All-Party Parliamentary Group on Science and Technology in Agriculture

Food Standards Agency consultation on proposals for a new framework in England for the regulation of precision bred organisms used for food and animal feed

Submission by the All-Party Parliamentary Group on Science & Technology in Agriculture (APPGSTA)

Introduction

The All-Party Parliamentary Group on Science and Technology in Agriculture welcomes the opportunity to contribute to this consultation, which marks an important next step towards a more streamlined regulatory approval process for food and feed products developed using precision breeding techniques such as gene editing.

The All-Party Group first led the way in calling for new precision breeding techniques such as gene editing to be removed from the scope of restrictive GMO rules inherited from the EU. A milestone was reached in March this year with the passing into law of the Genetic Technology (Precision Breeding) Act.

Properly implemented, the Act could pave the way for England to take a leading position in the research, development and commercialisation of precision bred products.

Importantly, this offers the potential to support and deliver on the Food Standards Agency's policy objectives for a healthier, safer and more sustainable food supply. Near-market precision breeding research currently at field trial stage, for example, includes innovations to improve nutrition (vitamin enriched tomatoes, Omega-3 enriched oilseeds), to make food safer (low-arparagine wheat), to reduce food waste (non-browning potato), and to reduce methane emissions in livestock production (high lipid barley).

Until relatively recently, there were serious concerns that the FSA was proposing to establish a regulatory process for precision bred food and feed products similar to that currently applied to GMOs and novel foods, potentially involving separate risk assessment, expert committee scrutiny, public consultation, approval in both Houses of Parliament and Secretary of State sign-off for each application.

Such a process would have been wholly disproportionate to the evidence of risk, and out of step with the regulatory approach already adopted in many countries around the world.

Many people within the scientific and breeding communities, as well as others including this APPG, worked hard to present evidence to the FSA regarding the overwhelming scientific consensus that the products of precision breeding pose no greater risks than products obtained through conventional breeding methods.

It is encouraging that the evidence presented to FSA scientists and officials has been acknowledged and is reflected in plans for a more simplified approach, which this APPG strongly supports.

The APPG also strongly supports the Food Standards Agency in differentiating between precision bred products and GMOs, and in clearly explaining why imposing separate labelling and traceability requirements for precision bred products would not only be disproportionate and discriminatory, but also unenforceable.

The simplified approach also mirrors proposals from the EU Commission in not requiring separate risk assessment, traceability or labelling of precision bred products where they are considered to be equivalent to their conventionally bred counterparts.

However, it is critical that the scientific evidence and underlying rationale of the Act that precision bred products pose no new or additional risks compared to conventionally bred is upheld in the detailed implementing rules, and that over-precautionary or 'just in case' information requirements are not introduced which might discriminate against PB products, or convey the impression to consumers that PB products should be treated differently, and may therefore constitute a greater risk in food safety terms.

As detailed in this submission, these concerns apply particularly to the basic information requirements associated with the Tier 1 notification process for PB plants, the scope and remit of the audit process to verify applicants' self-determination of tier status, the data requirements proposed for Tier 2 applications, and the starting assumption built into the FSA's plans that all PB animal products will automatically require a risk assessment and will therefore be classified as Tier 2.

We recognise that much of the detail behind these concerns remains to be clarified in the technical guidance yet to be published by the Food Standards Agency, but it is nevertheless critical to establish that statutory information required as part of the PB product approval process is proportionate to the evidence of risk, does not discriminate against PB products or give rise to unwarranted consumer perceptions of increased risk, and does not duplicate or extend requirements already addressed by existing practice and regulatory processes, for example plant variety registration and seeds marketing regulations in relation to food crops.

Consultation Questions: Pre-Market Authorisation Process

1) Triage and two-tiered system

Tier 1 PBOs: Developers will apply the ACNFP criteria to determine tier and notify the FSA of the PBO status. Tier 1 notification is acknowledged by the FSA. When the authorisation decision is taken by the Secretary of State, the FSA will communicate this to the developer and, if the decision is to authorise the PBO for food/feed, place it on the public register.

a) 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]

b) 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]

c) 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]

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

It appears reasonable to conduct an audit process to verify the self-determination of Tier 1 PBOs in practice and to ensure the technical guidance is relevant and fit-for-purpose.

However, to minimise uncertainty for developers, and to ensure the notification and audit process does not experience 'mission creep' given the scientific advice that a bespoke risk assessment is not necessary for Tier 1 PBOs, the scope and remit of the audit process must be clear, as must the value and purpose of the information requirements associated with the triage and notification process.

For example, basic (Model 1) information requirements range from factual descriptions of the nature and purpose of the genetic change, the intended uses and history of safe use of the species in question to much more 'open' questions such as a description of the measures taken to minimise off-target effects, or to check for antinutritional factors.

Without clear technical guidance, these potentially open-ended, risk assessment-type questions could attract widely differing responses from applicants in terms of the level of detail submitted, which in turn could set precedents or expectations which are disproportionate to any evidence of risk.

Given that Defra will have already assessed and confirmed that these products are PBOs, and therefore equivalent to conventionally bred products, FSA must explain the value and purpose of this information, particularly in relation to so-called 'off-target effects': firstly because the primary objective of the breeding process is to remove unwanted characteristics, and existing statutory requirements check that new varieties are genetically uniform and stable; secondly because these are potentially open-ended questions (it is not possible to prove a negative); and thirdly because no off-target effects identified could possibly be attributed to the precision breeding process, since natural mutations are happening all the time.

Greater clarity is also required in relation to the scope and remit of the pre-approval audits FSA is proposing to carry out to verify the self-determination of Tier 1 PBOs in practice and to ensure the technical guidance is relevant and fit-for-purpose. This must not lead to disproportionate burdens for developers through potentially open-ended requests for information more usually associated with a risk assessment process, and not currently required for conventionally bred crops or products.

Similarly, in relation to plants, it is important that information requested by FSA does not duplicate or extend requirements which are already covered by the plant breeding and variety registration process, for example screening for known antinutritional factors such as glycoalkaloids in potatoes or glucosinolate levels in oilseed rape.

Indeed, the FSA consultation document refers to existing General Food Law, but does not explicitly acknowledge the role of existing plant breeding and seeds regulations in providing an independent and transparent assurance of the quality and performance of each new agricultural crop variety.

FSA must also be mindful of the potential impact its statutory information requirements might have on public and consumer perceptions of risk in relation to PBOs, particularly if the information is intended to be included on a public register. The Agency must avoid giving the

impression that PB products may have a different risk profile, so need to be treated differently, however well-intentioned and keen it is to be seen to be providing reassurance to consumers.

In the interests of ensuring proportionality and non-discrimination, to future-proof the legislation, and to avoid giving the impression that PB products have a different risk profile so need to be treated differently, the All-Party Group therefore advises that the statutory information required in relation to Tier 1 PB products, and which could appear on the FSA public register, should comprise:

- Nature and purpose of the genetic change.
- Method(s) used to make the change.
- Identification of parts intended for use as food and feed and intended uses.
- History of safe use for food and feed of the relevant species.

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

Please see response to (d) above

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

Self-determination of PBO tier status based on a triage and notification procedure offers a proportionate approach to the marketing approval of PB products which have already been confirmed by Defra as PBOs and which therefore pose no greater risks than conventionally bred products.

The potential disbenefits can arise from uncertainties regarding the interpretation of the triage questions and potential 'gold plating' as described under (d), above

Similarly, greater clarity and certainty is also required in relation to the scope and remit of the pre-approval audits FSA is proposing to carry out to verify the self-determination of Tier 1 PBOs in practice and to ensure the technical guidance is relevant and fit-for-purpose. This must not lead to disproportionate burdens for developers through potentially open-ended requests for information more usually associated with a risk assessment process, and which are either already covered or not currently required for conventionally bred crops or products.

g) 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]

As described under (d) above, clear and unequivocal technical guidance is required in relation to the information requirements to be provided in support of Tier 1 notifications, to insure against 'mission creep' given the scientific advice that a separate risk assessment process is not necessary for Tier 1 PBOs.

Tier 2 PBOs: These would be subject to an application to the FSA, similar to other regulated products. Developers would apply the ACNFP criteria to determine tier. Developers with PBOs for use in food and feed falling within Tier 2 would be required to submit an application with the accompanying data described in ACNFP's Model 1. Applications would be subject to a

bespoke risk assessment and risk management process. When the authorisation decision is taken by the Secretary of State, the FSA will communicate this to the developer and, if the decision is to authorise the PBO for food/feed, place it on the public register.

a) 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]

b) 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]

c) 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]

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

Statutory validation of PBO status by Defra provides confirmation that a notified PBO could equally have been developed using traditional breeding methods.

Ant additional compositional/allegenicity/toxicological data requirements for Tier 2 PBO must be based on plausible hypothesis of risk, otherwise the proposed provisions for Tier 2 are sufficiently similar in principle to those currently applied to GMOs. Such an approach would make it uneconomic and impracticable to incorporate Tier 2 PBOs into mainstream breeding programmes.

This would result in a *de facto* ban on Tier 2 PBOs, which would not deliver on the FSA's policy objectives to enable innovation and reduce unnecessary burdens on developers.

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

Developers would be unlikely to invest in long-term breeding programmes for Tier 2 PBOs due to the uncertainties of risk assessment requirements that inherently impose higher safety and risk assessment standards for Tier 2 PBOs than for equivalent conventionally bred products.

Furthermore, the All-Party Group strongly challenges the proposal in 8.24 that all PB animal products will automatically require a risk assessment and there be classified as Tier 2. Given Government policy that precision bred traits could occur conventionally, and that Defra will have already notified the animals as PBOs, assessment of animal-derived PB food and feed products must be justified and based on robust evidence of risk in the same way as for plants. The link suggestion that consumers "wanted greater reassurance" for animals than for plants is spurious and potentially misleading. Seeking greater reassurance is not the same as wanting stricter regulation. Costs would be added with no benefit in terms of food safety and the policy objectives would not be met.

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]

The FSA's policy objectives to ensure precision bred products are regulated proportionately to risk, to support innovation in the food system which brings benefits to consumers, and to reduce unnecessary burden to developers, cannot be delivered without clear, science-based safety assessment guidelines that do not discriminate against precision bred products compared to conventionally bred.

Any additional safety assessment of Tier 2 PBOs must be based on a plausible scientific hypothesis of risk. Guidelines which clearly describe the required data for developers, and the scientific basis in terms of risk, are needed to reduce the potential for uncertainty, or differential interpretation by both applicants and regulators.

Consultation Questions: Public Register

The Act makes provision for the FSA to establish and maintain a public register which will provide details of PBOs authorised for use in food/feed.

a) 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]

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

A public register provides the transparency required to allow freedom of choice in supply chains, provided the information provided is factual and, as previously stated, does not convey the incorrect impression that PB products represent a greater risk than their conventionally bred equivalents.

In addition, the All-Party Group would draw attention to commitment by the British Society of Plant Breeders (BSPB) to maintain a public register of all precision-bred plant varieties approved for sale in the UK, so enabling choice and openness of information within the supply chain.

The BSPB register will complement the Defra and FSA registers of approved PBOs, enabling farmers and growers to identify which crop varieties have been developed using precision breeding techniques, and so providing the basis for producers and their supply chains to provide information in response to market and consumer demand.

c) 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]

Subject to the preceding observations, the proposal has the required elements for implementation.

Consultation Questions: Traceability

In relation to traceability the proposal is that no requirements beyond the existing traceability provisions in General Food Law which apply to all food and feed are necessary.

a) 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]

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

The proposed approach ensures that the provisions of general food law are applied equally to all products and therefore do not present unreasonable or unnecessary barriers to policy implementation, or the delivery of the overall policy objective of a proportionate and transparent regulatory system.

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

The benefits of the proposed approach lie in applying a proven system that is already in place, and no additional or disproportionate regulatory costs are incurred.

d) 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

In relation to crop-derived PB food and feed products, the consultation document fails to recognise the additional assurance provided by existing seeds marketing regulation, which already imposes full traceability on all plant reproductive materials, and therefore provides further justification for not adding new traceability requirements.

Consultation Questions Enforcement (England)
As part of the proposed regulatory framework for food/feed from PBOs, the FSA is proposing enforcement powers and tools for Local Authorities and Port Health Authorities ("enforcement authorities") in England. The Act does not allow for criminal sanctions beyond those available in existing food/feed law which may be used in respect of food/feed consisting or containing PBOs where appropriate.

a) 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]

b) 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]

c) 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]

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

Existing enforcement rules apply equally to all products and therefore do not introduce discrimination against PBOs or derived food and feed products.

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

Existing enforcement rules apply equally to all products and therefore do not introduce discrimination against PBOs or derived food and feed products.

e) What level(s) of monetary penalty do you think would be appropriate in respect of the "relevant breaches" outlined in the consultation document?

Making good for damage caused.

h) 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]

The proposal has all the elements required to implement the policy objectives.

Consultation Questions: Assessment of Impact
We have carried out an assessment of the impact arising from our proposals.

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

b) 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**]

c) 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**]

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

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

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

g) Please explain your reasons for your position [Free text]

While the All-Party Group is not in a position to validate implementation costs for official authorities, the cost estimates appear to be reasonably low which should be a guiding principle to ensure that the development of PBOs and derived food and feed products is not unfairly disadvantaged by regulation compared to the products of other plant breeding methods.

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