FSA Board Meeting - September 2023

FSA Board Meeting - September 2023: Video and Minutes

The agenda and papers for the FSA Board Meeting on Wednesday 20 September 2023.

Video of FSA Board Meeting September 2023

Minutes of FSA Board meeting - September 2023

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FSA Board Meeting - September 2023: Agenda and Papers

Agenda and papers for the FSA Board meeting on 20 September 2023. Le Havre and Caen Suite, Novotel, Southampton.

The agenda for this meeting includes:

- Genetic Technology (Precision Breeding)
- Annual Report: Freedom of Information Requests, External Complaints Internal and Whistleblowing Cases
- Annual Animal Welfare Report 2022/23
- Incidents and Resilience Annual Report 2022/23
- Risk Analysis Process and Regulated Products Service Update
- Report from the Director for Wales
- Annual Report from the Chair of the Audit and Risk Assurance Committee (ARAC) and Report from September ARAC meeting

9:00 - Chair's Introduction

Professor Susan Jebb presents the minutes and actions from the previous FSA Board meeting in June2023 and presents the Chair's report.

FSA 23-09-01 - Minutes of the FSA Board Meeting on 21 June 2023

FSA 23-09-02 - Actions Arising

9:20 - Chief Executive's Report to the Board (FSA 23-09-03)

Emily Miles presents the Chief Executive's report to the FSA Board.

FSA 23-09-03 - Chief Executive's Report to the Board

9:50 - Genetic Technology (Precision Breeding)

Rebecca Sudworth and Rebecca Lamb introduce a paper, which outlines proposals for the regulation in England of Precision Bred Organisms for use in food and feed.

FSA 23-09-04 - Genetic Technology (Precision Breeding)

10:30 - Annual Report: Freedom of Information Requests, External Complaints and Internal Whistleblowing Cases (FSA 23-09-05)

Julie Pierce, Noel Sykes and Jenny Desira introduce a report to inform the Board's oversight of these three areas of work.

FSA 23-09-05 - Annual Report: Freedom of Information Requests, External Complaints and Internal Whistleblowing Cases

10:45 - Annual Animal Welfare Report 2022/23 (FSA 23-09-06)

Junior Johnson and Kevin Maher introduce paper, which provides an update on FSA activities delivered through the 'Deter, Prevent, Detect, Enforce' Animal Welfare Action Plan and its objective of making ongoing improvements to animal welfare in slaughterhouses in England and Wales. This paper also highlights additional work completed in the period.

FSA 23-09-06 - Annual Animal Welfare Report 2022/23

11:05 - Break

11:25 - Incidents and Resilience Annual Report 2022/23 (FSA 23-09-07)

Junior Johnson and Jodie Wild introduce a paper, which provides an overview of the work undertaken by the Incidents and Resilience Unit (IRU) to carry out food and feed incident response/prevention and outlines the challenges faced in 2022/23.

FSA 23-09-07 - Incidents and Resilience Annual Report 2022/23

11:40 - Risk Analysis Process and Regulated Products Service Update (FSA 23-09-08)

Rebecca Sudworth, Lexi Rees and Chris Rundle introduce a paper, which has been prepared to update the Board on the performance of the FSA's Risk Analysis process and the Regulated Products Service (RPS).

FSA 23-09-08 - Risk Analysis and Regulated Products Service: Regular update to FSA Board

12:00 - Report from the Director for Wales (FSA 23-09-09)

Report by Nathan Barnhouse, Director for Wales

FSA 23-09-09 - Report from the Director for Wales

12:15 - Annual Report from the Chair of the Audit and Risk Assurance Committee (ARAC) and Report from September ARAC meeting (FSA 23-09-10 and INFO 23-09-01)

The Chair of the Audit and Risk Assurance Committee (ARAC) Timothy Riley presents a summary of the work undertaken by the FSA ARAC during 2022/23 in accordance with the ARAC's Terms of Reference.

FSA 23-09-10 - Annual Report from the Chair of the Audit and Risk Assurance Committee (ARAC)

INFO 23-09-01 - Report from September ARAC meeting

12:30 - Report from the Chair of the Business Committee (INFO 23-09-02)

The Chair of the Business Committee, Mark Rolfe, presents a report from the Business Committee meeting that took place on 11 September 2023.

INFO 23-09-02 - Report from the Chair of the Business Committee

12:45 - Reports from the Chairs of the Food Advisory Committees (Oral Reports)

Oral updates on the recent meetings and activities or the Northern Ireland Food Advisory Committee (NIFAC) and the Wales Food Advisory Committee (WFAC).

12:50 - Any Other Business

12:55 - Question and Answer Session

13:05 - End of meeting

Questions to the Board

We are keen to ensure, as far as is practical, that questions are addressed in the discussion at the Board meeting. Notwithstanding discussions on the day, all questions will receive a written reply within 20 working days of the meeting.

Questions 1 and 2

These questions were not related to a board paper for this meeting, so will be answered via regular correspondence.

Questions 3 to 11 are from Claire Robinson, Co-Director of GM Watch on the Genetic Technology (Precision Breeding) paper

Question 3

Regarding risk assessment of “precision bred organisms” (PBOs), the FSA says, "In designing our recommended approach, officials have been mindful of the need for proportionality, taking into account scientific advice that there is no evidence that these food and feed products are inherently riskier than those produced by traditional breeding." However, absence of evidence is not evidence of absence. What empirical evidence does the FSA, ACNFP, or DEFRA hold showing that "PBOs" are no riskier than traditionally bred ones?

Please note that opinions and assertions, if unsupported by empirical data, are not valid evidence of risk or safety. Relevant empirical data would consist, for example, of detailed proteomics and metabolomics data comparing "PBOs" with traditionally bred parent varieties, or animal feeding studies comparing diets containing these two types of organism.

Question 3: Answer

The ACNFP recognised that most organisms produced by PB will be similar in risk profile to their traditionally bred counterparts, where the same change has been achieved and a risk assessment is not required. By definition, the spectrum of genetic changes introduced by precision breeding techniques are identical to those that occur during natural mutagenesis. However, the off-target rate (i.e. the probability of genetic changes in genetic regions that were not intended to be altered) is dramatically lower. As a comparison, chemical mutagenesis of wheat (a technique that falls under the definition of traditional breeding) introduces around one mutation per 200,000 DNA base pairs (equivalent to 50,000 mutations per genome), whereas modern CRISPR techniques often produce no detectable off-target effects (i.e. they alter only a single DNA base-pair).

It is possible that in some instances unintended effects may occur, but this is also the case with organisms produced through traditional breeding. Some organisms produced by traditional breeding may have risks, such as modification of antinutritional factors or alteration of the allergenic potential. These risks are currently managed under due diligence requirements. During the planning and production of PBOs, developers are expected to take all reasonable measures to identify and limit any such unintended mutations.

Question 4

The FSA states: "Current scientific evidence suggests that PBOs present no additional risk when compared to traditionally bred organisms (TBOs)(footnote 1)." Footnote 1 cites an FAO report, which, inter alia, states, "the provisions [Codex guidelines on food safety risk analysis] on newly expressed substances (mostly referring to the toxicity and allergenicity of recombinant proteins) may not apply to gene editing interventions of type SDN1 and SDN2, which are unlikely to generate the expression of a new substance".

However, this is incorrect. An overview states that in SDN-1 applications (which is often claimed to be the simplest and most nature-mimicking form of gene editing and to not involve intentional introduction of foreign DNA) of CRISPR/Cas gene editing, "new mRNAs and corresponding

proteins can be formed at each individual target site, which in turn may cause subsequent unintended effects". What is the justification of the ACNFP and the FSA for not requiring molecular analytical characterisation (including proteomics), which could identify new and potentially dangerous proteins, for each "PBO"?

Question 4: Answer

Any change to the genomic material of an organism has the potential to have consequences on the sequences and conformations of resulting mRNA and proteins, whether obtained by Precision Breeding or by Traditional Breeding. The ACNFP triage criteria have been designed to identify possible food safety issues which could result from precision breeding above and beyond those present in a traditionally-bred equivalent. The data required by both models 1 and 2 include an evaluation of the likely impact of the intended edit on genomic features at the site of insertion, and on their functions, as well as information on any likely significant alteration in protein expression and/or change in its allergenic potential.

Significant genomic changes, including unintended ones, have occurred in agricultural products during the course and evolution of traditional breeding practices. Food Business Operators are legally responsible for ensuring that food is safe. Developers incorporate safeguards into their breeding practices to ensure they can identify any unintended consequences of the process, for example, any undesirable effects resulting from the initial breeding process are backcrossed out to achieve the final product and these methods have developed products which have consistently been consumed safely across the world over thousands of years. Breeders not only apply safeguards in the development of new varieties to remain compliant with the law, but also to protect their reputations and to ensure they can continue to market their products.

Precision bred organisms do not differ from traditionally bred organisms in terms of the presence of unintended effects, and some precision breeding methods are associated with producing fewer unintended effects than have been found in traditionally bred varieties. By definition, the spectrum of genetic changes introduced by precision breeding techniques are identical to those that occur during natural mutagenesis. However, the off-target rate (i.e. the probability of genetic changes in genetic regions that were not intended to be altered) is dramatically lower. As a comparison, chemical mutagenesis of wheat (a technique that falls under the definition of traditional breeding) introduces around one mutation per 200,000 DNA base pairs (equivalent to 50,000 mutations per genome), whereas modern CRISPR techniques often produce no detectable off-target effects (i.e. they alter only a single DNA base-pair).

It is possible that in some instances unintended effects may occur, but this is also the case with organisms produced through traditional breeding. Some organisms produced by traditional breeding may have risks, such as modification of antinutritional factors or alteration of the allergenic potential. These risks are currently managed under due diligence requirements. During the planning and production of PBOs, developers are expected to take all reasonable measures to identify and limit any such unintended mutations.

However, as with traditional breeding, developers of precision bred varieties will perform multiple crosses with any newly-generated line in order to remove any undesirable effects from the final organism and/or to combine the precision-bred trait with other traits present in commercial varieties.

Question 5

The ACNFP's Model 1 risk assessment focuses only on the intended genetic change: "Largely descriptive assessment of safety risks associated with the intended genetic change, requiring initial data to ensure the intended compositional changes, where relevant to the quality or safety of food/feed, have been achieved." The FSA definition of Model 2 reads: "In addition to the

information and data required in Model 1, data would also be required to determine whether the intended change has introduced any further changes."

Peer-reviewed surveys of the literature show that gene editing induces many unintended changes and that organisms of the type that the UK government would call "precision bred" could pose risks to health and the environment that are different from, and go beyond, those posed by traditionally bred organisms

- https://www.frontiersin.org/articles/10.3389/fpls.2019.00525/full
- https://www.mdpi.com/2223-7747/10/11/2259
- https://doi.org/10.1186/s12302-020-00361-2
- https://www.mdpi.com/2673-6284/10/3/10
- https://www.mdpi.com/2223-7747/12/9/1764

Given this significant body of evidence, what justification does the FSA have for stating "we do not consider it proportionate to mandate all developers to produce and maintain all the additional evidence, as required with Model 2, to support the Tier determination"?

Question 5: Answer

Our objective for this recommendation is to provide a proportionate framework, taking account of the protections already offered in existing food law, and the similarity of PBOs to other traditionally bred varieties that do not require pre-market assessment. We do not consider it proportionate to mandate all developers to produce and maintain all the additional evidence that may be requested for any PBO as the framework has been designed to ensure that where potential risks are identified, FSA officials are able to request the particular information necessary to ensure that the specific PBO under scrutiny can safely be placed on the market. This would be the case for many of the products, such as those exhibiting 'traits previously unknown in conventional breeding', described in the reference cited above. If such information and/or data is not provided for an assessment to be made or does not satisfactorily address concerns over potential risks to safety or any other concerns, the FSA will not put forward the PBO for authorisation to be placed on the market. Notably, the scientific literature referenced above recommends this 'product-based' rather than 'technology-based' assessment process.

Technical guidance will be available to all developers to support the triage process, and we will consult on this once we have developed it.

For further assurance, the FSA will establish an audit process for notifications. This would allow the FSA to monitor the effectiveness of guidance in helping applicants determine tier status and help us understand if any changes should be made to the regulatory framework or associated guidance.

Question 6

The FSA definitions of Model 2 data requirements ("data would also be required to determine whether the intended change has introduced any further changes" and "Provision of additional compositional data in order to allow screening for wider phenotypic changes. Extra compositional data … would be considered at the outset for all PBOs to capture any wider consequences of the genetic change") at first glance look promising, as they would encompass potential effects from the numerous unintended mutations brought about by gene editing processes (see overview) – albeit the FSA wishes to reject Model 2 as not "proportionate".

However, the more detailed ACNFP definition is problematic: "Further compositional data relevant to the context of the genetic change (i.e., depending on the host organism and what can be anticipated from the nature of the induced change) is required." Because of the relatively new and

experimental status of gene editing in agriculture, neither GMO developers nor the scientific community can know in advance "what can be anticipated", in terms of unintended effects, from the induced change. This is why generic investigations, such as comprehensive molecular analysis and animal feeding studies, must be carried out for each “PBO”, in addition to specific investigations as relevant to the individual “PBO”.

Does the FSA agree that the full range of changes brought about by PB techniques, including the unintended ones, can affect safety and must be individually assessed in each case? If the FSA does not agree, on the basis of which empirical data does it justify its stance?

Question 6: Answer

It is possible that in some instances unintended effects may occur, however this is also the case with organisms produced through traditional breeding. During the planning and production of PBOs, developers are expected to take all reasonable measures to identify and limit any such unintended mutations. Both data requirement models developed by the ACNFP require a description of the analysis or procedures undertaken to minimise the potential for unintended alteration of the organism’s genetic material (so-called “off-targets”), and confirmation of the absence of any transgenic DNA used in the production of the PBO. Information requirements on the anticipated consequences of the intended change (as part of both data requirement models) already go beyond those required for the same trait obtained by traditional breeding. Both models propose a bespoke assessment to give the FSA the flexibility to adapt safety assessments on a case-by-case basis according to any concerns that have been identified for individual PBOs, and to enable it to respond effectively to future advancements in scientific understanding and technological innovations.

The Board has discussed the data requirements proposed by the ACNFP and asked for further detail on data for each model and a decision will be made shortly in terms of the appropriate amount of data to be required from developers. We will soon be launching a public consultation on the detailed proposals of the new regulatory framework to enable consumers and other stakeholders to provide further views.

Question 7

Regarding the compositional data that is foreseen to be required under Model 2, it is not enough to ask if there have there been any changes in the amount of protein, fat, carbohydrates, etc., along the lines of the information on the side of a breakfast cereal packet. It’s not how much protein that is important but what types of proteins are present. If the PB has produced a novel mutant and a potentially toxic protein, gross compositional analysis will miss it. It’s the same for other substances: hence the need for proteomics and metabolomics to give in-depth information about what the PB has done. Will the data requirements under Model 2, if implemented, mandate that such data is provided?

Question 7: Answer

In addition to general profiles in amount of protein, fat, carbohydrates (etc…), Model 2 requires applicants’ compositional data reflecting the levels of secondary metabolites relevant to the species or the anticipated changes, which are pertinent to nutrition, toxicology or allergenicity.

Developers would need to have the requisite compositional data to perform the triage for Tier 1 and Tier 2 pathways to a food or feed marketing authorisation. The example of a novel protein that is considered toxic given above would raise concerns within the initial descriptive information during the triage process for either Model, as developers would need to confirm, at this stage, whether the PBO has been designed to introduce changes that are expected to elevate

significantly the toxicity of any food or feed derived from the organism. If such changes could elevate toxicity, the PBO would be assigned to Tier 2, which would require a bespoke case-by-case risk assessment to address the specific concerns in relation to safety.

Question 8

The story of the gene-edited cattle that were claimed by the developer to contain no unintended changes but turned out (thanks to a voluntary non-mandated investigation by FDA scientists) to contain bacterial DNA and antibiotic resistance genes is well known, see:

- https://www.independentsciencenews.org/news/fda-finds-unexpected-antibi…
- https://www.independentsciencenews.org/health/gene-editing-unintentiona…

According to the developer's claim, these cattle would have been presented to the UK regulator as Tier 1.

What provisions will be implemented by DEFRA, ACNFP, or the FSA to ensure that organisms claimed by the developer to be "precision bred" do not contain such unintended and potentially dangerous changes in their genome? And what provisions will ensure that the PBO does not contain unintended insertions of fragments of plasmids encoding the gene editing tool introduced into the cells (see this) ; also, multiple copies of entire plasmids were found in the hornless cattle)?

Question 8: Answer

Before a Precision Bred animal can be marketed it must first be authorised by Defra Secretary of State, who will determine whether the animal is a PBO and whether the genetic changes made negatively impact health and welfare or not. SoS will be advised by two different scientific committees before making these decisions.

The Advisory Committee on Releases to the Environment (ACRE) will consider all of the genetic changes that have been introduced through modern biotechnology and advise Defra SoS on whether the organism meets the criteria (for being considered a PBO) set out in the Act. In order to do this, Defra will require notifiers to supply descriptions of the methods used to introduce precision bred changes, and to identify off-target alterations in the PBO. Notifiers must also confirm that no transgenic material remains in the PBO and describe how they have confirmed this.

Using their expertise, ACRE will be able to ascertain whether any off-target alterations (should any exist) present a risk to human health or the environment and include this in any reporting. An information sharing system will be in place between Defra and the Food Standards Agency (FSA). Should any off-target alterations raise concerns around safety for food and feed use, the FSA will have responsibility for considering this further through the Tier 2 regulatory system.

Defra will not be mandating whole genome sequencing (WGS) as part of this evidence package. This is because WGS datasets are generally less precise than other shorter sequencing methods, as well as being more difficult to interpret. This becomes even more pronounced when considering the types of changes typically introduced through precision breeding (I.e. very small, single DNA base pair edits), in which it is often impossible to determine what is a true off-target impact of the genome editing technique, and what is an alteration that has arisen spontaneously during the natural breeding process that followed. There are other methods that provide more effective testing such as SITE-Seq, which involves mapping all potential off targets of the editing construct that is being used and then individually sequencing those regions of the genome to ascertain whether the precision bred animal contains off-targets in those regions.

Whilst Defra will not be mandating WGS, breeders may choose to produce this data. Moreover, if ACRE feel that the information provided is not sufficient to assess regulatory status, more evidence may be requested from the notifier before concluding the appraisal and making a recommendation to Defra SoS.

The onus will be on the notifier to ensure that all genetic changes introduced using modern biotechnology have been characterised and included in a notification, and Defra will not perform additional laboratory studies to validate evidence provided. This is in line with processes currently used by Defra to authorise the deliberate release of GMOs. However, notifiers will be required to keep record of their experimentation and may be audited if there are concerns around non-compliance. Notifiers found to have released or marketed a GMO as a PBO will be subject to criminal sanctions under existing GM legislation. Alongside the reputational damage that would result, this is considered to be a strong deterrent for notifiers submitting incomplete or inaccurate evidence of any genetic changes made.

The definition of a PBO provided by the Act will exclude organisms containing fragments of plasmids encoding the gene editing tool introduced into the cells as these would not occur in traditionally bred or naturally occurring organisms. During the planning and production of PBOs, developers are expected to take all reasonable measures to identify and limit any such unintended effects. Both data requirement models developed by the ACNFP require a description of the analysis or procedures undertaken to minimise the potential for unintended alteration of the organism's genetic material (so-called "off-targets"), and confirmation of the absence of any transgenic DNA used in the production of the PBO. Information requirements on the anticipated consequences of the intended change (as part of both data requirements models) will provide more insight and reassurance on the safety of a PBO than what is in place for the same trait obtained by traditional breeding, which would be expected to have the same phenotypes.

The Models propose a bespoke assessment to give the FSA the flexibility to adapt safety assessments on a case-by-case basis according to any concerns that have been identified for individual PBOs. This is to ensure that novelty and/or altered nutritional and compositional values, can be fully considered in our safety assessment before being placed on the market, and to enable the regulatory system to respond effectively to future advancements in scientific understanding and technological innovations.

We recognise that precision breeding in animals presents a separate debate, and this has been reflected by the way in which UK Government has developed this policy. Further legislation is under development to safeguard the welfare of precision-bred animals (which we do not expect to be in place until 2025) before a framework for precision bred animals can be finalised. We will use this to consider any additional risks presented by precision bred animals and if necessary suggest any changes to our approach for pre-market assessment of PBOs of animal origin for use in food and feed.

Question 9

The FSA recommends "that industry has legal responsibility for undertaking initial triage and determining whether a PBO is Tier 1 [not requiring risk assessment] or Tier 2 [requiring some risk assessment]. The FSA would undertake a risk assessment only for Tier 2 products."

What justification does the FSA make to the public for delegating the responsibility of deciding whether or not a product requires risk assessment to the industry manufacturing the product? Can the FSA assure the public that GMO developers will not act with the same disregard for public health and the environment as, for example, the lead, asbestos, pesticides, and plastics industries?

Note that given the minimal information required from the PBO developer under the FSA's preferred Model 1 risk assessment, no regulatory agency will have the knowledge base on which to decide if a PBO belongs in Tier 1 or 2. So the industry will have free rein to claim that any product it comes up with should not be regulated, and the regulator will have no grounds on which to challenge this claim.

Question 9: Answer

Under Article 7(1) of the Food Safety Act 1990, it is a criminal offence to “render food injurious to health with the intent that it shall be sold for human consumption”, and provisions in Article 14 (4) of General Food Law 178/2002 specify that “In determining whether any food is injurious to health, regard shall be had:

(a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;
(b) to the probable cumulative toxic effects;
(c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers”.

Genetically modified organisms will still be subject to the statutory requirements in legislation for genetic modification of organisms. Only organisms that have been determined to have precision bred status by the Defra Secretary of State will follow regulations outlined in the Precision Breeding Act and be subject to the proposed triage and authorisation process. Whilst we have recommended industry to take legal responsibility for tier classification, this is limited to products that have been approved through the Defra confirmation process.

Our recommendation is consistent with the existing process used by developers when applying for other regulated product authorisations, where they take the responsibility to follow the guidance and submit applications to the appropriate regimen. For both Models 1 and 2, developers of PBOs will need to obtain the necessary amount of data to enable them to conduct the triage prior to applying for authorisation.

For further assurance, the FSA will establish an audit process for notifications, and we are currently in the process of designing this. This would allow the FSA to monitor the effectiveness of guidance in helping applicants determine tier status and help us understand if any changes should be made to the regulatory framework or associated guidance.

Question 10

FSA says it "will continue to make full use of safety labelling where it is appropriate for particular consumers. In the case of PBOs, this might include, for example, information about changes in allergens or information for people with certain health conditions." Yet it appears that under Model 1, the FSA's preferred risk assessment model, such information will not be provided – and it may not even be provided under Model 2 because the developer can claim they didn't "anticipate" such changes. So how will the FSA ensure that the PBO developer provides such information?

Question 10: Answer

Developers wishing to market PBOs are subject to General Food Law and Food Safety Act requirements. This requires them to follow due diligence at all steps of development, which includes consideration of aspects such as allergen levels.

Plant breeders who wish to market their precision bred plant varieties on national lists will also need to add their varieties to a new ‘England-only Variety List for Precision Bred Varieties’ through an application process. Existing labelling legislation on allergens - for example, Article 21

of retained EU Regulation 1169/2011, would still apply to PB food as it does for traditionally bred food. In practice, a Precision Bred product that created an allergen risk that was not present in traditionally-bred equivalent products would, by definition, be subject to a bespoke risk assessment via Tier 2. We consider these legislative controls to provide a reasonable level of assurance that PBOs will not have a higher risk profile than their traditionally-bred equivalents.

It is the responsibility of developers and food business operators to understand any risks to consumption attributable to their products prior to placing them on the market. This is the case for all food developers and food business operators and would not apply exclusively to those involved in the development/distribution of PBOs.

Question 11

PBOs will not be labelled for consumers. How will the FSA maintain its remit to ensure food safety in the event of unexpected allergic or toxic reactions to a PBO – for example, as a result of unintended changes to proteins mentioned in our question 2 above? As far as consumers will know, "a tomato is just a tomato", so if they are not normally allergic to tomato, but are made ill by a mutant protein in a PBO tomato, they are highly unlikely to even report it to the FSA or any medical authority. Thus the problem will not be traced back to the culprit PBO. Does the FSA agree that an absence of labelling on PBOs undermines traceability in the event that a PBO turns out to be dangerous?

Question 11: Answer

PB food will be subject to the same labelling requirements as traditionally bred foods. The FSA will have the ability to propose conditions of use for PBOs including safety labelling should it be appropriate for specific categories of consumers as would be the case for any food.

Both models developed by the ACNFP require a description of the analysis or procedures undertaken to minimise the potential for unintended alteration of the organism's genetic material (so-called "off-targets"), and confirmation of the absence of any transgenic DNA used in the production of the PBO.

General Food Law food requires food to be traceable through all stages of production, processing, and distribution and this will also apply to PBOs. Food businesses must be able to identify their suppliers and the businesses they have supplied. These requirements apply equally to food consisting of or containing PBOs. The risks presented by traditionally bred food/feed will apply to PBOs unless the precision breeding has eliminated that risk. The General Food Law traceability requirements will enable food to be traced and issues investigated and addressed as much for PB food as for its traditionally bred counterparts.

Questions 12 to 19 are from Prof. Erik Millstone, Emeritus Professor of Science Policy, University of Sussex regarding the Genetic Technology (Precision Breeding) paper

Question 12

Why has the FSA chosen to repeat the complacent claim that "Current scientific evidence suggests that PBOs present no additional risk when compared to traditionally bred organisms …" and is ignoring the literature that provides extensive evidence of unintended genetic changes from gene editing, the consequences of which are unknown?

Question 12: Answer

The ACNFP recognised that most organisms produced by PB will be similar in risk profile to their traditionally bred counterparts, where the same change has been achieved and a risk assessment is not required. By definition, the spectrum of genetic changes introduced by precision breeding techniques are identical to those that occur during natural mutagenesis. However, the off-target rate (i.e. the probability of genetic changes in genetic regions that were not intended to be altered) is dramatically lower. As a comparison, chemical mutagenesis of wheat (a technique that falls under the definition of traditional breeding) introduces around one mutation per 200,000 DNA base pairs (equivalent to 50,000 mutations per genome), whereas modern CRISPR techniques often produce no detectable off-target effects (i.e. they alter only a single DNA base-pair).

It is possible that in some instances unintended effects may occur, but this is also the case with organisms produced through traditional breeding. Some organisms produced by traditional breeding may have risks, such as modification of antinutritional factors or alteration of the allergenic potential. These risks are currently managed under due diligence requirements. During the planning and production of PBOs, developers are expected to take all reasonable measures to identify and limit any such unintended mutations.

Question 13

Given that our current understanding of nutrition, allergenicity and food intolerance, are incomplete, often equivocal and frequently contested, and given that so-called ‘Precision Bred’ (or PB) technology is not precise, but evolving rapidly, and our knowledge of its future trajectory and consequences are rudimentary, why does the FSA propose to allow firms to categorise their own PB foods and feed as Tier 1, and consequently escape the type of scrutiny that would be required to ensure that those products are definitely safe?

Question 13: Answer

Under Article 7(1) of the Food Safety Act 1990, it is a criminal offence to “render food injurious to health with the intent that it shall be sold for human consumption”, and provisions in Article 14 (4) of General Food Law 178/2002 specify that “In determining whether any food is injurious to health, regard shall be had:

(a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;
(b) to the probable cumulative toxic effects;
(c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers”.

Protections within the Food Safety Act, 1990 and General Food Law ensure that food and feed which is placed on the market is as safe as it can be. Food businesses must be able to identify their suppliers and the businesses they have supplied. These requirements apply equally to food consisting of or containing PBOs. The risks presented by traditionally bred food/feed will apply to PBOs unless the precision breeding has eliminated that risk. The General Food Law traceability requirements will enable food to be traced and issues investigated and addressed as much for PB food as for its traditionally bred counterparts.

Precision breeding methods can target organisms in a more precise way than traditional breeding processes. All breeding processes can create unintended consequences and so our approach must remain proportionate to the safety issues and there is no current evidence that off-target effects or the presence of recombinant DNA in organisms qualifying for PBO definition, whether intentional or unintentional, poses a greater risk than those present as a result of traditional breeding.

Additionally, enforcement action can be taken where appropriate to ensure businesses comply with obligations under the Precision Breeding Act. It will be unlawful to place PBOs on the market for use in food and feed which have not been authorised for use as food or feed and local authorities will be able to withdraw any products marketed not in accordance with a pre-market authorisation. Enforcement authorities will have the powers conferred in the Act to carry out their respective functions including inspection, examination, search and seizure and powers and enforcement tools including stop, monetary and compliance notices. For further assurance, the FSA intends to establish an audit process for notifications. This would allow the FSA to monitor the effectiveness of guidance in helping applicants determine tier status and help us understand if any changes should be made to the regulatory framework or associated guidance.

Question 14

Given that the information to be provided to the FSA for Tier 1 products will so minimal, how can the FSA sustain its claim to ensuring that all foods offered for sale in the UK will be safe?

Question 14: Answer

Under Article 7(1) of the Food Safety Act 1990, it is a criminal offence to “render food injurious to health with the intent that it shall be sold for human consumption”, and provisions in Article 14 (4) of General Food Law 178/2002 specify that “In determining whether any food is injurious to health, regard shall be had:

(a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;
(b) to the probable cumulative toxic effects;
(c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers”.

For both Models 1 and 2, developers of PBOs will need to obtain the necessary amount of data to enable them to conduct the triage prior to applying for authorisation.

For Tier 1 organisms, developers will have to ensure that their organisms meet the criteria for Tier 1 set by the ACNFP and confirm that the PBO is derived from a species that has a prior history of safe consumption in the UK or EU, that it has not been designed to introduce significant changes to the nutritional quality of the organism currently consumed that are likely to be disadvantageous to consumers, that the PBO is not designed to introduce changes that are expected to elevate significantly the toxicity or allergenicity of any foods/feeds derived from it, and that there are no other features of the PBO that may cause food or feed safety concerns.

Question 15

The FSA is proposing that firms sponsoring PB foods allocated to Tier 2 should provide the FSA and ACNFP with the data required of Tier 1 plus evidence that the intended change had been achieved. Why are sponsors of both Tier 1 and 2 not also required to identify all the unintended changes that resulted from the gene editing processed? Without information about unintended changes, judgements of safety can never be conclusive.

Question 15: Answer

The ACNFP recognised that most organisms produced by PB will be similar in risk profile to their traditionally bred counterparts, where the same change has been achieved and a risk assessment is not required. By definition, the spectrum of genetic changes introduced by

precision breeding techniques are identical to those that occur during natural mutagenesis. However, the off-target rate (I.e. the probability of genetic changes in genetic regions that were not intended to be altered) is dramatically lower. As a comparison, chemical mutagenesis of wheat (a technique that falls under the definition of traditional breeding) introduces around one mutation per 200,000 DNA base pairs (equivalent to 50,000 mutations per genome), whereas modern CRISPR techniques often produce no detectable off-target effects (i.e. they alter only a single DNA base-pair).

It is possible that in some instances unintended effects may occur, but this is also the case with organisms produced through traditional breeding. Some organisms produced by traditional breeding may have risks, such as modification of antinutritional factors or alteration of the allergenic potential. These risks are currently managed under due diligence requirements. During the planning and production of PBOs, developers are expected to take all reasonable measures to identify and limit any such unintended mutations.

The data requirements for products that are assigned to Tier 2 will be determined on a case-by-case basis. In some cases this may include a requirement to document the consequences of any unintended changes, if these are deemed relevant to FSA's ability to fully assess the safety of a Precision Bred product.

Question 16

Why is the FSA is assuming (in Section 6 of FSA Board paper FSA-23-09-04) that traceability can be accomplished, and enforced, by following a hard-copy or virtual paper-trail? That proposal ignores the crucial lesson of the 2013 'Horsegate Saga', which showed that paper trails do not always provide truthful, let alone complete, information. Following paper trails may on occasions reveal the stage(s) at which unsafe ingredients were added, or when and where unsafe processes occurred, but paper-trails alone can never be entirely reliable or sufficient.

Question 16: Answer

General traceability throughout the food chain is underpinned by the requirements in General Food Law and is in place to ensure that food is traced and followed through all stages of production, processing, and distribution. The General Food Law traceability requirements will enable food to be traced and issues investigated and addressed as much for PB food as for its traditionally bred counterparts.

In scenarios where General Food Law may not have captured or detected malicious attempts to circumvent regulation, there are proportionate enforcement powers in food law to ensure businesses comply with regulations. Food business operators are legally required to identify their immediate suppliers as well as the businesses to which their products are supplied (a "one up, one down" approach).

Businesses are obliged to provide this information to competent authorities, if requested. Appropriate enforcement action will be undertaken for any businesses which are not compliant with these regulations. Enforcement authorities will have the powers conferred in the Act to carry out their respective functions including inspection, examination, search and seizure and powers and enforcement tools including stop, monetary and compliance notices.

Additionally, the FSA's National Food Crime Unit - that was set up in response to the 'Horsegate' incident, responds to food crime through detecting, investigating and disrupting serious fraud and related criminality within food supply chains, across England, Wales and Northern Ireland. Its remit also encompasses drink and animal feed including any criminal actions of producers, processors, suppliers or traders operating overseas.

Question 17

How do the FSA and ACNFP reconcile their claim that regulatory requirements should be proportional to the risks, with their knowledge that judgements about risks and safety are often uncertain, given the limited, equivocal, incomplete and contested evidence that is available? A set of measures cannot be proportional to uncertain risks; since the denominator is indeterminate, proportionality cannot be adjudicated. Or is the FSA prepared to restrict its policy recommendations only to risks that can be and have been accurately quantified?

Question 17: Answer

The FSA is science and evidence led, and we proactively and continuously review evidence relevant to food and feed safety. This applies equally to Precision Breeding as it does to other areas of food safety. Our proposals on PBOs are based on the best available scientific advice. They are designed to be proportionate and balance other legitimate factors in addition to the advice provided by ACNFP.

Traditionally bred food and feed also carries uncertain risks and is not subject to the level of oversight proposed for PBOs. PB technology can reduce the number of genomic changes that may pose risks that could equally be found in traditionally bred varieties, but our consumer research has indicated that consumers would like some regulatory oversight given that this is a relatively new technology.

Our regulatory position is consistent with that of other countries where policy officials have also considered the scientific evidence and have either removed or reduced the regulatory burden applied to certain agricultural organisms derived from precision breeding, or are in the process of doing so (e.g. the recent EU proposal for the regulation of NGTs).

We acknowledge that precision breeding technology is rapidly evolving, and – as with all of our authorisation processes - we will ensure that our policy will remain up to date and robust by monitoring developments in scientific understanding and technological advances. Through the bespoke risk assessment embedded in the framework, we can continue to assess any new risks that may emerge, and we will seek to retain some regulatory flexibility to increase (or decrease) the regulatory oversight as evidence evolves.

Question 18

The proposal that sponsors of PBOs should provide the FSA with information on, inter alia, "…the predicted impact of change on composition and allergenicity" would only be appropriate if our knowledge about, and understanding of, food intolerance and allergenicity were robust and comprehensive, but they are neither. Why is the FSA recklessly risking both public health and its own reputation?

Question 18: Answer

Under Article 7(1) of the Food Safety Act 1990, it is a criminal offence to "render food injurious to health with the intent that it shall be sold for human consumption", and provisions in Article 14 (4) of General Food Law 178/2002 specify that "In determining whether any food is injurious to health, regard shall be had:

(a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;
(b) to the probable cumulative toxic effects;
(c) to the particular health sensitivities of a specific category of consumers where the food is

intended for that category of consumers".

The risk posed by PBOs as defined by the Act would not differ from the risk posed by traditionally bred organisms; for instance, in their capacity to contain allergens or be the causes of food intolerances. The FSA continuously monitors allergens in all foods to ensure that our risk assessments are informed by the most recent developments in scientific understanding about allergens, and we actively fund research into allergens and food intolerance to progress scientific understanding in these areas (e.g. Detection and Quantification of Allergens in Foods and Minimum Eliciting Doses in Food-Allergic Individuals (ThRAII) project. Please also refer to our website for more information on the FSAs research projects concerning Food Hypersensitivity).

In addition to this we expect applicants to apply the required due diligence during the planning and development stages for PBOs. The ability of precision breeding techniques to enable developers to predict some of these impacts provides an additional level of protection for PBOs compared to traditionally bred organisms. PBOs that raise concerns over allergenicity would be considered through the Tier 2 process and risk assessed on a bespoke case-by-case basis, to ensure that PBOs that are placed on the market are as safe as any other food or feed. Existing labelling legislation on allergens - for example, Article 21 of retained EU Regulation 1169/2011, would still apply to PB food as it does for traditionally bred food.

We also note that it is possible that specific allergens could be removed from certain varieties (e.g. gluten free wheat) using precision breeding technology, which would improve the safety of certain food for consumers with food allergies. Some developers are also using this technology to create foods with increased nutritional benefits with the aim of improving public health more generally.

Question 19

How will the FSA respond in the future when some brands start to label their products as 'free from gene-edited ingredients'?

Question 19: Answer

All food business operators - including those that would be involved in developing and distributing PBOs, who wish to voluntary label their products would need to remain compliant with retained EU regulation 1169/2011. We would not wish to discourage this.

There is the potential for voluntary PB free labelling, like any labelling, to be misleading to consumers. In the case of PBOs, it would depend on a number of factors including the PBOs authorised for food and the possibility of their presence in a food (e.g. labelling a wheat variety PB free when no PB wheat varieties have been authorised may be misleading). And, of course the situation would not remain static as time progresses, and the number of authorised PBOs increases. We will take a view on a case-by-case basis taking account of the particular food, and what has been authorised at that time. It would remain the responsibility of the food business to ensure that any products advertised as 'PB-free' can be proven to be so through a robust evidence trail.

It is a criminal offence under regulation 10 of the Food Information Regulations 2014 for developers to fail to comply with labelling regulations in retained EU regulation 1169/2011.

Questions 20 to 22 are from Kierra Box, GM Freeze regarding the Genetic Technology (Precision Breeding) paper

Question 20

In the report on The Genetic Technology (Precision Breeding) Bill prepared for the FSA board meeting on the 14th September 2022 it is stated that “Information given to consumers so that they can make informed decisions, cuts across the FSA’s entire mission…FSA will play its part in convening and collaborating with others to ensure that consumers’ interests are put first.”

However, the “proposals for the regulation in England of Precision Bred Organisms for use in food and feed” (23-09-04) do not cover labelling and defer to Defra. In what ways are the FSA working with Defra to ensure that consumer-interest is being protected when it comes to the labelling of PBOs?

Question 20: Answer

Defra have stated that they are not proposing to mandate the labelling of PB food or feed as precision bred. This is consistent with traditionally bred varieties that do not require the breeding method to be included in labelling. The FSA has shared the results of its consumer research with Defra and is currently working with Defra to ensure that information about PBOs that have been developed is publicly available on both the Defra register and on the FSA PB food and feed register. Consumers informed our researchers that they supported the use of a register as a source of information, and on the grounds of transparency. Consumers also wanted the FSA to ensure that PB food is safe and we have designed a regulatory framework that ensures that all PBOs require authorisation prior to placement on the market, and that any PBOs that raise any concerns in terms of novelty, nutritional value or composition will be risk assessed to ensure that they are safe for consumers. Safety labelling will still apply as it does to all foods placed on the UK market, so information on allergens, for example, would be required where necessary. Retained EU Regulation 1169/2011 would still apply to PB food as it does for traditionally bred food.

Question 21

How will consumers be able to connect the food that they buy to what is presented in the FSA’s proposed public register?

Question 21: Answer

We are proposing to include the following information on the public register:
a) The name of the authorised PBO;
b) The details of the authorisation holder;
c) The purpose of the edit;
d) The date of the authorisation;
e) Any conditions of authorisation;
f) The unique reference number (URN) for each authorised PBO;
g) A link to the relevant entry on the Defra register confirming the status of a PBO;
h) Details of the relevant risk assessment for each Tier 2 PBO.

We have included information that consumers told us they would like to have such as what PBOs have been authorised to be used in food and placed on the market, the purpose of the edit (why the organism has been precision bred), and which organisation developed the organism. Once placed on the market, PBOs will be recognised as equivalent to TBOs. There is no information about traditional breeding methods on labelling and it will not be mandatory to identify precision breeding methods on labelling. The Register has not been designed as a public reference for individual products that have been made from authorised PBOs but will help consumers to understand the extent to which PBOs are being used in food.

Consumers will be able to access information on PBOs through other sources, such as the planned register of confirmed PBOs maintained by Defra, as well as industry-maintained registers. PBOs will also be subject to the same national listing requirements as traditionally bred varieties. These extra sources of public information should further assist consumers with understanding which PBOs are being used in their food.

Question 22

How will safety labelling be maintained for PBOs without end-to-end traceability?

Question 22: Answer

Under Article 7(1) of the Food Safety Act 1990, it is a criminal offence to “render food injurious to health with the intent that it shall be sold for human consumption”, and provisions in Article 14 (4) of General Food Law 178/2002 specify that “In determining whether any food is injurious to health, regard shall be had:

(a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;
(b) to the probable cumulative toxic effects;
(c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers”.

FBOs will also have to comply with existing labelling legislation - for example, Article 21 of retained EU Regulation 1169/2011, which mandates the labelling of certain substances or products causing allergies and intolerances, would still apply to PB food as it does for traditionally bred food.

Additionally, where there are any safety concerns relating to the effects of consuming a PBO on specific categories of consumers (e.g. allergens), under the models proposed by the ACNFP, the FSA can impose safety labelling as a condition of authorisation.

General traceability throughout the food chain is underpinned by the requirements in General Food Law and is useful to ensure that food is traced and followed through all stages of production, processing, and distribution. FBOs will need to maintain compliance with these well established traceability requirements which will enable food to be traced and issues investigated and addressed as much for PB food as is the case for traditionally bred varieties.

Questions 23 to 35 are from Pat Thomas, Beyond GM/A Bigger Conversation regarding the Genetic Technology (Precision Breeding) paper

Question 23

Preliminary research based on publicly available sources and presented at a recent European Parliament event by the German Federal Agency for Nature Conservation suggests that 94% of gene edited (precision bred/new genomic technique) products would fall into the fully deregulated category 1 (similar to FSA’s Tier 1 category and which requires no proof of safety – health or environmental – and will require no labelling or traceability).

The question is twofold: How can the FSA guarantee that this high influx of novel engineered foods – which have never been widely consumed, and for which there is no baseline from which to measure safety – is safe? Will the FSA make public the research it is using to justify its claims for the safety of PBOs?

Question 23: Answer

Under Article 7(1) of the Food Safety Act 1990, it is a criminal offence to “render food injurious to health with the intent that it shall be sold for human consumption”, and provisions in Article 14 (4) of General Food Law 178/2002 specify that “In determining whether any food is injurious to health, regard shall be had:

(a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;
(b) to the probable cumulative toxic effects;
(c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers”.

UK Food Business Operators (FBOs) will also have to remain compliant with well-established General Food Law traceability requirements, that will enable food to be traced and issues investigated and addressed as much for PB food as for traditionally bred varieties.

Under the FSA draft proposals, both models proposed by the ACNFP would involve the risk assessment of any PBO for use in food or feed developed from a species that has no history of safe consumption. These would be considered Tier 2 PBOs. Tier 1 PBOs will consist of organisms from species that have a prior history of safe consumption and where the effects of any genomic changes do not fall outside the expected ranges of variation associated with existing traditionally bred or naturally occurring varieties.

Any changes that may alter the allergenicity, toxicity or nutritional value of an organism so as to raise concerns over the quality or safety of the organism, or any other concerns, would be classed as Tier 2 organisms. This is to ensure that all PBOs are as safe as traditionally bred foods prior to being placed onto the market.

The mandatory notification under the Tier 1 pathway is to support transparency, traceability and enforcement as it will mean Tier 1 PBOs will also require authorisation prior to placement on the market and will be listed on the register of PB food and feed. For Tier 2 PBOs, the additional risk assessment and consideration of any other legitimate factors will ensure that any risks identified are properly understood and that conditions of authorisation can be put in place prior to placement on the market where necessary (such as mandatory safety labelling for certain categories of consumers with allergies or food intolerances). Tier 2 PBOs will also be listed on the register.

The FSA remains fully committed to transparency. Throughout the development of the Precision Breeding Bill – now the Precision Breeding Act 2023, and subsequently as we develop secondary legislation relating to it, we have and will continue to engage with stakeholders, hold public Board meetings and publish the meeting agendas, papers, case studies, minutes, and reports of the ACNFP and of any consumer research we continue to do in this area. In terms of the framework, the Board has agreed that all PBOs will need to be added to the public register so that consumers can understand what PBO food and feed is authorised for placement on the market and obtain further information about individual PBOs that have been authorised. We will also be holding a public consultation on our proposed framework for the regulation of PBOs to ensure that the public and stakeholders can have a say in what we do.

Question 24

The board paper makes several references to an application process (1.2, 3.6, 3.9, 7.3, Annex 1, Annex 3). This is misleading since the Genetic Technology (Precision Breeding) Act mandates a notification rather than application process and this language is used throughout Part 2: Precision

bred organisms: release, marketing and risk assessments. Will FSA correct this language in the board papers to reflect that developers (”notifiers”) need only to notify government and FSA of their intent to market a PBO and that – whichever implementation option is chosen (3.6) – no formal application is necessary to do so?

Question 24: Answer

Part 2 of the Act refers to procedures that Defra will administer when receiving notifications from developers for confirmation of PBO status by Defra SoS. PBOs for food and feed will be subject to additional regulatory pathways to obtain authorisation for placement onto the market by the DHSC SoS.

Tier 1 PBOs will require authorisation through notification, which will help to ensure that all authorised PBOs for use as or in food or feed will be placed on a register that will be publicly accessible. These will be PBOs that are developed from species that have a history of safe consumption, do not raise any compositional concerns in terms of allergenicity and/or toxicity and do not raise any other safety concerns. While these PBOs could be treated in the same way as their traditionally bred counterparts, the FSA has considered the information it has received from consumers that some degree of regulatory oversight would provide assurance and transparency, and the Board has agreed that all PBOs will need to be placed on the public register.

PBOs for use in food or feed that are considered novel or raise concerns over allergenicity and/or toxicity or raise any other safety concerns will be classed as Tier 2 PBOs. Tier 2 PBOs will require developers to submit an application and the necessary data for FSA officials to conduct a bespoke risk assessment prior to advising the SoS whether to authorise the PBO for placement onto the market.

Question 25

The board paper recommends three implementation options (3.6). There seems little difference between these other than a bit of paperwork in what is essentially a don’t-ask-don’t-tell system of deregulation. The recommendation is to approve “exemption” as the option for processing Tier 1 “applications”. In this category, “If the applicant determines the PBO to be appropriate for Tier 1, no further action is required, and the product could proceed straight to market”. Since there is no approval process, this is not an application but a notification – will FSA change the language of the board paper to reflect this?

Question 25: Answer

In the board paper policy officials have recommended the implementation of the “notification” option. Paragraph 3.7 states: “On balance, we recommend that notification for Tier 1 products is the most appropriate, providing stronger assurance that regulations were being followed and supporting our previous commitment to publish a public register of all PBOs lawfully placed on the market for use in food and feed.” This would apply to authorisations for Tier 1 PBOs while an application would be required for developers seeking to obtain a food or feed marketing authorisation for Tier 2 PBOs. While the Board has endorsed the proposal of a notification system, this proposal will form part of the public consultation that we will be launching on the future regulatory framework for PBO food and feed.

Question 26

The Board paper makes frequent mentions that PBOs present no additional safety risk TBOs ( ). The only actual reference provided in the paper (and in the ACNFP statement) is that given in

footnote 1, FAO 2023) (2.1). However, the UK Act encompasses and allows for further developments which are not covered in the FAO analysis. Defra officials have repeatedly stated that the methods covered in the Act go much further than the SDN categories which are the main focus of the FAO paper. Will the FSA undertake and publish in detail an accurate assessment which applies to the Act specifically and also consider and publish how it will maintain review and oversight of what is recognised to be a rapidly developing field?

Question 26: Answer

The intended genetic change in a precision bred organism must, by definition, be the same as one that could exist in a traditionally bred equivalent and will therefore have the same safety profile as a traditionally bred organism. Any "additional safety risk" could therefore only arise from an unintended ('off-target') change. The rate of such changes (i.e. the probability of genetic changes in genetic regions that were not intended to be altered) is dramatically lower in precision breeding techniques than as compared to some approaches used in traditional breeding. As a comparison, chemical mutagenesis of wheat (a technique that falls under the definition of traditional breeding) introduces around one mutation per 200,000 DNA base pairs (equivalent to 50,000 mutations per genome), whereas modern CRISPR techniques often produce no detectable off-target effects (i.e. they alter only a single DNA base-pair).

It is possible that in some instances unintended effects may occur in precision-bred organisms, but this is also the case with organisms produced through traditional breeding. Some organisms produced by traditional breeding may have risks, such as modification of antinutritional factors or alteration of the allergenic potential. These risks are currently managed under due diligence requirements. During the planning and production of PBOs, developers are expected to take all reasonable measures to identify and limit any such unintended mutations.

Both of the models proposed by the ACNFP for the regulation of PBOs for use as or in food and/or feed enable FSA officials to conduct bespoke case-by-case assessments and consider any other legitimate factors for Tier 2 PBOs. This is to ensure that any risks identified resulting from novelty and/or composition can be properly understood and that appropriate controls can be placed as conditions of authorisation where necessary. The proposals have also been designed to enable the FSA to capture future technological advancements in food production and assess any different types of risk, if any, the products developed may present. This will enable the FSA to continue to ensure that food and feed that is placed on the UK market will continue to be safe in the future, and that the UK is in the best possible position to benefit from innovations in food production that are designed to improve sustainability, food security and environmental and public health.

The FSA proposals on the regulation of PBOs for use as/in food or feed are based on the best scientific evidence currently available. The FSA acknowledges that precision breeding technology is rapidly evolving, and we will ensure that our policies will remain up to date and robust by monitoring global developments in scientific understanding and technological advances. The ACNFP terms of reference include "highlighting any key research or surveillance gaps in relation to bringing PBOs to the food/feed market and identify those areas which are considered a priority" and we frequently conduct and/or contribute to research projects on food hypersensitivity to ensure that we are able to identify new risks and enhance our risk assessment processes and policy responses to new scientific evidence that comes to light.

The FSA remains fully committed to transparency. The ACNFP is an independent Scientific Advisory Committee (SAC) which operates to the highest standards of openness and transparency. ACNFP meeting agendas, papers, minutes and reports are published in a timely manner, and this has been, and will continue to be the case for all SAC meetings where precision breeding has been and will be discussed. Our proposals mean that all PBOs that are authorised for placement onto the market will be listed on a public register. We will also be holding a public

consultation on our proposed framework for the regulation of PBOs to ensure that the public and stakeholders can have a say in what we do.

Question 27

The Board paper states that the ACNFP has seen no evidence that PBOs are intrinsically more hazardous than TBOs (2.2). This is referenced as "footnote 2". However, the statement in footnote 2 provides no information about the how this conclusion is reached; no literature is cited (except the misleading FAO 2023), no review is given of how the actual scope of the Act, as operationally described by Defra, has been considered although there is a mention of "case studies" but these are not referenced so it is impossible to determine their relevance. It is hard to see how this fits with the FSA's claim to transparency. In the interests of transparency will the FSA publish full details of the materials and methods used by ACNFP to support its conclusion and confirm that it did consider the actual scope of the Act as operationally described by Defra?

Question 27: Answer

The FSA remains fully committed to transparency. The ACNFP is an independent Scientific Advisory Committee (SAC) which operates to the highest standards of openness and transparency. ACNFP meeting agendas, papers, minutes and reports are published in a timely manner, and this has been, and will continue to be the case for all SAC meetings where precision breeding has been and will be discussed. Throughout the development of the Precision Breeding Bill – now the Act, and subsequently as we develop secondary legislation in relation to it, we have and will continue to engage with stakeholders, hold public Board meetings and publish the meeting agendas, papers, minutes, and reports of our SAC meetings and the results of any consumer research we continue to do in this area. We will also be holding a public consultation on our proposed framework for the regulation of PBOs to ensure that the public and stakeholders can have a say in what we do.

Based on their review of case studies (published in the ACNFP Statement July 2023, Annex A) and their knowledge of the wider literature, ACNFP members did not find evidence that PBOs (as confirmed by ACRE) are intrinsically more hazardous than traditionally bred organisms; instead of the breeding method used to produce the organism, they concluded that it was the trait targeted that could lead to phenotypes of concern regarding the safety of food or feed. The FSA has worked with Defra throughout the preparation of the Bill - now the Act, to ensure that food and feed safety was prioritised and will continue to do so. The scope of the Act was designed to ensure that future innovations in modern biotechnology would also be captured by the regulations, meaning that any new risks presented by the food or feed products of future genetic technologies can be assessed through the bespoke case-by-case risk assessment that would apply in response to any food safety concerns. The FSA will continue to actively monitor global developments in the scientific understanding of the impacts of applying modern biotechnology in the development of food and feed to ensure that its policy on the regulation of precision bred organisms remains relevant and effective.

Question 28

The Board is asked to agree that additional traceability requirements do not need to be implemented, as General Food Law is sufficient for managing food safety incidents (5.7). We have previously recommended that accurate audit trails could be a way to provide traceability for PBOs in the marketplace. However, this is contingent on a commitment to transparency. Will the FSA ensure that there is adequate information in the public register for Tier 1 and Tier 2 PBOs to allow full traceability in the supply chain, in order to facilitate both safety and consumer choice?

Question 28: Answer

All PBOs for use as or in food or feed will receive unique identifiers and the following information will be available on the register:

a. The name of the authorised PBO;
b. The details of the authorisation holder;
c. The purpose of the edit;
d. The date of the authorisation;
e. Any conditions of authorisation;
f. The unique reference number (URN) for each authorised PBO;
g. A link to the relevant entry on the Defra register confirming the status of a PBO;
h. Details of the relevant risk assessment for each Tier 2 PBO.

The information included on the register has been selected on the basis of its ability to support transparency, traceability and enforcement, and on the information that consumers have told us they would like to see. The FSA will be holding a public consultation on its regulatory proposals, and we will also consider any suggestions that are made as a result of this, which concern the information available on the register.

General traceability throughout the food chain is underpinned by the requirements in General Food Law and is useful to ensure that food is traced and followed through all stages of production, processing, and distribution. FBOs will need to maintain compliance with these well established traceability requirements which will enable food to be traced and issues investigated and addressed as much for PB food as for traditionally bred varieties.

In scenarios where General Food Law may not have captured or detected malicious attempts to circumvent regulation, there are proportionate enforcement powers in food law to ensure businesses comply with regulations. Food business operators are legally required to identify their immediate suppliers as well as the businesses to which their products are supplied (a “one up, one down” approach).

Businesses are obliged to provide this information to competent authorities, if requested. Appropriate enforcement action will be undertaken for any businesses which are not compliant with these regulations. Enforcement authorities will have the powers conferred in the Act to carry out their respective functions including inspection, examination, search and seizure and powers and enforcement tools including stop, monetary and compliance notices.

It is important to also be aware that under Article 7(1) of the Food Safety Act 1990, it is a criminal offence to render food injurious to health with the intent that it shall be sold for human consumption.

Question 29

Although the board paper talks about a public register, it also provides FSA with a worrying get-out clause in terms of what will be on the register. This suggests that if the implementation option to exempt Tier 1 PBOs is adopted, Tier 1 PBOs will not need to be listed in the FSA’s public register (4.5). This would leave only a tiny percentage of likely Tier 2 PBOs listed on the register. The paper further suggests that consumers could consult the ACRE register and a planned British Society of Plant Breeders register for more information.

The purpose of the public register is to provide independent information to consumers. ACRE has no mandate for providing public information and certainly is not independent. In addition, The Genetic Technology Act maintains that a government register is a “may” – unlike the FSA register, which is a “must”. The British Society of Plant Breeders has made clear its support for wholesale deregulation of all types of GMO plants. Neither group is independent. Whichever implementation option is chosen, will FSA guarantee that all PBOs, Tier 1 and Tier 2, will be

included on the FSA public register?

Question 29: Answer

In the board paper, policy officials have recommended the implementation of the “notification” option. Paragraph 3.7 states: “On balance, we recommend that notification for Tier 1 products is the most appropriate, providing stronger assurance that regulations were being followed and supporting our previous commitment to publish a public register of all PBOs lawfully placed on the market for use in food and feed.” Implementing the “notification” option would mean that all PBOs, not just Tier 2 PBOs, will require authorisation and will be placed on the FSA register of PB food and feed, and the Board was clear that his would be the case.

Question 30

The board paper makes several references to the lack of FSA resources to conduct its own independent assessments of PBOs (3.1, 3.5, 4.4). The FSA’s assessment of PBOs that go into either Tier 1 or Tier 2, therefore, relies on those supplied to Defra by ACRE – a committee, analysis has shown, composed almost entirely of individuals with a vested interest in the deregulation of genetically modified crops and foods. These ACRE assessments are made on the basis of a self-certification by the developer.

FSA’s Food You Can Trust strategy defines its overall role as providing food that is safe, food that is what it says it is and food that is healthier and more sustainable. The question is twofold: Has a lack of resources meant the FSA has chosen ‘strategic ignorance’ over independent case-by-case assessment? and How can consumers trust the FSA if it will not – or cannot, due to lack of resources – make independent assessments of genetically engineered PBOs intended for human consumption?

Question 30: Answer

ACRE will be responsible for confirming whether notified organisms meet the definition of a PBO as prescribed by the Act. Organisms that do not meet the requirements of the definition of a PBO will be treated as GMOs and regulated as such.

Once they have been confirmed by ACRE as marketable PBOs, to obtain a food and/or feed marketing authorisation through the FSA, developers will need to have the necessary food safety data available to undertake the triage that determines whether their organism is a Tier 1 or Tier 2 PBO. Both models incorporate a bespoke case-by-case risk assessment for any PBOs that are considered novel, or that may raise concerns over composition (i.e. nutritional value, allergenicity and/or toxicity levels) or where any other safety concerns may be identified (e.g. PBOs with stacked PB modifications, each previously authorised individually - these could present new risks, or engineering of an organism to produce something that it doesn’t produce normally (rather than a change in level of production)). These assessments will be overseen by our independent scientific advisory committees that have the requisite expertise to assess PBOs, and all authorised PBOs will be placed on a public register of PB food and feed and the system used to determine Tier 1 or Tier 2 PBOs will be audited. At the FSA, our Scientific Advisory Committees are independent, and all committee members must openly declare any conflicts of interest. The Secretariat maintains a register of interests for all members which is updated and published online regularly.

Question 31

The board paper states (2.6) “views provided by industry representatives, trade bodies, academic institutions, and consumer bodies in England, Wales, and Northern Ireland. Industry put forward

compelling arguments for a high level of deregulation while other stakeholders encouraged more caution." In its official response to the 2021 consultation on genetic technologies that: "Most individuals (88%) and businesses (64%) supported continuing to regulate such organisms as GMOs. Non-governmental organisations (NGOs) were evenly split (50%). A slightly higher proportion of public sector bodies (55%) and academic institutions (58%) did not support continuing to regulate such organisms as GMOs."

Clearly, along with consumers, the majority of businesses – indeed the majority of respondents – support regulation and public sector bodies and academic institutions, which made up only around 1% of the responses analysed, were in the minority numerically and in terms of their views. The question is threefold: Which "industry" are you referring to in the board paper – the biotech industry, the food industry or some other industry/ies? What research is the statement that industry supports a "high level of deregulation" based on and will you make this reference public? Will you provide details of the metric FSA uses to assign a relative 'weight' and importance to industry concerns versus the concerns of consumers?

Question 31: Answer

The FSA has engaged with stakeholders across the food industry - which included FBOs that were not directly involved in the development of PB food and feed and sectors that would not include precision bred food and feed in their supply chains (e.g. the organic sector). This was to gather views during the initial development of the Act and throughout the design of the proposed regulatory framework. In this Board paper, 'industry' refers more specifically to plant and animal breeders and those FBOs with an interest in obtaining authorisation to place PB food and feed on the market. These include but are not limited to the biotech industry.

We know that these industries are supportive of a high level of deregulation. Since precision bred organisms, by definition, are those that have the same genetic changes as could be achieved through traditional breeding, some countries have removed them from regulation and instead treat them in the same way as traditionally bred organisms. This is attractive to industry as it reduces the costs of bringing products to market and facilitates trade.

However, in the UK, our consumer research on precision breeding informed us that consumers saw the benefits of precision bred food and feed, but wanted some degree of regulatory oversight for further assurance and it is for this reason that we have proposed a framework which includes mandatory notification for PBOs where appropriate, and an application pathway for PBOs where aspects of novelty and/or composition require a risk assessment.

We believe that our proposals are proportionate and balanced in terms of mandating the regulatory oversight of all PB food and feed for placement on the market in the UK as requested by consumers, while enabling industry to invest in innovation without the excessive costs and time involved in bringing products to the market (as would have been incurred under GMO regulation), when the risk profiles of these organisms do not warrant such extensive requirements. Consumers, wider industry and all other stakeholders will have the opportunity to provide further views on the proposals when we launch the public consultation in due course.

Question 32

The board paper says: "We recommend that industry has legal responsibility for undertaking initial triage" (3.2) and in determining whether a PBO is Tier 1 or Tier 2. It asks for the Board to decide "whether industry should be legally responsible for completing triage and how this should be implemented" (3.14). The question is threefold: If the recommendation is that FSA shifts the responsibility for completing triage onto industry, what purpose does the FSA serve?

What evidence do you have that industry is happy to shoulder the responsibility for non-labelled PBO ingredients which will undergo nothing more than a rubber-stamping exercise before being put into the food system? Does FSA recognise that proposals to not include Tier 1 PBOs in its register will hamper enforcement officers' ability to "continue to perform their duties when undertaking official roles"? (6.1)

Question 32: Answer

The proposal for developers to be legally responsible for completing triage is aligned with other, well established, regulated products regulation (e.g. Novel Foods, Food Additives etc), whereby developers have the legal responsibility to identify the requirement for regulation and submit an application to the FSA as part of the authorisation process for their product. Developers wishing to place their PBO onto the market as food or feed, will be required to submit either a Tier 1 notification, or Tier 2 application as part of the authorisation process. This will mean that all PBOs will require authorisation and will be listed on the FSA's register of PBO food and feed once authorised.

The FSA's purpose is to ensure that food is safe, is what it says it is, and does not mislead consumers. It is with this purpose in mind, that the Board has agreed to a mandatory notification process (rather than treating PBOs in the same way as TBOs that do not require notification to the FSA) and that the bespoke case-by-case risk assessment will be available where novelty, or potential compositional risks are identified. This approach enables the FSA to implement conditions of authorisation where required and will make it possible for all PBOs authorised to be placed on the market for use as/in food and feed to be registered on the public register which can be used as a reference tool for enforcement officers.

Our draft proposals have been produced following extensive engagement with stakeholders involved at all stages of the development, production, supply chain and marketing of food and feed products. We have consulted a range of breeders and developers who are likely to seek PBO authorisation, as well as stakeholders from sectors such as organic farming who will not be using precision breeding within their supply chains. Our draft proposals are, on balance, reflective of these discussions, and shaped by Board discussion. We are also due to launch a public consultation in November, which will give all stakeholders a formal opportunity to respond before proposals are finalised.

Question 33

With any change in food regulations, consumption habits or product availability there comes an opportunity for fraud. In promoting the notion that PBOs are a) something that could have been created through traditional breeding and b) undetectable and indistinguishable from traditionally bred organisms, FSA is, we believe, both facilitating and participating in food fraud. Should one of the 8 in 10 individuals in the UK who wish to avoid genetically engineered foods, unknowingly purchase a so-called "natural" food containing unlabelled PBOs, they could rightly claim they had been deliberately misled both by what the label says and by what it fails to say.

This could lead to prosecutions under Food Safety Act 1990 and the Fraud Act 2006, as well as potential prosecutions under advertising law (e.g. misleading advertising regulations and, more generally, the CAP Code). Has FSA considered the damage this would do to its reputation and the reputation of the UK food system, and what advice has FSA taken on this?

Question 33: Answer

Once further delegated legislation is passed to enact the powers in the Genetic Technology (Precision Breeding) Act, it will be legal for certain PBOs (once authorised) to be sold as food or

feed in the UK and PBOs will be recognised as equivalent to TBOs. There is no law stating that traditional breeding methods must be stated on food labelling, and similarly, there will be no legal requirement for PBOs to be labelled as having been precision bred. Any claims made by FBOs regarding PBOs will still need to comply with retained EU regulation 1169/2011 (i.e. fair information practices set out in Article 7, and mandatory food information set out in Article 9). It will not be misleading for people to consume PBOs when there is no information about the PBO in the label, but if a product is described as PBO-free and contains PBOs then this would be found to be misleading. It will also be an offence to omit any food safety information such as allergens on labels where necessary. Labelling in itself does not prevent deliberate food fraud.

The FSA is committed to preventing and combating food crime, defined as serious fraud and related criminality in food supply chains, and the National Food Crime Unit is a dedicated law enforcement function of the Agency that was set up in response to the horse meat fraud incident that occurred in 2013, and has successfully disrupted and prosecuted food crime since its inception. We also provide advice and guidance to FBOs on how to prevent fraud and remain compliant with food regulations.

Question 34

The Board paper specifically refers to only one of the FSA's declared principles for GE regulation - namely proportionality. Assuming the other principles haven't been jettisoned and are still regarded as important, will the Board give greater emphasis to the principle of transparency than is given in this paper? Specifically, will the Board ensure that the "evidence requirements" for all PBOs as set out in Annex 1 of the paper will be a) published in full as part of the Public Register or published elsewhere and b) the consideration of this evidence in the "triage" and other stages (by the ACNFP or officials) be made publicly available?

Question 34: Answer

Transparency is one of the five principles that we believe should underpin the regulation of PB food and feed.

The advice that comes out of risk analysis is based on science and evidence, not on wider political or public pressures. Our risk analysis process is world-leading in food safety regulation and puts transparency, public understanding and trust at its heart.

In accordance with the FSA’s code of practice on openness, relevant information about our risk assessments has been included in the public register and where appropriate, consultation has been undertaken in the development of risk management advice. We will keep and make available records of our decisions, to enable consumers and other stakeholders to:

- See the basis on which decisions have been made;
- Make an informed judgement about the quality of our processes and decisions.

We are proposing to include the following information on the public register:

a) The name of the authorised PBO;
b) The details of the authorisation holder;
c) The purpose of the edit;
d) The date of the authorisation;
e) Any conditions of authorisation;
f) The unique reference number (URN) for each authorised PBO;
g) A link to the relevant entry on the Defra register confirming the status of a PBO;
h) Details of the relevant risk assessment for each Tier 2 PBO.

The information included on the register has been selected on the basis of its ability to support transparency, traceability and enforcement, and on the information that consumers have told us they would like to see. The FSA will be holding a public consultation on its regulatory proposals, and we will also consider any suggestions that are made as a result of this, which concern the information available on the register.

Question 35

The board paper suggests that “an audit process could be established” to determine/monitor “the effectiveness of guidance in helping applicants determine tier status” (3.10) The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2019 mandates a five-year review of GMO regulations against intended objectives to assess whether those objectives remain appropriate. Will FSA commit to a similar audit process of its removal of regulatory control from PBOs. which will look not just at whether FSA has helped developers escape the “burdens” (3.1, 3.9) and “barriers” (2.9) of regulation but how impactful, effective and protective the decision to remove regulation has been?

Question 35: Answer

There is no intention to mandate a five-year review of PBO regulations; however, this does not preclude the FSA from reviewing its policies. On the contrary, we conduct and contribute to research across regulated products to ensure that we are aware of new scientific evidence and technological developments and how these could impact on our policies and to ensure that we are able to identify emerging risks and respond to these effectively. Where a need arises to adjust or amend regulations, we can do so. Precision breeding is a fast-moving field and consequently we will closely monitor the types of PB products under development that may reach the UK market and will continue to review this information once businesses begin submitting PB notifications and applications to the FSA.

Question 36 is from Sarah Hathway, Soil Association regarding the Genetic Technology (Precision Breeding) paper

What existing food and feed traceability methods, referred to in the FSA response to the literary review, will FSA be utilising for PBO's to safeguard consumer interests and consumer choice, prevent food fraud for example, where products outside the scope of the genetic technologies act are being released and marketed as PBOs, and to enable co-existance with organic and other supply chains that have to remain GMO free?

Question 36: Answer

General traceability throughout the food chain, to which we referred to in our response to the literature review on analytical methods for the detection of precision bred products, is underpinned by the requirements in General Food Law and is useful to ensure that food is traced and followed through all stages of production, processing, and distribution. Food Business Operators will need to maintain compliance with these well established traceability requirements which will enable food to be traced and issues investigated and addressed as much for PB food as for traditionally bred varieties, and organic farmers and food businesses will be able to exclude PBOs from their supply chains. Defra is the UK Government department responsible for policy on coexistence with conventional and organic agriculture, and does not expect the organic market to be damaged by the measures in the Precision Breeding Act as there are practices that can be adopted to successfully maintain separate agricultural supply chains.

In scenarios where malicious attempts to circumvent regulation are identified, there are proportionate enforcement powers in food law to address businesses’ non-compliance. Food

business operators are legally required to identify their immediate suppliers as well as the businesses to which their products are supplied (a “one up, one down” approach).

Businesses are obliged to provide this information to competent authorities, if requested. Appropriate enforcement action will be undertaken for any businesses which are not compliant with these regulations. Enforcement authorities will have the powers conferred in the Act to carry out their respective functions including inspection, examination, search and seizure and powers and enforcement tools including stop, monetary and compliance notices.

Additionally, the FSA’s National Food Crime Unit, which was set up in response to the horsemeat incident, ensures to tackle food crime through detecting, investigating and disrupting serious fraud and related criminality within food supply chains, across England, Wales and Northern Ireland. This also encompasses drink and animal feed including any criminal actions of producers, processors, suppliers or traders operating overseas.

Among the benefits of the regulatory models proposed by the ACNFP, is that all PBOs for use as or in food or feed will require authorisation for placement on the market, and the publicly available PB food and feed register will provide details on all authorised PBOs which adds security in terms of preventing products outside the scope of The Act from being released and marketed as PBOs. There is also additional legislation within regulated products which helps to prevent unauthorised food from being placed on the market. For example, under the Genetically Modified Food (England) Regulations 2004 it is a criminal offence to place a GMO on the market without authorisation or which does not satisfy the relevant conditions of an authorisation (Article 4.2 of EC 1829/2003).

Both of the models proposed by the ACNFP for the regulation of PBOs for use as or in food and/or feed also enable FSA officials to conduct bespoke case-by-case assessments. This is to ensure that any risks identified concerning novelty, composition and/or nutritional value, can be properly understood and that conditions of authorisation (for example, allergen labelling) can be applied where necessary.

Question 37 is from Steven Jacobs Business Development Manager OF&G regarding the Genetic Technology (Precision Breeding) paper

As the largest certifier of organic land in the UK Organic Farmers & Growers CIC is deeply concerned that the Genetic Technology Bill does not provide sufficient regulatory oversight to maintain food supply chain integrity.

Our questions relate to the organic sector, the market and the operations for food producers, food processors, distributors, storage and retailers, and for organic food customers.
We represent farmers and food businesses who have been working within a very clear and highly successful regulatory framework for decades.
Their livelihoods, the food that they produce and the framework they depend upon are all intrinsically linked and are all fundamental to the support of healthy food and healthy ecosystems across this United Kingdom.

1. What are the detailed proposals for monitoring, evaluating and reviewing the role out of products under the Act? If these are not yet fully prepared would the board please advise us as to the timeline for delivery?
2. Will PBO production operations be allowed to take place in all of the four nations of the UK? And will this include production and marketing?
3. How does the board envisage the operations of the National Food Crime Unit will operate with regard to investigations of possible fraudulent activity involving the use of PBOs?
4. How does the board envisage the organic sector will operate and will maintain consumer confidence across the four nations of the UK and with export markets outside of the UK?

Question 37: Answer

Part 1: The proposals for monitoring, evaluating and reviewing the roll out of products under the Act are detailed in the ACNFP's July statement on Precision Bred Organisms (PBOs) - Model options and data requirements for triage and Tier assignment of PBOs.

We are soon to launch a public consultation on the detailed draft proposals for the future regulatory framework for PBOs, including how we intend to apply models proposed by the ACNFP.

The FSA is also considering the establishment of an audit process for Tier 1 Notifications that will be used to monitor how developers are conducting the triage of PBOs. Detailed technical guidance will be available for developers prior to delegated legislation implementing the powers in The Act becoming law, which we anticipate will happen by the end of 2024.

Part 2: The Precision Breeding Act applies to England only. In Scotland, Wales and Northern Ireland, Precision Bred Organisms (PBOs) will continue to be classed as genetically modified organisms and regulated under that legislative regime, since the Precision Breeding Act does not apply there.

Under the UK Internal Market Act 2020 (UKIMA) market access principle of mutual recognition, PBOs developed in, or imported into, England, and which meet the relevant requirements for sale there, can be directly sold on the Scottish and Welsh markets unless a formal UKIMA exclusion request has been granted. The scope of the mutual recognition principle only extends to direct sale of the authorised goods. Domestic regulations in Scotland or Wales relating to use after sale would apply.

PBOs 'produced' in Scotland, Wales and Northern Ireland cannot be placed on the local market unless they are authorised under domestic GMO legislation and meet the relevant requirements for marketing and sale there (including GMO labelling).

Part 3: The FSA is committed to preventing and combating food crime, defined as serious fraud and related criminality in food supply chains, and the National Food Crime Unit (NFCU) has successfully disrupted and prosecuted food crime since its inception and its remit extends to processors, suppliers or traders operating overseas. Serious fraud involving the use of PBOs would be investigated in the same way as any other allegation of serious fraud and intelligence and/or evidence gathering methods available to law enforcement that are relevant to that investigation would apply. A NFCU response is determined by assessing the gravity of the fraud. This will include considerations of the degree of planning and co-ordination in committing it, the impact of the fraud across geographical regions and boundaries, and the financial loss and other harm to the public and industry. This will apply to PB foods as it does with all other foods.

It is important to note that there are proportionate enforcement powers in food law to ensure businesses comply with regulations. Food business operators are legally required to identify their immediate suppliers as well as the businesses to which their products are supplied (a "one up, one down" approach). Businesses are obliged to provide this information to competent authorities, if requested. Appropriate enforcement action will be undertaken for any businesses which are not compliant with these regulations under the Precision Breeding Act. Information obtained from the audit of systems, records and paperwork will allow enforcement officers to continue to perform their duties.

Part 4: Organic farming policy sits within the remit of Defra and not the FSA. However, we note that the Government is not amending the organic regulations as a consequence of this Act and as such, precision bred crops will still be regulated as GMOs for the purposes of the organic regulations. This means that precision bred crops cannot be classed as organic.?

Whilst PBOs developed or imported into England can be sold within Scotland and Wales, if the PBO is subject to a further processing production step in Scotland or Wales, under the UKIM Act it would be considered to be produced in that nation. PBOs produced in Scotland and Wales cannot be placed on the local market (but could be sold into England if they met the relevant requirements for sale there).??

Defra have contracted an organisation to facilitate a dialogue on the successful coexistence of different agricultural production systems. Defra do not expect the organic export market to be damaged by the measures in this Act as there are practices that can be adopted to successfully maintain separate agricultural supply chains. We encourage organic stakeholders to hold further discussions with Defra on the issues of organics.

Question 38 is from James McCulloch, Head of Animal Feed, Agricultural Industries Confederation regarding the Genetic Technology (Precision Breeding) paper

Could the Board please consider making a recommendation that the Government take a closer look at implications for the free movement of precision bred products across the UK given the terms of the UKIMA. The UK animal feed industry would ask for detailed business guidance from UK Government on the UKIMA implications in order to avoid costly product recall procedures of precision bred products.

Question 38: Answer

Under the mutual recognition principle of the UK Internal Market Act 2020 (UKIMA), precision bred organisms (PBOs) developed in, or imported into, England can be directly sold on the Scottish and Welsh markets unless a formal UKIMA exclusion request has been granted. The mutual recognition principle only relates to the sale of goods. Domestic regulations in Scotland or Wales relating to use after sale would apply.

If the PBO is subject to a further significant production step in Scotland or Wales, under the UKIMA it would be considered to be produced in that nation. However, PBOs ‘produced’ in Scotland and Wales cannot be placed on the local market unless they are authorised under local GMO legislation and meet the relevant requirements for marketing and sale there (including GMO labelling).

Defra and the FSA are in the process of preparing secondary legislation (and accompanying guidance relevant to its application) which will confirm what PBO developers and food business operators will need to take account of with regard to the implications of the UKIMA on the placement on the UK market and trading of PBO food and feed.

The application of the market access principles of the UKIMA are not unique to the Precision Breeding Act. The Department of Business and Trade, as the department responsible for UKIMA, has published guidance for traders on complying with the UKIMA market access principles.

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