safety of novel and GM foods, supports the idea of a proportionate approach to the safety assessment of food and feed, that takes account of the scale of effect of any change on the food. They note that off-target effects or the presence of recombinant DNA, whether intentional or unintentional, may pose no greater risk than traditional breeding. However, this is entirely dependent on the site and size of the off-target effect or recombinant DNA fragment. We will seek to ensure that any new regulatory measures will be designed to take account of this concern.

3.3 Precision breeding technologies, such as gene editing, include a range of approaches which provide a precise way of introducing genetic changes, for example to confer disease resistance, making the whole breeding process more efficient and responsive to identified needs.??As such there are environmental benefits such as reduced use of pesticides and fertilisers, as well as the potential to develop more nutritious foods, increased food production, increased resilience to climate change and reduced costs to farmers and lower carbon footprints.

3.4 The UK is internationally renowned for our scientific excellence in genetics and genomics and now we have exited the EU, we have an opportunity to fully explore what this technology has to offer. With no change to current legislation, food and feed produced with this technology would be regulated as though they were GMOs. Measures in this Bill seek to change this and align us with many countries outside the EU that do not regulate precision bred organisms as GMOs.

3.5 Consumer research has indicated that the more informed consumers were, or became, the more accepting they were of precision bred or genome edited (GE) food. Research also suggests that consumers tended to find GE food more acceptable than GM food. Most consumers felt it would be appropriate to regulate GE foods separately from GM foods - having recognised them as two separate techniques that should be treated as such. Overall, most consumers wanted thorough regulation and transparency if GE foods reach the UK market.

3.6 Maintaining consumer trust is vital. The powers contained within the Bill will allow for the establishment of Defra's notification system and an evidence-based pre-market FSA authorisation process for feed and food products developed using precision bred organisms (PBOs) that is proportionate and protective of consumers. It will improve public accessibility to more sustainable and nutritious food while supporting innovation and harnessing the benefits of new and emerging technologies.

3.7 This legislation would only apply in England. At the time of writing the Welsh Executive and Scottish Government have not indicated that they wish to adopt the measure proposed by Defra to change the definition of GMO and introduce a new regulatory framework for food and feed. On 23 May Defra Secretary George Eustice and Scottish Secretary Alister Jack called on Scotland to join the bill in a letter to Scotland's First Minister Nicola Sturgeon and Rural Affairs Secretary Mairi Gougeon. A similar letter was sent to Wales First Minister Mark Drakeford from George Eustice and Welsh Secretary Simon Hart.

3.8 Northern Ireland continues to comply with EU Law under the current terms of the Protocol on Ireland/Northern Ireland, as covered in Annex II, which includes existing EU GMO legislation. The EU have undertaken their own review and launched a consultation on new genomic techniques, due to close in July 2022.

3.9 The FSA is committed to four-nation working and continues to work closely with Food Standards Scotland, FSA Wales and NI to understand their views around Precision Breeding (PB). Whilst the changes proposed are England only, due to the UK Internal Market Act market access principles, these changes will have implications for the devolved nations. It is likely that it will not be possible to prevent the sale of genome edited products authorised in England from being sold elsewhere in Great Britain, irrespective of the regulatory regimes in place in any of the devolved nations. We are considering how best the Common Framework for Food and Feed Safety and Hygiene (FFSH) may be utilised to manage the implications of the issue.

3.10 The FSA are working with the devolved nations, Defra and other partners to consider consumer information options which will be underpinned by the best evidence. A consumer education project has been commissioned to build consumer confidence and understanding to encourage safe, healthy and sustainable choices. We are aware of PB products in the pipeline, and some already available in other countries, that could offer consumer benefits.

3.11 In September 2021, the Board agreed the principles for GE regulation which are Safety, Transparency, Proportionality, Traceability and Building consumer confidence (Annex A). The FSA will be responsible for developing a new regulatory framework for authorisation based on these principles. Precision bred foods will only be permitted if our risk assessment judges them to: not to present a risk to health, not to mislead consumers, and not to be nutritionally disadvantageous.

4. Conclusions

4.1 The Bill was introduced into the House of Commons on 25 May. Second reading is on 14 June, and we expect the Bill to be in Committee stage by the end of June/early July.

4.2 The Board is asked to:

- Discuss the new Genetic Technology (Precision Breeding) Bill
- Note the parliamentary process and timelines

Annex A

Principles for GE regulation

There are 5 key principles that should underpin GE regulation:

1. Safety – as a food and feed safety regulator, we need to ensure that the regulatory framework reflects our role to ensure products produced using technologies such as GE are safe.
2. Transparency – the regulatory framework must be clearly communicated and accessible to consumers and other stakeholders, with stakeholder participation in the development and operation of the framework, maximising open access to information.
3. Proportionality – the regulatory framework should allow specific safety issues associated with GE products to be adequately assessed without the risk of measures that are too stringent (e.g., to ensure foods produced through some conventional breeding methods are not covered in this category).
4. Traceability – Some edits that are made by GE are identical to those mutations introduced by natural variation and therefore could not be detected by routine testing. The inability to

detect GE needs to be considered particularly in relation to labelling and enforcement of GE products. Any new framework needs to allow us to understand the processes by which the product has been developed.

5. Building consumer confidence – the regulatory framework must demonstrate that consumer needs and views have been considered.