

From Susan Jebb FSA Chair

Susan.Jebb@food.gov.uk

To: All Peers

Cc: Welsh Government Lesley Griffiths MS, Minister for Rural Affairs and North Wales, and Trefnydd Lynne Neagle MS, Deputy Minister for Mental Health and Wellbeing

1 November 2022

Dear Parliamentarian,

The Genetic Technology (Precision Breeding) Bill

I am writing to you, and other members of the House of Lords, to share an update on our current approach to creating a regulatory framework for precision bred food and feed products. This follows on from the Bill's proceedings in the House of Commons ahead of the passage of the Bill in the House of Lords.

The Food Standards Agency (FSA) is an independent, non-ministerial government department with a statutory responsibility to ensure that food is safe and that public health is protected in relation to food in England, Wales and Northern Ireland. This includes risk analysis on food and animal feed safety risks for England, Wales and Northern Ireland.

Our vision is to ensure we maintain a food system in which food is safe, food is what it says it is and food is healthier and more sustainable. We are committed to a risk-based and proportionate regulatory system that protects public health, while also supporting innovation and new technologies where they offer societal benefits. I would be pleased to arrange a meeting if you would be interested to discuss our work.

Part 3: Food and Feed Produced from Precision Bred Organisms

The Genetic Technology (Precision Breeding) Bill, which only applies to England, seeks to remove food and feed products produced from precision bred organisms such as

Floors 6 & 7, Clive House 70 Petty France, London SW1H 9EX Email: <u>Susan.Jebb@food.gov.uk</u>

For information on the FSA's Privacy Policy, click here.



food.gov.uk/ratings

gene editing from the regulatory requirements applicable to the environmental release and marketing of genetically modified organisms for food and feed uses.

Part 3 of the Bill proposes to introduce powers that will empower the FSA to create a proportionate framework for regulating precision bred organisms, a public register for precision bred organisms authorised for use in food and feed and an inspection and enforcement regime. If approved, this framework will inform advice to Ministers on which precision bred organisms should be authorised to be used in food and feed placed on the market in England.

I recognise the interest in this Bill and I am keen that the FSA provides as much information as we can as the Bill continues its passage through Parliament.

Our current progress on developing a future framework

We are conducting two phases of consumer research, building on our previous research in 2021. Phase one, collecting quantitative data, was completed in August 2022. Key findings are included in our published <u>September Board Paper</u>. We publish all our <u>research</u> on precision breeding online to ensure we are open and transparent to consumers and industry. Phase two focuses on gathering qualitative data via a citizens' forum approach. This work will soon be in the field with a view to being completed before the end of the year.

The FSA held a series of stakeholder workshops in August and September with industry bodies, consumer interest and civil society organisations in England and Wales, as well as stakeholders in Northern Ireland. We presented our thinking on the future regulatory framework for precision bred food and feed and listened carefully to stakeholder views. We intend the workshops to be the beginning of a continuing conversation with stakeholders.

The FSA is considering a range of potential approaches to traceability. We are also planning a public register which would provide a list of all precision bred organisms authorised for use in food and feed. The FSA is exploring this as an important tool to aid traceability and for enforcement officers, industry and consumers, including how it could provide assurance that the precision bred organism was safe to enter the market for food and feed uses.

Summary of our regulatory approach

We want to enable you to be sufficiently informed on our progress to developing a proportionate regulatory framework for precision bred organisms for use in food and

Floors 6 & 7, Clive House 70 Petty France, London SW1H 9EX Email: <u>Susan.Jebb@food.gov.uk</u>

For information on the FSA's Privacy Policy, click here.

FOOD HYGIENE RATING



food.gov.uk/ratings

feed. The accompanying factsheet sets out more detail on how and why precision bred organisms will be authorised for use in food and feed under the new regulatory framework, including our plans for traceability measures, understanding the international position on similar products and the implications for the Precision Breeding Bill on Wales, Northern Ireland and Scotland.

My officials (<u>precisionbreeding@food.gov.uk</u>) working on this would be pleased to provide any additional information you would feel beneficial. Also, you have the opportunity to discuss the science with the FSA Chief Scientific Advisor Professor Robin May at the technical drop-in session being hosted by Lord Benyon, 1-2pm on Tuesday 8 November, Committee Room 2A.

Please do not hesitate to contact me to discuss any strategic questions you may have.

Yours sincerely,

Susan Jebb

Professor Susan Jebb OBE, PhD, FRCP (Hon), FMedSci FSA Chair

Floors 6 & 7, Clive House 70 Petty France, London SW1H 9EX Email: <u>Susan.Jebb@food.gov.uk</u>

For information on the FSA's Privacy Policy, click here.





food.gov.uk/ratings

Annex A: Genetic Technology (Precision Breeding) Bill factsheet

What is precision breeding (PB)?

Precision Breeding (PB) is a term used to describe a range of modern biotechnologies that enable DNA to be edited in organisms efficiently and precisely to produce outcomes that could also occur through traditional breeding or by natural processes.

Are PBOs (Precision Bred Organisms) the same as GMOs (Genetically Modified Organisms)?

No. PBOs must have been able to occur through traditional breeding or natural processes, with the resulting plant or animal equivalent to a plant or animal which has been traditionally bred. In contrast, GMOs typically contain much larger genetic changes, such as the insertion of functional genetic material from unrelated species, that would not typically occur through natural breeding.

Why do PB food and animal feed (feed) need to be regulated?

While the technologies used in PB are considered safe, some of the changes to food and feed may potentially result in new risks to specific consumers. For example, a tomato that has been precision bred with enhanced levels of vitamin D will be assessed so that information and safety advice can be provided on any potential risks. Consequently, it is important that any risks are considered and communicated to consumers. Similarly, if a company had used PB techniques to make an allergenic food no longer allergenic, the FSA would ensure its safety and check whether it was safe for people with a food allergy to consume. Robust and proportionate regulation is necessary to build consumer confidence and awareness around PB food and feed. This will ensure that the potential benefits of PB food and feed such as enhanced nutrition and increased climate resilience can be realised.

How will the FSA regulate PB food and feed?

The Bill proposes powers for the Defra Secretary of State to make regulations that will allow the FSA to create a new regulatory framework for PB food and feed for England. The FSA Advisory Committee on Novel Food and Processes (ACNFP) has set up an expert sub-committee that will advise on applications prior to authorisation. The FSA's initial proposal is that all applications for PB food and feed authorisations will be screened for similarity to traditionally bred varieties. The authorisation process will use two tiers of assessment, with products that meet the tier 1 criteria able to be authorised more quickly:

Floors 6 & 7, Clive House 70 Petty France, London SW1H 9EX Email: <u>Susan.Jebb@food.gov.uk</u>

For information on the FSA's Privacy Policy, click here.

FOOD HYGIENE RATING



food.gov.uk/ratings

• **Tier 1:** Will be used for applications of products most like traditionally bred varieties where the risk is understood and not of concern for consumers. The detailed criteria for assessing tier 1 applications are still being developed, informed by expert scientific advice from the independent Advisory Committee on Novel Food and Processes (ACNFP).

• **Tier 2:** Where the initial screening does not allow the risk to be understood, there will be additional scrutiny of the application.

Is it possible to detect if a product or ingredient has been precision bred?

As PB makes targeted genetic changes that can also occur through traditional breeding, there is not currently a test able to determine if a product on the market has a trait achieved using PB techniques rather than traditional breeding.

What traceability requirements will be in place for PB food and feed?

Traceability is the ability to trace and follow a food, feed, food-producing animal or substance intended, or expected, to be incorporated into a food or feed, through all stages of production, processing and distribution. It is a key element of food safety and is important, for example, when withdrawing or recalling unsafe food. Currently, General Food Law (Article 18 of retained Regulation (EC) 178/2002) requires food business operators to ensure they have in place systems and procedures to identify businesses they have supplied.

Traceability will apply to PB food and feed as it does to other products and the Bill proposes powers to introduce specific requirements to secure traceability of precision bred food and feed in England. There are plans for a public register to hold details of PB food and feed and any specific traceability measures for PB food and feed implemented under the Bill will be supported by details published on the register.

How does this reform affect Wales, Northern Ireland and Scotland?

The market access principles of the United Kingdom Internal Market (UKIM) Act 2020 mean that PB food and feed approved by FSA, and either produced in or imported into England, would also be marketable for direct sale to farmers and consumers in both Scotland and Wales. Since the Bill applies substantively to PB food and feed products for placing on the market in England, for PB food and feed products to be authorised for production or direct import into Wales and Scotland, businesses operating in Wales and Scotland would still need to apply under the existing UK legal framework for GMOs. PBOs authorised in England will not be permitted to be sold in Northern Ireland under

Floors 6 & 7, Clive House 70 Petty France, London SW1H 9EX Email: <u>Susan.Jebb@food.gov.uk</u>

For information on the FSA's Privacy Policy, click here.

FOOD HYGIENE RATING



food.gov.uk/ratings

the current terms of the Protocol on Ireland/Northern Ireland. For those products to be placed on the market in Northern Ireland they will need to comply with existing EU law, which includes being authorised by the EU and labelled as GMOs.

What is the position of the EU on PBOs?

The EU has recognised, following an EC <u>study</u> on new genomic techniques published in April 2021, that there is a need to explore current and future GMOs legislation in relation to 'New Genomic Techniques (NGTs)' and their products. The study concluded that it may not be justified to apply different levels of regulatory oversight to similar products with similar levels of risk, as is the case for plants conventionally bred versus those obtained from certain NGTs. The EU has recently consulted (April-July 2022) on the future regulations of plants, and their food and feed products, obtained using NGTs. This indicates that the EU may consider taking a similar approach to that of the UK in creating a new regulatory regime for PB plants, where the genetic changes could have arisen through traditional breeding or natural processes. The EU is now conducting an impact assessment, to be finished in quarter 2 of 2023, which will inform any new legislation for NGTs. Until any such legislation to regulate NGTs becomes legal and enters the Official Journal of the EU, PBOs would still be considered as GMOs and would therefore need to be authorised and labelled as GM (Genetically Modified) before being placed on the EU market.

What are consumers' attitudes towards PB food and feed?

The FSA has conducted research into consumer attitudes on gene editing and precision breeding and this work is ongoing.

- In 2021, we ran both quantitative and qualitative research with consumers
- In August 2022, we ran a representative quantitative survey of 4,200
- consumers across the UK.
- This autumn we are conducting qualitative research in England, Wales and Northern Ireland to explore consumer information wants and needs on PB, and their views on the FSA's proposed regulatory framework.

Once finalised, the findings of the FSA's consumer research will be published here: <u>Consumer perceptions of genome edited food | Food Standards Agency</u>

Floors 6 & 7, Clive House 70 Petty France, London SW1H 9EX Email: <u>Susan.Jebb@food.gov.uk</u>

FOOD HYGIENE RATING



For information on the FSA's Privacy Policy, click here.

food.gov.uk/ratings

What assurances is the FSA offering consumers that PB food and feed are safe?

The FSA will only authorise products for sale if they are judged to present no risk to health, do not mislead consumers, and do not have lower nutritional value than their traditionally bred counterparts.

Which other food are subject to additional regulation by the FSA?

The FSA uses several regulatory frameworks to ensure that food and feed products requiring extra scrutiny are safe before they can be placed on the market. This includes food and feed additives, novel food and food and feed from genetically modified organisms. The frameworks for these regulated products exist in retained EU law. The arrangements for precision bred food and feed provide an opportunity for the FSA to design a bespoke regulatory framework for England, proportionate to the risks posed.

Floors 6 & 7, Clive House 70 Petty France, London SW1H 9EX Email: <u>Susan.Jebb@food.gov.uk</u>





food.gov.uk/ratings

For information on the FSA's Privacy Policy, click here.