The Food Standards Agency and the Genetic Technology (Precision Breeding) Bill

Shaping a future regulatory framework for precision bred food and feed products.

As the **Genetic Technologies (Precision Breeding) Bill** ("the Bill") progresses through Parliament, this information provides some background information about the role the FSA plays in regulating food and feed and how we intend to develop a new regulatory framework to support the objectives of the Bill.

Our role in regulating food and feed products

The Food Standards Agency (FSA) is an independent, non-ministerial government department with a statutory responsibility to protect public health and otherwise protect the interests of consumers in relation to food in England, Wales and Northern Ireland. The FSA also has responsibility for labelling policy in Wales and Northern Ireland, and for nutrition policy in Northern Ireland. We take an evidence-based scientific approach, to deliver effective and proportionate regulation to protect consumers whilst providing choice and allowing responsible businesses to innovate.

We are responsible for advising Ministers on the market authorisation of certain new food and feed products, including those produced through genetic technologies. We work closely with the UK Government, and the governments in Wales and Northern Ireland and with Food Standards Scotland who advise the Scottish Government. We are committed to joint decision-making as set out in the Provisional Food and Feed Safety and Hygiene (FFSH) Common Framework.

We will work alongside relevant officials as we develop a proportionate regulatory framework for regulated products from precision breeding (PB) techniques as part of the Bill.

Our approach to developing a proportionate regulatory framework

The Bill is currently progressing through the various stages of Parliamentary scrutiny. The Bill proposes a change to the legal definition of Genetically Modified Organisms (GMOs) which would remove certain organisms produced by PB techniques from the scope of GMOs.

Part 3 of the Bill proposes to introduce powers that will empower the FSA to create a proportionate framework for regulating Precision Bred Organisms (PBOs). If approved, this framework will form the basis upon which PB food and feed products are to be authorised to be placed on the market in England.

This briefing sets out more information about how a future regulatory framework for PBOs could work in practice and some of the options we are considering. The aim of this briefing is to enable Parliamentarians and stakeholders to understand what the practical implications of these powers are, and how they might be used.

Detailed proposals for a proportionate framework will be developed with input from our Board, Ministers and Government departments, from our independent scientific advisory committee, the Advisory Committee on Novel Foods and Processes (ACNFP), and in line with commitments set out in the FFSH Common Framework.

Alongside these commitments, the FSA will also fulfil its responsibility, as a regulator, for open and transparent policy making. This will be achieved through engagement with key stakeholders in industry and discussions across government and with consumers. The FSA has an open-door policy on engagement, and we strive to build and maintain strong relationships with non-Governmental organisations who have an interest in this policy area.

The FSA will put in place an engagement strategy to be implemented over the coming months, and which will include a range of stakeholder workshops, including with industry, developers and marketers of these PBO products. This engagement will be followed by a formal public consultation to give consumers, enforcement authorities and industry the chance to provide written comments on draft proposals and legislation.

Our principles

A regulatory framework would contain an authorisation process for food and feed products produced using PB technology.

This process will follow the five key principles agreed at our Board meeting in September 2021:

- **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 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 specific safety issues associated with PB products to be adequately assessed without the risk of measures that are too stringent (for example, to ensure foods produced through some conventional breeding methods are not drawn into 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 definitively identify changes arising from gene editing (GE) 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.

Seeking input from all four nations in the UK is a fundamental part of the way that the FSA authorises any new product. In the case of PBOs, whilst the Bill applies to England only, under the FFSH Common Framework we are committed to UK-wide decision making that gives the opportunity for any special considerations across the UK to be captured about the regulation of PBOs.

Quick guide: how a regulatory framework for PB products could work

At this early stage, we are exploring the possibility of a two-tiered approach to provide an authorisation process, which is proportionate, transparent, and based rigorously on the science. This will be subject to further consultation and review.

This proposal of a two-tier approach would be proportionate to the broad definition of PBOs contained in the Bill, encompassing both minor changes that might typically result from traditional breeding, and the potential for major changes that, while theoretically possible using traditional breeding, could significantly alter the nature or composition of the consumed product.

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.

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.

How might this two-tier system operate?

Tier 1

This includes precision-bred food assessed as low-risk, because it is sufficiently similar to food and feed bred by traditional methods. Traditionally bred food and feed is not subject to an authorisation process by the Food Standards Agency. These PBOs would be authorised rapidly.

A product where the genetic change results in food or feed similar to that produced through traditional breeding which don't require a review, and where the level of any risk to consumers is accepted would fall under Tier 1. Tier 1 would also apply to food or feed in which the nature of the genetic change achieved by precision breeding is highly unlikely to have resulted in a significant change in composition, either directly or indirectly, to the part of the plant or animal that is eaten.

Tier 2

A precision bred organism in which there is likely to have been a significant change in the composition of the product that is typically eaten. Such changes may, for instance, include alternations to the type or level of nutrients or allergens within the product to a level beyond that usually seen in products based on conventionally bred organisms. Such products would be authorised under Tier 2. Here further evidence of safety and a more detailed risk assessment would be required prior to an authorisation decision. These would inevitably take longer but in most cases should still be very much quicker than authorising a novel food or feed.

A public register for PBOs

As with some other categories of regulated products, the FSA would publish a register of PBOs authorised for use in food and feed. This register would be available online, in a searchable format that enabled producers, consumers and enforcement officers to check which products were authorised.

Governance – ensuring we have checks and accountability

There are a number of ways we ensure that the safety of regulated products can be appropriately assessed for risk and that decisions about authorisation are informed by evidence.

When a PB product application is received, the ACNFP and the FSA’s Science, Evidence, and Research Division would carry out these risk assessments.

Following an FSA recommendation to the DHSC Minister to authorise a product, a ministerial decision will be taken and, if authorised, the product will be added to our online register for PB food and feed.

Throughout the process for both Tier 1 and 2, the FSA Board would operate as it does for any other risk analysis issues or regulated product, receiving appropriate information and progress reports about products going through the authorisation process. For non-routine issues, that are likely to include the early products passing through the precision breeding authorisation route, the Board may request further detailed advice from FSA experts, discuss the recommendations, and provide advice and assurance to Ministers on any significant, high profile or complex cases.

Information and evidence

The FSA would initially assess all applicaltions for their suitability to be dealt with in Tier 1. In order to be confirmed as Tier 1, the FSA intends to make an assessment of the information and evidence provided about:

- The nature of the genetic changes
- The outcome of the changes – what the change is designed to achieve as well as changes that may occur as a secondary consequence
- The intended use of the product
- Whether the product is similar to those with a history of safe use

In the majority of cases, we are working to the assumption that information provided to Defra at the start of the process would be sufficient for a determination about whether the product falls into Tier 1 or Tier 2. This means that applicants would only have to supply information to government once, rather than apply separately to two different processes. The FSA is working closely with Defra and Food Standards Scotland on defining the requirements for the initial application in order to reduce the burden on applicants and to ensure that the process is proportionate.

Key points – what you need to know

We have provided additional information about how we are progressing our ideas about the regulation of PBOs for use in food and feed:

- **We still have to consult on our ideas:** information in this paper about how the process would work is in draft form only and is subject to change. The process we put in place will depend on the final content of the Bill, and on the outcome of our consultation.
- **We will work closely with Ministers and officials in all four nations of the UK:** In line with commitments in the UK Food and Feed Safety and Hygiene (FFSH) Common Framework, the FSA, which also operates in Wales and Northern Ireland, will work with teams in Wales and Northern Ireland, and with Food Standards Scotland, to ensure that officials and Ministers in all four nations have the opportunity to provide input into policy development decisions.
- **We will put in place clear criteria and evidence requirements:** The FSA intends to use clear criteria and evidence requirements (to be developed with the Advisory Committee on Novel Foods and Processes (ACNFP) and its subcommittee), to identify PBOs that do not need a detailed risk assessment, because the nature and scope of the change is similar to traditionally bred varieties where the level of risk to consumers is currently accepted within the community.

What we are going to do next

The FSA will work with Defra and Food Standards Scotland, to develop a proportionate and rational approach to the regulation of PBOs for use in food and feed. If agreed, we would use the powers proposed in the Bill to develop the detail of the framework in secondary legislation and supplementary guidance. This would all be subject to public consultation.

The FSA Board will hold a further public discussion at its meeting on 14 September on the policy and science underpinning the Bill.