The Genetic Technology (Precision Breeding) Bill: Consumer Information, Traceability and Developing Other Elements of the New Regulatory Framework for Precision-Bred Food and Animal Feed

FSA 22-03-05 - This paper provides an update to the Board on the delivery of the new regulatory framework, sets out considerations around traceability of PB food/feed, and seeks Board input in respect of consumer information on PB food.

1. Summary

1.1 At the time of writing the UK Government's Genetic Technology (Precision Breeding) Bill ("the Bill") is at a late stage of its passage through Parliament.

1.2 The FSA continues work to develop a new regulatory framework for precision-bred organisms (PBOs) for use as food and animal feed in England ("PB food/feed"). This paper seeks Board input in respect of consumer information on PB food, sets out considerations and current thinking around the traceability of PB food/feed and provides an update on progress and an indicative timescale for delivery of the new regulatory framework.

1.3 The Board is invited to:

- **Discuss** the provision of consumer information on PB food and **agree** next steps.
- **Note** the considerations and current thinking on traceability for PB food/feed and the further work to be undertaken.
- **Note** the key proposed features of, and considerations in relation to, the public register of PBOs authorised for use as food/feed.
- **Note** the second statement on PBOs from the Advisory Committee on Novel Foods and Processes (ACNFP) and the next steps in developing policy on a robust science-based pre-market authorisation system for PBOs for use as food/feed.
- **Note** the indicative timescale for the work being undertaken to develop and deliver the new regulatory framework and that continued resource from across the FSA will be needed to deliver this.

2. Introduction

2.1 With the Genetic Technology (Precision Breeding) Bill at a late stage in its passage through Parliament, the FSA continues its work to design a proportionate regulatory framework for PBOs for use as food/feed in England. This will be taken forward through secondary legislation made by ministers exercising powers provided by the Bill.

2.2 Our overall objective is to build a new regulatory framework in England that will ensure that PBOs are at least as safe as their conventional counterparts before they can be authorised for placing on the market as food/feed. The new framework will be proportionate to the risks presented and must engender public trust that PBOs for use as food/feed are regulated effectively.

2.3 **Section 1** of this paper discusses the recently published FSA research, 'Consumer Perceptions of Precision Breeding' and considerations around the provision of information to consumers about PB food.

2.4 **Section 2** discusses considerations around traceability of PB food/feed taking into account existing legal requirements under General Food Law.

2.5 **Section 3** outlines plans for the public register of authorised PBOs, discusses the second statement of the ACNFP on PBOs published on 23 January 2023 and outlines ongoing work and indicative timescales for developing a proportionate regulatory framework for the authorisation of PBOs produced for use as food/feed.

3. Section 1: Consumer Information

The FSA's Role and the Consumer Interest

3.1 A summary of policy responsibilities across the UK in respect of food labelling and information can be found at **Annex A**. Transcending these policy responsibilities is the FSA's statutory responsibility under the Food Standards Act 1999 to protect the interests of consumers in relation to food, defined by that Act to include interests in relation to the labelling, marking, presenting or advertising of food, and the descriptions which may be applied to food.

3.2 Accordingly, the FSA is expected to form an independent and evidence-based view about what outcomes are in the best interests of consumers, and the role of consumer information in achieving these outcomes. We will do this by considering consumer views alongside those of other stakeholders and weighing the benefits and risks of a range of approaches before reaching a conclusion about how we can protect public health and ensure consumer interests are protected in the development of the new regulatory approach.

Food Labelling

3.3 As with any other food, existing food information legislation will apply to PB food. The overall objectives of this legislation are to achieve a high level of health protection, ensure that consumers are appropriately informed about food and can make informed choices and to prevent practices that may mislead consumers.

3.4 The UK Government's position is that there should be no requirement to distinguish PB food in labelling or other information for consumers and, consequently, there is no power for ministers to implement this in the Bill. There are, however, existing powers under the Food Safety Act 1990 to make secondary legislation to regulate the labelling and description of food which could potentially be used to lay down labelling/information requirements for PB food.

3.5 PBOs for food use must be determined as safe by the FSA and authorised before they can go on sale in England. This means that labelling will not be required for the purposes of safety for PB food solely because it is PB. However, just as with any other food, PB food may have specific safety labelling for particular consumer groups where this is necessary, for example, information on allergens for consumers with food hypersensitivities.

Legislative Implications Across the UK

3.6 The Bill applies only to England. However, under United Kingdom Internal Market Act 2020 (UKIMA) market access principles, foods/feeds which are, or contain, PBOs authorised in England (which have been produced in, or imported into, England) can be sold lawfully in Wales and Scotland. This is the case even though existing legislation regulating Genetically Modified Organisms (GMOs) for use as food/feed would continue to apply in those countries and the PB foods/feeds may be, or contain, PBOs which are not also authorised as GMOs.

3.7 The UKIMA does not apply to processing after sale. Any PB food/feed which is sold in Wales or Scotland under UKIMA market access principles would, if further processed there, be subject to legislation regulating GMOs. In order for the processed product to be placed on the market in those countries it would need to be authorised and labelled in accordance with GMO legislation or otherwise sent to a third country provided it meets relevant domestic law.

3.8 At the time of writing, under the current terms of the Protocol on Ireland/Northern Ireland ('NI Protocol'), PB foods/feeds (which are or contain PBOs authorised in England which have been produced in, or imported into, England) would not be permitted to be placed on the market in NI unless the PBO is authorised, and the product labelled, in accordance with European Union (EU) GMO legislation. However, under the Windsor Framework published on 27 February 2023 it would be possible for a range of retail products from Great Britain, including food, to be brought into NI for placing on the NI market only. We must continue to ensure that food/feed complies with applicable law in NI and need to understand how the UKIMA and Windsor Framework would interact in practical terms. The FSA will therefore continue to follow developments closely and ensure that these are taken this into account as we develop policy.

3.9 The FSA advises the Welsh Government on food safety and standards in Wales, and we will carefully consider the interests of consumers in Wales when forming a view about consumer information in relation to PB food.

3.10 Welsh Ministers are concerned that the additional regulatory complexity described above will create challenges for compliance with, and enforcement of, established GMO legislation in Wales. In December 2022, Welsh Ministers laid a Legislative Consent Memorandum (LCM) before the Senedd, with the majority of members voting to withhold consent on the Bill. The LCM also covers the fact that the Bill does not require PBOs to be labelled as such and that the Welsh Government wants to protect Welsh consumers' rights to choose whether to purchase food products which contain PB ingredients.

3.11 The Welsh Government intend to review their current approach to gene editing including PB and to consider whether there is evidence to support a policy change. FSA officials are maintaining a close working relationship with Welsh Government counterparts during the development of the new regulatory framework for England and the FSA Chair has met regularly with Welsh Ministers.

3.12 Through our four-nation approach, the FSA will continue to work collaboratively across England, Wales and Northern Ireland, and with Scotland (whose ministers are advised by Food Standards Scotland), using Common Framework Agreement mechanisms.

Consumer Research

3.13 The latest research on consumer perceptions of precision breeding was published on 9 March 2023. A summary can be found in **Annex B**.

3.14 Consumers told us that:

- they saw a range of risks and benefits to PB food but on balance consumers thought the benefits outweighed the risks if properly regulated;
- they trust the FSA to regulate PB food;
- the public register builds towards confidence and reassurance;

- more proactive information provision (public education campaign, education in school curriculum, labelling, for example) would reassure them that regulation was happening;
- they wanted labelling to enable them to make choices at the point of purchase.

3.15 When considering the pros and cons of labelling, consumers focused strongly on the need for transparency about food to enable informed choice as an important principle. For PB food, the need for transparency was associated with consumer perceptions about food safety. Consumers were particularly focused on information that enabled people with any concerns to avoid PB food.

3.16 This is consistent with many similar studies the FSA has conducted on how consumers perceive risk. What consumers are often expressing by asking for proactive information provision is that transparency gives them confidence. It is not unusual for people to ask for advertising campaigns, education in schools and labelling to provide this transparency, as these are the touchpoints that spring most immediately to mind. This is not specific to precision breeding, and the Board will need to consider the approach to PB food in the context of current and future modern food biotechnologies where consumers may state similar preferences.

Wider Stakeholder Engagement

3.17 The FSA continues to offer stakeholders across England, Wales and Northern Ireland the opportunity to comment, challenge and provide input into our policy development. In addition to our engagement with consumers via the research, we have engaged directly with consumer interest groups, civil society groups and key industry partners.

3.18 **Consumer bodies and civil society group**s represented the views of consumers, making the case for mandatory labelling to build trust and enable consumer choice. There was some recognition from consumer bodies of the limitations of labels and how consumers already struggle with the amount of information on packs. However, stakeholders in these groups were clear that they considered mandatory labelling as the only way to give consumers choice.

3.19 **Supply chain industries** emphasised the importance of informing consumers about the benefits of PB and identified the FSA as having a convening role to bring together information from different sources. They were clear that mandatory labelling was not needed for authorised PB food determined as safe by the FSA.

Determining the Consumer Interest

3.20 Determining the consumer interest in relation to consumer information on PB food is complex because there is no single solution that delivers all of the desired benefits. For consumers and consumer-representative groups, mandatory labelling is an attractive option because:

- consumers say this is what they would prefer because it promotes transparency and choice;
- it provides some assurance to consumers that their food is safe, and well regulated;
- it is considered easy to implement, and there are some similar precedents for mandatory labelling, for example with GMOs used as food; and
- consumers who wish to avoid PB foods can do so more easily.

3.21 However, it is important to consider the options in the context of the following, which are discussed in the subsequent paragraphs:

- evidence about how consumers use labelling, which suggests that labelling alone does not change consumer behaviour;
- evidence about the impact of labelling on consumer choice and consumer trust in food;
- the full range of ways in which consumers get information about their food;
- the challenges for enforcement of new consumer information requirements.

How Might Consumers Use PB Labelling?

3.22 Evidence shows that consumers are most likely to focus on information regarding price, quality and value for money when making purchasing decisions. Specific consumer groups with particular motivations to read labels (for example for medical reasons or to ensure that their food meets environmental or animal welfare standards) will make purchasing decisions based on information on labels. If there was labelling to distinguish PB food, consumers could use this information to avoid products with perceived safety or environmental risks, or to choose products with health or environmental benefits.

3.23 Our consumer research tells us that consumer understanding of PB food is very low. When prompted, consumers do recognise the potential benefits, but they are also concerned about the perceived safety of PB food and that methods of production may damage the environment. This explains why consumers feel strongly that labelling to distinguish PB food is important for transparency and choice. In this context, it is likely that those consumers who do consult labels would most often use such labelling to avoid PB food.

Potential Impact of Presence or Absence of PB Labelling

3.24 Food labelling and other sources of consumer information are fundamental to maintaining trust in the food system. Consumers would prefer PB food to be labelled to distinguish it as PB because it gives them confidence that they know what is in their food. If PB food is not labelled, there is a risk that consumers will lose trust in the food system. It is difficult to predict whether this is likely to happen if there is no mandatory labelling to distinguish PB food. Our consumer research shows that when the technology is clearly explained to people, concerns about PB food are reduced and there are other methods of production of which consumers are generally unaware such as novel food processes which are not indicated on labelling.

3.25 Conversely, there is a risk that introducing labelling to distinguish PB food will reduce trust in the food system because labelling is associated with safety concerns. The requirement to label GMO products is widely believed to have fuelled safety concerns rather than reducing them, resulting in an almost complete absence of foods consisting of, or containing, GMOs in the UK and EU. This could be regarded as decreasing consumer choice. In contrast, products from animals fed on GMO feed do not require labelling to indicate this; these products are ubiquitous and accepted by UK consumers without general loss of trust in food safety and integrity.

3.26 When considering these impacts, it is important to bear in mind that:

- There is no evidence that PB products will be less safe than conventionally bred products, and each individual product will undergo a safety assessment before being placed on the market;
- Our consumer research shows that consumers want the potential benefits from PB products, including products that are healthier, more sustainable and better for the environment.

The Range of Ways in Which Consumers Get Information About Food

3.27 As discussed above, labelling is just one way that consumers get information about food. Choices about food are influenced by deliberate processes, where consumers make conscious choices and plans; by unconscious processes where choices are made quickly without deliberation; and through the indirect effect of background factors which may reflect the influence of the culture or society that we inhabit.

3.28 As a trusted regulator the FSA has a role to play in providing consumer information. One of the options to consider alongside, or as an alternative to labelling, is whether the FSA should play an extended role in the case of PB food, for example through enhancing and extending the public register of authorised PBOs (see **Section 3**) and/or doing more to inform consumers about

PB food. It will also be important to keep abreast of developments from food businesses and civil society and consumer organisations who are likely to provide more information as PB products are developed for market and as the detail of the regulatory approach is confirmed.

3.29 The provision of labelling/information about food on a voluntary basis is always open to industry. This is subject to the requirements of food information legislation for providing voluntary information and general requirements, including that consumers are not misled.

3.30 Voluntary labelling or other information will often be provided for marketing purposes, for example to highlight particular benefits of food such as environmental benefits or to amplify health benefits for which claims are being made in accordance with relevant legislation. The advantage of a voluntary approach would be that producers could respond to consumer need for information and tailor the approach on a case-by-case basis. The disadvantage is that there may be a lack of consistency in the way information is presented. Regardless of the position on mandatory labelling, we will continue to explore how we can work with industry to ensure that information about PB food is accurate and consistent and in the best interests of consumers.

3.31 If labelling is most likely to be used by consumers who wish to actively avoid PB food, an option could be to work with food businesses to develop a 'PB free' labelling and industry assurance scheme. This would be similar to current schemes for organic food, or Fairtrade products. Based on these examples, it is likely that 'PB free' products would be more expensive due to the cost of administering such a scheme. Conversely, this would avoid the costs of labelling and assurance being applied to all PB food (see below).

Challenges for Enforcement

3.32 The Bill defines 'precision bred organisms' as organisms containing changes of a kind that could have been introduced through existing breeding methods. As with any new variety of crop or breed of animal, it is possible to sequence the genome and identify any changes that have been introduced. However, it is currently difficult or impossible to determine whether the change has been introduced by traditional methods or by PB methods, meaning there is no test that could be used for enforcement purposes to check that labels are accurate.

3.33 This means that enforcement and industry assurance of any mandatory labelling to distinguish PB food would be based on the audit of systems and records. This presents a challenge to enforcement and brings inherent risks of deliberate misdescription or mislabelling. However, these risks are not specific to PB food and exist in relation to other aspects of food standards such as country of origin labelling where systems are in place which maintain the trust of consumers.

3.34 For those consumers who wish to avoid PB food, this inherent risk – although no higher than for other aspects of food information that cannot be verified by testing – may be unacceptable. This is another factor in favour of a 'PB-free' scheme, as this could have additional and more rigorous independent verification and assurance to meet consumer expectations, for example, similar to the organic and Fairtrade food schemes. As noted above, this is likely to add extra costs. Providing this additional verification and assurance for all PB food would add extra cost to the whole PB food market, making it less affordable, reducing the incentives for food businesses to innovate and bring new products to market, and reducing potential benefits.

3.35 Another consideration for enforcement is the interaction with the UKIMA and Protocol on Ireland/Northern Ireland ('NI Protocol') as detailed above. For different reasons, it will be important that PB food and feed can be identified in the Welsh, Scottish and Northern Ireland markets. However, it should be noted that UK enforcement authorities (and industry) already have to ensure compliance with existing legislation such that PB products produced in other countries cannot enter the UK market without being authorised as GMOs and labelled as such.

3.36 Mandatory labelling to distinguish PB food could facilitate domestic enforcement and determine whether products would be suitable for export to a certain extent – but there are also other solutions that will need to be explored further. This could include enhanced information for traceability purposes as discussed in **Section 2**.

International Approaches to PB Food/Feed

3.37 Information on the approaches to PB food/feed internationally can be found at **Annex C**. The European Commission is analysing how EU rules might be changed in relation to what they call 'new genomic techniques' for plants and we understand that proposals could be published in Summer 2023. These proposals will be relevant to understanding the potential future trade implications with regard to PBOs authorised in England for use as food/feed.

3.38 A 2022 Food and Agriculture Organisation (FAO) report on Gene Editing and agrifood systems (footnote 1) advocates a harmonised, transparent, science-based global system based on transparent science-based consideration of risks in which new traits in food are included in a label where there are fundamental changes to its composition and that production method labelling should not be mandatory. This is consistent with our fact-finding which shows that countries that do not regulate PBOs as GMOs do not require labelling distinguishing PB food/feed.

Consumer Information: Conclusions / Recommendation

3.39 There is no single, simple solution that can meet the needs of consumers and deliver the potential benefits of healthier, more sustainable food whilst maintaining trust in the food system, improving food security and avoiding additional costs to food producers and consumers.

3.40 Given the factors at play outlined above we recommend that the FSA should continue to keep the provision of consumer information on PB food/feed under review. There will be further opportunities to explore the case for mandatory labelling to distinguish PB food as the FSA develops the new regulatory framework; learns more about the products that developers are likely to bring to market; how the market might respond; and if, and how, consumers' attitudes change over time. The FSA will also take into account the effect of the UKIMA, developments with regard to the NI Protocol and Windsor Framework and the implications of the UK position on PB food/feed for international trade.

3.41 PB is just one of a number of modern biotechnologies that has the potential to support the development of healthier and more sustainable food and help improve animal welfare in future. In deciding about the best approach for PB food/feed, we will need to keep in mind that this may set a precedent for the regulation of future technologies, for example whether there is an expectation that any new food production technology should be described on the food label. As part of our ongoing engagement with consumers and stakeholders, we will use the opportunity to explore these future issues.

4. Section 2: Traceability

Background

4.1 Under General Food/Feed Law, traceability is the ability to trace and follow food/feed, food-producing animals or substances intended or expected to be incorporated in food/feed, through all through all stages of production, processing and distribution. Food business operators must be able to identify their immediate suppliers as well as the businesses to which their products are supplied (a "one up, one down" approach). This information must be provided to competent authorities, if requested. Traceability is an essential food/feed law concept and will apply to PB food/feed just as with other food/feed.

4.2 Whether food/feed is traceable depends only on the ability to trace and follow it through the supply chain. The ability to identify products through testing is not the only method for securing traceability and policy on consumer information (including labelling) is also independent of traceability. As outlined in paragraph 3.32 it is not currently possible to test for PB food/feed due to its similarity with its conventional counterparts.

4.3 The Bill will provide ministers with a power to 'impose requirements for the purpose of securing traceability in relation to food or feed produced from precision bred organisms that is placed on the market in England.' It is for the FSA to advise ministers in that regard. Proposals in this paper on the traceability of PB food/feed relate to England only given the extent of the powers in the Bill, recognising the challenges to compliance and enforcement in the other UK countries.

Objective and Options

4.4 FSA's central objective for the traceability of PB food/feed is to ensure that it is no different to its conventional counterparts in terms of the ability to trace and remove it from the market in the event of an incident.

4.5 The question is whether, for the purposes of traceability, there is a need to require that specified additional information should accompany PB food/feed along the supply chains identifying it as such to achieve this objective. Such additional information could for example indicate that food/feed is or contains PBOs and provide any identifier assigned when the PBO was authorised.

4.6 There are effectively two options:

- Determine that traceability requirements under General Food Law are sufficient to achieve the above objective and consequently that there is no current need for ministers to exercise powers in the Bill to require additional information to accompany PB food/feed along supply chains; or
- Determine that additional information to accompany PB food/feed along supply chains is necessary to address the challenges outlined below. The FSA would then develop policy and secondary legislation to specify what this information should be, with a view to advising ministers to exercise relevant powers in the Bill.

Food/Feed Safety

4.7 The pre-market authorisation system for PB food/feed the FSA is developing will ensure that authorised PB food/feed will pose no greater food safety risk than its conventional counterparts. It is our view that traceability requirements would not need to be enhanced for reasons of food/feed safety.

Challenges and Practicalities

4.8 Evidence has been gathered from workshops with internal and external stakeholders and colleagues from across the FSA to help inform consideration of issues around traceability. Some stakeholders were of the view that if there were no requirements for additional information to accompany PB food/feed along supply chains, challenges relating to the UK internal market from the legislative implications set out in paragraphs 3.6-3.8 and to external trade would arise.

4.9 However, these challenges are less about traceability itself. They are more about the ability of industry to distinguish, via mandatory information, PB food/feed as such, whether products are suitable for use as, or in, food/feed for the UK and external markets and the ability of UK enforcement authorities to determine compliance with relevant rules at any point along the domestic food/feed supply chains.

4.10 These challenges arise in part because of the current practical inability to test for PB food/feed and in part because they are inherent in the food system and not unique to PB food/feed. For example, there are challenges to enforcement in relation to products of novel processes, organic food, and to an extent food labelled with a country of origin, where it is not possible to test to verify its precise status. As noted in paragraph 3.35 UK industry and enforcement authorities already have to ensure compliance with existing legislation in order that PB products produced in other countries cannot enter the UK market without being authorised as GMOs and labelled as such.

4.11 The bottom line with any food and feed supply (including trade) is that the supplier must ensure that the products in which they deal meet the requirements of the customer, including the legal requirements of the market into which they are selling. Businesses exporting to Northern Ireland already have to take steps to ensure that products are compliant with EU law; the challenges are not unique to PB. This can be achieved through commercial contracts specifying supply chain controls, supported by documentation and audit without the need for additional traceability requirements. Other approaches including independent certification could also be adopted as is the case with organic food.

4.12 It has also been suggested that additional information might reduce the risk of fraud. However, the risk of food fraud is inherent in the food system, especially where there is no test to determine authenticity. Fraud risks around PB food/feed will need to be mitigated by using the same approaches to detecting and preventing fraud applied to similar product types that cannot be identified through testing such as those mentioned above via audits of systems and records and focused investigations of the supply chain where fraud is suspected.

4.13 We understand that proposals for changes to the way in which new genomic techniques are regulated in the EU may be published in Summer 2023. These could result in a greater degree of alignment with the new regulatory framework envisaged in England and there is potential for them to reduce the regulatory burden of compliance between the two different regimes. This might help with the challenges with trade with the EU including those related to the NI Protocol. As such it is important to keep these issues under review as we develop the new regulatory framework.

Impact Assessment

4.14 The FSA will need to prepare a formal impact assessment and conduct a formal public consultation on proposals for the future regulatory framework for PB food/feed, including any proposals on enhanced traceability requirements before inviting ministers to exercise Bill powers to bring forward any secondary legislation in this regard. A very basic assessment is below.

4.15 No additional costs to industry would arise from maintaining the current approach to traceability under General Food Law which applies equally to PB food/feed. Costs to industry would arise if specified information distinguishing PB food/feed was required to accompany it along supply chains, including costs associated with segregation from its conventional counterparts at all stages. Costs to Local Authorities would arise from the need to enforce the authorisation requirements in relation to PB food/feed and the complexities of enforcement arising from the effect of the UKIMA, which could be mitigated to some extent by requiring that additional information accompanies PB food/feed.

Consumer Information Considerations

4.16 If there were to be requirements for consumer labelling to distinguish PB food, this would not in itself necessitate requirements for additional information to accompany PB products along the food supply chain. This is covered by general provisions in current food information legislation which requires food businesses to pass information along supply chains to facilitate compliance with all relevant requirements right down to operators ultimately producing and labelling food products for the retail market.

Traceability: Conclusions

4.17 Existing traceability requirements in General Food Law provide strong assurance throughout food/feed supply chains. Additional traceability requirements for PB food/feed requiring information that distinguishes it along supply chains may mitigate some of the challenges outlined above. However, the need to take such information at face value where an audit of systems and records has not been carried out and the inability to conduct tests to check for PB means that limitations around enforcement and industry assurance would remain.

4.18 At this stage we do not envisage that additional traceability requirements beyond those in General Food Law will be necessary. However, further work will be undertaken as we develop policy to understand the trade and enforcement aspects, including how the Windsor Framework and UKIMA will operate in practical terms.

5. Section 3: Developing Other Aspects Of The New Regulatory Regime For PB Food/Feed

Public Register

5.1 The Bill provides a discretionary power for ministers to make regulations to require the FSA to establish and maintain a public register of information relating to PBOs authorised for use as food/feed in England. The intention is that, as with other regulated products, there will be a public register to provide information on PBOs authorised for use as food/feed. The FSA shared information with parliamentarians about this during the passage of the Bill.

5.2 The register could include, for example, information about the type and nature of the authorised PBO, any unique reference / identifier it has been given, links to the published scientific risk assessment, legislation by which the product has been authorised etc.

5.3 Our consumer research indicates that consumers supported the idea of a register of PBOs. They said that although they might not use it themselves, they felt strongly it should exist for transparency and provide assurance that PB food/feed was being regulated effectively. It could therefore help engender consumer trust in PB food and its regulation.

5.4 The register will be of importance to consumers, but it may have been interpreted by some as a key vehicle for providing information to consumers. While it would be a public resource accessible to all including consumers, industry and enforcement authorities, which will provide information on PBOs authorised for use as food/feed, there are limitations to its use for providing information specifically for consumers.

5.5 Whether the register would be an appropriate vehicle for providing enhanced information for consumers would need to be considered in the light of further policy development. A key consideration within this will be digital inequality, where modern technological solutions are not accessible to all members of the general public.

Second Statement of the ACNFP on PBOs

5.6 The Board was updated in September 2022 on the establishment and progress of the newly formed Products of Genetic Technology (PGT) subcommittee of the ACNFP. The subcommittee has since published two statements in relation to a tiered approach to regulation, including detailed information on the criteria for determining the regulatory route.

5.7 The ACNFP published its second statement on the current scientific understanding of the food/feed safety risks for PBOs on 23 January 2023. This will be used to inform the development of a regulatory approach. The statement reiterated the ACNFP supports a two-tier system to allow a proportionate review of PBOs where food or feed safety could be impacted. It also

highlights that there is no evidence that PBOs are intrinsically more hazardous than traditionally bred organisms. However, the ACNFP has been asked to consider where additional review, beyond the due diligence that applies to all food/feed, would be justified for PBOs.

5.8 The statement identified triage questions for PBOs that, where met, would prompt a further review to assure that all risks are identified and managed. These are:

- **Novelty** – where the organism would otherwise require assessment as a novel food;
- **Composition** – when there is a significant change in composition that impacts the food / feed safety risks in relation to toxicity, nutritional quality or allergenicity.
- **Other safety concerns** – in line with the precautionary principle this is intended to provide a route for further review in the rare cases where there is significant uncertainty around the impact on safety for a PBO, outside the considerations detailed above.

5.9 The intention would be that further review would be considered on a case-by-case basis and tailored to the reason(s) for which the PBO has been flagged for further review. The ACNFP will now be piloting the approach and further developing the data requirements to support the process.

Continued Development of the New Regulatory Framework

5.10 The Bill provides a discretionary power for ministers to regulate the placing on the market in England of PB food/feed and to assign the FSA with functions in that regard. In anticipation of this, the FSA is developing the new regulatory framework for pre-market assessment of PB food/feed. PBOs will only be permitted for food use if our risk assessment judges them to: not to present a risk to health, not to mislead consumers, and not to be nutritionally disadvantageous.

5.11 Information from the ACNFP subcommittee will be used to generate scientific guidance for applicants in order to provide greater certainty on the expectations of the assessment for each of the triggers. A joined-up approach between Defra and the FSA to deliver their respective responsibilities is being developed to provide a consistent experience for applicants. It is anticipated that this process will evolve over time as more experience is gained.

Next Steps

5.12 We propose to continue developing our understanding of consumer views about PB and how to provide the information they need. We will continue developing the public register which will contain information for all about PB organisms that have been authorised for use in food and feed in England.

5.13 We will continue our engagement with consumers, industry, other government departments and enforcement authorities over the coming months which will focus on policy options for the pre-market authorisation system, the public register and enforcement. We will consider the best ways of pro-actively providing information on the proposed framework for assessing PBOs for food/feed and the criteria that will have to be met before authorisation can be recommended to help increase consumer understanding of precision breeding, provide assurance about its regulation in relation to food/feed and increase consumer confidence and trust.

5.14 As regards the wider picture, we will work with Defra to explore how modern food production techniques should be described to help avoid multiple and confusing terminology on food labels and to ensure that labelling requirements take into account emerging and future food technologies such as novel proteins, cell cultured meat and precision fermentation. We will continue to develop our understanding of the types of PB food/feed for which early applications are likely to be received and when these might be expected. We will also continue to monitor how other countries approach the regulation of PB food/feed in order to learn from their experiences.

Timescales/Resources

5.15 The passing of the Bill would be a significant milestone. However, ongoing resource from across the FSA will be required to develop all the elements of the new regulatory framework. This will include further policy development, ongoing stakeholder engagement, preparing draft secondary legislation, assessment of impact and conducting a public consultation before the FSA can present its final proposals to ministers. An indicative timescale for this work can be found at **Annex D**.

6. Conclusion

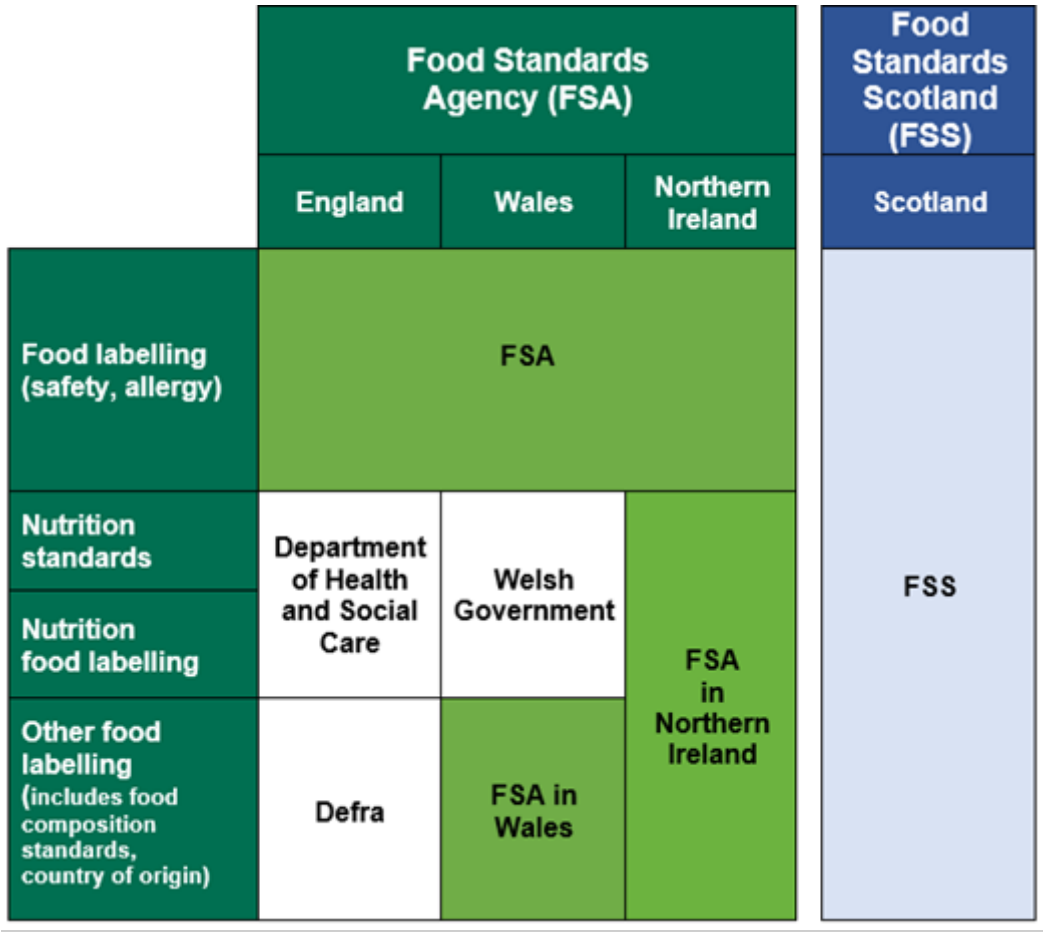
6.1 The Board is invited to:

- **Discuss** the provision of consumer information on PB food and **agree** next steps.
- **Note** the considerations and current thinking on traceability for PB food/feed and the further work to be undertaken.
- **Note** the key proposed features of, and considerations in relation to, the public register of PBOs authorised for use as food/feed.
- **Note** the second statement on PBOs from the Advisory Committee on Novel Foods and Processes (ACNFP) and the next steps in developing policy on a robust science-based pre-market authorisation system for PBOs for use as food/feed.
- **Note** the indicative timescale for the work being undertaken to develop and deliver the new regulatory framework and that continued resource from across the FSA will be needed to deliver this.

Annex A

Policy Responsibilities: Labelling, Composition and Nutrition

The FSA has policy responsibility for food safety labelling including allergen labelling. Food labelling and composition policy, where not related to food safety, rests with the Department for Environment, Food and Rural Affairs (Defra) in England and with the FSA in respect of Wales and Northern Ireland. Nutrition labelling policy rests with the Department of Health and Social Care (DHSC) in England, the Welsh Government and with the FSA in respect of Northern Ireland. European Union (EU) food labelling and nutrition labelling law applies directly in Northern Ireland under the current terms of the NI Protocol, although the FSA retains policy responsibility for areas in which national rules are permitted under EU law. In relation to Scotland, FSS has policy responsibility for all these areas.



Annex B

Overview of Consumer Research: 'Consumer Perceptions of Precision Breeding'

Methodology

1. Survey data on consumer views of precision breeding (PB) was collected in August 2022 by Ipsos on behalf of the FSA. The sample size was 4,177 participants. (1,900 participants from England 1,016 from Wales, 1,005 from Scotland and 256 from Northern Ireland (NI). Data was weighted to be representative of the UK. The full report for the quantitative survey can be found here: Survey of public attitudes towards precision breeding.

2. This was followed by deliberative re convened consumer groups that ran in October. 97 participants from England, Wales and NI took part and groups were split into 5/6 people for discussion. The first workshops provided consumers with information on precision breeding and captured initial views on risks and benefits. The second workshop discussed the FSA's proposed approach to regulation of precision-bred organisms (PBOs) and their views on what information they would like in order to make decisions around purchasing foods which are, or contain, PBOs ("PB food").

3. The full report with the quantitative and qualitative findings was published on 9 March.

Awareness and knowledge

4. There was very low awareness of PB in the workshops. In addition, there was low knowledge of conventional breeding techniques (e.g., the use of chemicals / irradiation to trigger

mutations). This supported the survey findings. When asked if they had heard of PB, and before a definition was provided, only 8% of respondents in the survey said they had heard of it and knew what it was. 16% said they had heard of it but did not know what it was, and 75% had never heard of it.

Acceptability of PB foods

5. Consumers felt the use of PB was more acceptable in plants (54%) than in animals (35%), something which was echoed in the qualitative workshops. Previous research on novel foods and technologies has reported similar findings and a similar pattern was identified in the 2020 GE survey.

6. Once a definition of PB foods had been provided to survey respondents, there was a soft level of support for PB food products being on sale in the UK with 50% of participants saying yes PB food products should be for sale, but of these 36% said that they should probably be for sale. 29% said no, and 21% said don't know.

7. Fifty percent of respondents thought that PB food would be safe to eat. One in five (22%) thought it would be unsafe and 28% did not know. The figure was lower in NI where 42% of participants thought it would be safe.

Risks and benefits of PB

8. Positives noted by participants in the workshops were that PB could help with sustainability and climate change. It could help improve nutrition, food availability and affordability. It could increase returns for farmers and help with UK food security (potentially reducing imports) and global food shortages.

9. Negative views were that it was un-natural and essentially a re-brand of GM. Top concerns were about unknown long-term health and environmental impacts. Some participants thought it could negatively impact on food prices if PB products are expensive, or conversely consumers need to pay more to avoid PB products. There were concerns about transparency and the impact of consumer choice. There were questions about who was profiting from PB and who was accountable. There were concerns around not being able to trade with the EU and lowering food standards to allow trade with other countries.

10. While there were of range of views, many participants felt that the benefits of precision breeding may outweigh the risks, as long as PB foods are carefully regulated. Half or more of respondents in the survey said they would be willing to try PB dairy (52%), processed foods (for example, bread or chocolate) (56%), cereals/grains/flour (59%), or fruits and vegetables (59%). Consumers expressed the lowest willingness to try PB meat (44%). Consumers were more likely to say they were willing to eat PB foods if it came with benefits. The options presented include PB foods having health benefits, safety benefits for people with food hypersensitivities, improved taste, being cheaper, benefits to the environment, being more resilient to climate change, and improving animal welfare. Over six in ten respondents (60%~65%) would be willing to try a PB food if they knew it came with one of the benefits listed, although around a fifth indicated that none of the presented benefits/differences would make them willing to eat PB foods.

The FSA's proposed regulatory framework, and consumer information needs

11. To maintain trust, consumers in the workshops wanted strict regulation, through testing, and transparency on decision making, funding and which foods are PB foods. There was support for the two-tier system framework, although concern that Tier 1 would not be rigorous enough, and desire for more information about categorisation.

12. Having information on whether foods have been precision-bred is important to consumers. Just over three quarters (77%) of survey respondents said that it was very or fairly important to

know if they were buying a food item that had been precision-bred, or contains precision-bred ingredients, before they buy it, with 15% saying it was not important and 8% that they did not know. A similar proportion (77%) said it was important to know which specific ingredient had been precision-bred, and the reason for that (78%).

13. The findings in the workshops supported the quantitative findings. Despite understanding the mandatory labelling requirements, and challenges around traceability and labelling, participants still strongly wanted PB foods to be labelled. Participants supported the idea of a register of authorised PBOs, but felt it needed to be accompanied by labelling to ensure consumers were properly informed when it matters (at the point of purchase). Participants said they may not use a register themselves, but they still felt strongly that it should exist for transparency and saw knowing that a register exists and that someone had checked the safety of PB foods as a source of reassurance.

Annex C

International Approaches to PB Food/Feed

European Union: The European Commission is analysing how it might change EU rules on what they call "new genomic techniques" (NGTs) for plants. They have not given any indication of potential change in relation to animals. On 29 April 2021, the Commission published a study regarding the status of NGTs under EU law. The Commission then conducted a public consultation from 29 April to 22 July 2022 to inform an initiative to explore the suitability or otherwise of the EU GM regulatory regime for plants developed using NGTs and food and feed derived from such plants and potential options for a new framework. The Commission has stressed that they are not pushing for deregulation and are considering a wide range of options for appropriate regulation. We understand that proposals for new EU rules on NGTs could be published in Summer 2023.

Argentina: In 2015, Argentina became the first country in the world to develop regulatory criteria for gene editing and other new breeding techniques (NBTs). Now known globally as the "Argentina model," Argentina only regulates genome-edited plants with permanent insertion of foreign DNA, which they consider to be GMOs. For every gene-edited organism proposed for placing on the market, a dossier must be submitted to the Argentine Biosafety Commission which will determine whether it should be regulated as a GMO or are exempt. Gene-edited products that have not gone through this process are considered to be, and regulated as, GMOs by default. There is no legally mandated label for genetically engineered food, GMOs or gene-edited foods and no public register.

Canada: In June 2022, Health Canada published new guidelines meaning those gene-edited crops that meet the criteria set for food not considered novel food could be treated the same way as conventional crops. That would mean they would not be required to go through their pre-market safety evaluation used for GM crops. There is also a voluntary transparency initiative for gene-edited plants that are developed for food use but are not considered a novel food. This initiative enables developers to provide Health Canada with concise information about their products and obtain a decision on non-novel status within 60 days, after which the decision is published. This allows the public to have information on the types of gene-edited plant products that may be used as food in the country. There is no requirement for specific labelling.

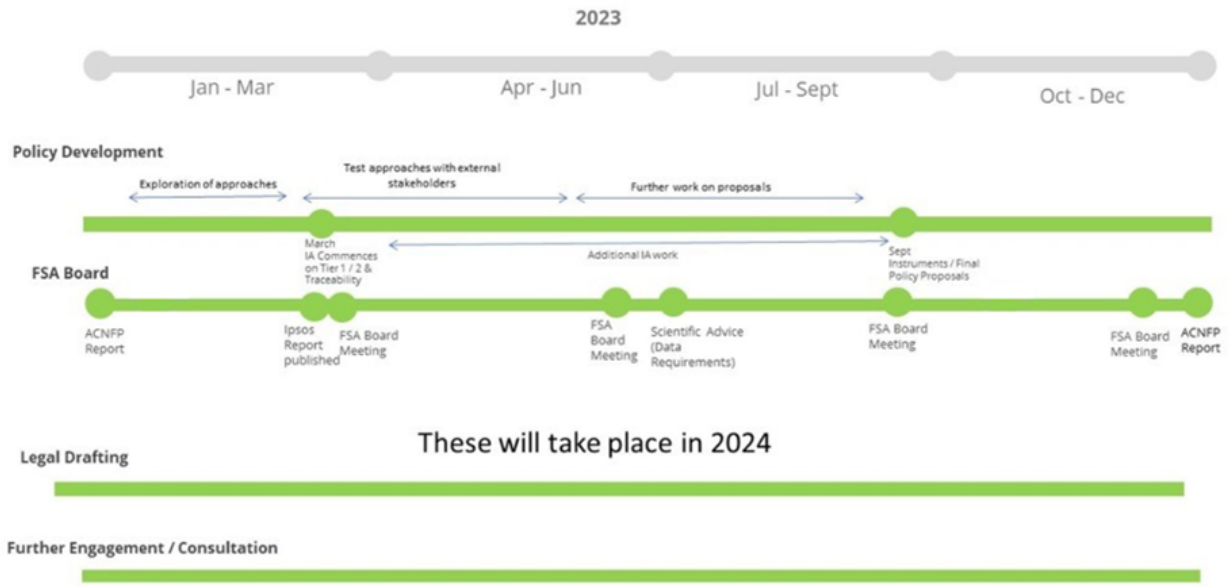
Japan allows gene-edited products to be sold to consumers without safety evaluations provided the techniques involved meet certain criteria. It has introduced three gene-edited products to date: fleshier red sea bream, high-growth tiger puffer fish, and a Gamma-Aminobutyric Acid (GABA) enriched tomato. Referred to in the media as a 'super tomato,' it features five times the normal amount of GABA, an amino acid linked to lower blood pressure, further to tweaks to genes in the tomatoes that normally limit GABA production. Foods derived from genome editing do not

need to be distinguished in product labelling, but industry is encouraged to share information with consumers. A voluntary labelling scheme was set up in October 2019. Notifications for genome-edited products are published on the relevant Japanese Government websites.

Switzerland: Further to a referendum in 2005 Switzerland implemented (and maintain) a moratorium on GM. In 2022, while extending a moratorium for genetically engineered organisms in principle until the end of 2025 the Swiss Parliament asked the government to propose details on the use of gene editing and other NBTs on plants and seeds by 2024 such that plants developed through gene editing techniques that do not contain transgenes would no longer be considered GMOs. In the meantime, existing Swiss law governing GM law and the moratorium on GM remain in place.

Food and Agriculture Organisation of the United Nations (FAO): In its 2022 Food and Agriculture Organisation (FAO) report on Gene Editing and Agrifood Systems report the FAO advocates framing labelling rules in "a harmonized global system based on transparent science-based consideration of risks, in which new traits in food would be included in a label if they represented fundamental change in the composition of the food" and envisages that an indication of the "production method would not be a mandatory labelling requirement."

Indicative Timescale for work to establish the new regulatory framework.



1. https://www.fao.org/documents/card/en/c/cc3579en