Guidance on responding to the FSA Consultation on 'Precision Breeding'.

The Food Standards Agency is consulting on a new authorisation framework to regulate the use of precision bred organisms (PBOs) in food and feed products in England. Although the legislation is only apples to England we know that under the terms of the UK Internal Markets Act (UKIMA) PBOs are likely to be marketed throughout the UK and it is important that responses are received from the whole country.

The framework aims to consider any environmental or economic risk these organisms and products produced form them could pose on a case-by-case basis, and to ensure that all associated food safety and food supply chain integrity risks are proportionately assessed, managed and communicated to Ministers to inform their decision on whether the organism is safe to be marketed for use in food and feed.

The new rules are meant to ensure that the FSA fulfils its duty to ensure that precision bred organisms will only be authorised if they are judged:

- not to risk health
- not to mislead consumers
- not to have lower nutritional value than their traditionally bred counterparts

It is important that everyone who is interested in, or concerned about, the food and farming system and the provenance and quality of the food we eat and grow, should respond to this consultation.

The use of genetically modified organisms (GMOs), including PBOs, is prohibited in organic food and farming.

We have raised serious concerns over the Genetic Technologies (Precision Breeding) Act, including specific issues relating to organic food and farming. These are highlighted in a joint position statement supported by key players in the organic sector. Please read this before responding to the consultation.

How to make respond the consultation.

You can find the consultation pack here.

There are two ways to respond to the FSA's consultation:

- You can use the online form.
- Or you can submit a letter via email to precisionbreeding@food.gov.uk.

If you choose to submit a letter do the following:

1. Make the subject header clear, e.g. SUBMISSON: Consultation on proposals for the regulation of precision-bred organisms used for food and animal feed.
2. At the top of your letter say you are submitting your response as an individual/small business/etc and request that you receive an email acknowledgement that your response has been received.
3. Say if you want your answers to remain confidential or not.
4. Consider a short introductory paragraph on why you are responding – do you support the FSA's plans to remove certain products of modern biotechnology from the scope of GM regulations? If not, what concerns you about the FSA's plans? How will it affect you or your business?
5. Try to address your points in the same order as they appear on the online form (see below).

6. The FSA consultation pack doesn't support the labelling of PBOs– we suggest, given that labelling is vital for consumer information and trust, for transparency and enforcement, that you talk about labelling anyway.

The FSA has produced a consultation pack with additional information. You may wish to read this before answering the consultation.

When you respond remember:

- Keep your comments focused on the FSA's/government's proposals.
- You don't have to answer every question. The online form allows you to make a short submission by just filing in the first page.
- The longer consultation only has 6 main questions but underneath each main question is a series of sub-questions. You can choose to answer only those questions where you have a strongly held view or particular expertise.
- Most of the questions follow a similar pattern: multiple choice (agree/disagree) followed by space for free text. You do not have to put anything in the free text boxes if you don't want to or don't feel confident to.
- We provide some more guidance below, but it is important to use your own words

Closing date for responses is **8 January 2024**.

Suggestions for answering the consultation questions

Questions 1 and 2

These questions cover the pre-market authorisation and 'triage' process which FSA proposes to adopt. This places genetically modified precision-bred organisms into one of two categories, or tiers. Once the Defra Secretary of State has accepted the self-certification statement of a biotech developer about a particular GMO/PBO:

- Tier 1 products go straight to market without any additional scrutiny
- Tier 2 products may require additional scrutiny but after this process can also go straight to market

It is proposed that neither tier 1 nor tier 2 GMO/PBOs will be labelled.

For **question 1**, the first three sub-questions (Q1a-1c) gauge how much you agree/disagree with the proposed two tier approach and tier one. There are then four sub-questions (Q1d-1g) which are free text. Some thoughts you may wish to consider here are:

- Changing from regulation to no regulation at all is not proportionate, especially since the safety profiles of these new GMOs have yet to be established.

- The FSA is an independent government agency, but it does not appear to have done any independent thinking about GMO/PBOs. Instead, it is following a highly contested government narrative that GMO/PBOs are the same as natural or traditionally bred plants and animals and that self-certification is appropriate and safe. Allowing the developers of GMO/PBOs to self-certify the status and safety of their own work is not a proper audit process and does not fulfil the FSA's mandate for "food you can trust".

- The FSA relies heavily on the 'independent scientific advice' of the Advisory Committee on Novel Foods and Processes (ACNFP). However, it is clear most ACNFP members have declared

commercial or institutional conflicts of interest, and this means that the Committee is not independent of industry. This might mean that where there is doubt, the benefit of that doubt will likely be for the developer rather than for precaution and safety.

- The main beneficiaries of this two-tiered approach are the developers who are being allowed to self-certify the status of their precision-bred organism. Whereas consumers and businesses that wish to or legally must (e.g. all organic businesses) remain GM-free do not benefit and the removal of labelling for GMO/PBO products means the FSA cannot fulfil its promise for "food that is what it says it is".
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Question 2 follows a similar format and asks for views on the tier 2 process.

The first four sub-questions (Q2a-Q2d) gauge how much you agree/disagree with the tier 2 approach. The next three questions (Q2e – Q2g) are free text. Some thoughts you may want to consider here are:

- The premise that precision-bred organisms are different from other GMOs is scientifically unsound and a poor basis for regulatory decisions. Precision-bred organisms are GMOs, as the Genetic Technology Act 2023 makes clear and as such they must be excluded form organic production. Precision breeding is a marketing term, not a scientific discipline, and these new GMOs carry all the same risks, uncertainties, and novel challenges of older style GMOs. If they are to be allowed onto the market, they should be fully regulated and labelled.

- The FSA has not produced or provided any research or estimate of what percentage of GMO/PBOs will fall into each category. Independent estimates suggest that upwards of 94% of GMO/PBOs will fall into the tier 1 category, and therefore enter the market unlabelled and untraceable.
- The cost of Tier 2 assessment doesn't appear to have been included in the estimate of costs stated in the information pack.
- The description of the proposed pre-market audit process provided in the consultation pack is insufficient in detail to allow respondents to comment on whether it will be adequate in mechanism to assess compliance with the tier requirements.

Question 3

This question concerns the FSA's plans to create a public register held on a government website, as an alternative to on-product labelling.

The first sub-question (Q3a) gauges how much you agree/disagree with this approach. The next two questions (Q3b-Q3c) are free text. Some things you may wish to consider are:

- It is not clear if the proposed public register is separate from the register which Defra must create under other provisions in the Genetic Technologies act. The FSA should show and demonstrate independence by maintaining a separate register.

- It is not clear how user friendly the register will be – e.g. whether it will include the name of products that include GMO/PBOs or simply the variety of plant. It is entirely unclear how consumers are expected to use it to aid their food choices in supermarkets, restaurants and other food outlets.

- FSA consumer surveys have shown that most consumers would not use, or know to use, the register unless there is product labelling. Without being alerted to the presence of GMO/PBOs on a food label, there is no trigger to look for further information on a government website.

- A public register is not a substitute for product labelling. The public register does not adequately inform consumers of the nature of the food they may be buying. The FSA's own research has shown that without product labelling to alert consumers to the presence of GMO/PBOs in a food item, there is no reason for consumers to consult a register. This finding of the FSA consumer surveys was left out of the consultation information pack.

- Without labelling, businesses will find it difficult to avoid PBOs in their food supply and farmers will not be able to choose what they feed their animals.
- The consultation pack states that it is 'not appropriate for us to ask about mandatory labelling', referring to the lack of a specific provision for labelling in the Precision Breeding Act. However, there are also no provisions for not labelling in the Act i.e. labelling is not prohibited. Furthermore, the Act, contains a clause which enables regulations to modify the legislation. It is therefore appropriate for the consultation to allow respondents to state a preference for labelling given the clear preference for this option stated in prior FSA consultations (July 21 and March 23).

Question 4

This question looks at the traceability of GMO/PBOs in the food/feed system and gauges views on the proposal that these require no special traceability beyond what it already in place for non-GMO food/feed.

The first sub-question (Q4a) gauges how much you agree/disagree with this approach. The next three questions (Q4b-Q4d) are free text. Some things you may wish to consider are:

- The traceability provisions in general food law, known as 'one up/one down', are inadequate in an increasingly long and complex food chain. With one up/one down, traceability can be easily lost in commodity products that are blended (e.g. milk from multiple farms in a dairy) or dissected and mixed through the supply chain (e.g. animals for meat production). During product recall and food safety investigations, auditing via a one up/one down trail of records is slow and time consuming. This is a disadvantage if, for instance, a PBO were to cause widespread allergic reactions or toxic effects. It may also be beyond what many small and medium size businesses are able to implement. In addition, a consumer experiencing a reaction to a particular PBO food would not report it because there would nothing to alert them to the fact that this is a GMO/PBO. End-to-end traceability would be very difficult and potentially unreliable with the FSA's proposed system.
- Food fraud can present very real risks to consumer safety. Lack of traceability could significantly increase the risk of serious fraud in the food system. The National Food Crime Agency recently reported to the FSA that they have a large number of criminal cases to work through and are currently at capacity. This suggests food fraud is a significant issue that requires sufficient resource and a robust framework if the FSA wish to combat such criminal activity.

- The FSA says there is a lack of evidence that PBOs are intrinsically riskier to consumers. The absence of evidence is not the same thing as proof of safety and this deviates from the precautionary approach that is generally applied in food safety matters. PBOs are so new that there is no evidence at all on their safety or risks. The precautionary principle should continue to apply to regulation of GMO/PBOs.

- The FSA recently commissioned a literature review on detectability of GMO/PBOs. The Government narrative is that GMO/PBOs are identical to traditionally bred and/or naturally occurring organisms and therefore cannot be detected. The literature review disagreed with this and concluded that the scientific literature shows that detection methods do exist, that they can be developed further, and that detection is a cornerstone of traceability and necessary to

support enforcement. The FSA appears to be rejecting the conclusion of its own literature review in favour of the deregulatory agenda and is not 'following the science' on this issue.

Question 5

This question considers enforcement. The FSA is proposing that Local Authorities and Port Health Authorities in England should be responsible for enforcement (they are already responsible for enforcement where GMOs are concerned). No special or new power for criminal prosecutions is being proposed.

The first three sub-questions (Q5a-Q5c) gauge how much you agree/disagree with this approach. The next four sub-questions (Q5d-Q5g) are free text. Things you may wish to consider are:

- What the FSA is proposing is essentially the maintenance of the status quo since it is already the duty of local authorities and port health authorities to enforce existing GMO regulations. How can these authorities do their job if the products are not labelled and if traceability is limited to insufficient one up/one down systems?

Question 6

This question considers the wider impact of deregulation of GMO/PBOs.

The first six questions (Q6a-Q6f) gauge how much you agree/disagree with this approach. The last question (Q6g) is free text. Things you may wish to consider are:

- The consultation pack says quite clearly that FSA has not performed a full impact assessment on the impacts of deregulation.

- The only impacts the FSA recognises is the inconvenience caused – to 75 plant breeding businesses, 346 Local Authorities and 37 Port Health Authorities – by the few hours it will take to read the new regulations.

- Familiarisation with the new rules is not the only impact of deregulation. When contamination occurs or a food product is recalled due to a safety concern, for example, it can result in significant economic losses for everyone involved in the supply chain, including farmers, processors, distributors and retailers. In its consideration of impacts, the FSA has ignored:

    - The implications for 'traditional breeders and organic sector' are not adequately addressed in these proposals. The supply of non-GMO/PBO food and feed isn't a matter of choice for organic businesses as implied in the consultation pack. The assumptions and estimates in the document give no consideration to the extra costs and burdens that will have to be borne by the organic sector.
    - Impacts on trade, especially where UK regulations differ from those of trade partners.
    - Consumer's right to know what they are eating and their ability to judge this at any point of sale.
    - The cost and economic losses associated with a product recall if a GMO/PBO causes a toxic or allergic reaction.

- In place of a full and thorough impact assessment, FSA has chosen to rely upon the information in an earlier Defra Impact Assessment which was published with the draft Genetic Technology Bill. This impact assessment was found to be "not fit for purpose" by the government's Regulatory Policy Committee because it:

- Did not adequately consider and discuss the full range of potential impacts arising from the creation of a new sub-category of GMO.
- Did not sufficiently considered and discussed the full range of impacts on small- and medium-sized businesses.
- Needed to explain more clearly how the introduction of a new sub-category will not undermine the stated policy intention of reduced regulatory burden.
- Needed to include greater discussion of the impacts arising from labelling and traceability.
- Needed to revisit the assumption relating to the devolved administrations (DAs) and what impact this will have on them across the various scenarios.
- Failed to include a detailed assessment of the competition, innovation, consumer and environmental impacts.

End