Summary of stakeholder responses: Consultation on proposals for a new framework in England for the regulation of precision bred organisms used for food and animal feed

This consultation sought stakeholder views on a new regulatory framework in England for the regulation of precision bred food and animal feed.

Introduction

This consultation was issued on 8 November 2023 and closed on 8 January 2024. The consultation sought responses from consumers, stakeholders in relevant sectors, non-government organisations, enforcement bodies and third-party assurance organisations on policy proposals for a new framework for the regulation of Precision Bred Organisms (PBOs) used for food and feed in England under the Genetic Technology (Precision Breeding) Act 2023 (footnote 1) (the Act).

The key proposals on which the consultation sought views were:

- A two-tier, pre-market authorisation process
- A public register of PBOs authorised for use in food/feed
- Proposals for traceability
- Enforcement provisions

A full impact assessment was not completed since the total impact of the proposals is estimated to be below the minimum threshold of +/-£10m; however, in line with the obligation to assess the impact of the policy proposals, the Food Standards Agency's (FSA) assessment of impact was included in the consultation. Respondents were invited to comment on the FSA's conclusions in this assessment.

More information on the assessment of impact can be found in Section 9 of this Summary of Responses. Each section of this Summary of Responses deals with a theme and provides a summary of the comments received and the stakeholders who made them. The FSA's considered responses to stakeholders' comments are provided at the close of each section. A summary of next steps resulting from stakeholder comments is set out in Section 10 (Conclusion and next steps).

The FSA is grateful to those stakeholders who responded and sets out a list of those who gave their consent to be named in Annex A.

1. Executive summary

1.1 The draft proposals set out in the consultation were informed by the FSA 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.

1.2 The consultation provided the option to respond to questions using an online consultation response form (please see Annex B for a blank copy of this form). The first section of the form collected demographic information from respondents such as location and whether they were responding as an individual or on behalf of an organisation. The first section also asked respondents to state their level of agreement with the intentions of the Genetic Technology (Precision Breeding) Act and provide their reasons. The second section of the form asked respondents to provide their level of agreement or support for the proposals and to respond to long form open questions as well.

1.3 Respondents were also able to respond to the consultation via email. Not all of the responses received by email aligned with the structure of the online form. As a result, the email responses are not reflected in the percentages outlined in the tables contained in this summary (where this differs this is indicated). However, views submitted have been included in the thematic analysis of responses on the specific proposals. For responses to the questions in the second section of the consultation, we have stated the total number of respondents who responded to each question.

1.4 The consultation ran for two months from 8 November 2023 until 8 January 2024. A total of 412 responses were received, of which 358 were received via the online consultation response form. Of these online responses, 79% were from respondents in England, 9% were from Scotland, 4% were from Wales and 2% were from Northern Ireland and 6% were from outside the UK. 66% of total (online form and email) respondents identified as consumers with 34% coming from a range of stakeholders, including businesses, academics and farmers, as well as organisations representing wider groups of stakeholders.

1.5 In some cases, the responses received, either in relation to specific sections of the consultation or the policy more generally, cover challenges that are either out of scope of the FSA's policy responsibility for precision breeding or its wider statutory remit in relation to England. Examples include responses relating to non-safety related labelling and non-safety related traceability. Whilst we recognise the relevance of these issues to precision breeding policy, they are issues that the FSA is limited in its capacity to address and therefore we consider these issues to be out of scope of the consultation. For this reason, whilst we have still referenced the views of respondents with respect to these issues, we have not directly proposed actions to address them beyond passing the information to the responsible departments.

1.6 We also received comments from respondents regarding the FSA's approach to independent scientific advice. The work of the independent committees and working groups that advise us helps to ensure that our advice is based on the best and most recent scientific evidence. We consider the advice provided by the Advisory Committee on Novel Foods and Processes (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. The ACNFP is recruited in accordance with the Cabinet Office guidelines and any enquiries regarding the committee or recruitment process for its members should be addressed to the ACNFP Secretariat.

1.7 A full breakdown of issues that fell outside the scope of the consultation and the FSA's observations of them is included in Annex D.

1.8 There is a very strong correlation between respondent's rejection of the fundamental objectives of the Act and rejection of the detail of the proposals on which the consultation sought views. Since the objective of the Act is to regulate plants, animals and food and feed products developed using precision breeding technologies proportionately to risk (and by extension remove

such organisms from the scope of legislation regulating the use of Genetically Modified Organisms (GMOs) in food and feed (footnote 2) in relation to England), this suggests that the concerns of stakeholders who do not support the objectives of the Act cannot reasonably be addressed by the regulatory approach which is being proposed. Changes to the FSA's proposals to adequately address these concerns would potentially result in them not being aligned to the overall objective of the policy as underpinned by the Act and would therefore be incompatible with it. Conversely, respondents who supported the objective of the Act generally support the proposed approach to regulation. This correlation suggests that for these respondents the FSA's proposals are adequately aligned to the objectives of the Act.

1.9 These correlations are apparent throughout the statistical data gathered from questions asked in the second part of the consultation (to varying degrees). We feel it is important to consider this within the context of quantitative responses and have therefore provided additional breakdowns showing how different views are split between those who support the Act's objectives and those who do not. However, given these are only inferences it is not possible to draw more nuanced conclusions from the statistical data and therefore our responses are primarily focused on the more detailed narrative responses received.

1.10 Following publication of this summary report, our findings will be discussed by the FSA Board, in public, on 20 March 2024. Our analysis of responses to this consultation has not identified any reason to revisit the fundamental decisions made by the FSA Board in September 2023. However, feedback from respondents has identified some issues with how we deliver the proposals that the FSA can address through non-legislative means without any changes to the fundamental approach. These issues are discussed in more detail later in this response.

1.11 Following the outcomes of discussion with the FSA Board on 20 March 2024, we intend to proceed with plans to implement secondary legislation based on the agreed approach of the FSA Board expressed at its meeting on 20 September 2023, including plans for:

- A two-tiered approach to regulation of PBOs to encompass applications where the potential safety risks are understood (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).
- Making businesses 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, to require a notification to the FSA.
- PBOs, meeting the criteria for the Tier 2 regulatory route, determined using the triage criteria set by the FSA, to require an application to the FSA and go through an FSA safety assessment.
- All PBOs, regardless of whether businesses determine them to be Tier 1 or Tier 2, to be subject to authorisation and on a public register of PBOs authorised for use in food and feed before they can be placed on the market.

1.12 Whilst we have not identified anything through our analysis of responses to alter our fundamental approach on the structural aspects of the regulatory framework, we recognise that stakeholders have expressed a range of views in response to the detailed questions that have been asked in the consultation on how we implement the approach. We have responded to these views at the end Sections 3-9 of this summary of responses indicating what, if any, action the FSA intends to take in response to the comments raised. In cases where the FSA does not intend to take action, we have indicated our reasons for this. We have also set out our overall conclusions and next steps in Section 10.

2. Methodology

2.1 The consultation asked a mixture of closed (multiple choice) and open (free text) questions. All responses were reviewed in full. The closed questions were analysed using basic statistics to show the percentages of answers selected by respondents and results have been rounded to the nearest 1%. In some instances, this means total responses to questions do not always equate to 100%.

2.2 A thematic analysis of the responses to the open questions was carried out, during which the key themes were identified and logged for each response. Some responses received by email and by the online form did not answer the consultation questions directly; these contributions have been included in the summaries of the most relevant sections. Many of the responses to questions repeated themes and issues throughout. Hence, rather than report on views on individual questions, this document instead provides a summary of the main themes and key points raised by respondents in each section.

2.3 The consultation was split into 5 sections which focused on different areas:

- The pre-market authorisation process (this was broken down into 2 sections covering responses and themes related to Tier 1 processes and responses and themes related to Tier 2 processes)
- The Public Register
- Traceability
- Enforcement
- Assessment of Impact

2.4 The summary of responses follows the same structure and includes official responses from the FSA at the end of each section. Respondents were asked whether they were replying as an individual or in an official capacity on behalf of an organisation or institution. This has been drawn upon where relevant to characterise the views of different types of respondents.

Scope:

2.5 The consultation document highlighted that the areas in scope of the consultation were the main proposals for a new regulatory framework for PBOs for food/feed, including:

- a pre-market authorisation system designed around the classification of PBOs into two tiers, based on independent scientific advice relating to risk.
- a public register of PBOs for food/feed which have received marketing authorisations.
- provisions for enforcement of requirements under the new framework.

2.6 The consultation also highlighted the UK Government position that there is no justification for the provision of labelling distinguishing all precision bred (PB) food as such on grounds of consumer safety. As with any food, if there is a need to provide safety information for a particular population group, (for example, hypersensitive consumers or people with certain health conditions) this can be required as appropriate. The UK Government has been clear that there are no plans to require labelling of products to indicate they have been produced using PB techniques. Labelling falls within the policy remit of Defra in England. Labelling was discussed extensively during the passage of the Bill and there is no provision for labelling in the Act. It was therefore not appropriate for us to ask about mandatory labelling in the consultation.

2.7 We received a high volume of responses on topics which were outside the scope of the consultation as they relate to issues which are beyond the policy responsibilities of the FSA in relation to England. We have nevertheless included them in this summary of responses in the interests of transparency to ensure that all stakeholders' responses and views are fully captured. Annex D provides an overview of the issues that fall out of scope of the consultation and the FSA's observations on these.

3. Section 1 of online consultation form - Overview of respondents and Precision Breeding Act

3.1 In total, 412 responses were received, of which 358 were submitted via the online form and 54 were received via email.

3.2 The consultation questionnaire 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 Precision Breeding Act.

3.3 The consultation sought views from stakeholders on proposals for a new regulatory framework for the regulation of PBOs used for food and feed in England.

3.4 Organisations of the following types submitted responses:

- Plant breeders and developers
- Trade bodies representing sectors involved in the food and feed supply chain
- Agricultural unions
- Food production and retail businesses
- Non-Governmental Organisations (NGOs) and charities
- Organic sector businesses (certification organisations)

3.5 We asked respondents if they were responding as an individual or as an organisation. However, where responses are representative of a wider group of stakeholders, we have only counted this as one response. We have not performed any additional statistical weighting of these responses; however, we have made clear distinctions in our analysis, wherever possible, to demarcate the views of individuals from the views of larger organisations.

3.6 Table 1 shows the breakdown of respondent type of all responses received.

Table 1: Breakdown of percentage of respondent type

Respondent type	% of respondents
Consumer	66%
PBO Developer	9%
Farmer	7%
Other	5%
Academic	4%
NGO	3%

Respondent type	% of respondents
Trade Association	3%
Food Retailer	2%
Organic Certifier	1%

3.7 Table 2 shows the breakdown of responses received from individual's and organisations.

Table 2: Breakdown of responses received from individuals vs organisations

Response type	% of respondents
Individual	80%
Organisation	20%

3.8 Table 3 shows the breakdown of respondents' locations. The "other" category included responses from individuals and organisations based in the European Union and United States. We also received 2 individual responses from Australia and Argentina.

Table 3: Breakdown or respondents' locations

Location	% of respondents
England	79%
Wales	4%
Northern Ireland	2%
Scotland	9%
Other	6%

3.9 Table 4 shows the levels of support for the intentions of the Precision Breeding Act (all respondents).

Table 4: Respondents' level of support for the intentions of the Precision Breeding Act (Question 8 in the consultation form)

Level of support for the intentions of the Precision Breeding Act	% of respondents
Strongly support	16%
Support	2%
Neutral or don't know	1%
Do not support	4%
Strongly do not support	77%

3.10 Section 1 of the online form closed by asking respondents to provide specific comments for their reasons for their answer to question 8. A wide range of themes were identified from the responses to this question, covering both the negatives and benefits brought about by the Act.

3.11 The majority of responses that did not support the intentions of the Act opposed the use of modern biotechnologies in general, citing reasons including the potential harm to the environment and the impacts on biodiversity, as well as the potential safety risks caused by unintended consequences of genetic modification (GM). Respondents opposing the objective of the Act (which is to regulate plants, animals and food and feed products developed using precision breeding technologies proportionately to risk) argued that the regulations for GMOs are sufficient and should be applied to PBOs. Respondents in this group often used phrases such as "precision bred GMOs" and refuted the decision to remove PBOs from the legal definition, claiming that there is no scientific evidence to suggest that PBOs are different to GMOs.

3.12 Another prominent theme amongst those who did not support the Act was a concern that there are no provisions for food and feed containing or consisting of PBOs to be labelled. Some respondents expanded on this concern explaining that labelling is important for consumers to have a choice about buying food products which may contain a PBO.

3.13 Some respondents added that their concerns about the safety of PBOs stemmed from a belief that there is not enough research on PBOs and no evidence of safety.

3.14 We also received comments, mostly from the scientific and research community as well as businesses in the plant breeding sector, that highlight precision breeding as being as safe as traditional breeding methods and needs to be regulated in a proportionate way, stressing the importance of not stifling the progress of innovation and preventing benefits being created for consumers. Some comments called for precision breeding to be subject to the same level of regulation as traditional breeding, and that requiring PBOs to go through any pre-market assessment and authorisation is neither proportionate nor required.

3.15 Supportive respondents recognised that the Act provides an opportunity for increased innovation within the food system, adding that using technologies such as gene editing is vital for addressing global issues including the impact of climate change and food security.

3.16 The majority of supportive respondents highlighted that the provisions in the Act could enable businesses and consumers to access the benefits of gene editing technology resulting in more sustainable food sources, improving food security, lowering food prices and assisting with the efforts to reduce the impact of the food system on climate change.

3.17 A common theme amongst supporters of the intentions of the Act was to stress that the proposals for deregulation and the potential benefits would not come at a cost of reduced safety, generally believing that there is good evidence to suggest that PBOs are not intrinsically riskier than traditionally bred organisms (TBO).

3.18 There is a very strong correlation between respondents' rejection of the objectives of the Act and rejection of the detail of the proposals on which the consultation sought views. Since the objective of the Act is to regulate plants, animals and food and feed products developed using precision breeding technologies proportionately to risk (and by extension remove such organisms from the scope of the legislation regulating the use of GMOs in food and feed in relation to England), this suggests that the concerns of stakeholders who do not support the objectives of the Act cannot reasonably be addressed by the regulatory approach proposed. Changes to the FSA's proposals to adequately address these concerns would potentially result in them not being aligned to the overall objective of the policy as underpinned by the Act and would therefore be incompatible with it. Conversely, respondents who supported the objectives of the Act generally support the proposed approach to regulation. This correlation suggests that for these respondents the FSA's proposals are adequately aligned to the objectives of the Act.

3.19 These correlations are apparent throughout the statistical data gathered from questions asked in the second part of the consultation (to varying degrees). We feel it is important to consider this within the context of quantitative responses. We have therefore provided additional breakdowns showing how different views are split between those who support the Act's objectives and those who do not. However, given these are only inferences it is not possible to draw more nuanced conclusions from the statistical data and therefore our responses are primarily focused on the more detailed narrative responses received.

4. Section 2 - Responses to questions:

4.1 Part two of the consultation questionnaire asked respondents to provide their views on the policy proposals for the regulatory framework. 181 out of 358 online respondents started part 2 of the online form.

Table 5: Percentage of respondents who started section 2 vs those who only completed Section 1

Would you like to complete Section 2 to provide detailed responses on the individual proposals?	% of respondents
Yes	51%
No	49%

4.2 Table 5 above shows the breakdown of respondents who started section 2 vs those who only completed section 1. It is important to note that not all of the respondents who started section 2 provided a detailed response to every question.

4.3 Of the 49% of respondents who did not complete Section 2, 88% of this group indicated that they do not support or strongly do not support the intentions of the Act.

5. Premarket authorisation process – Two-tier approach:

Background and proposal:

This section of the consultation focused on the FSA proposals for a two-tiered regulatory framework. These proposals included plans for:

- adopting data requirements in line with the ACNFP model 1 proposal,
- notification system for Tier 1,
- assessment for Tier 2, and,
- determination of the regulatory route (Tier 1 or Tier 2) to be the responsibility of applicants, based on FSA set criteria.

Consultation Questions: Pre-Market Authorisation Process – Triage and Two-Tier System

Tiering / Tier 1 PBOs

Summary of responses

5.1 Questions 11-13 asked respondents to specify to what extent they agree or disagree with certain statements about the policy proposals relating to the Tier 1 regulatory route for PBOs, specifically:

5.2 To what extent do you agree with the FSA using a two-tiered approach for the pre-market authorisation of precision bred organisms used in food and feed?

Table 6: Level of agreement for the FSA using a two-tier approach for the pre-market authorisation of PBOS used in food and feed

Level of agreement	% of respondents (of 172 responses)	% of respondents that support or strongly supported the intentions of the Act	% of respondents that strongly do not support, do not support or feel neutral towardsthe intentions of the Act
Strongly agree	17%	66%	0%
Agree	8%	30%	1%
Neutral	4%	0%	5%
Disagree	6%	2%	7%

Level of agreement	% of respondents(of 172responses)	% of respondents that support or strongly supported the intentions of the Act	% of respondents that strongly do not support, do not support or feel neutral towardsthe intentions of the Act
Strongly disagree	65%	2%	87%

5.3 To what extent do you agree that the proposal for Tier 1 notifications meets the FSA's policy objectives [as outlined in paragraph 7.9 of the consultation document]?

Table 7: Level of agreement that the proposal for Tier 1 notifications meets the FSA's policy objectives

Level of agreement	% of respondents (of 164 responses)	% of respondents that support or strongly supported the intentions of the Act	% of respondents that strongly do not support, do not support or feel neutral towardsthe intentions of the Act
Strongly agree	18%	66%	0%
Agree	6%	23%	0%
Neutral	6%	5%	7%
Disagree	8%	2%	10%
Strongly disagree	62%	5%	83%

5.4 To what extent do you agree or disagree that the proposal for Tier 1 notifications is feasible?

Table 8: Level of agreement that the proposal for Tier 1 notifications is feasible

Level of agreement	% of respondents (of 166responses)	% of respondents that support or strongly supported the intentions of the Act	% of respondents that strongly do not support, do not support or feel neutral towardsthe intentions of the Act
Strongly agree	13%	50%	0%
Agree	10%	34%	2%
Neutral	7%	9%	7%
Disagree	8%	2%	10%
Strongly disagree	61%	5%	82%

Questions 14-17: Tier 1 PBOs / Audit

5.5 Questions 14-17 asked respondents to provide more detail on their view about the initial audit process for Tier 1 PBOs, to provide details of any barriers which exist that may prevent the policy objective being met, benefits and disbenefits of the approach and details of what is missing from the proposal.

Summary of responses

5.6 Respondents who did not support the intentions of the Act expressed the view that the notification process did not provide a sufficient level of scrutiny or testing of PBOs prior to their authorisation for use in food and feed. The primary reason cited by this group of respondents was that there is a risk that precision breeding may bring about unintended consequences due to off target effects, leading to potential safety concerns. Some responses also stated that the policy objective of proportionality cannot be achieved through the Tier 1 process as the criteria for Tier 1 is not clear. NGOs in opposition to the proposals and some consumers also expressed a concern about missing information in relation to the audit process and concern that some notifications will not be audited, resulting in unchecked PBOs being granted an authorisation. Some of these responses also called for the FSA to commit to certain levels of audits, details of costs and a commitment to publish the results.

5.7 Furthermore, some respondents, including NGOs in opposition to the use of modern biotechnology and some consumers, criticised the Tier 1 process for exempting Tier 1 PBOs from safety testing without the necessary research in place to confirm they are safe for use as food and feed, effectively allowing the industry to “self-certify” through the notification process. They add that this contradicts the FSA’s role to safeguard public health and protect the interests of consumers in relation to food.

5.8 Respondents in opposition also took this opportunity to express concerns that PB food and feed products will be unlabelled and therefore the process lacks transparency, impacting

consumer choice and trust in the FSA.

5.9 There were a number of comments from businesses involved in the plant breeding industry (including developers, breeders, farmers ranging from individuals, small-medium enterprises (SMEs) and large multinational organisations) and from the wider scientific community that the Tier 1 proposal is proportionate. Respondents cited the risk profile of Tier 1 PBOs and the existing due diligence and high levels of seed regulations that the industry already face, and that the Tier 1 process is supported by the assessments carried out by Defra and the Advisory Committee on Releases into the Environment (ACRE).These respondents also recognised the benefits of wider assurance and there was support in principle for an audit process. Supportive respondents recognised that the audit process will provide the benefit of reassurance and confidence for consumers and regulators on the safety of PBOs and the correct application of the triage criteria.

5.10 The majority of these respondents also expressed concerns about the uncertainty in interpreting the triage criteria, arguing that the proposal risks “gold plating” what should be a lighter touch regulatory step for Tier 1 PBOs. The specific concerns raised centred around potential of “open-ended requests for information” and calls for the process to be robust, measurable and repeatable to ensure efficiency.

Food Standards Agency response

5.11 As noted above, a purely statistical assessment of the responses showed the majority of opposition to the Tier 1 proposals came from respondents who oppose the intentions of the Act. Those who support the act were generally supportive of our proposals, although did ask for more detail on the technical elements of the framework.

5.12 The Act itself envisages a more proportionate approach to regulation than current frameworks as PBOs are deemed equivalent to TBOs, where no pre-market assessment is required before being marketed in food or feed. Many of the comments received were opposed to any approach that reduced safety assessment requirements and the action necessary to address these would be incompatible with the intention of the Act. We have passed these comments on to Defra as the policy owner for consideration.

5.13 Noting the intentions of the Act and our need to deliver a regulatory approach consistent with it, the consultation responses did not provide any compelling evidence to adopt an alternative approach and will therefore proceed with a two-tiered approach to regulation with a notification system for businesses applying through the Tier 1 regulatory route (supported by an audit system). After reviewing and considering all responses received on proposals for tiering and on Tier 1 PBOs, the FSA will be continuing as proposed with the implementation of this aspect of the pre-market authorisation process.

5.14 Many respondents provided comments on the detail of the proposals, and we accept the requirement for more detailed information on how the regulation will work set out in comments received from consumers, NGOs, individual farmers and a range of other organisations (including developers and food manufacturers). The FSA is producing detailed technical and administrative guidance which will provide potential applicants (and wider stakeholders) with the information required to facilitate applications and provide transparency on the process. The technical guidance is being developed based on the FSA Board’s decisions and in line with the advice of the ACNFP, as outlined in statements on the ACNFP website. The guidance is being developed with advice from independent international experts and will be independently peer reviewed prior to review and agreement by ACNFP. The FSA is also committed to engaging with stakeholders on the technical guidance to ensure it is as clear as possible for end users.

5.15 We note the concerns raised that the Tier 1 proposal does not make provision for safety assessment. The ACNFP recognises that PBOs can contain changes equivalent to those which

could have happened through traditional breeding and that for many the safety implications will be fully understood. This provides the basis for the FSA's two-tiered approach to regulation. The consultation responses did not provide any new evidence to challenge this view. Responses did reemphasise the importance of clear criteria to ensure PBOs were correctly classified between tiers, and we will be addressing this in the technical guidance.

5.16 The FSA's proposal is designed to be proportionate and to provide adequate assurances on safety. The approach we have taken for Tier 1 is broadly aligned to approaches taken by other international regulators. However, the FSA Board had asked for more detailed consideration of an audit approach prior to authorisation. Consultation responses that considered this approach recognised the need for extra assurance and supported its inclusion, and we have therefore incorporated plans for an audit system into our proposals. We noted the potential weaknesses in the audit approach highlighted by some respondents and in developing our approach we will ensure the audit provisions will provide sufficient scrutiny on Tier 1 notifications. Should this audit process identify non-compliance with the FSA's technical guidance or the regulations, the FSA will be able to request a full Tier 2 application.

5.17 Some respondents raised concerns over the notification process and how this will effectively allow businesses to "self-certify" the status of their PBOs. The FSA and other government departments will carry out steps prior to authorisation. We will refer to precision bred confirmations issued by the Secretary of State and informed by independent advice provided by ACRE, which will confirm that the organism could have been produced through traditional breeding methods and is therefore equivalent to TBOs (which are not subject to pre-market authorisation for food/feed use) with respect to release into the environment.

5.18 The new regulatory framework will not operate in isolation but rather within a wider legislative framework of food law. This wider legislative framework already places statutory obligations on food and feed businesses, including the obligations in General Food Law (footnote 3) (Assimilated Regulation 178/2002), which prohibits businesses from placing food or feed on the market if it is unsafe.

5.19 The PB regulations will require triage questions to be answered to conclude that a PBO meets the Tier 1 criteria, and a notification to be submitted providing mandatory information supporting the applicant's conclusions. The proposed regulations will also require businesses to follow the triage questions by law. Technical guidance will be provided to support applicants in answering these triage questions, in line with the FSA's function in Section 7 of the Food Standards Act 1999 (footnote 4) which amongst other things empowers the FSA to provide food safety advice to businesses.

5.20 The existing provisions in food law, coupled with the advice provided to businesses in the form of technical guidance, will create a sufficient deterrent to non-compliance since any businesses found to be non-compliant with the process laid down in technical guidance would be in breach of their wider obligations in food law to ensure that the food and/or feed they intend to market is safe.

5.21 We consider this sufficient assurance that the notification process for Tier 1 will be followed correctly by businesses, with the added assurance of the audit system to keep checks on non-compliance. For this reason, we do not consider any reason to make changes to this part of the proposals.

5.22 As outlined in paragraph 5.8, some consumers expressed a concern that the proposal does not require PBOs to be identified using labelling. Our general response to this issue can be found in Annex D which covers issues that are out of scope of the consultation and FSA observations on these issues.

Tier 2 – Bespoke risk assessment

Summary of responses:

5.23 Questions 18-20 asked respondents to specify to what extent they agree or disagree with certain statements about the policy proposals relating to bespoke risk assessment for Tier 2 PBOs, specifically:

5.24 To what extent do you agree with the FSA conducting bespoke risk assessments for Tier 2 PBOs prior to them being authorised for use in food/feed?

Table 9: Level of agreement that the FSA should conduct bespoke risk assessments for Tier 2 PBOs prior to them being authorised for use in food and feed

Level of agreement	% of respondents (of 162 responses)	% of respondents that supported or strongly support the intentions of the Act	% of respondents who strongly do not support, do not support or feel neutral towards the intentions of the Act
Strongly Agree	15%	23%	13%
Agree	6%	7%	6%
Neutral	23%	63%	9%
Disagree	3%	7%	2%
Strongly disagree	52%	0%	71%

5.25 To what extent do you agree that the proposal for Tier 2 applications meets the FSA's policy objectives [as outlined in paragraph 7.9 of the consultation document]?

Table 10: Level of agreement that the proposal for Tier 2 applications meets the FSA's policy objectives

Level of agreement	% of respondents (of 159responses)	% of respondents that supported or strongly support the intentions of the Act	% of respondents who strongly do not support, do not support or feel neutral towards the intentions of the Act
Strongly agree	7%	21%	2%

Level of agreement	% ofrespondents (of 159responses)	% of respondents that supported or strongly supportthe intentions of theAct	% of respondents who strongly do notsupport, do not supportor feel neutral towardsthe intentions of the Act
Agree	4%	9%	2%
Neutral	16%	23%	14%
Disagree	16%	42%	7%
Strongly disagree	57%	5%	76%

5.26 To what extent do you agree or disagree that the proposal for Tier 2 applications is feasible?

Table 11: Level of agreement that the proposal for Tier 2 application is feasible

Level of agreement	% of respondents(of 160 responses)	% of respondents that supported or strongly support the intentions of the Act	% of respondents who strongly do not support, do not support or feel neutral towards the intentions of the Act
Strongly agree	5%	17%	1%
Agree	4%	12%	2%
Neutral	14%	20%	13%
Disagree	18%	49%	8%
Strongly disagree	58%	2%	77%

5.27 Questions 21-23 asked respondents to provide more detail on their views about the proposal for bespoke risk assessments for Tier 2 applications, to provide details of any barriers which exist that may prevent the policy objective being met, benefits and disbenefits of the approach and details of what is missing from the proposal.

5.28 Broadly, most stakeholders were accepting of the principle of incorporating a mechanism for bespoke safety assessment into the framework. The comments on this aspect of the proposals were generally more focused on the circumstances where an assessment would be required, as well as the substance of that assessment.

5.29 Developers expressed general concern that the Tier 2 process could be too burdensome and uncertain to warrant the investment in the production of potential Tier 2 PBOs. Some developers, whilst raising concerns, suggested that there is room for flexibility through bespoke safety assessments leading to expediated authorisations for certain PBOs.

5.30 Some developers and related businesses argued that confirmation of PBO status issued by the Secretary of State would confirm that the PBO could have been developed through traditional breeding and as such should not require additional safety assessments because there is not intrinsically higher risk associated with PBOs. Relatedly, developers also expressed the need for the FSA and Defra to communicate associated assessment processes clearly to reassure consumers of the safety of PBOs and their use.

5.31 Developers stated that the Tier 2 process would present challenges due to the uncertainties of the bespoke safety assessment process and requirements. Specifically, developer responses explained that additional compositional data requirements to cover allergenicity, nutritional quality and toxicology must be based on a credible risk hypothesis. A process that requires overly detailed data requirements, analysis, additional research, and review would add unnecessary costs and time to product development, which, in turn would lower the economic viability of developing Tier 2 products. These barriers have the potential to stifle innovation and neutralise the benefits of the Tier 2 process.

5.32 Responses also requested that the technical guidance offers more clarity about what constitutes “significant changes” with respect to the compositional criteria of the triage questions (nutritional quality, allergenicity and toxicity). Most developers recognise that products must be safe but feel that the Tier 2 proposals are too stringent due to the reasons expressed above and could result in barriers to the FSAs innovation goals and a “de-facto ban” on Tier 2 products. A few responses were more critical of the Tier 2 process, explaining that it is too similar to the existing GMO regulations for innovation and efficiencies to be realised, neutralising the benefits of Tier 2 PBOs for consumers and businesses.

5.33 Some responses from developers also added that more information is required about the process for Tier 2 authorisations, specifically on the timescales for approval, any associated fees with the processes, ensuring that they are justifiable and appropriate. A few responses specifically mentioned the disproportionate impact this could have on SMEs seeking to develop PBOs for use as food and feed.

5.34 Multiple developers and some other organisations supportive of the proposals raised a query about the scope of existing Novel Food Regulation (assimilated Regulation (EC) 2015/2283 (footnote 5)). They asked how they relate to Tier 2 PBO determination and whether certain products would require multiple authorisations before being deemed appropriate for use as food and feed.

5.35 The majority of consumers who provided detail to their responses were not in support of the Tier 2 proposals. They, along with NGOs and campaigners expressed similar concerns to those raised about the notification and audit process for Tier 1. The majority of responses from these groups assert that the policy objectives of proportionality and transparency cannot be met due to the requirement for developers to triage their own applications into either Tier 1 or Tier 2 and the lack of clarity on Tier 2 classification.

5.36 Responses also covered the lack of information on the bespoke safety assessment preventing detailed comments on the feasibility of the system. Some respondents also added that

guidance should emphasise the need for more comprehensive data from developers, including but not limited to “whole genome sequencing” to ensure unintended impacts are monitored and assessed.

Additional stakeholder comments:

5.37 Respondents were asked to provide detail about what they feel is missing from the proposals to ensure that the policy objective could be met. These comments were similar to those provided earlier in the section as detailed above but have been included here for completeness.

5.38 Developers and some other supportive organisations were concerned about the absence of clear, science-based safety assessment guidelines which describe the required data to minimise uncertainty about what a bespoke process might entail, including the types of analyses, duration, and potential requirements. Additionally, they felt that there is a lack of clarity on how Defra and the FSA will collaborate when applicants seek simultaneous approvals for cultivation and marketing in England as well as the lack of information about how the framework aligns with the Novel Food regulations.

5.39 Respondents that did not support the proposals identified common themes with respect to what was missing from the proposals. Most responses raised the general concern that the Tier 2 process is missing the detail to provide assurances that the process will sufficiently assess the risk, safety and unintended effects of edits. There were calls for the inclusion of more comprehensive analysis to address a perceived lack of data being requested from developers. Some respondents suggested that “whole genome sequencing” and “omics” (metabolomics and proteomics) data should be mandated.

5.40 A small group of respondents (mostly individuals and some NGO/campaign groups) raised further detail about the concerns of unintended impacts of PBOs, with some respondents specifically referencing the impact of stacked edits. They explain that the proposals do not account for potential unintended consequences such as increased herbicide use, evolution of pathogens triggered by disease resistant PBOs and other environmental risks.

Food Standards Agency response:

5.41 As with responses regarding the Tier 1 proposals, the majority of opposition to the plans for bespoke safety assessment came from those who oppose the objective of the Act, who argued for a more stringent approach to assessment. However, we also received opposition from respondents who were in support of the Act. These respondents argued for the opposite approach, suggesting that the proposals were already too stringent. The overarching theme from all respondents was that more detail was required.

5.42 Concerns about the potential level of detail required and specific data requirements for a Tier 2 application will be addressed through non-legislative means in the form of technical guidance to support businesses applying through the framework. We will clarify the details of bespoke safety assessment processes through this guidance, including data requirements and timelines, to ensure that the right level of information is made available to FSA assessors to inform and carry out an effective pre-market safety assessment. As stated in our response regarding Tier 1 proposals, the development of this guidance will involve input from relevant experts and an independent peer review process. We are also committed to engaging with stakeholders to ensure the guidance is as clear as possible for end users.

5.43 We note that in some responses that there was uncertainty about how the Tier 2 process for PBOs interacts with the existing Novel Food regulations. The triage criteria will specifically capture novelty as a potential factor that warrants further assessment. We will ensure that PBOs that would otherwise be considered novel (if developed using traditional breeding methods) are excluded from the scope of the Novel Foods Regulation but still subject to an appropriate level of

assessment. Where a PBO is considered to trigger novelty triage criteria, the PBO will be subject to the bespoke Tier 2 safety assessment and as this assessment will cover the novelty of the organism, an additional assessment will not be required under the Novel Foods regulatory regime.

5.44 Some responses asked how the FSA and Defra plan to collaborate on applications for cultivation and marketing. At present, the framework will require two separate applications to be made. The FSA is working with Defra to ensure that join up occurs wherever possible to minimise the burden on applicants.

5.45 The proposed information required from applicants asks for confirmation of the procedures undertaken to limit unintended alterations of their PBO's genetic material. Applicants identifying any safety concerns during triage (in line with the triage questions) will be required to submit an application under the Tier 2 process, where those concerns can be fully assessed during the bespoke safety assessment. We are satisfied that this approach sufficiently addresses concerns about safety and makes adequate consideration of the risk of off target and unintended effects of precision breeding techniques.

5.46 The regulatory framework will be incorporated into the existing infrastructure for regulatory services which the FSA delivers already. The FSA has the necessary capacity within its science, evidence and research division and associated independent scientific advisory committees to assess risk in accordance with the bespoke safety assessment requirements that will be set out in technical guidance.

5.47 Given the commitments the FSA has made towards producing technical guidance and the steps that we plan to take to ensure that it is subject correct amount of expert scrutiny, we expect the issues raised around the bespoke safety assessment requirements to be fully addressed by the implementation of the technical guidance.

5.48 We note the comments from respondents calling for a more stringent process and those that have argued that any assessment is unnecessary. We wish to reiterate that our intention is to develop a proportionate framework that protects food safety without creating unnecessary burdens towards innovation in food and feed industries in line with the objectives of the Act. We consider the plans for bespoke assessment to be sufficient in achieving this and therefore we intend to proceed with this element of the proposals.

6. Public Register

Background:

6.1 The Act provides a discretionary power in Section 27 for the Secretary of State to make regulations to require the FSA to establish and maintain a public register of information relating to PBOs which have been granted marketing authorisation for use as food/feed in England.

Summary of responses:

6.2 Question 24 asked respondents to what extent do they agree that the proposal for a public register meets the FSA's policy objectives [as outlined in paragraph 7.9 of the consultation document]?

Table 12: Level of agreement that the proposal for a public register meets the FSA's policy objectives

Level of agreement	% of respondents (of 161 responses)	% of respondents that supported or strongly supported the intentions of the Act	% of respondents who strongly do not support, do not support or feel neutral towards the intentions of the Act
Strongly agree	17%	53%	3%
Agree	11%	33%	3%
Neutral	11%	7%	13%
Disagree	8%	2%	10%
Strongly disagree	53%	5%	70%

6.3 Questions 25 and 26 asked respondents to provide details of the benefits and disbenefits of the proposal and if there is anything missing which prevents the objective from being met. Responses to these questions were polarised between the groups who supported and didn't support the proposals.

6.4 The majority of developers and other supportive responses outlined that the public register provides transparency on authorised PBOs and enables freedom of choice within supply chains, acknowledging that this is vital for consumers, farmers and other stakeholders to make informed choices and gain intelligence about what PBOs are coming to market. Plant breeders and developers expressed strong support for transparency, asserting that breeding methods are safe.

6.5 Developers also expressed some concerns about the register, citing that excessive or irrelevant information could risk creating a stigma and/or false perceptions about the safety of PBOs. Multiple responses stressed the importance of ensuring the information contained on the register is relevant to users and shouldn't be overcomplicated. Distinguishing between Tier 1 and Tier 2 was given as an example of unnecessary detail as this does not relate to the safety of the product. Some responses were also unsupportive of including a unique reference number (URN) as this may cause confusion between different registers. Another theme was the importance of ensuring the join up between the Defra and FSA registers to reduce burden for developers and minimise confusion for businesses and consumers.

6.6 Whilst broadly supportive of a public register, consumers and most NGOs raised concerns about accessibility of the register for consumers, emphasising that it is inadequate without on-package labelling for products containing PBOs.

6.7 A few responses from NGOs and their members also highlighted in this section that the public register is insufficient to complement and support traceability, especially with the absence of on-product labelling and that developers should provide details of a validated detection method for products. Further concerns were raised that register will not be accessible for all end users – namely consumers.

6.8 The majority of consumers that provided a response to this section stated that they would prefer to have products labelled than to access a public register and that their ability to choose products that don't contain PBOs would not be supported by the information contained on the register.

6.9 Most developers and supportive respondents felt that the proposal for the public register contained all of the necessary information for it to achieve the policy objective. Some respondents in this group advised that the register should support the Defra and British Society of Plant Breeders (BSPB) Registers. One response suggested there should be a space for developers to include "Additional information" such as links to genome sequences or an accession for germplasm if the PBO has been deposited in a gene bank.

6.10 Some of the more detailed responses from NGOs outlined that they feel the public register should include:

- URNs and QR codes for use throughout supply chain
- Tier status of a PBO
- Whether a Tier 1 PBO notification was audited
- Techniques used to alter the genome
- Assessment of off-target effects
- Quantities of a PBO being produced
- A list of specific products in which a PBO is used

6.11 Some other respondents said that the above information is necessary to ensure that the public register can support effective traceability and the lack of requirement for developers to supply detection methods could hinder monitoring and enforcement.

6.12 Furthermore, some respondents outlined that there should be a period of time where an interested party could object to or challenge a PBO authorisation which has been placed on the register, prior to it entering the food system.

Food Standards Agency response:

6.13 Although a high level of respondents indicated that the proposal for the public register did not meet the FSA policy intentions, most respondents were generally supportive of the concept of a public register. The opposition generally stemmed from the efficacy of the register being limited due to the absence of product level information (labelling of PB food/feed).

6.14 We acknowledge that in the absence of labelling, the usability of the register as a product level consumer tool is impacted. However, in the context of the UK Government policy and the decisions made to date by Ministers and Parliamentarians, we have worked to propose a public register which is as useful as is reasonably possible for both consumers and businesses.

6.15 With regards to the concerns raised about the lack of labelling in the proposals, please refer to Annex D for the FSA response to this issue.

6.16 Some respondents suggested that there should be a period where a PBO authorisation listed on the register can be challenged. All valid notifications and applications for PBO authorisation will be published on the FSA's register of regulated products applications. This register will make stakeholders and consumers aware of applications progressing through the authorisation process. This will provide transparency to stakeholders and consumers, and the opportunity to review and provide comment to the FSA, should there be a reason to do so.

6.17 The register will contain information regarding PBOs authorised for food/feed once the processes have been completed and authorisations granted. In the case of PBOs subject to the Tier 2 regulatory route, relevant information from the bespoke safety assessment will be included on the register, which will indicate the level of scrutiny the PBO has been subject to. All PBOs

authorised for use in food and feed will have the same regulatory status, regardless of the route to authorisation. Therefore, there is no justification or need to explicitly distinguish between PBOs authorised via Tier 1 and Tier 2 on the public register.

6.18 Some respondents emphasised the need for join up between the FSA's and Defra's respective registers, as well as registers maintained by industry. We recognise the benefits that a joined-up approach could bring, and we are working closely across government to ensure that the registers complement each other whilst maintaining clarity and ease of use.

6.19 We received a wide range of views from respondents on the data fields that are required the register, but without a clear consensus on what additional fields may be needed or useful, we do not propose to amend the proposed list of fields at this stage but have noted the suggestions. We will continue to monitor the efficacy of the register and the way in which consumers and stakeholders are provided with information on PBOs authorised for use in food and feed.

6.20 Based on the general support for establishing a public register of PBOs authorised for use in food and feed, we intend to proceed with this element of the proposals.

7. Traceability

7.1 The FSA considers existing General Food Law traceability requirements (Article 18 (footnote 6)) to be proportionate and sufficient to support our central policy objective and that they will allow food and feed businesses to work with existing familiar requirements without creating any further burden. The FSA therefore proposed that no traceability requirements for food/feed containing or consisting of PBOs beyond those in General Food Law should be adopted at this time. Enforcement officers will be able to use information obtained from the audit of systems, records and paperwork to ensure that only authorised PBOs are marketed for sale, in addition to the FSA's Public Register of PBOs authorised for food/feed. This would not prevent approaches such as the adoption of independent certification schemes for food/feed which excludes PBOs, should there be a viable market.

Summary of responses

7.2 Question 27 asked respondents to what extent do you agree or disagree that the proposal to use existing provisions in General Food Law for traceability meets the FSA's policy objectives [as outlined in paragraph 7.9 of the consultation document]?

Table 13: Level of agreement that the proposal for using existing provisions in General Food Law for traceability meets the FSAs policy objectives

Level of agreement	% of respondents (of 169 responses)	% of respondents that supported or strongly supported the intentions of the Act	% of respondents who strongly do not support, do not support or feel neutral towards the intentions of the Act
Strongly agree	22%	80%	2%
Agree	4%	11%	1%

Neutral	4%	2%	4%
Disagree	4%	2%	5%
Strongly disagree	66%	5%	89%

7.3 Consumers largely disagreed with the proposal to use existing provisions in General Food Law for traceability for the FSA to meet its policy objectives. The primary concern raised in this section was that traceability would be ineffective without mandatory labelling / identification along supply chains, and that consumer confidence, trust, choice and protection would suffer as a result.

7.4 Some consumers expressed a concern that the “one up/one down” approach to traceability is weak, especially in complex systems such as the food chain where there is a risk that products containing PBOs could be mixed with non PB products. Some other respondents expressed a concern that inadequate traceability provisions could increase the risk of public health or environmental complications in the event of safety incidents, and that associated recall procedures would be made more difficult.

7.5 Some consumers also raised a concern that the FSA has chosen not to take forward recommendations made by LGC Ltd (in conclusions made in FSA commissioned research) to conduct further research into the feasibility of establishing analytical methods for the detection of PBOs. They argued that detection methods could enhance the FSA’s proposal for traceability and that the recommendations should have been adopted by the FSA.

7.6 A small number of consumer responses also raised that the traceability proposals will prevent transparency in the food chain, and this could disproportionately impact SMEs who could find it difficult to follow guidance, possibly leading to increased incidences of food fraud in relation to the use of PBOs as well as inadvertent non-compliance.

7.7 NGOs echoed the concerns of consumers in their responses, adding that the rapid proliferation of PBOs in the food system creates a risk that PBOs will not be able to be effectively managed and risks mitigated in the event of a safety related incident.

7.8 Along with some consumer responses, some NGOs also raised concerns about the impact that the traceability proposals would have on organic producers and manufacturers. This is due to these businesses being having a legal obligation to not include PBOs in their supply chain to qualify for Organic status and the difficulty of doing this without mandatory traceability and labelling/identification.

7.9 Supportive respondents, mostly made up of developers, scientific research institutes and societies, trade bodies and other businesses supported the proposal, citing that the provisions for traceability in General Food Law (footnote 7) are applied equally to all products and don’t present any unnecessary barriers to policy implementation for a transparent traceability system. These respondents also commented that the existing provisions have a strong track record for delivering safe products through the supply chain to consumers.

7.10 Most responses from consumers, individual farmers and NGO groups reiterated their concern that the proposals did not include provisions or recommendations for the labelling of PBOs and PB products along supply chains, adding that this is missing from the proposal for effective traceability. Some responses took this further to say that safeguards are missing from the traceability proposal as the risks of PBOs are still to be fully understood.

7.11 Supportive respondents including developers, trade associations and agricultural unions expressed that the proposal on traceability with respect to food and feed should not be viewed in isolation and there must be recognition for the additional assurance provided by the current seeds marketing regulations, which imposes full traceability on all plant reproductive materials.

7.12 Some respondents also suggested that the FSA could make use of and collaborate with existing assurance schemes (such as Red Tractor) to enhance the proposal.

Food Standards Agency response:

7.13 As outlined above, a large proportion of responses raised concerns relating to the lack of labelling / identification along supply chains and how this could impact the effectiveness of traceability of PBOs. Please refer to Annex D for our response regarding labelling.

7.14 Responses also followed a similar trend to other sections of the consultation, where respondents who opposed the intentions of the Act strongly did not support the conclusion that existing General Food Law traceability provisions were sufficient for meeting the FSA's policy objectives in this area. Many of the responses from those who supported the intentions of the Act, including those involved in food and feed supply chains, agreed that the proposal meets the FSA's policy objective.

7.15 The overarching suggestion from respondents who opposed the FSA's proposals in this area was to impose mandatory labelling on PBOs used in the food and feed chain to aid traceability. This is not something that is compatible with the UK Government position or objectives for the policy and therefore cannot be implemented at this time. In absence of further suggestions within the FSA's remit that could be reasonably implemented, we intend to proceed as outlined in the consultation and not implement further traceability requirements beyond those in General Food Law on PBOs at this time.

7.16 The FSA's central policy objective for the traceability of food/feed from PBOs is to ensure that it can be identified and removed from the market in the event of an incident, taking into account the levels of traceability required to achieve the same objective for TBOs. Therefore, we would like to reinforce that the proposal for traceability of PBOs is in relation to food safety and that additional traceability requirements are not in the remit of the FSA. With regards to food safety, General Food Law provides trusted and effective mechanisms for food safety related traceability which includes mechanisms for safety related recall procedures and the monitoring of where products may be mixed within the supply chain. Therefore, we do not deem it necessary nor appropriate to introduce traceability provisions in addition to those in General Food Law.

7.17 The research carried out by LGC Ltd recommended investing in more research to establish if detection is consistently possible and, if so, the best methods of detection available, and then to identify opportunities for future detection method development. The FSA formally responded to the recommendations made in this research report stating that we did not intend to take forward any of the recommendations in the context of precision breeding policy at this time but welcomed further research in the area.

7.18 Irrespective of the recommendations, the report also concludes that the current deficit of suitable methods to detect and identify PBOs precludes accurate quantification. We do not currently consider detection as practical due to the capability and capacity required for delivery, nor proportionate to the risks posed.

7.19 Additional comments were received from stakeholders regarding the challenges for organic producers and businesses who are legally required to exclude PBOs from their supply chains and others who may wish to exclude PBOs from their products. As with labelling, this is out of scope of the FSAs remit in England and rests with Defra. We have passed these comments on to Defra for consideration.

7.20 Some responses suggested the use of existing seed marketing regulations as an additional traceability tool. As above, this is out of scope of the FSA's remit and has been referred to Defra who have policy responsibility for seed regulations in England.

8. Enforcement

Background:

8.1 Powers in the Act, alongside existing food and feed law powers, enable the facilitation of a 'paperwork and audit' approach. Information obtained from the audit of systems, records and paperwork will allow enforcement officers to continue to perform their duties when undertaking official controls. They will also be able to consult the FSA's Public Register of PBOs authorised for use in food and feed.

8.2 The Act contains the following enforcement powers, to be used by officials acting as 'inspectors' in local authorities and port health authorities in England, that we intend to implement through secondary legislation:

- **Powers that enable the investigation of potential breaches**:
  - powers of entry, inspection, examination, search and seizure;
  - powers to take copies of documents, photographs and samples;
  - powers to impose requirements; and
  - powers to require the provision of information.
- **Enforcement notices to compel specific actions** – these are compliance, stop and monetary notices.
- **Requiring the payment of costs** (for example, investigation costs, administration costs, costs of obtaining expert advice such as legal advice).

Summary of responses:

8.3 Questions 31-33 asked respondents to provide their level of agreement to questions about the proposals for enforcement of PBOs, specifically:

8.4 To what extent do you agree or disagree that the proposed enforcement regime meets the FSA's policy objectives [as outlined in paragraph 7.9 of the consultation document]?

Table 13: Level of agreement that the proposed enforcement regime meets the FSA's policy objectives

Level of agreement	% of respondents (of 157 responses)	% of respondents that supported or strongly supported intentions of the Act	% of respondents who strongly do not support, do not support or feel neutral towards the intentions of the Act
Strongly agree	14%	54%	0%
Agree	5%	17%	1%

Level of agreement	% of respondents(of 157responses)	% of respondents that supported or strongly supported intentions of the Act	% of respondents who strongly do not support, do not support or feel neutral towards the intentions of the Act
Neutral	10%	17%	8%
Disagree	11%	5%	14%
Strongly disagree	59%	7%	78%

8.5 To what extent do you agree or disagree that the elements of the proposed enforcement regime are practical and deliverable?

Table 14: Level of agreement that the proposed enforcement regime are practical and deliverable

Level of agreement	% of respondents (of 152responses)	% of respondents that supported or strongly supported intentions of the Act	% of respondents who strongly do not support, do not support or feel neutral towards the intentions of the Act
Strongly agree	15%	54%	1%
Agree	5%	17%	1%
Neutral	9%	17%	6%
Disagree	7%	2%	8%
Strongly disagree	64%	10%	84%

8.6 To what extent do you agree that this proposal meets your need as a stakeholder?

Table 15: Level of agreement the proposed enforcement regime meets the needs of responding stakeholder

Level of agreement	% of respondents (of 152responses)	% of respondents that supported or strongly supported intentions of the Act	% of respondents who strongly do not support, do not support or feel neutral towards the intentions of the Act
Strongly agree	14%	54%	0%
Agree	6%	22%	0%
Neutral	7%	12%	5%
Disagree	6%	2%	7%
Strongly disagree	67%	10%	88%

8.7 Questions 34 and 35 asked respondents to provide details of any barriers to the policy objective being met and benefits and disbenefits of the proposal.

8.8 Generally, most developers and some consumers were supportive of the proposals for the enforcement regime outlined in the consultation document. When asked about barriers, benefits and disbenefits, supportive responses emphasised that existing enforcement rules apply equally to traditionally bred products and there should be little to no difference for PBOs given their approval from Defra and the FSA that they are safe. The responses also state that the proposal will also help reduce and prevent discrimination and stigma against PBOs and PB food and feed products. Some responses emphasised that the existing enforcement provisions in the UK are well established and prioritise safety, transparency within the supply chain and legality.

8.9 We received detailed feedback from Trading Standards Wales (TSW), which represents the twenty local authority (LA) Trading Standards Services across Wales. Whilst this response provided general support for the proposed approach it also outlined some of the challenges that PBO policy could create, particularly in relation to enforcement authorities in Wales. These concerns are covered later in this section.

8.10 Other than the response received from TSW, we received no additional concerns raised by enforcement authorities across the UK.

8.11 Those who did not agree that the policy objectives could be met, the proposals were deliverable and that stakeholder needs were met, offered a range of responses to questions 34 and 35. The majority of responses from consumers and NGO organisations reiterated concerns that there are no provisions for labelling and that this will hinder the ability of LAs to effectively manage the additional requirements for PB enforcement. Many respondents explained that labelling impacts on consumer choice.

8.12 Some consumers also expressed concern that the enforcement regime does not include sufficient information and sanctions to prevent food fraud which puts consumers' health at risk. Many consumers and some NGO responses raised concerns that the FSA, LAs and Port Health Authorities (PHAs) do not have the required resources.

8.13 Another theme raised by these groups of respondents was the impact on the organics sector, criticising the proposals for having disbenefits for those wishing for the freedom of choice to avoid PBOs and introducing increased costs to keep supply chains PB free and for those legally required to segregate PBOs out of supply chains.

8.14 Question 36 invited respondents to provide what level(s) of monetary penalty they think would be appropriate in respect of the “relevant breaches”. Reponses received varied in specificity and level agreement that monetary penalties are appropriate for the relevant breaches.

8.15 The majority of consumer responses felt that monetary penalties should be very high so that they are an effective deterrent to businesses. Some responses were very specific with the level of penalty with suggestions including: £1,000,000, 1% of turnover or £10,000 (whichever is greater), A few consumers raised the view that penalties should be proportionate to the impact caused by a breach and that in some cases, criminal sanctions should be considered, especially in the event of loss of life. NGO responses echoed the view that penalties must be high enough to act as a deterrent and not simply absorbed as a part of the “cost of doing business”.

8.16 Some consumers and most developers and industry expressed the view that monetary penalties should be proportionate and should “make good damage done”. There were also strong views from developers and trade bodies that criminal sanctions should not form a part of the proposals.

8.17 Question 37 asked respondents if they feel anything is missing from the proposal which would prevent the policy objective from being met when implemented.

8.18 Developers and those in support of the proposals explained that the proposed enforcement regime would be able to effectively operate for PBOs in England and that there are no missing details. One developer raised a question about how the enforcement regime will operate in relation to Wales, Scotland and Northern Ireland.

8.19 Other supportive responses praised the use of Improvement Notices for non-compliance.

8.20 Most consumer and individual farmer responses, as well as NGOs, TSW and the Farmers’ Union of Wales (FUW), reiterated concerns about the lack of labelling provisions and the FSA’s decision not to pursue detection methods as being barriers to the proposed enforcement regime being able to operate successfully. Some responses explained that without these tools, enforcement officers will not be able to carry out their duties in relation to PBOs – especially outside of England where legislation regulating GMOs will continue to apply unchanged.

8.21 Some consumer responses raised the concern again that criminal sanctions are not a part of the proposals and recommended that they should be considered for certain breaches. This concern was also raised by a small number of organisations, including TSW which highlighted that this could cause some confusion between other food related enforcement regimes, where criminal sanctions exist.

8.22 TSW also expressed concern about the uncertainty regarding the course of action if enforcement notices are not complied with adding that without criminal sanctions, enforcement might need to be considered under other existing food/feed legislation, further complicating investigations related to PBOs.

8.23 More concerns were raised, specifically from consumers and farmers based in Scotland and some in Wales (including the response from the FUW), regarding the differences in enforcement regimes in different parts of the UK. Specifically, these concerns referenced the impact of the United Kingdom Internal Market Act 2020 (footnote 8) (UKIMA) and Windsor Framework on enforcement and questions were raised regarding how enforcement will work in Wales, Northern Ireland and Scotland where the Precision Breeding legislation will not apply. These respondents pointed to the practical challenges that some businesses may face to remain compliant with

devolved legislation related to GMOs where PBOs have been sold legally into other parts of the UK but are then subject to significant processing and by virtue of this would then fall outside the scope of UKIMA or Windsor Framework (footnote 9) provisions.

Food Standards Agency response:

8.24 The impact that the enforcement proposals could have on LAs and PHAs was raised by a number of respondents – specifically how the proposals will draw on already stretched resources, requiring additional spending and costs. Whilst we recognise that there will be some additional costs, these would fall under the remit of the New Burdens Doctrine (footnote 10). This framework states that all new burdens on local authorities in England must be properly assessed and fully funded by the relevant Government department.

8.25 To assist LAs and PHAs, the FSA will publish guidance on the PB enforcement regime for food and feed in England. We also plan to produce guidance for LAs and PHAs in Wales and District Councils in Northern Ireland on when existing GMO regulations would apply to PBOs in those countries. We will share details of this work with Food Standards Scotland (FSS) so they can decide what information should be provided to local authorities in Scotland.

8.26 We recognise that there will be a degree of regulatory divergence as the policy proposals - like the Act itself - apply in England only. We want to support authorities in Wales, Northern Ireland and Scotland to ensure that enforcement measures in devolved legislation continue to operate effectively. To do this the FSA is working with other Government departments to explore areas where further clarity is required, such as regarding the definition of a ‘significant production step’, so that we can provide relevant and effective guidance for the enforcement of GMO regulations where PBOs are in the supply chain in Wales, Scotland, and Northern Ireland.

8.27 Following an implementation period, the policy will be assessed which will allow for costs to be assessed and reviewed and guidance to be updated if necessary.

8.28 As described in the summary of responses, we received a range of suggestions for what an appropriate monetary penalty would be in respect of the “relevant breaches”. We are grateful for the responses, and these are being considered alongside an analysis of comparative penalties in similar regimes. An outline of penalties will be provided in the published guidance.

8.29 Some responses called for criminal sanctions to form a part of the proposed enforcement regime. This is not possible due to the powers outlined in Section 20(3)(a) of the Act and, as such, only civil sanctions can be used for enforcement of the Act and legislation made under it. However, 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 (footnote 11), The Food Safety and Hygiene (England) Regulations 2013 (footnote 12) 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.

8.30 With regards to the response that referenced complexities of the enforcement regime, specifically on incidents of non-compliance with notices, the FSA will consider this feedback. As mentioned above, the FSA will issue enforcement guidance for local authorities to provide clarity on the enforcement tools available. The FSA regularly provides guidance to support Local Authorities and District Councils to carry out responsibilities in relation to enforcement. Guidance on enforcement of the precision breeding regulations will lay out the traceability requirements for PBOs, including supply chain controls and auditable supporting documentation and paperwork, which are contained within existing General Food Law. Additionally, the Food and Feed Law Codes of Practice (footnote 13) will assist authorities with issuing and enforcing notices, as well as providing guidance on escalation procedures.

8.31 With the above in consideration, the FSA does not propose to make changes to its broader proposals for measures to be included in secondary legislation to establish a new enforcement regime for PBOs. However, consultation feedback will help inform the detail that will be laid out in guidance, where applicable. This includes, for example, determining the appropriate level of monetary penalty for any breaches of the precision breeding regulations.

9. Assessment of impact

Background:

9.1 The FSA determined that the direct impact of the proposed regulatory framework for PBOs fell below the minimum threshold of +/- £10m (footnote 14) . As such, a full impact assessment was not required. However, in line with the obligations to policy making and best practice, we assessed the impact of the proposals consulted on and included our findings in the consultation, inviting stakeholders' comments.

Summary of responses:

9.2 Questions 38-41 asked respondents if they agree with certain statements about the FSA's assessment of impact, specifically:

9.3 Do you agree with the assumptions and estimates used to calculate one-off familiarisation costs to businesses?

Table 16: level of agreement with the FSAs assumptions and estimates to determine familiarisation costs for businesses

Agreement	% of respondents (of 151 responses)	% of respondents that supported or strongly support the intentions of the Act	% of respondents who strongly do not support, do not support or feel neutral towards the intentions of the Act
Yes	12%	38%	2%
No	46%	10%	60%
Don't know	42%	52%	39%

9.4 Do you agree with the assumptions and estimates used to calculate one-off familiarisation cost to Local Authorities in England, Wales and Northern Ireland?

Table 17: Level of agreement with the FSAs assumptions and estimates to determine familiarisation costs for local authorities in England and Wales and district councils in Northern Ireland

Agreement	% of respondents (of 148 responses)	% of respondents that supported or strongly support the intentions of the Act	% of respondents who strongly do not support, do not support or feel neutral towards the intentions of the Act
Yes	2%	2%	2%
No	46%	2%	63%
Don't know	52%	96%	36%

9.5 Do you agree with the assumptions and estimates used to calculate one-off training cost to Local Authorities in England?

Table 18: Level of agreement with FSAs assumptions and estimates to determine one-off training costs for local authorities in England

Agreement	% of respondents (of 147 responses)	% of respondents that supported or strongly support the intentions of the Act	% of respondents who strongly do not support, do not support or feel neutral towards the intentions of the Act
Yes	3%	5%	3%
No	44%	3%	59%
Don't know	52%	92%	38%

9.6 Do you agree with the impacts that the FSA has identified within this consultation?

Table 19: Level of agreement with the impacts the FSA has identified

Agreement	% of respondents (of 149 responses)	% of respondents that supported or strongly support the intentions of the Act	% of respondents who strongly do not support, do not support or feel neutral towards the intentions of the Act
Yes	19%	72%	1%

Agreement	% of respondents(of 149responses)	% of respondents that supported or strongly support the intentions of the Act	% of respondents who strongly do not support, do not support or feel neutral towards the intentions of the Act
No	66%	5%	88%
Don't Know	14%	23%	11%

9.7 Question 42 asked respondents if they are of any additional impacts of the proposed new regulatory framework that the FSA has not identified in this consultation.

Table 20: Awareness of additional impacts that the FSA has not identified as a part of the consultation

Response	% of respondents (of 149responses)	% of respondents that supported or strongly support the intentions of the Act	% of respondents who strongly do not support, do not support or feel neutral towards the intentions of the Act
Yes	61%	20%	77%
No	39%	80%	23%

9.8 Questions 43-45 invited respondents to provide more detail to their answers above as well as provide an overview of impacts that have not been considered. Responses received were fairly broad from those who felt that the impacts had not been adequately assessed with some clear themes amongst them.

9.9 The most frequently raised concern with regards to impact was to highlight the absence of a comprehensive impact assessment carried out by the FSA, with particular emphasis on the reliance on a Defra Impact Assessment deemed "not fit for purpose" by the government's Regulatory Policy Committee (RPC) and that there is a disproportionate impact on the organics sector which has not been suitably considered.

9.10 Concerns raised by the organics sector and traditional breeders specify that the proposals and impact assessment make no provision for the fact that it is a legal requirement to exclude GMOs from supply chains to be organic compliant. Moreover, some respondents outlined that the organic sector will not be able to choose whether or not to use PBOs due to legal requirements associated with organic certification. This will put additional burdens and costs on stakeholders within the organic supply chain which have not been assessed for this consultation.

9.11 Another prominent theme was around potential trade barriers, especially with the EU and Northern Ireland. Respondents from all groups expressed the view that costs related to trade had not been adequately considered and that the consultation lacked clarity about how the regulations

will interact with the UKIMA. Specifically, concerns were raised about the impact on producers and manufacturers based in Wales, Scotland and Northern Ireland who will not be able to use PBOs and PBO products where a “significant production step” is made outside of England.

9.12 Some respondents highlighted the potential competitive disadvantages that businesses in other parts of the UK may face in comparison to businesses in England.

9.13 Likewise, the difference in enforcement regimes was also raised with respect the costs and challenges of enforcing GMO regulations in Wales, Scotland and Northern Ireland, especially without labelling.

9.14 A few respondents highlighted the potential environmental impact of PBOs, expressing concerns about biodiversity, genetic diversity, and the long-term consequences for land and livestock and that the regulations could be in breach of the Environment Act.

9.15 Some respondents, mainly consumers and some NGO groups reiterated concerns about the safety of PBOs, arguing that the cost of public health, namely allergic reaction incidents and the associate costs on business and government had not been considered. Specifically, there were a number of concerns that the potential costs of product recalls could have a significant impact on businesses.

9.16 The majority of responses who answered “Don’t know” to questions 38-40 added in the free text boxes that the reasons for this are that they are not in a position to assess and comment on future costs but that they mostly agree with the FSAs assessment.

9.17 Developers and other industry stakeholders did not express specific concerns or outline areas where costs may have been miscalculated whilst noting that it is difficult to assess at this stage, recognising the challenges of this kind of assessment prior to implementation. Some referenced international approaches where new regulations have allowed SMEs to successfully develop products for the local market.

9.18 A number of respondents took the final question as an opportunity to provide final comments to the consultation overall.

9.19 Most concerns raised here were reiterations of themes covered earlier in this summary. They focused on:

- That PBOs are not required to be labelled;
- That the safety of PBOs is yet to be proven;
- The impact on the environment caused by PBOs;
- Requests for the FSA to apply the precautionary principle in the drafting of new regulations for PBOs;
- Critiques of the scientific evidence and neutrality of ACNFP;
- Concerns that the consultation process has not been carried out in line with the Cabinet Office Consultation Principles.

9.20 Other respondents provided additional comments on the benefits that the proposals may bring about. These were:

- The potential for PBOs to bring about health and cost benefits for consumers;
- Benefits for the environment and contributions to carbon emission reductions;
- The enabling and promotion of scientific innovation in the UK ;
- Improving the competitive position of the associated industries in the UK and internationally.

Food Standards Agency Response:

9.21 The majority of the additional impacts raised by respondents that were not covered by the assessment of impact are indirect impacts and therefore do not fall within the scope of the assessment of impact for this consultation.

9.22 Some of the additional impacts identified were in relation to out of scope issues such as labelling and segregation of the supply chain for organic sector businesses.

9.23 Additionally, approximately half of respondents either agreed or didn't know whether the assumptions and estimates were correct for one off and familiarisation costs. For those who disagreed, no additional calculations to provide missing information were provided.

9.24 We recognise that there could be costs associated with these impacts when the legislation is implemented. The FSA will continue to monitor the effectiveness of the regulatory framework, and the resultant impacts, and report to the FSA Board accordingly.

10. Conclusion and next steps

10.1 Based on our analysis of all responses and the corresponding conclusions that we have made with respect of each aspect of the proposals (as detailed throughout this document), we have not identified any reasons that would warrant recommendations to the FSA Board for a change in the fundamental approach to regulation that was agreed by the FSA Board in September 2023 and detailed in the consultation.

10.2 We therefore intend to proceed as planned in line with the approach agreed by the FSA board, including plans for:

- A two-tiered approach to regulation of PBOs 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 to 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, to 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, to 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, to 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.

10.3 However, we do recognise that there are areas which require additional information, guidance and/or engagement, and we have expanded on this in our responses to each section of the consultation. In these sections we have confirmed that the FSA intends to proceed with plans to:

- Develop technical guidance to provide potential applicants (and wider stakeholders) with further clarity and the information required to facilitate applications. This guidance is being developed with advice from independent international experts and will be independently peer reviewed prior to review and agreement by ACNFP. The FSA is also committed to engaging with stakeholders on the technical guidance to ensure it is as clear as possible for end users.
- Provide local authorities in England with guidance to assist with enforcement of the regulations. We also plan to produce guidance for LAs and PHAs in Wales and District Councils in Northern Ireland on the application of existing GMO regulations to PBOs. We

will share details of this work with Food Standards Scotland (FSS) so they can decide what information should be provided to local authorities in Scotland.
- Continue to engage across Government, where relevant, to assist with interrelated issues associated with the implementation of the new regulatory framework, noting that on some of these issues the FSA is limited in its capacity to influence.

10.4 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.

10.5 We will present these findings at the public meeting of the FSA Board on 20 March 2024, where they will be invited to discuss our findings and agree our next steps.

Annex A: List of respondents

Below is a list of the organisations that responded. We have not included responses from individuals or from organisations what requested their response be kept anonymous.

- Agricultural Industries Confederation
- Agricultural and Horticultural Development
- APPGSTA - All-Party Parliamentary Group on Science & Technology in Agriculture
- Beyond GM
- Biodynamic Association
- BioIndustry Association
- British Association of Feed Supplements
- British Retail Consortium
- British Sugar
- Burnside Farm Foods
- Centre for Integrated Research in Biotechnology
- Community Supported Agriculture Network UK
- Corteva Agriscience
- CropLife Europe
- Ecotone
- European Food and Fermentation Culture
- Euroseeds
- Farmers Union of Wales
- Food and Drink Federation
- Friends of the Earth
- Frontier Agriculture Ltd
- GeneWatch
- GM Free Somerset
- GM Freeze
- GMWatch
- Government Chemist
- IFST
- J.R. Simplot Company
- John Innes Centre
- KWS UK Limited
- Lallemand
- Lossiemouth House

- LS Plant Breeding Ltd
- MoyPark
- NFU
- NIAB
- Norwich Research Park
- Organic Arable
- Organic Farmers and Growers
- Poyntzfield Herb Nursery
- Quadram Institute
- Rothamsted
- Royal Society
- Royal Society of Biology
- RSPCA
- SA Certification Ltd
- Slow Food UK
- Soil Association
- South Norfolk Green Party
- Syngenta
- The British Society of Plant Breeders
- The Food Life
- The Grain and Feed Trade Association
- The Sainsbury Laboratory, Norwich
- Tozer Seeds
- Trading Standards Wales
- Traditional Norfolk Poultry Ltd
- UK Flour Millers
- Unicorn Grocery

Annex B: Format of online consultation form

Section 1

Information about respondents and their level support for the intentions of the Genetic Technology (Precision Breeding) Act 2023

1): What is your name? [Free text]

2): What is your email address? [Free text]

3): Do you want your response to be confidential [Yes/No]

4): Are you responding as an individual or an organisation? [Individual/Organisation]

5): If you are responding on behalf of an organisation, please name the organisation. If you are an individual, please leave blank. [Free text]

6): How would you describe yourself/your organisation? [Consumer/Developer/Farmer/Other]

7): Where are you/your organisation based? [England/Wales/Northern Ireland/Scotland/Other]

8): To what extent do you support the intentions of the precision breeding act, to remove certain products of modern biotechnology from the scope of GM regulations and regulate them in a more proportionate way? [Strongly agree/Agree/Neutral or Don’t know/Disagree/Strongly disagree]

9): Please explain your reasons for your answer to question 8. [Free text]

10): Would you like to complete Section 2 to provide detailed responses on the individual proposals? [Yes/No]

Section 2

Pre-market authorisation process

11): To what extent do you agree with the FSA using a two-tiered approach for the pre-market authorisation of precision bred organisms used in food and feed? [Strongly agree/Agree/Neutral or Don’t know/Disagree/Strongly disagree]

12): To what extent do you agree that the proposal for Tier 1 notifications meets the FSA’s policy objectives in paragraph 7.9 of this consultation document? [Strongly agree/Agree/Neutral or Don’t know/Disagree/Strongly disagree]

13): To what extent do you agree or disagree that the proposal for Tier 1 notifications is feasible? [Strongly agree/Agree/Neutral or Don’t know/Disagree/Strongly disagree]

14): Please provide details of your thoughts towards the initial audit process for Tier 1 PBOs [Free text]

15): Please provide details of any barriers that may exist which are preventing the policy objective being met or the proposal being implemented [Free text]

16): Please provide details of what you think the benefits and disbenefits of this approach are [Free text]

17): If you feel there is anything missing from our proposal which would be required to ensure that the policy objectives can be met, or the proposal can be implemented please provide any additional comments you have on the Tier 1 process here. [Free text]

Pre-market authorisation process (continued)

18): To what extent do you agree with the FSA conducting bespoke risk assessments for Tier 2 PBOs prior to them being authorised for use in food/feed [Strongly agree/Agree/Neutral or Don’t know/Disagree/Strongly disagree]

19): To what extent do you agree that the proposal for Tier 2 applications meets the FSA’s policy objectives in paragraph 7.9 of this consultation document? [Strongly agree/Agree/Neutral or Don’t know/Disagree/Strongly disagree]

20): To what extent do you agree or disagree that the proposal for Tier 2 applications is feasible? [Strongly agree/Agree/Neutral or Don’t know/Disagree/Strongly disagree]

21): Please provide details of any barriers that may exist which are preventing the policy objective being met or the proposals being implemented [Free text]

22): Please provide details of what you think the benefits and disbenefits of this approach are [Free text]

23): If you feel there is anything missing from our proposals which would be required to ensure that the policy objectives can be met, or the proposal can be implemented please provide any additional comments you have on Tier 2 process here [Free text]

Public Register

24): To what extent do you agree that the proposal for a public register meets the FSA's policy objectives in paragraph 7.9 of this consultation document? [Strongly agree/Agree/Neutral or Don't know/Disagree/Strongly disagree]

25): Please provide details of what you think the benefits and disbenefits of this approach are [Free text]

26): If you feel there is anything missing from our proposal which would be required to ensure that the policy objectives can be met, please provide any additional comments on the Public Register here. [Free text]

Traceability

27): To what extent do you agree or disagree that the proposal to use existing provisions in General Food Law for traceability meets the FSA's policy objectives in paragraph 7.9 of this consultation document? [Strongly agree/Agree/Neutral or Don't know/Disagree/Strongly disagree]

28): Please provide details of any barriers that may exist which are preventing the policy objective being met or the proposal being implemented [Free text]

29): Please provide details of what you think the benefits and disbenefits of this approach are [Free text]

30): If you feel there is anything missing from our proposal which would be required to ensure that the policy objectives can be met, or the proposal can be implemented please provide any additional comments you have on Traceability here. [Free text]

Enforcement

31): To what extent do you agree or disagree that the proposed enforcement regime meets the FSA's policy objectives in paragraph 7.9 of this consultation document? [Strongly agree/Agree/Neutral or Don't know/Disagree/Strongly disagree]

32): To what extent do you agree or disagree that the elements of the proposed enforcement regime are practical and deliverable? [Strongly agree/Agree/Neutral or Don't know/Disagree/Strongly disagree]

33): To what extent do you agree that this proposal meets your need as a stakeholder? [Strongly agree/Agree/Neutral or Don't know/Disagree/Strongly disagree]

34): Please provide details of any barriers that may exist which are preventing the policy objective being met or the proposal being implemented [Free text]

35): Please provide details of what you think the benefits and disbenefits of this approach are [Free text]

36): What level(s) of monetary penalty do you think would be appropriate in respect of the 'relevant breaches' outlined in the consultation document? [Free text]

37): If you feel there anything missing from our proposals which would be required to ensure that the policy objectives can be met, or the proposal can be implemented please provide any additional comments you have on Enforcement here. [Free text]

Assessment of impact

38): Do you agree with the assumptions and estimates used to calculate one-off familiarisation costs to businesses? [Yes/No/Don't know]

39): Do you agree with the assumptions and estimates used to calculate one-off familiarisation cost to Local Authorities in England, Wales and Northern Ireland? [Yes/No/Don't know]

40): Do you agree with the assumptions and estimates used to calculate one-off training cost to Local Authorities in England? [Yes/No/Don't know]

41): Do you agree with the impacts that the FSA has identified within this consultation? [Yes/No/Don't know]

42): Are you aware of any impacts of the proposed new regulatory framework that the FSA has not identified in this consultation? [Yes/No]

43): Do you agree with the wider impacts identified in this consultation? [Yes/No/Don't know]

44): Please explain your reasons for your position [Free text]

Annex C: Glossary of terms

ACNFP – Advisory Committee on Novel Foods and Processes. An independent expert committee comprising of scientists and specialist experts from a wide range of scientific disciplines, who actively advise the FSA on matters pertaining to novel foods, traditional novel foods, food and feed products of genetic technologies and novel food processes including food irradiation.

ACRE – Advisory Committee on Releases into the Environment. ACRE is an advisory non-departmental public body, sponsored by Defra. ACRE provides statutory advice to ministers on the risks to human health and the environment from the release of GMOs.

Application - The legal process under which developers must apply to the FSA for a marketing authorisation for a PBO for food/feed that they have determined as a Tier 2 PBO.

Developer – Those developing PBOs for food/feed and submitting notifications (Tier 1 PBOs) or applications (Tier 2 PBOs) for pre-market authorisation.

Enforcement – The actions taken by authorised officers, under law, to ensure compliance with regulations laid out in relevant legislation, or to address instances of non-compliance where a relevant breach or an offence is determined to have occurred.

FSA – Food Standards Agency

Genetic Modification / GM - Process of altering the genome of a living thing. In England, this would only apply if it has been altered in a way that could not have occurred naturally. Genetic modification allows us to produce plants, animals and micro-organisms with specific qualities. Genetic modification allows just one individual gene, or a small number of genes, to be inserted into a plant or animal. GM may also stand for 'genetically modified'.

Genetically Modified Organism / GMO – Plants and animals that have had their genome altered in a way that could not have occurred either naturally or by means of traditional breeding are known as GMOs.

Notification – The legal process under which developers must notify the FSA about a PBO for food/feed that they have determined as a Tier 1 PBO to seek a marketing authorisation.

Precision Bred Organism / PBO – An organism that has had its genome edited using precision breeding techniques. Under the Precision Breeding Act (footnote 15) , this is distinct from a Genetically Modified Organism (GMO).

Precision Breeding – Precision Breeding refers to techniques, such as gene editing, used to make precise changes to the genome of plants or animals. These changes, which could also have been obtained by traditional breeding techniques, allow obtaining targeted beneficial changes. This is different to genetic modification (GM), which produces crops containing genetic changes that could not have occurred through traditional breeding.

Traceability - The ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.

Traditional Breeding (methods) – Traditional breeding refers to techniques using a wide range of conservative tools or traditional processes to develop or improve desirable traits in plants or animals and select their presence in offspring. Traditional processes are defined in Section 1(6) of the Genetic Technology (Precision Breeding) Act 2023.

Annex D: Issues out of scope of the consultation and FSA observations

We received a high volume of responses on topics which were outside the scope of the consultation and/or were related to issues which are beyond the policy responsibilities of the FSA in relation to England. We have nevertheless included them in this summary of responses in the interests of transparency to ensure that all stakeholders' responses and views are fully captured. These topics and the FSA's observations on them are set out below.

1. Non-safety related consumer labelling

Comments were received from stakeholders from various sectors and consumers indicating that they were keen to see PBO food and feed products labelled for consumers. In England, policy responsibility for food compositional labelling (where not related to safety) rests with Defra. As stated in the consultation, the UK Government position is that there is no justification for the provision of labelling distinguishing all PB food as such on grounds of consumer safety and it has been clear that there are no plans to require labelling of products to indicate they have been produced using precision breeding techniques. We have discussed the relevant issues and consultation responses with the appropriate Government departments where policy responsibility does not rest with the FSA in England.

2. PBO Definition:

Comments were received from stakeholders including some NGOs and consumers in opposition to PBOs being separated from the definition of GMOs. This is the responsibility of Defra and was included in the Genetic Technology (Precision Breeding) Act 2023 which was passed by Parliament and now forms part of the law in relation to England. We have shared these comments with Defra.

3. Scientific Advice / Advisory Committee on Novel Foods and Processes

Some respondents justified their concerns about the FSA's proposals and the overall approach to precision breeding policy by criticising the FSA's approach to receiving independent scientific advice and the role and work of the ACNFP. Some respondents directly disagreed with the conclusions made by the ACNFP in statements issued in September 2022, January 2023 and July 2023.Others challenged the independence of the committee, citing concerns around conflicts of interest. Whilst we acknowledge the importance of the ACNFP's advice in the wider context of the FSA's proposals, the scope of the consultation only covers the policy decisions made further to the independent scientific advice, and not the independent scientific advice itself. Further

information on the ACNFP's role, including how conflicts of interest are managed, can be found on their website.

4. Effects of UK Internal Market / Act

Concerns were raised about the interaction of the proposals with the UK Internal Market Act 2020 and the effects in the other nations of the UK. These issues are being considered separately with other relevant government departments including the Department for Business and Trade which has overall policy responsibility in this area. The FSA will produce guidance for enforcement authorities in England and for those in Wales and Northern Ireland where existing enforcement provisions including those in legislation regulating GMOs (which will remain unchanged in those countries) will continue to be used.

5. Non-safety related traceability identification / labelling:

Policy responsibility for non-safety related traceability information (e.g. providing information on production method along the food / feed supply chain) in relation to England rests with Defra. The proposals put forward in the consultation focused on safety related aspects of traceability. Specific concerns related to non-safety related traceability has been relayed to Defra. Included within this area is the issue of detection which was raised by a number of respondents. The FSA commissioned a literature review on analytical methods for the detection of precision bred products and published a response to this research in September 2023 setting out our thinking.

6. Organic Supply Chain

We received a number of responses indicating potential impact of the proposals on the organic supply chain. These issues related to identification/traceability as outlined above in particular the ability of the sector to exclude PBOs from their supply chains to meet organic standards. These concerns have been relayed to Defra who also in addition to non-safety related aspects of traceability have overall policy responsibility for organic food and feed standards.

7. Technical Guidance:

Responses from a wide range of stakeholders registered concerns about the content of technical guidance which supports the two-tier pre-market authorisation process. Whilst we recognise and appreciate the comments received at this stage, the details of the guidance were out of scope of the consultation. There will be separate engagement with stakeholders on the FSA's technical guidance prior to the adoption and publication of final guidance.

1. The Genetic Technology (Precision Breeding) Act 2023
2. Legislation regulating the use of Genetically Modified Organisms in food and feed
3. General Food Law (Assimilated Regulation 178/2002)
4. Food Standards Act 1999
5. Novel Food Regulations (Assimilated Regulation (EC) 2015/2283)

6. General Food Law (Article 18)
7. General Food Law (Article 18)
8. The UK Internal Market Act 2020
9. The Windsor Framework
10. The New Burdens Doctrine
11. The Food Safety Act 1990
12. The Food Safety and Hygiene (England) Regulations 2013
13. The Food and Feed Law Codes of Practice
14. Better Regulation Framework Guidance
15. Defined in Section 1 of the Genetic Technology (Precision Breeding) Act 2023.