Precision Breeding – Response to Public Consultation and Next Steps

FSA 24-03-05 - Report by Chris Stockdale.

1. Summary

1.1 At the meeting of the FSA Board in September 2023, the Board agreed to the draft proposals for the new regulatory framework for Precision Bred Organisms (PBOs) for use in food and feed, subject to public consultation. The secondary legislation to implement these proposals is now being drafted and is expected to be laid before Parliament later this year.

1.2 The Board is asked to:

- **Note** the approach to secondary legislation and expected timeline.
- **Discuss** the summary of responses to the consultation about the FSA's proposed approach.
- **Agree** to the next steps for implementation.

2. Introduction

2.1 The draft proposals set out in the consultation were informed by the Board's discussions in a number of public meetings in 2022 and 2023 culminating in the FSA Board on 20 September 2023, where the Board agreed on their preferred approach for precision breeding policy for food and feed, subject to public consultation.

2.2 In discussing the proposals, the Board agreed that:

- A two-tiered approach to regulation of PBOs is required to encompass applications where the potential safety risks are understood and not of concern (**Tier 1**), and those for which the safety risks may require more detailed scrutiny, for example where the changes significantly alter the composition of the consumed organism (**Tier 2**).?
- Businesses should be legally responsible for ensuring that PBOs are submitted for authorisation under the correct process (Tier 1 or Tier 2).
- PBOs meeting the criteria for the Tier 1 regulatory route, determined using triage criteria set by the FSA, would require a notification to the FSA.
- PBOs, determined using the triage criteria set by the FSA to meet the criteria for the Tier 2 regulatory route, would require an application to the FSA and go through an FSA safety assessment.
- All PBOs for use in food and feed, regardless of whether businesses determine them to be Tier 1 or Tier 2, must be communicated to the FSA via a notification or application, authorised and included on a public register of PBOs permitted for use in food and feed before they can be placed on the market.

2.3 In addition, the Board asked for more detail about how the FSA can check that businesses have followed the triage process correctly when identifying Tier 1 PBOs. The Board also discussed the challenges related to enforcement, traceability/identification (in particular the concerns raised by the organic sector) and the potential impacts in devolved administrations due to the implications of the UK Internal Market Act (UKIMA) and Windsor Framework.

3. Public Consultation – Background

3.1 The FSA's public consultation on proposals for a new framework in England for the regulation of PBOs used for food and animal feed opened for public comment on 8 November 2023.

3.2 Stakeholders who had previously engaged with the FSA on precision breeding policy were notified directly via email and invited to respond. All Local Authorities in England and Wales, District Councils in Northern Ireland, and subscribers to FSA website alerts were also notified of the launch. Following launch, the consultation received attention from a number of industry media outlets and non-Governmental organisations (NGOs) leading to news stories and engagement with the FSA.

3.3 The consultation invited respondents to respond via an online form. This was structured into two parts. Part One collected demographic data from respondents as well as asking for their level of support for the intentions of the Genetic Technology (Precision Breeding) Act 2023 ("the Act"). Part Two asked respondents to provide their views on the policy proposals for the regulatory framework. This section focused on questions related to the pre-market authorisation process, the public register, traceability, enforcement and the FSA's assessment of impacts. Respondents were also given the option of providing an email response.

3.4 The consultation ran for two months, closing on 8 January 2024. 412 total responses were received, of which 358 were received via the online consultation response form. Of these online responses, 79% (285) were from respondents in England, 9% (32) were from Scotland, 4% (13) were from Wales and 2% (8) were from Northern Ireland. The remaining responses were from respondents from outside the UK. These statistics do not include responses received via e-mail, since not all email respondents provided information on their location.

3.5 66% of total respondents identified as consumers. The remaining 34% of responses came from a range of stakeholders, including businesses, academics and farmers, as well as organisations representing wider groups of stakeholders. NGOs who responded to the consultation were generally groups with an interest in – and a fundamental objection to – the use of modern biotechnology in food and agriculture.

3.6 Demographic data is provided in graphs in **Annex D**.

3.7 The FSA's analysis has considered all responses on individual merit without prejudice or association with separate published responses or editorial articles published in response to the consultation. Where a response is representative of a wider group of stakeholders, we have counted this as one response. In some cases, the responses from organisations were representative of the views of thousands of stakeholders, for example the response from the National Farmers Union (NFU) was made on behalf of 45,000 farmers and growers. We have not performed any statistical weighting of responses; however, we have made clear distinctions in our analysis, wherever possible, to demarcate the views of individuals from the views of larger organisations.

3.8 Following a detailed analysis of all responses received, the FSA has now published its summary of responses.

4. Consultation Conclusions with respect to Plans for Secondary Legislation

4.1 Our analysis has not identified any reason to revisit the fundamental decisions made by the FSA Board in September 2023.

4.2 Our summary of responses goes into detail on the specific issues raised by all respondents, providing quantitative and qualitative information on the nature of responses. Broadly, we can divide respondents into two categories – those respondents who chose only to respond to Part 1 of the response form (in order to register their opposition to the Act), and those who provided more granular comments on the detail of the proposals for the framework. Around half (51%) of respondents chose to complete Part 2 of the response form and give detailed responses on the FSA proposals.

4.3 The responses revealed a range of themes (see **section 5**) with a mixture of support for and opposition to the FSA's proposals and UK Government's objectives (underpinned by the Act) for the policy in general. We feel it is important to acknowledge this wider opposition to the policy from respondents, but also to restate that the Act has been subject to democratic processes in each House of Parliament, debated and agreed before being entered into statute. We have responsibilities within the Act with respect to food and feed, and in line with our statutory duty towards food and feed safety we intend to continue with plans to implement a new regulatory framework, in line with the decisions made at the September Board, that provides adequate assurance on the safety of PBOs.

4.4 Responses relating to the FSA's proposals were generally focused on the technical details around the regulatory process, rather than the fundamental approach to regulation. Elements such as the tiered approach, the requirement for bespoke safety assessments and the general requirement for pre-market authorisation will all be laid out in secondary legislation, creating statutory duties where required. The FSA will use other means outside of legislation to support the measures contained in secondary legislation, including supplementary guidance in certain areas to ensure the new framework functions effectively. It is these non-legislative measures that will provide the technical detail that respondents have asked for. Further engagement with stakeholders and across Whitehall will facilitate the development of guidance for potential applicants and enforcement authorities. We expect this engagement and the resultant guidance in these areas to address many of the issues raised by respondents.

4.5 Our summary of responses outlines the feedback we received in more detail, and how we plan to proceed with the development of this guidance. This is summarised in **Annex B.**

4.6 We are now working with Defra (Department for Environment, Food and Rural Affairs) on the drafting of secondary legislation in line with powers granted to Ministers under the Act. A Statutory Instrument (SI) made by the Minister of State (Defra) and subject to affirmative resolution in each House of Parliament will establish the regulatory framework. We expect this SI to be laid in the summer, with Parliamentary debates after summer recess. The powers relevant to the use of PBOs in food and feed are covered by Parts 3, 4 and 5 of the Act and will be used to set out:

- An authorisation process for PBOs used in food and feed.
- A public register for all PBOs that have been authorised for use in food and feed.
- An enforcement regime to ensure compliance with the regulations.

4.7 The legislation will outline the fundamental approach to regulation agreed by the Board in September 2023, including the statutory obligations on businesses (to determine the regulatory route for their PBO for which they are seeking authorisation and provide relevant information to the FSA); the FSA (to administer the regime, carry out assessments on Tier 2 PBOs, make recommendations to Ministers on authorisations and maintain the register of PBOs authorised for food/feed); and Ministers (to make decisions on the authorisation of PBOs for food/feed in relation to England).

4.8 This will provide sufficient detail on the framework to enable businesses to understand their obligations and that instances of non-compliance can be identified as relevant breaches. This will ensure that the FSA (and enforcement authorities) have the powers to take action in

respect of businesses which, either inadvertently or purposefully, do not meet their obligations under the framework.

4.9 In line with the Board's steer that the new system should be responsive to future scientific developments and agile enough to keep pace with both innovation and evidence of safety, the FSA is developing detailed technical guidance to support the regulatory process. This guidance will be subject to review as the science and technology in this area evolves, ensuring that the technical guidance remains fit for purpose.

4.10 The development of this technical guidance is underway, and a draft will be reviewed by the Advisory Committee on Novel Foods and Processes (ACNFP) on 1 May 2024. The draft technical guidance will then be published in summer to facilitate engagement with stakeholders, ahead of Parliamentary debates (expected to take place after summer recess).

4.11 The Board is asked to **note** this approach and the timeline for secondary legislation and the development of guidance set out in **Annex A**.

5. Detailed Themes for Discussion

5.1 We have identified several key themes in responses to the consultation which we feel the Board may wish to discuss. We have included within these themes the level of general opposition from respondents to the intentions of the Act, since this context is useful in understanding the drivers behind many of the detailed responses provided to part 2 of the consultation.

5.2 Other themes in this section are more about the detail around implementation of the regulatory service, they do not alter the fundamental regulatory approach and, as explained above, we consider are better addressed through non-legislative means, either directly by the FSA or in collaboration with other Government departments.

5.3 Some themes present challenges that are either out of scope of the FSA's policy responsibility for precision breeding, or outside of the FSA's wider statutory remit in relation to England, specifically consumer labelling and traceability measures not related to addressing food safety issues. This limits the FSA's abilities to adapt the policy to address the issues raised. We remain committed to cross-Government working and as well as making other Government departments generally aware of the nature of responses received during the consultation period, we have passed on the specific feedback we received on those themes to those departments and devolved administrations.

5.4 In many of the themes, a spectrum of views was expressed by different stakeholder groups. This paper highlights the key points from our analysis of responses. A detailed summary of responses is available to those wishing to read about any of these issues in more detail.

5.5 The main themes (categorised as things directly within the remit of the FSA, and broader implications beyond our remit) that we are inviting the Board to discuss are stakeholder reactions to:

Broader implications beyond the FSA's remit

- **The intentions of the Act** (footnote 1) – 77% of respondents indicated that they strongly do not support the intentions of the Act. The majority of respondents indicating this view were consumers (who made up 66% of total respondents). 16% of respondents expressed strong support for the intentions of the Act. This group included respondents from research institutes, developers, breeders and trade associations.

- **Labelling** – A recurring theme for several groups was the absence of requirements for mandatory labelling. There were calls from organic sector respondents for labelling to aid segregation. Perceptions of the safety of PBOs and the need for consumer choice were common themes in calls for labelling from consumers.

Within the FSA's Remit

- **Implementation of the regulatory framework** – Most industry respondents responded positively to our plans for the framework but highlighted that much of the detail is being left to the FSA's technical guidance, and that there is still a level of uncertainty around the substance of this guidance. Groups representing the organic sector and NGOs opposed the plans and argued for a more stringent approach to assessment, as well as enhanced traceability measures and mandatory labelling.

- **Science and evidence** – Common criticisms from NGOs and some consumers were related to the FSA's approach to scientific advice and the decisions that have been made in implementing this advice. More broadly, some respondents directly criticised the role of the ACNFP and raised concerns over conflicts of interest. Some respondents also opposed our decision not to pursue analytical methods for the detection of PBOs to facilitate traceability.

- **Impacts on the UK Internal market** – Whilst the broad operation and effect of the UKIMA is not directly within the FSA's remit, as a three-nation organisation, we recognise our responsibility to consider impacts on the UK internal market. 15% (footnote 2) of responses came from respondents in Wales, Northern Ireland and Scotland, and many organisation responses were from UK wide organisations. We also received feedback from Trading Standards Wales, representing Local Authority Trading Standards services across Wales. Across these responses, there were concerns raised regarding impacts due to the effect of the UKIMA and Windsor framework. The comments were largely reflective of the previous discussions had by the FSA Board on the matter.

5.6 Of most relevance to the FSA with respect to further work that we are undertaking is the feedback received on the implementation of the regulatory framework. The overarching view from respondents across the spectrum is that more detail is required on the technical aspects of the framework and that without more certainty on the substance of the technical guidance, it is difficult for them to fully assess the proposals.

5.7 The content of the technical guidance was not explicitly included in the scope of the consultation; however, we recognise the relevance of this guidance to the efficacy of the framework, and the views that were provided with respect to the FSA's approach to guidance, i.e. that the guidance should explain rather than embellish or 'gold plate' requirements laid down in the secondary legislation. With this in mind, we are currently developing an engagement plan to support the development of this guidance.

5.8 As stated in paragraph 4.10, the FSA intends to publish the technical guidance in draft form over the summer. This will give stakeholders the opportunity to review the guidance - and respond to user testing questions to ensure the clarity of the guidance - before the final draft is agreed and published in the autumn.

5.9 In addition to the requirement for technical guidance, we remain committed to developing guidance for enforcement authorities in England to assist with new responsibilities in relation to the enforcement powers in the regulations, and guidance for authorities in Wales and Northern Ireland to ensure that the interactions with the UKIMA and Windsor Framework are understood.

5.10 A detailed summary of the findings relevant to each of these themes is included in **Annex B**.

5.11 In many cases, respondents have raised issues that cannot be solved by the FSA in isolation. Here we focus on elements that the FSA can directly influence. We recommend that the Board considers our findings in the summary of responses (summarised in **Annex B**) in full before agreeing to our proposed next steps.

5.12 The Board is asked to **discuss** these findings.

6. Next Steps

6.1 Following discussion with the FSA Board on the outcomes from consultation and alongside the legislative timeline for secondary legislation, officials will take forward the various strands of work necessary to prepare the FSA for delivery of the new regulatory service.

6.2 As discussed in paragraph 4.4, there are non-legislative solutions that the FSA can implement to address some of the concerns raised by respondents (as outlined in **Annex B**). Following the timeline in **Annex A**, we plan to publish our finalised technical guidance for assisting businesses with applying for a PBO food/feed authorisation to coincide with Parliamentary debates on secondary legislation. Enforcement guidance will be issued to Local Authorities prior to the coming into force of the precision breeding regulations.

6.3 Where we have considered the comments from respondents and have not identified any reason to adjust our policy, we intend to proceed with our proposals as they were presented in consultation.

6.4 We will therefore properly focus on what is within the FSA's remit and continue with plans to:

- Produce technical guidance for potential applicants to support compliance with the regulatory framework, including any engagement required to ensure that this guidance provides reasonable and effective assistance in complying with the regulations.
- Produce enforcement guidance for Local Authorities in England to assist with the delivery of new enforcement powers, as well as guidance for Local Authorities in Wales and District Councils in Northern Ireland to ensure that the interactions with the United Kingdom Internal Market Act 2020 and Windsor Framework are understood.
- Make the necessary adaptations to the FSA's regulated products applications portal and the register of regulated products applications to ensure that the FSA can receive and manage PBO applications and develop the new public register of PBOs authorised for use in food and feed.
- Analyse the business needs of the FSA in terms of what resources will be required to deliver on the FSA's new responsibilities, including horizon scanning to better understand the volume and substance of early applications and how this will evolve post implementation.
- Further develop internal processes and the criteria and process for the audit of a proportion of Tier 1 notifications.
- Manage the transition towards delivering the precision breeding application service, including how progress with the new framework can be regularly reported to the Board via the Business Committee. This will allow the Board to discuss, in public, the progress made on a quarterly basis and advise accordingly.

6.5 Some of the issues raised were on matters where the FSA has limited scope on which to take action. On these points, we have provided feedback to, and will continue to work with, other Government departments to aid understanding of stakeholder perspectives. This will be the case on matters such as co-existence with organic supply chains, labelling of PBOs for food and feed and understanding the effects of the UKIMA and Windsor Framework.

6.6 The Board is asked to **agree** to the next steps for implementation.

7. Conclusions

7.1 Following discussion with the Board, the Executive will press forward with the plans outlined in this paper for secondary legislation and live running of the new precision breeding regulatory framework.

7.2 The Board is asked to:

- **Note** the approach to secondary legislation and expected timeline.
- **Discuss** the summary of responses to the consultation about the FSA's proposed approach.
- **Agree** to the next steps for implementation.

Annexes

Annex A - Timeline for Secondary Legislation and Guidance

Annex B – Detailed Summary of Themes

1. Reaction to the Intentions of the Act

1.1 66% of respondents identified as consumers. The prevalent view was that consumers who responded did not support the intentions of the Act. 56% of consumers who responded did not complete part 2 of the response form, and therefore did not give detailed views on the FSA's proposals for the regulatory framework.

1.2 Where consumers provided detailed responses in part 2, the main concerns focused on how consumer choice would be affected by a lack of labelling (see labelling section), and concerns over the safety of PBOs (see science and evidence section).

1.3 The total number of responses from consumers is 242. Whilst this is a significant proportion of our total responses, this is still relatively low and may not be representative of the wider population. By comparison, Defra's consultation on the regulation of genetic technologies in January 2021 received a total of 6,440 responses, including 3,083 responses from individuals.

1.4 Our most recent consumer insights tracking data on precision breeding (provided in **Annex C**) indicates that awareness of precision breeding is still low, which may have affected consumers' ability to respond to the consultation with detailed qualitative responses.

1.5 The reaction to the intentions of the Act is covered in Fig. 4 (footnote 3) of **Annex D**, with 77% of respondents overall indicating that they "strongly do not support" the intentions of the Act. The majority of respondents in this category were consumers; however, respondents from some other stakeholder groups also expressed this view. These other groups included NGOs and farmers (particularly those involved in organic farming).

1.6 Conversely, 16% of respondents indicated strong support for the intentions of the Act. This group included respondents from research institutes, developers, breeders and trade associations. In most cases, these respondents went on to give detailed comments on the FSA's proposals.

1.7 It is important to note that the substance of opposition from consumers largely stems from opposition to the overarching policy rather than the specific proposals put forward in the consultation. This policy is underpinned by the Act, which has already been written into UK statute via democratic Parliamentary processes. Many of the issues highlighted by consumers, notably mandatory labelling, were actively discussed in Parliamentary debates during the passage of the Act, where amendments were put forward but failed to gain sufficient support.

1.8 These views largely reflect the ongoing strength of feeling we have felt from some groups throughout the life cycle of this policy. Whilst we acknowledge these views, we cannot directly respond to criticisms of the overarching policy but have made Defra officials and Ministers aware of the feedback.

2. Labelling

2.1 Whilst the consultation focused on fixed questions related to the FSA proposals, respondents were also invited to give broader comments in relation to the intentions of The Act and any other views they considered relevant to the policy. In many cases, respondents provided views on other areas that, whilst pertinent to wider discussions around precision breeding, are not within the FSA's responsibilities under the Act.

2.2 We received 10 responses from stakeholders from the organic sector. These respondents were a mixture of organic businesses and organic bodies representing much larger groups of organic stakeholders. Responses from these bodies are considered to be representative of the views of their collective stakeholders. Given this reach, we consider responses received from organic stakeholders to be largely reflective of the organic sector as a whole.

2.3 These respondents expressed their opposition to the intentions of the Act and elements of the FSA's proposals. This led on from earlier engagement with the organic sector, which raised questions to the Board at the September 2023 Board meeting. We have maintained a regular and ongoing dialogue with stakeholders in this sector throughout the development of our precision breeding policy.

2.4 The main objections from this sector relate to traceability, identification and labelling, and the impact the current proposals will have on organic businesses who will have a legal duty to ensure their supply chains are PBO free. They argue that in the absence of specific measures for the traceability of PBOs and mandatory labelling, organic businesses will face additional segregation costs and challenges to ensure their supply chains remain PBO free.

2.5 Labelling is an issue that extends wider than the organic sector, and this was a recurring theme raised by consumers and NGOs in consultation responses. Consumer respondents were concerned that the Act does not mandate labelling and that, whilst it is recognised that the FSA does not have direct responsibility for it, respondents were concerned that labelling is not being recommended. NGOs presented similar views, arguing that consumer research (including research conducted by the FSA) indicates a consumer preference for labelling.

2.6 Respondents gave different reasons for their desire for labelling; a common theme was a desire for consumer choice, and how this could be limited without clear labelling. Another reason was related to perceptions over safety of PBOs (see science and evidence section). Some respondents also highlighted that the efficacy of the public register and how its accessibility for consumers is reduced when not paired with on-product labelling.

2.7 The issues surrounding labelling, and the findings of our consumer research, were discussed by the FSA Board at previous Board meetings and at length at the March 2023 meeting. Whilst it is important to acknowledge these findings and report them to the Board, the substance of these views is generally in line with the evidence presented to the Board in previous Board papers and consumer research reports.

2.8 The co-existence of organic supply chains with others and the issue of labelling are important issues in the wider policy underpinned by the Act; however, these are both areas of policy that are the responsibility of Defra in relation to England, and not the FSA. We have provided feedback on the consultation responses to Defra who will continue to engage with relevant sectors on these matters.

3. Implementation of the regulatory framework

3.1 We received responses from a range of industry stakeholders including developers, retail organisations and agricultural bodies. Most industry stakeholders offered broad support for the proposals with cautious optimism.

3.2 This was not true for all sectors, however, and in the case of sectors that require PBO free segregated supply chains (e.g., the organic sector – see labelling section), concerns were expressed in relation to a lack of additional specific traceability and labelling measures and the increased challenges and costs that setting up voluntary systems of segregation and identification could bring that sector. We also received broad objections from NGOs, who challenged the scientific evidence upon which our framework is based (see science and evidence section).

3.3 Of those in support, there was a general call for more clarity and certainty around the technical detail of the proposals in several key areas – Content of technical guidance, audit requirements and safety assessment guidelines for Tier 2 PBOs.

3.4 On technical guidance, many industry respondents expressed the need to avoid “mission creep” by adding unnecessary burdens on developers via requirements set out in guidance. Developers are generally concerned about the level of data and evidence they will be expected to collect and review on their PBO in order to reach the necessary conclusions to determine Tier 1 status.

3.5 Industry respondents generally felt that the proposal for an audit system would be a reasonable way to provide assurance on Tier 1 notifications; however, they emphasised the need to clearly define the scope of the audit process and for the FSA to provide more clarity on what the requirements would be.

3.6 Whilst most industry respondents generally supported proposals for a two-tiered system, some had concerns around the Tier 2 safety assessment guidelines and emphasised the need for these requirements to be based on a plausible hypothesis of risk, accounting for the equivalence with conventionally bred organisms that is established by the PBO confirmation issued by Secretary of State (Defra).

3.7 Some respondents went further and registered opposition to the FSA conducting safety assessments in any form on Tier 2 organisms, arguing that any level of safety assessment on PBOs is disproportionate. Generally, industry respondents agreed that requirements should be less stringent than the current requirements for the assessment of Genetically Modified

Organisms (GMOs), and that applying unnecessary requirements could make it uneconomic and impractical to incorporate Tier 2 PBOs into mainstream breeding programmes, which could limit the impact of benefits that PBOs could bring to the food and feed supply chain (and consumers).

3.8 Many of these issues are things that will be addressed by the FSA in the coming months as we continue to develop our technical guidance. We acknowledge the concerns that uncertainty around the technical requirements is bringing, and we will therefore come forward with more details soon on how interested parties can pass comment on draft guidance before the FSA adopts and publishes final guidance prior to the coming into force of secondary legislation. A full timeline, including key milestones, is included in **Annex A**.

4. Science and Evidence

4.1 We received some responses that focused on the scientific advice that underpins our proposals. Some of these responses focused on specific conclusions made by the FSA on the safety of PBOs, whereas others provided more general criticisms of the mechanisms by which the FSA receives independent scientific advice. These criticisms were used in part to justify further criticisms of the FSA's policy proposals with respect to the route to authorisation for PBOs, as well as other aspects of the regulatory framework.

4.2 Responses of this kind were received from NGOs and consumers. In the case of NGOs, several of these groups chose to publish their responses to the FSA, in full, on their websites. Consumer responses generally followed similar themes to those covered in the detailed responses of NGOs. The FSA's analysis has considered all responses on individual merit without prejudice or association with separate published responses or editorial content on the consultation.

4.3 NGO responses called for a more precautionary approach, arguing that PBOs carry similar risks to organisms that are subject to a more stringent assessment under current GMO regulations and therefore there is no justification for any change in approach when assessing PBOs. There were also objections to the two-tier approach, arguing that all PBOs should be subject to a safety assessment. Many of these responses also objected to a notification process for Tier 1 PBOs, stating that businesses should not be allowed to determine the regulatory route to authorisation.

4.4 NGOs also commented on the reliance on the advice of the ACNFP, highlighting perceived conflicts of interest amongst its members and asserting that this could lead to biased decisions in favour of developers, compromising precaution and safety.

4.5 The ACNFP is an independent scientific advisory committee of the FSA, established in line with powers in the Food Standards Act 1999 for the purpose of providing advice to the FSA, including on matters related to food and feed products of genetic technologies. Members are recruited by open competition. The Committee comprises of experts who cover a range of scientific disciplines and includes consumer representation. These experts provide scientific insight, advice and the technical knowledge needed to evaluate the safety of PBOs for use in food and feed.

4.6 All potential conflicts of interest are managed in line with government guidance. All ACNFP members complete a declaration of interests statement which can be found on their profiles on the ACNFP website. At the beginning of each meeting, all members are asked to declare any potential conflicts of interest according to the FSA advisory committee good practice guidance. A member declaring a conflict of interest does not participate in the conversation or leaves the room whilst the conversation takes place; this is recorded in the minutes of the meeting.

4.7 The work of the independent committees and working groups that advise the FSA helps to ensure that our advice is based on the best and most recent scientific evidence. We consider the

advice provided by ACNFP on precision breeding to be the best scientific advice available to us through existing and longstanding arrangements for the provision of independent scientific advice. Our proposals in the consultation are underpinned by this independent scientific advice, in line with the FSA's principles of science and evidence-led policy making. Given the independence of the ACNFP, the substance of their advice or its validity in respect of policy making is not within the scope of the consultation.

4.8 To maintain transparency of the role the advisory committees play in the policy decision making process, the scientific advice made to the FSA by the ACNFP and the minutes of the meetings leading to this advice are published on the advisory committee website and are publicly available.

4.9 Notwithstanding this, we acknowledge the concerns around how scientific advice has been applied to certain policy decisions, notably the proposal to implement a notification-based system for Tier 1 PBOs and the requirement for industry to determine which regulatory route to apply through. However, Tier 1 PBOs will need to be authorised before they can be placed on the market, requiring the FSA to provide advice to inform a ministerial decision, and we consider our proposals for an audit system as part of the Tier 1 process to be a proportionate solution to encourage and monitor business compliance with the triage requirements.

4.10 We also received some criticisms over the decision not to pursue analytical methods for the detection of PBOs to facilitate traceability. NGOs disagreed with our response to the literature review on analytical methods for the detection of precision bred products. Our response is clear on our reasons for our decision, and we do not plan to revisit or reverse this decision.

5. Impacts on the UK Internal Market

5.1 15% of responses (footnote 4) came from respondents in Wales, Northern Ireland and Scotland, and many of the organisation responses that were received came from groups representing stakeholders across the UK. Since The Act covers England only, some respondents gave comments on how businesses and enforcement authorities may be impacted due to the effect of the UKIMA and the Windsor Framework.

5.2 Some respondents highlighted the potential competitive disadvantages that businesses in other parts of the UK may face in comparison to businesses in England. The England-only aspect of the Act could create a range of challenges for industry, as PBOs will be regulated under GMO regulations in Wales, Scotland and Northern Ireland. Requirements for businesses to remain compliant with devolved legislation (where PBOs are sold legally into other parts of the UK but are then subject to further processing) and to meet the criteria set by Farm Assurance Schemes in different nations has raised concerns about competition.

5.3 Some Welsh respondents gave specific views on the impact of precision breeding policy in Wales. They highlighted that the proposals do not adequately consider the position of the Welsh Government on Precision Breeding (who laid a Legislative Consent Memorandum on the grounds that the impact of the Act on Wales had not been properly considered, as well as concerns related to trade and a lack of labelling) and general concerns about the implications of UKIMA on Welsh businesses and farmers, including competitive disadvantages that may be felt by Welsh farmers and businesses, and the potential impact on consumer choice.

5.4 The consultation did not prompt a high volume of responses from Local Authorities or District Councils, with no formal engagement from authorities in England, Northern Ireland or Scotland. However, we did receive some feedback from Trading Standards Wales, representing Local Authority Trading Standards services in Wales, who recognised the practical challenges that could be created by the absence of mandatory labelling or PBO specific traceability measures.

5.5 These authorities were supportive of the enforcement proposals but raised some concerns over the lack of criminal sanctions, and how enforcement in relation to PBOs may be further complicated if enforcement officers need to consider offences under other existing food/feed law.

5.6 Many of these challenges have been discussed by the FSA Board at previous meetings and were outlined in the consultation. The effects of the UKIMA present wider challenges for devolved policy, and implications related to precision breeding cannot be considered in isolation but rather as a case in point. We recognise that these challenges remain important issues for businesses and authorities, and we are providing feedback to the Department for Business and Trade, who are the lead department on the UKIMA.

5.7 On civil sanctions, the power to create an enforcement regime with respect to the use of PBOs in food and feed is underpinned by Parts 3, 4 and 5 of the Act. Section 28(4) stipulates that legislation made under the Act may not create criminal offences and as such only civil sanctions can be used for enforcement of the Act and legislation made under it.

5.8 PBOs will be subject to existing food law by default, and therefore enforcement officers will be able to rely on existing powers to impose criminal sanctions, such as those contained in the Food Safety Act 1990 and The Food Safety and Hygiene (England) Regulations 2013, to determine an offence and take action accordingly. This means that, in instances where precision bred food is involved in a food incident and deemed to be unsafe, enforcement officers will have the power to apply criminal sanctions where an offence can be determined.

5.9 The enforcement powers specific to PBOs will be used to address relevant breaches of the precision breeding regulations in cases where businesses have failed to act in compliance with obligations established by the regulations. We consider this proportionate, given the enforcement powers already at the disposal of enforcement officers through existing food law.

5.10 However, we acknowledge the feedback we have received from businesses and local authorities on the complexities and the FSA remains committed to issuing guidance to these groups to help encourage compliance with the regulations and understanding of the enforcement tools available. We will also maintain discussions across Whitehall with other Government departments on the wider implications for the UK internal market.

Annex C – Precision breeding – Tracking Consumer Views

In September 2023 the FSA collected views from consumers on their knowledge and acceptability of precision breeding via our consumer tracker run by You.Gov. There were 2057 respondents, 1892 in England, 103 in Wales, 62 in Northern Ireland. Scotland were not included.

As this is the first wave run via You.Gov and the sample does not include Scottish respondents, this wave is not directly comparable with the last wave run via Ipsos in March 2023. However, results are very similar.

Awareness

Levels of awareness of precision breeding are still low. Findings from the You.Gov survey report that only 6% of respondents said they had heard of PB and knew what it was. 10% said they had heard of it but did not know what it was. 83% said they had never heard of it. Although not directly comparable these findings have not changed since the last wave of questions run by Ipsos in March 2023.

Younger age groups were more likely to be aware, or at least have heard of PB (25% 16-34 compared to an average of 17% across age groups who said they knew what PB was or had heard of it). People from London (21%) the Southwest (20%) and Wales (21%) were also more likely to say they had heard of PB.

Acceptability

Almost half (49%) of respondents said PB in plants was acceptable. 21% said it was unacceptable. 18% said neither and 12% did not know.

In line with our previous survey and tracker, acceptability in animals was much lower with 28% of respondents saying it was acceptable in animals. 42% said it was unacceptable, 18% said neither, and 12% did not know.

Men were more likely than women to find PB acceptable. 54% of males vs 43% of females found it acceptable in plants. This was even more pronounced in animals 40% vs 17%. Younger age groups also found PB more acceptable. 53% of 16–34-year-olds compared to 46.5% in those over 35 thought it was acceptable in plants. 31% of 16–34-year-olds vs 26.5 of over 35's in animals.

Annex D – Headline Statistics from Consultation

Where possible, statistics provided in graphs are representative of the total number of responses (412). This is the case for the graphs in *Fig. 1* and *Fig. 2*. The graphs in Fig. 3 and Fig. 4 are based only on responses made via the online consultation form (358). E-mail responses did not uniformly provide the required information to be included in the graphs in Fig. 3 and Fig. 4, so these responses have been excluded from those graphs.

Fig. 1 – Respondent type

Fig. 1 shows a bar chart which displays the number of respondents broken down by respondent type. The Y axis shows the different respondent types, and the X axis shows the number of respondents. From top to bottom, the number of respondents for each category are: Organic certifier (4) Food retailer (8), NGO (11), Trade association (13), Academic (15), Other (19), Farmer (30), Developer (33), Consumer (274).

Fig. 2 – Response type

Fig. 2 shows a pie chart displaying the % of individual vs organisation responses. The segments show that 20% of responses were from organisations and 80% of responses were from individuals.

Fig. 3 – Respondent location

Fig. 3 shows a bar chart which displays the number of respondents broken down by location. The Y axis shows the different locations, and the X axis shows the number of respondents. From top to bottom, the number of respondents in each location are: Other (20), Scotland (32), Northern Ireland (8), Wales (13) and England (285).

Fig. 4 – Level of support for the intentions of The Act

Fig. 4 shows a bar chart which displays the level of support for the intentions of the precision breeding Act. The Y axis shows the different levels of support, and the X axis shows the number of respondents. From top to bottom, the number of respondents in each category are: Strongly do not support (277), do not support (14), neutral or don't know (2), support (7) and strongly support (58).

1. Statistics on level of support for the intentions of the Act are taken from online form responses only (358 out of 412)

2. Statistics on respondent location are taken from online form responses only (358 out of 412)

3. Online form responses only.

4. Online form responses only.