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Genetic Technology (Precision Breeding) Bill

October 2022

This paper updates on the progress of the UK Government's Genetic Technology (Precision Breeding) Bill and outlines the FSA's approach to developing an appropriate and proportionate regulatory framework for products produced in England, using precision breeding (PB) techniques.

The FSA is committed to openness and transparency. This paper was submitted to FSA board members for discussion on 26th September 2022. The FSA board were asked to:

- **Note** progress so far, and the outline forward timetable for developing the new regulatory framework (which is subject to the passage of the Government's Bill through Parliament and may change).

- **Comment**
  - on the direction of travel for the development of the FSA's detailed regulatory policy, based on science and evidence, including an authorisation process for Precision Bred Organisms (PBOs), which will enable the FSA to assess products classed as PBOs by Defra/ACRE (Advisory Committee on Releases to the Environment)
  - on the merits of different options for providing consumers with information on PB products, to inform the next phase of policy development

- **Agree**, in principle, to the FSA continuing to explore:
  - a tiered approach to the authorisation process for products classed as PBOs
  - a public register of authorised PB food and feed, as a tool for consumer information and confidence, and to aid traceability and enforcement of PBO food and feed authorisations

Following the open board discussion on the contents of this paper, the FSA board agreed, in principle, to developing a regulatory framework involving a tiered approach, and the development of a public register of PBOs that have been authorised for food and feed uses.

Introduction

The aim of the UK Government's Genetic Technology (Precision Breeding) Bill is to alter the definition of Genetically Modified Organisms (GMOs) in England to exclude certain organisms created by genetic technologies in ways which could have occurred naturally or been produced by traditional breeding.

The enabling powers granted to the Secretary of State (DHSC) under Part 3 of the Bill in practice allow the FSA, following initial confirmation of PBO status, as assessed by Defra/ACRE (Advisory Committee on Releases to the Environment) to:

- determine the regulatory approach for all food and feed produced by Precision Breeding (PB) techniques, to ensure they are safe for consumers,

including a proportionate risk assessment when the FSA judges that this is necessary;
- establish and maintain a public register of authorised PBOs for food and feed uses;
- put in place arrangements to ensure the identification and traceability of food and feed produced by PB; and for the regulations to be administered and enforced.

The Bill is currently expected to continue its passage through the House of Commons after summer recess, and to enter the House of Lords in October. Royal Assent could be achieved, at the earliest, by the end of 2022. This is subject to agreement of both houses and may not take place until early 2023. Once the Bill achieves Royal Assent, Secretary of State (DHSC) will be expected to make an affirmative statutory instrument (SI) on how PBOs for food and feed uses are regulated (based on advice from the FSA). The FSA will need to be ready to demonstrate how the new powers in these regulations will be used in practice.

Policy development on secondary legislation will continue at pace whilst the Bill is passing through Parliament. There are some procedures which cannot commence before Royal Assent. These include a public consultation, clearance through Government committees, work to finalise the SI and Explanatory Memorandum, Ministerial sign-off, and scrutiny by the House of Commons and House of Lords.

While the UK Government's Bill applies in England only, it is important that the new regulatory framework for England is developed jointly with input from officials and stakeholders across the UK, in line with commitments set out in the Common Framework for Food and Feed Safety and Hygiene (FFSH).

Authorisation of PBOs in England will have impacts on the UK internal market. In Wales and Scotland, PBOs will still be classified as Genetically Modified Organisms (GMOs) and as such PBOs produced in (or imported directly into) these countries will need to be compliant with GMO legislation. However, under the UK Internal Market Act 2020, goods legally produced in (or imported into) England can be marketed for direct sale in Wales and Scotland.

PBOs authorised in England will not be permitted to be sold in Northern Ireland. In order for those products to be placed on the market in NI they will need to comply with existing EU law, which includes being authorised and labelled as GMOs.

Principles for developing the new regulatory framework

In September 2021 the FSA Board reconfirmed its position that existing regulations should be updated to reflect new scientific and technological advances in genome editing. The Board agreed five key principles to guide the FSA's approach to developing a new framework:

- **Safety** – as a food and feed safety regulator, we need to ensure that the regulatory framework reflects our role in ensuring products produced using

technologies such as precision breeding (PB) are safe.

- **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.
- **Proportionality** – the regulatory framework should allow any specific safety issues associated with PB products to be adequately assessed without the risk of measures that are too stringent (e.g., to ensure foods produced through some traditional breeding processes are not covered in this category).
- **Traceability** – some edits that are made by PB are identical to those mutations introduced by natural variation and therefore could not be detected by routine testing. The inability to detect the use of PB needs to be considered particularly in relation to labelling and enforcement of PB products. Any new framework needs to allow us to understand the processes by which the product has been developed.
- **Building consumer confidence** – the regulatory framework must demonstrate that consumer needs and views have been considered.

The FSA has been developing evidence-based proposals that follow these agreed principles. In June 2022 the FSA Board were updated on the objectives and policy proposals included in the Bill, including the FSA's responsibility for developing a new future-fit regulatory framework for authorising PBOs.

The Bill creates a power to put in place a bespoke regulatory framework that will protect consumers, whilst allowing responsible businesses to innovate, supporting the UK's position as a world-leading centre for science and research.

The pace of technological change in the food system continues to accelerate. The FSA takes an anticipatory approach to regulation, responding quickly to fast-moving developments in the food sector here and abroad. As the trusted voice on food standards, the FSA remains committed to protecting consumer interests, and making it easier for businesses to meet their obligations and do the right thing to protect public health.

Precision breeding technologies use genome editing methods to make targeted changes to an organism's DNA. These are changes that could have been made through traditional breeding or natural processes.

The long-standing regulatory framework for GMOs was not developed with precision breeding technologies in mind. The requirements of the GMO risk assessment are extensive. This is to manage potential safety risks arising from technologies that

introduce genes from other species into organisms used as food, and to provide assurance to consumers. The Bill will enable PBOs to be designed and grown under a more proportionate regulatory regime. With no change to current legislation, food and feed produced from precision bred technologies would continue to be regulated as though they were GMOs.

Developing the outline framework and next steps for policy development

Alongside the passage of the Bill through Parliament, the FSA published information on our website about how a future regulatory framework for PBOs could work in practice, and some of the options we are considering for assessment and authorisation.

The FSA expects to be able to deliver a tailored, proportionate framework for the regulation of PBOs; one that ensures that the products that go through our assessment process are brought to market under a shortened timeframe (compared to other regimes), without compromising food safety or consumer confidence.

FSA officials are continuing to explore the possibility of a tiered approach to the authorisation process – one which is proportionate, transparent, and based rigorously on the science and evidence. This will be subject to further public consultation and review.

- **Tier 1:** All applications for PB food and feed authorisations are screened for similarity to traditionally bred varieties where the risk is understood and not of concern for consumers. Products that meet tier 1 criteria will be authorised more quickly than tier 2. The detailed criteria for assessing tier 1 applications is still being developed, informed by expert scientific advice from the independent Advisory Committee on Novel Foods and Processes (ACNFP).

- **Tier 2:** Applications for PB food and feed authorisations where the Tier 1 screening does not allow the risk to be understood, are subject to an additional step. These applications require a proportionate risk assessment to determine the level of risk for consumers.

A tiered approach would be proportionate to the broad definition of PBOs contained in the Government's Bill. Detailed proposals, using evidence gathered through consumer research and stakeholder engagement, will be developed with input from:

- the FSA Board
- the Advisory Committee on Novel Foods and Processes (ACNFP), including its Subcommittee on Products of Genetic Technologies,
- Ministers and Government departments (across the four nations).

There are several workstreams that will feed into the development of the FSA's regulatory framework. Underpinning all of these is a need to ensure that the

framework is designed in a way that ensures consumers have clear, accessible, and appropriate information about what PB products are, and how they will be regulated. The FSA is developing policy proposals for:

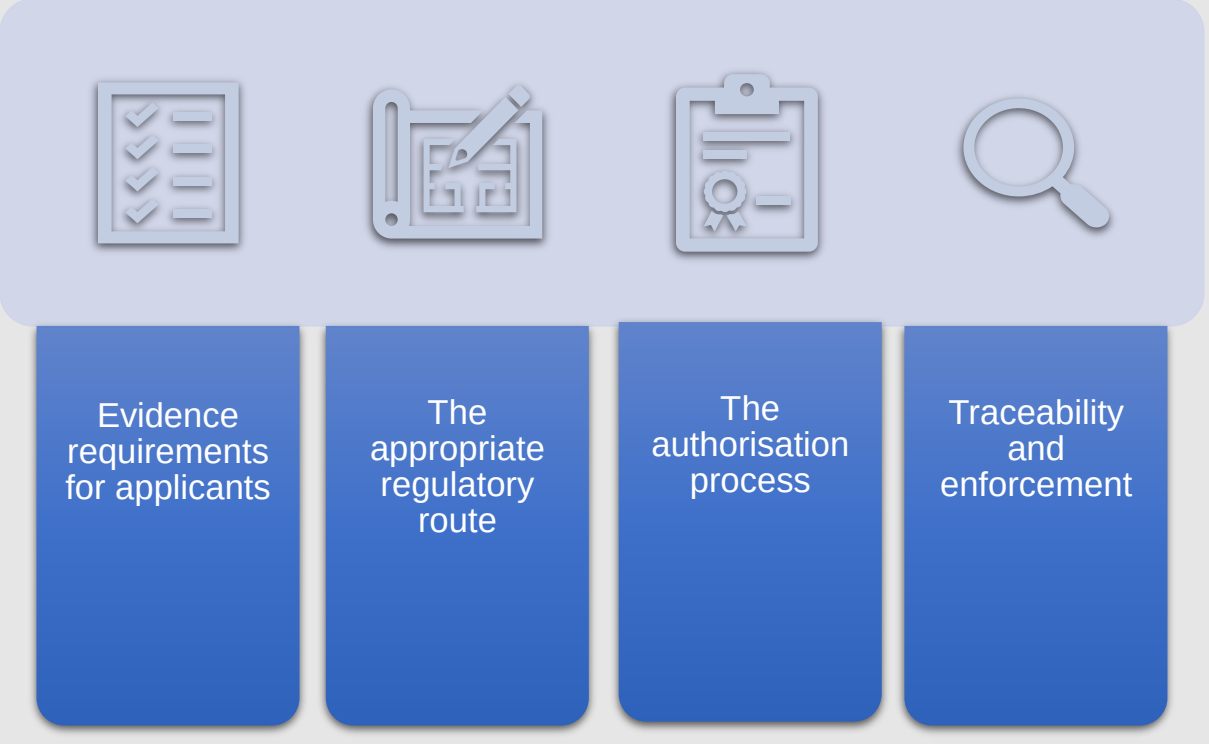
- **evidence and data requirements for applicants:** The FSA is working closely with Defra and ACRE to design evidence requirements that are efficient and effective for applicants. The FSA will set out clear and proportionate requirements for evidence from applicants, which may include measures to aid traceability - (e.g. genetic information).

- **the appropriate regulatory route:** Advised by ACNFP, the FSA is developing clear, evidence-based criteria that would be used to determine which PB products would require greater scrutiny through tier 2.

- **the authorisation process**: The FSA will set out detailed proposals for how products will be authorised (including appropriate consultation), and how decisions will be taken and communicated.

- **traceability and enforcement**: The FSA is exploring the most appropriate way to ensure that PB products can be identified and traced throughout the food chain. This will include guidance for enforcement authorities to ensure ongoing compliance with regulations.

Figure 1: Building the regulatory framework



Science and evidence

FSA officials have been building a deeper evidence base for the new policy framework. Crucial to this has been to further understand the scientific basis for our approach to appropriately triaging PBO applications on a proportionate, case-by-case basis.

To support and inform the FSA's policy development, the independent ACNFP and its new sub-committee[1] (the ACNFP Products of Genetic Technologies sub-committee) has been tasked with considering the science behind these technologies.

The ACNFP and its sub-committee have been commissioned to provide expert scientific advice on:

- using a tiered approach for product assessment
- the potential criteria for defining tiers, using case studies
- determining what information would be requested from applicants to support classification and review of a PBO (building on the assessment of PBO status undertaken by Defra)
- developing technical guidance for applicants on the information the FSA would need to assess a PBO before entering the market

In developing their advice, the ACNFP (through its subcommittee) is considering the policy intentions of the Bill, with an emphasis on the need for a proportionate assessment based on the nature of the risks, and the likely impacts and outcomes following changes made to the organism. This would encompass both changes that might typically result from traditional processes and have a similar food safety risk; and the potential that, while possible using traditional breeding, the likelihood of producing the change would be rare and could significantly alter the nature or composition of the end (consumed) product.

The subcommittee is also developing a number of case studies of known (and anticipated) developments in the PB field, to test their thinking on how a proportionate approach could work in practice. The FSA will take the outcomes of this work into account when developing an assessment process that is in line with the principles outlined above.

The Board is asked to note this approach to help shape our ongoing work with scientific experts. We will bring further, detailed proposals for any tiered approach (and their criteria) to the Board in December. Any approach developed by the FSA, with others, will be subject to further, public consultation and review following passage of the Bill.

[1] Membership includes ACNFP experts in genetic technologies as well as experts in toxicology, ethics, and a consumer representative.

Traceability

The FSA has a long-standing commitment to ensuring that food is traced and followed through all stages of production, processing, and distribution. This is supported by The General Food Law Regulation and will apply to PBOs as much as any other food or feed. The Government's Bill proposes powers to put in place provisions to aid the traceability of PBOs in food and feed. Any new framework needs to allow the FSA to understand the processes by which the product has been developed.

As with other categories of regulated product, the FSA is proposing to establish and maintain a public register of authorised food and feed containing or derived from PBOs. We are exploring this as an important tool for enforcement officers, industry and consumers, including how it could provide assurance that the PBO was safe to enter the market for food and feed uses.

The FSA is also exploring the possibilities, feasibility and limitations of detecting genome edited products in food and feed, including those produced through PB. Further research is being scoped to guide our policy development, including whether it will be possible in practice for enforcement officers to test for the presence of PBOs. This research will highlight whether detection of PB products is achievable and whether this could be used as a way of securing traceability. The Board will be kept up to date as work progresses.

Consumer research

Maintaining consumer trust is vital. The FSA safeguards consumer confidence and interests by putting the consumer first when developing policy. Enhancing the FSA's evidence base on consumer perceptions and information needs as the Government's Bill progresses through Parliament continues to be a priority.

The FSA first commissioned research into consumer perceptions of genome edited (GE) food in January 2021. The key findings (published in July 2021) suggested that there was very low knowledge of GE food across the UK, and that most consumers wanted thorough regulation and transparent labelling, should they reach the UK market. As part of the FSA's flagship Food and You 2 consumer research (published in July 2022) people also reported greater awareness and knowledge of genetically modified (GM) food (9% had never heard of GM food) than GE food (42% had never heard of GE food).

In July 2022 the FSA commissioned new research, across two phases of fieldwork. Both phases are being run across the UK to ensure representative data and conclusions.

Phase one, collecting quantitative data, was completed in August 2022.
Only 8% of respondents said they had heard of PB, 16% said they had heard of it (but didn't know what it was), and 75% said they had never heard of it all. Just over three-quarters (77%) of participants said they would want information about PB products (if they had been precision bred or contained precision bred ingredients)

before purchasing them. *To note, survey results have been slightly adjusted from the FSA board paper of 26th September 2022 to reflect a subsequent data update. This will be included in the full report and will be published on the FSA website on 5 October 2022.*

Phase two (running from October), will use qualitative methodologies, where research participants will have more information about PB before their perceptions are unpacked and explored further. This research will focus on the reasons behind information wants and needs, and views on the FSA's proposed regulatory framework.

Information given to consumers so that they can make informed decisions, cuts across the FSA's entire mission. Consumer information is a complex policy issue, and the FSA has differing policy responsibilities in respect of it that vary across the UK (in particular in reference to compositional standards and labelling, where responsibilities are distributed across different Government departments). Industry, representative bodies, and consumer groups also have a role to play to ensure that consumers are well informed about food and feed.

Consumer information generally refers to the information consumers use when making choices about food and provides reassurance that their food is trusted, safe, and what it says it is. Information concerning a food, provided by Food Business Operators (FBOs) to the final consumer, is considered 'food information' and is governed by regulations on food information to consumers. It is also a legal requirement for FBOs to ensure that food information is not misleading. It is part of the FSA's responsibility to understand what information consumers value, to make informed decisions about food, including the safe use of food, or other health, economic, environmental, social and ethical considerations.

Findings from the FSA's most recent research (phase one, August 2022) show that it is important to consumers to have information about whether food has been precision bred. Therefore, providing consumers with appropriate information about PB products is an important part of the FSA's policy development work.

A public register, as outlined above, would provide a list of all authorised PBOs for food and feed use. The FSA also routinely publishes risk assessments, advice and the outcomes of decisions on individual regulated products. This means that consumers, industry, and other stakeholders always have access to detailed information about the product, any risks, and how these are managed. There are, however, many other ways in which to increase levels of consumer information and confidence. The range of options includes:

- targeted awareness campaigns
- industry-led or voluntary schemes
- batch/QR codes on product labels
- labelling (voluntary or mandatory)

It should be noted that this is not an exhaustive or mutually exclusive list, and the risks and opportunities of these options will be explored further. In England, Defra has responsibility for general labelling and for consumer information that is not about food safety. In line with the various statutory responsibilities for consumer information, some of these options may require cross-government working with other departments, and the FSA will play its part in convening and collaborating with others to ensure that consumers' interests are put first.

Further evidence from the new phases of consumer research will help inform the FSA's proposals for how we best protect consumers' interests relating to the provision of information about PBOs. The Board will be able to use this evidence to advise what is in the consumers' interest and how information should be provided to them, informing the FSA's policy proposals ahead of formal consultation.

Stakeholder Engagement

We continue to work openly and transparently to give all stakeholders the opportunity to provide comment on our developing policy proposals, to ensure they are fit for purpose. The FSA has been conducting formal and informal engagement with key stakeholders covering a full spectrum of views on the Bill.

This engagement will continue as we develop our plans, followed by a formal public consultation on draft legislation and policy proposals next year, giving all stakeholders the opportunity to feed into the developing framework.

Our current stakeholder engagement strategy is divided into two phases.

The first centres around three key workshops, which have been taking place since the end of August. The purpose of these workshops has been to allow a representative range of stakeholders to comment on our published proposed approach to the two-tier authorisation process for PBOs. One workshop sought to understand the views of stakeholders in the potential supply chain of precision bred food and feed; another brought together key stakeholders representing consumer interests; a third has been arranged specifically for stakeholders in Northern Ireland; and a fourth for civil society groups with an interest in the Bill. There has also been a workshop for staff across the FSA.

The second phase, starting later this autumn and building on the outputs from ACNFP, will engage with stakeholders on more detailed policy proposals ahead of secondary legislation, including the application process and proposed criteria for assessing PBOs. Stakeholders will also be updated on developments in the ACNFP's scientific advice.

FSA officials have been carrying out visits to scientific and industry-based research centres. Engagement with members of the House of Commons and the House of Lords is also underway, to support the passage of the Bill and future FSA regulations by ensuring that parliamentarians have good understanding of the Bill and FSA policy and its rationale.

Working across the UK

Although the PB Bill extends to England only, it has implications for consumers across the UK (as a result of the UK Internal Market (UKIM) Act 2020). The UKIM Act's market access principles allow for goods that meet the legal requirements for sale in England to be legally sold in other parts of the UK (except for Northern Ireland, where under the current Northern Ireland Protocol arrangements products on the market must comply with EU law).

Our Food and Feed Safety and Hygiene (FFSH) Common Framework, FSA-FSS Memorandum of Understanding (MoU) and Food Compositional Standards and Labelling (FCSL) Common Framework commit the FSA to joint working across the four UK nations when considering changes to retained EU law. This includes ensuring there is opportunity for four nation input and discussion, even where changes are introduced in one nation only.

Given its implications across the UK, regular four nation engagement has been taking place under the FFSH Common Framework to collaboratively develop the new authorisation process for PB food and feed. This is important not just to deliver on Common Framework commitments, but also to ensure that nation-specific considerations can be accounted for in the development of policy proposals. This collaboration is facilitated by weekly Common Framework discussions and daily policy update meetings attended by relevant officials from across the FSA and FSS.

The Welsh Food Advisory Committee has also been briefed and had the opportunity to ask questions.

In Wales and Northern Ireland, the FSA has additional policy responsibilities for Food Compositional Standards and Labelling (FCSL). The FSA in Wales and Northern Ireland is party to the Defra-led FCSL Common Framework, which includes policy on provision of food information to consumers. Defra did not establish early FCSL Common Framework discussion on the Bill across the four UK nations before it was introduced into Parliament.

Under the governance of the FCSL Common Framework, a four-nation Food Compositional Standards and Labelling officials group has been created. The purpose of this group is to bring together officials from the four nations to discuss issues relevant for FCSL policy. Once research with consumers has concluded, the FSA will need to reach a view on its preferred approach to how consumers should be provided with appropriate food information, to inform the FSA position that officials will voice at this forum.

To ensure that the FSA's remit and interests as a three-nation organisation are reflected, the FSA continues to work alongside Defra to ensure that officials across the four nations are engaged in regular discussions on policy development. We are also working closely with FSS to ensure the obligations we are party to under the two FSA Common Frameworks that intersect with the Bill are delivered.

The FSA has provided updates to Ministers in Northern Ireland (Department of Health and DAERA) and to the Welsh Deputy Minister for Mental Health and Wellbeing, to make them aware of the progress of the Bill, and for their feedback on outline proposals for the new regulatory regime. The FSA's Chair has met with the Welsh Minister and a meeting with NI Health and DAERA Ministers has been scheduled.

Key Dependencies

- **Resourcing**: The Programme of work that the FSA is responsible for as a result of the Government's Bill is dependent on significant and sustained levels of resourcing.
- **Timeframes:** Building and implementing the new regulatory framework is dependent on the passage of the Bill through Parliament and is subject to change.
- **Engagement and consultation with government departments (across the UK) and external stakeholders:** Developing an effective framework is dependent on close collaboration; working towards consensus on regulatory proposals, within narrow timeframes.
- **Independent scientific advice from ACNFP:** The integrity of our framework is reliant on robust and rigorous scientific evidence and requires complex decision making from ACNFP. Decisions must be made in a timely manner to facilitate policy development, but this process cannot be rushed.

- **Maintaining strong relationships with other government departments:** The successful implementation of the framework will be dependent on effective and constructive working relationships with officials in ministerial departments (including Defra and DHSC) and the establishment of new working practices on cross cutting PB issues.

This document was published as an FSA board paper here. Meeting minutes and written answers to questions will be published here.