GeneWatch UK response to FSA consultation on proposals for a new framework in England for the regulation of precision bred organisms used for food and animal feed

December 2023

This consultation response is public. It relates to the FSA's consultation on published 8th November 2023 (deadline 8th January 2024).[1] It concerns the subset of genetically modified organisms (GMOs) known as precision bred organisms (PBOs) which are covered by the Genetic Technology (Precision Breeding) Act 2023 (referred to as the Act).[2]

Before answering the detailed questions, we first note five issues not adequately covered by the consultation, regarding labelling, testing, animals, the environment, and public consultation.

We conclude that the proposals in the consultation are inadequate to meet the FSA's legal obligations.

1. ISSUES NOT COVERED ADEQUATELY BY THE CONSULTATION

1.1 Labelling

There are no questions in the consultation regarding the need to label food and feed produced from PBOs for consumers. The FSA attempts to justify this in paragraphs 7.11 to 7.13 of its background document. Yet this decision is in conflict with its own consumer research, which led the FSA itself to note, "*Most consumers felt labelling should always inform the consumer of the presence of GE ingredients using the full term 'genome edited'*"[3] and "*Workshop participants felt very strongly that precision bred products should be labelled as precision bred. While existing mandatory labelling would inform consumers of any changes to the characteristics of the product, participants felt that this would not be sufficient on its own. They argued that being able to identify precision bred products via labelling is critical for transparency, and therefore to consumer choice and public trust*".[4] The latter study also reports survey results in which, "*Survey respondents agreed, with nearly four in five (77%) saying it would be important when buying a food item to know if it had been precision bred, and nearly half (45%) saying it would be 'very' important. Only one in six (15%) say knowing this would not be important*". The FSA states in the consultation document that one of its aims is to "*provide consumers with assurance via the new regulatory regime and maintain confidence in the food system*". Yet, this cannot happen without labelling.
GeneWatch UK strongly supports the need for consumer labelling of PBOs. Full traceability and labelling are essential to:

- **allow GM-free products (including organic products) to continue to be sold, and to allow UK food and feed products to be traded with countries where PBOs continue to be regulated as GMOs.**
- **Keep track of imported products, which could contain PBOs and end up in untraceable or unlabelled products that might also be exported on to other countries.**
- **Allow consumer choice and maintain consumer trust in the food chain.**
- **Allow products to be withdrawn if anything goes wrong.**

The FSA bases its claim that labelling in not required on a statement that "*there is no scientific evidence that PBOs are intrinsically more hazardous than traditionally bred organisms*" (para 7.11). This claim is taken from advice provided by the Advisory Committee on Novel Foods and Processes (ACNFP).[5,6,7] This is a highly selective citation of the ACNFP's advice, which fails to recognise scientific uncertainties and also ignores consumers' desire for thorough safety testing.[8]

The FSA also claims (para 7.11 and 7.13) that safety information can be provided for a specific group (e.g., hypersensitive consumers or people with certain health conditions) 'as with any food'. But this fails to explain how this would work when the change is in a crop (and its seeds), not in a factory-made ingredient. For example, peas and wheat with enhanced iron content have been proposed as potential products, yet these could be harmful to people with haemochromatosis. Such peas or wheat could end up anywhere in the food chain if traceability and labelling proposals are not significantly strengthened, leaving consumers unaware about potential hazards to their health.

1.2 Testing

A key component of traceability is the availability of tests which identify the PBO. Currently, manufacturers of GMOs are required to provide a unique identifier (UI) and a validated testing method for all GMOs, so that testing can be undertaken, e.g., of food products, shipments, crops in farmers' fields, or to monitor GMOs in the environment.

The issue of detection of PBOs is discussed by the FSA in paras 8.55 to 8.60. The FSA notes that detecting PBOs may be difficult "*without prior knowledge of the altered genome sequence and suitable reference materials*" (para 8.57) and that, "*Enforcement bodies would require sufficient intelligence to know what they were looking for, as screening for PBOs is not possible in the same way as it is for GMOs*" (para 8.59). Mysteriously, instead of requiring companies marketing PBOs to provide "*prior knowledge of the altered genome sequence and suitable reference materials*", it chooses not take forward the recommendations of the report it commissioned and fails to require such validated tests. This has major negative implications for international trade.

For example, if a PBO tomato is released with no validated test, all countries which require such organisms to be regulated could refuse all imports of food containing tomatoes from the UK, because food containing the unregulated product would not be identifiable. Although some countries are deregulating, or considering deregulating, some plants produced using gene editing techniques, such steps are not universal, definitions differ (so that at least some PBO plant products will continue to be regulated as GMOs elsewhere) and most countries have not included gene edited animals in deregulation proposals (meaning PBO animal products are not deregulated, or likely to be deregulated, elsewhere). In addition, many countries (including the EU) do not allow (and are not expected to allow) PBOs in organic food. This means there is considerable potential for significant damage to export markets if food and feed containing PBOs cannot be identified and traced. The lack of validated tests also has significant implications for exports from England to Scotland and Wales (which have not deregulated PBOs) and to Northern Ireland (where the Windsor Framework applies). Further, the lack of a requirement to supply a validated test undermines the claimed potential for voluntary labelling to meet consumer preferences (para 7.13).

It is essential that companies are required to supply a validated test to identify their products and that this is included in the public register. Companies will have these tests in-house because they use them during product development and for quality assurance and in order to protect their intellectual property (since PBOs are patentable).

1.3 Animals

The FSA's background document states (para 7.4) that the Act removes precision bred plants and *vertebrate* animals from requirements applicable to the environmental release and marketing of GMOs. This is incorrect because the Act exempts all PBO animals in the taxonomic group Metazoa, other than humans (or a human admixed embryo) from regulation as GMOs (Clause 2(2)). This means that most non-vertebrate multicellular PBO

animals will be exempt from GMO regulation, including some that are commonly consumed as foods, such as shellfish and others that may play a role in food production, such as agricultural pests or bees.

Much confusion has arisen because the Act defines an extra step (an animal marketing authorisation) that is required for vertebrate PBO animals only (Clause 10) and which considers the health and welfare of the animal. This step is not required for non-vertebrates but the implication that non-vertebrate PBOs are not being deregulated is false and risks seriously misleading stakeholders and members of the public responding to the consultation. Further, no consideration of the risks of releasing such PBOs into the environment or food chain appears to have been made in any of the documents accompanying the development of the Act or the proposed regulations in this consultation. This has major implications, for example, for the shellfish industry and the marine environment.[9]

In addition, whilst the FSA refers to those PBO animals which will require an animal marketing assessment (i.e., vertebrates) in para 8.24, there is no information provided about how human and animal health and the environment will be protected in relation to the release of such animals into the environment or their products (meat, milk, eggs, fish, shellfish) into the food chain. The animal welfare assessment as envisaged in the Act does not cover the FSA's obligations under Part 3 of the Act (covering Food and Feed from Precision Bred Organisms). **If the FSA intends the consultation proposals to apply only to plant PBOs, it should state this explicitly in the consultation. If not, it should provide substantially more evidence that it has considered the potential hazards posed by animal PBOs, both vertebrates and non-vertebrates, and make this information and its specific proposals regarding both vertebrate and non-vertebrate animals available for consultation. In addition, the FSA must consider the serious negative impacts on trade of allowing unregulated PBO animal foods on the market, when these have not been deregulated (or proposed for deregulation) in other countries (including the EU).**

1.4 Environment

In addition to protecting human and animal health, regulations made under Part 3 of the Act should secure that "*the production of such food and feed will not have adverse effects on the environment*" (Clause 26(3)(b)(iii)). In paragraph 8.40 of the consultation document the FSA states that secondary legislation will stipulate that "*the production of the food/feed will not have adverse effects on the environment*". The Secretary of State declared on the face of the Bill that "*the Bill will not have the effect of reducing the level of environmental protection provided for by any existing environmental law*" (an Environmental Statement under Section 20(3) of the Environment Act 2012). The FSA's own risk analysis process (cited in para 8.28) states that environmental impacts are considered in both risk assessment and risk management. Yet, there is no information in the proposals regarding how this will be achieved.

There are a number of important legal obligations in this respect, including:

- UK environmental laws, including the Environment Act 2012, and associated environmental principles (environmental protection should be integrated into the making of policies; preventative action should avert environmental damage; the precautionary principle; environmental damage should as a priority be rectified at source, and the polluter pays principle)[10];
- The Cartagena Protocol on Biosafety (CPB) to the Convention on Biological Diversity, which includes requirements for living modified organisms (LMOs, which are living GMOs), including risk assessments and notifications when living GMOs are deliberately or unintentionally moved across borders.[11] PBOs fall within the definition of an LMO.[12]

- The EU-UK Trade and Co-operation Agreement (TCA)[13] which includes non-regression provisions to ensure that environmental protections are not reduced below the levels at the end of the transition period if that would affect trade or investment.

The FSA has based its proposals on a statement that "*there is no scientific evidence that PBOs are intrinsically more hazardous than traditionally bred organisms*" (para 7.11). This claim is taken from advice provided by the Advisory Committee on Novel Foods and Processes (ACNFP).[14,15,16] This is a highly selective citation of the ACNFP's advice which also states, "*Members commented that identifying potential food and feed safety risks associated with use of modern biotechnologies now and in the future is difficult...*".[17] Moreover, the ACNFP's remit is only to consider whether food is safe to eat, does not mislead the consumer and does not put consumers at a nutritional disadvantage. No consideration of environmental hazards or any legal requirements in relation to protection of the environment was involved at any stage. Reliance on the term "*there is no scientific evidence*" is not consistent with the precautionary principle in relation to the environment (a legal obligation). Further, the reference to "*inherent*" risk undermines the need to consider the interactions between a PBO and its environment: for example, the adverse effects of the increased use of herbicides which are likely to result from the blanket spraying of herbicide-tolerant PBO crops.[18] Other examples are provided in GeneWatch UK's submission to Defra's consultation on deregulation in 2021.[19]

It should also be noted that what might be considered environmental risks may also have impacts on food safety. For example, the risk that a virus evolves to overcome genetically engineered resistance in a GM animal (perhaps becoming more transmissible or virulent), or that some animals become infected but not sick (potentially creating a reservoir of infection that increases the transmission of disease) are required to be considered in current environmental risk assessments for GM disease-resistant animals.[20,21] Similar risks may arise with disease-resistant PBOs but appear to fall outside the scope of the proposed risk assessment process because environmental processes (in this case, the evolution of a pathogen in response to the release of the PBO) have been neglected.

In addition, under the provisions in the Act, PBOs not marketed as food or feed (such as PBO insects, fish or trees) could be released and might inadvertently contaminate the food chain. The FSA is silent on its role in such a situation.

Environmental monitoring is also an essential component of any system to detect any unexpected adverse effects.

The FSA's proposals are wholly inadequate in relation to ensuring that the production of PBO food/feed will not have adverse effects on the environment. The proposals do not meet the required legal obligations.

1.5 Public consultation

The FSA's proposed process removes the current requirement for GMO risk assessments to be published and subject to public consultation. Clause 26(6) of the Act makes provision for the FSA to include consultation processes as part of the regulations, but no such provision has been made. **The FSA has failed to provide any rationale for removing any public consultation from the process. Consultation is essential to ensure no hazards are missed and the public can have confidence in the robustness of the risk assessments.**

2. RESPONSES TO CONSULTATION QUESTIONS

2.1 Consultation question: 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 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 disagree**
c. *To what extent do you agree or disagree that the proposal for Tier 1 notifications is feasible?* **Strongly disagree**
d. *Please provide details of your thoughts towards the initial audit process for Tier 1 PBOs*
e. *Please provide details of any barriers that may exist which are preventing the policy objective being met or the proposal being implemented*
In the FSA's own consumer research, "*Participants were very clear in their desire for thorough safety testing of all new precision bred products. They wanted to know that risk assessments would have high standards and require strong evidence and that the FSA's work to regulate precision bred foods would be adequately funded so that consumers can trust that the processes are followed thoroughly*". [22] Yet, these proposals allow selected ('Tier 1') PBOs to bypass any safety testing. This is not consistent with the FSA's legal obligations to protect the food chain and the environment.
f. *Please provide details of what you think the benefits and disbenefits of this approach are*
The disbenefits are:

- Failure to protect the food chain and avoid environmental harms. Risk assessments (for food safety and environment) must be required for all PBOs in order to meet the FSA's stated aims and its legal obligations in this respect.
- The proposal to exempt 'Tier 1 PBOs' from risk assessments does not meet the needs and expectations of consumers as stated in the FSA's own research.
- Failure to conduct adequate risk assessments is likely to lead to harm to trade, due to inability to meet the legal requirements of other countries.

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]
Tier 1 should be dropped, so all PBOs go through a thorough risk assessment process for both food safety and environmental impacts.

2. *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**
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 disagree**
c. *To what extent do you agree or disagree that the proposal for Tier 2 applications is feasible?* Neutral. More work is needed (see f).

d. *Please provide details of any barriers that may exist which are preventing the policy objective being met or the proposals being implemented*
The risk assessment proposal is inadequate to meet the FSA's objectives and legal obligations (see f).
e. *Please provide details of what you think the benefits and disbenefits of this approach are*
- The proposal for limited risk assessments does not meet the needs and expectations of consumers as stated in the FSA's own research and is inadequate to meet the FSA's stated aims and legal obligations.
- Failure to conduct adequate risk assessments is likely to lead to harm to trade, due to inability to meet the legal requirements of other countries.

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

Although the consultation refers to "*unintended alteration of the organism's genetic material (so-called 'off-target effects')*" (para 8.14), it ignores additional problems that may occur through potential 'on-target' effects, which must also be included in any risk assessment.[23]
Environmental risk assessment (including all the relevant legal requirements) must also be included (as discussed in Section 1.4), and consulted on.
The FSA must clarify whether PBO animals (including vertebrates and non-vertebrates, such as insects and shellfish) are intended to be covered by this process and, if so, consider relevant evidence relating to health and environmental risks and issue a full public consultation in which these matters are considered (see Section 1.3).
Indirect and long-term effects must be included in any risk assessment, such as the risks associated with blanket spraying of herbicides on herbicide-tolerant crops, or the risk of evolution of pathogens in response to disease-resistant crops or animals.[24]
The process of risk assessment and risk management must include public consultation (see Section 1.5).

2.2 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?* **Disagree**. We support the existence of a register but disagree about its content (see c.).
b. *Please provide details of what you think the benefits and disbenefits of this approach are*

The failure to include a requirement for developers to provide a validated test has numerous disbenefits discussed above (see Section 1.2). The lack of risk assessments for Tier 1 PBOs and limited risk assessments for tier 2 PBOs mean that insufficient information will be included in the register to meet the FSA's aims and legal obligations.

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.*

The register must include a validated test provided by the developer, risk assessments for all PBOs (not just Tier 1) and these should be more comprehensive (particularly in relation to environmental risks, which have largely been ignored).

2.3 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 disagree**
b. *Please provide details of any barriers that may exist which are preventing the policy objective being met or the proposal being implemented*

At minimum, there should be a requirement for the developer to supply a validated testing method to be included in the public register (see Section 1.2), and for products to be labelled for consumers (see Section 1.1).

c. *Please provide details of what you think the benefits and disbenefits of this approach are*

Traceability and labelling are essential and the weakness of the proposals in this respect could lead to:

- Major loss of public trust in the integrity of the food chain;
- Major loss of markets for conventional and organic food, including any food from which the absence of PBOs allowed on the English market cannot be adequately demonstrated;
- Major cross-border friction with Scotland, Wales and Northern Ireland due to difficulties identifying which products meet legal requirements;
- Harm to human and/or animal health and/or the environment, due to difficulties tracking, identifying and recalling products should anything go wrong.

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.*

At minimum, there should be a requirement for the developer to supply a validated testing method (to be included in the public register), and for products to be labelled for consumers (as noted above).

2.4 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 disagree**
b. *To what extent do you agree or disagree that the elements of the proposed enforcement regime are practical and deliverable?* **Strongly disagree**
c. *To what extent do you agree that this proposal meets your need as a stakeholder?*

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*

Lack of a requirement for developers to provide a validated test, and lack of labelling, both seriously hamper the process of enforcement. Lack of environmental monitoring is also a major concern.

e. *Please provide details of what you think the benefits and disbenefits of this approach are*

Poor enforcement has the same downsides as inadequate traceability and labelling:

- Major loss of public trust in the integrity of the food chain;
- Major loss of markets for conventional and organic food, including any food from which the absence of PBOs allowed on the English market cannot be adequately demonstrated;
- Major cross-border friction with Scotland, Wales and Northern Ireland due to difficulties identifying which products meet legal requirements;
- Harm to human and/or animal health and/or the environment, due to difficulties tracking, identifying and recalling products should anything go wrong.

f. *What level(s) of monetary penalty do you think would be appropriate in respect of the 'relevant breaches' outlined in the consultation document?*

Monetary penalties must be sufficient to deter major negative impacts on trade caused by contamination incidents, which can run to billions of dollars.[25]

g. *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.*

The major omissions have been noted elsewhere in this response: labelling, validated tests and thorough health and environmental risk assessments (with public consultation).

2.5 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? 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?* Don't know
c. *Do you agree with the assumptions and estimates used to calculate one-off training cost to Local Authorities in England?* Don't know
d. *Do you agree with the impacts that the FSA has identified within this consultation?* No
e. *Are you aware of any impacts of the proposed new regulatory framework that the FSA has not identified in this consultation?* Yes
f. *Do you agree with the wider impacts identified in this consultation?* No
g. *Please explain your reasons for your position*

The impact assessment has completely ignored the following costs:

- Costs to food/feed businesses of major 'contamination incidents', leading to rejection of food/feed containing PBOs (or not proven to be PBO-free) from other countries' markets.
- Costs to food/feed businesses of taking additional voluntary steps to protect markets (such as additional segregation, testing and labelling) in order to meet consumer preferences and/or meet the requirements of markets in other countries.
- Costs to consumers of increased food prices resulting from both the above (contamination and/or additional steps needed to prevent contamination).
- Costs of environmental damage due to the failure to implement the environmental principles required by law (as outlined above).
- Legal costs associated with the lack of clarity over who would be liable for food safety incidents, environmental damage, or the economic risks of contamination.

Evidence regarding the potential magnitude of some of these costs is available in GeneWatch UK's submission to Defra's consultation on deregulation: the cost of contamination incidents, for example, can run to billions of dollars.[26]

Some of these risks could be mitigated if the FSA changed its proposals to include full food safety and environmental risk assessments and proper traceability and labelling requirements.

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