Genetic Technology (Precision Breeding)

FSA 23-09-04 - This paper outlines proposals for the regulation in England of Precision Bred Organisms for use in food and feed.

1. Summary

1.1 This paper invites the Board to discuss proposals for the regulation in England of Precision Bred Organisms for use in food and feed and confirm the preferred approach, which will be subject to public consultation.

1.2 The UK Government's Genetic Technology (Precision Breeding) Bill has now achieved Royal Assent and been confirmed as an act of Parliament (the Act). The Act contains powers for the Secretary of State to make Regulations making provision for regulating the placing on the market of food and feed produced from Precision Bred Organisms (PBOs) in England. This paper presents our detailed proposals and asks the Board to:

- **Decide** the preferred model for data requirements as part of the application and authorisation process;
- **Decide** the preferred option for implementation of the pre-market assessment process and legal route to authorisation;
- **Agree** the approach to provide an enhanced register of PBOs authorised for use in food/feed;
- **Agree** the proposals for enforcement and traceability; and,
- **Note** the implications of the UK Internal Market Act (2020) and the Windsor Framework.

1.3 Secondary legislation following the Precision Breeding Act is expected to be laid in summer 2024 and to come into force by the end of the year. Department of Health and Social Care (DHSC) Ministers have agreed to streamline the legislative process and deliver one joint package of Statutory Instruments (SIs), with the Department of Environment, Food, and Rural Affairs (Defra) as the lead Department.

1.4 Following the Board's confirmation of the preferred approach, the FSA will advise Ministers of the detailed proposals and, if supported, the proposals are likely to be subject to collective agreement from relevant Departments and Cabinet Committees before formal public consultation in Autumn 2023. That consultation will inform the final design of the regulatory approach.

2. Understanding and Managing Potential Safety Risk

2.1 Current scientific evidence suggests that PBOs present no additional risk when compared to traditionally bred organisms (TBOs) (footnote 1). This could justify the implementation of a fully deregulatory approach, with no assessment process or register. However, we appreciate that this technology has only recently been developed. Whilst we believe that the risk posed by PBOs is low, we think that a degree of regulation is necessary, on a precautionary basis. This will enable us to establish and maintain knowledge on what PBOs are being developed for use in food and feed. If issues arose following the implementation of the regulatory framework, which we consider to be a very low probability, then we would have a mechanism, via the register and our

relationship with the companies developing the organisms, to address it.

Independent Scientific Advice

2.2 The FSA commissioned independent scientific advice from the Advisory Committee for Novel Foods and Processes (ACNFP) to inform our approach to understanding and managing the potential safety risk from PBOs in food and feed. ACNFP advice has stated that it has seen 'no evidence that PBOs are intrinsically more hazardous than traditionally bred organisms (TBOs)' (footnote 2). However, it is recognised that a range of outcomes is possible from this rapidly developing technology. These justify scrutiny to ensure that risks are identified and effectively managed.

2.3 The starting point for the PB regulatory regime is the protections afforded in General Food Law, which already provide the basis for regulating TBOs. In this context, we have also considered whether all PBOs should be treated in the same way as TBOs, with no additional pre-market authorisation required. This would mean that after the determination of PBO status by Defra, no further regulation for use in food and feed would be required. However, taking into account the ACNFP advice that PB technology is rapidly evolving and consumer interest in the potential benefits and risks of PB, we agree that a pre-market assessment is an important safeguard. The subsequent decision to be made is how much additional safety assurance is needed to authorise PBOs.

2.4 ACNFP have provided advice for understanding and managing safety risk based on a system where PBOs are divided into two groups:

- **Tier 1:** PBOs that are very similar to traditionally bred varieties, which consumers are familiar with and for which potential safety risks are understood. There would be a simpler route to market.
- **Tier 2:** PBOs with traits where the risks are not fully understood. Specifically, this would include novelty or PBOs that have compositional changes which could affect toxicity or allergenicity, or other safety concerns where potential food and feed safety risks need further consideration. There would be a bespoke safety assessment process, including a more detailed examination of the characteristics of the PBO.

2.5 ACNFP have considered the data requirements by which PBOs could be placed in Tier 1 or Tier 2 and have proposed two models for consideration:

Model 1: Largely descriptive assessment of safety risks associated with the intended genetic change, requiring initial data to ensure the intended compositional changes, where relevant to the quality or safety of food/feed, have been achieved.

Model 2: In addition to the information and data required in Model 1, data would also be required to determine whether the intended change has introduced any further changes.

These differ in the breadth of evidence required. A summary of the two models put forward for consideration by the Board, is found in Annex 1.

Other Policy Considerations

2.6 In developing policy options for the pre-market authorisation of PBOs for use in food and feed, FSA officials have considered a range of other factors in addition to the safety advice from ACNFP:

- consumer research conducted by the FSA; showing that consumers felt the benefits of PB outweighed the risks if PBOs were properly regulated, and that they trust the FSA as a regulator (footnote 3).

- that PBO status will be confirmed by Defra SoS following advice from the Advisory Committee on Release to the Environment, with a register kept of all confirmed PBOs.
- views provided by industry representatives, trade bodies, academic institutions, and consumer bodies in England, Wales, and Northern Ireland. Industry put forward compelling arguments for a high level of deregulation while other stakeholders encouraged more caution.
- the wider regulatory context, in particular the protections in General Food Law (footnote 4) which place responsibility on food businesses to make sure that food and feed is safe, that claims made about food do not mislead consumers, and that businesses are required to put in place appropriate traceability assurance.
- implementation issues, including potential direct and indirect costs for consumers, industry, enforcement officers, and the regulator, and the need for any new system of regulation to be future-proofed.
- international approaches to the regulation of organisms within the scope of PB, both those currently in force and working proposals, which highlight the spectrum of regulatory approaches; this spectrum ranges from countries that have yet to state their intent to adopt new regulations, to countries which have proposed or implemented more deregulatory approaches, such as the EU and Canada respectively.

2.7 The FSA wants a proportionate system that allows consumers and industry to realise the benefits of PB as a technology, while also taking account of the fact that there may be potential risks. These techniques are being used to create varieties of plants that have the potential to contribute to healthier and more sustainable diets, including fruits and vegetables that are higher in nutrients or more palatable, and crops that are less input intensive or more tolerant of extreme weather.

Recommendation

2.8 Taking all these factors into account and the Board's previous steers, **we recommend a two-tier regulatory approach to understanding and managing risk using the data requirements in ACNFP Model 1 for Tier determination.**

Rationale

2.9 We are satisfied that the data requirements in Model 1 are sufficient to provide assurance that risk has been appropriately considered, and we do not consider it proportionate to mandate all developers to produce and maintain all the additional evidence, as required with Model 2, to support the Tier determination. Additional data requirements for the triage process may become a barrier to entry for developers, in particular for small to medium enterprises, and prevent benefits being realised for consumers. Only PBOs meeting the specific criteria defined by ACNFP would be placed in Tier 2 for additional scrutiny, where there may be additional safety risks and it is appropriate to do a bespoke safety assessment. In these cases, additional data would be requested to facilitate the assessment before authorisation can proceed.

2.10 The Board is asked to decide between the ACNFP's Model 1 and Model 2 for the data requirements for triaging PBOs.

3. The Legal Process Through Which PB Food and Feed Can Lawfully Be Placed On the Market In England

3.1 We have next considered the process for authorisation. As part of our ongoing work on wider regulatory reform, the FSA is considering streamlining the regulated products authorisation process. This is because some regimes are seen as disproportionately burdensome on applicants and the regulator. In designing our proposed approach to authorisation of PBOs, we have been

mindful of the lessons learned from this work. The regulator has a duty to taxpayers and must consider the trade-offs of using resource for this rather than for other priorities. Trade-offs can be made when it is possible to do so without compromising consumers' safety.

Recommendation

3.2 We recommend that industry has legal responsibility for undertaking initial triage and determining whether a PBO is Tier 1 or Tier 2. The FSA would undertake a risk assessment only for Tier 2 products.

Rationale

3.3 As before, our starting point is the protection afforded by General Food Law and the existing responsibilities for food businesses engaged in developing new varieties to understand and apply the regulatory requirements. The recommended approach is analogous to other regulated product regimes, such as Novel Foods, where industry must use clear criteria to establish if there is a regulatory route they must adhere to, and whether their product requires pre-market risk assessment.

3.4 After a PBO determination by ACRE, industry would apply the ACNFP criteria and only those products submitted to the FSA as Tier 2 would undergo a detailed risk assessment. As noted by ACNFP, PBOs are expected to be similar in risk profile to their traditionally bred counterparts, for which potential safety risks have to date been accepted by default. Tier 2 will afford additional protections for consumers as it will allow bespoke additional risk assessment of novel products. On the other hand, Tier 1 PBOs, which are sufficiently similar to traditionally bred varieties so as not to be a concern for consumers as their potential safety risks are understood, do not warrant bespoke risk assessments.

3.5 A secondary consideration is that a system requiring the FSA to individually assess every PBO for use in food and feed would, over time, require growing resources to administer for industry and for the FSA, adding significant delay and costs which would ultimately reduce benefits to consumers.

Implementation options

3.6 If the principle of industry responsibility for initial triage is accepted, we have considered three options for processing Tier 1 applications.

- **Exemption**: If the applicant determines the PBO to be appropriate for Tier 1, no further action is required, and the product could proceed straight to market.
- **Notification**: Applicants are legally required to notify the FSA about a Tier 1 determination. The FSA would then acknowledge receipt of the notification and confirm that the PBO can lawfully be placed on the market for use in food and feed.
- **Review**: Applicants are legally required to notify the FSA about a Tier 1 determination and provide supporting information. The FSA would perform a check (not a full safety assessment) to confirm that the guidance had been followed and the correct Tier determination made, before confirming that the PBO can lawfully be placed on the market for use in food and feed.

Recommendation

3.7 **On balance, we recommend that notification for Tier 1 products is the most appropriate option**, providing stronger assurance that regulations were being followed and supporting our previous commitment to publish a public register of all PBOs lawfully placed on the market for use in food and feed.

Rationale

3.8 It would be possible to require food businesses to notify us in a timely manner about PBO Tier 1 organisms for inclusion on a register and for this not to be linked to authorisation, but Ministers and the FSA have publicly committed to a register of all PBOs authorised for use in food/feed and making notification a legal step to authorisation would strengthen the credibility and integrity of the public register.

3.9 Given the Board's previous agreement that proportionality is one of their key principles, more burdensome and onerous options are not recommended and have not been drawn up in detail. Once the Board has reached a decision, we intend to explore with Defra the options for ensuring that the joint process of application to Defra and to the FSA is as efficient as possible.

3.10 **In all options, subject to there being additional resource available, an audit process could be established.** This would allow the FSA to monitor the effectiveness of guidance in helping applicants determine tier status, help us understand if any changes should be made to the regulatory framework or associated guidance, and act to deter developers from non-compliance, which would trigger penalties. We can undertake further work on this depending on the Board's steer about the preferred approach.

International approaches

3.11 The European Commission has recently announced proposals (footnote 5) for a decrease in regulatory requirements for plants produced from New Genomic Techniques, compared with current requirements under Genetically Modified Organism legislation. The proposals are for a notification-based system; for Category 1, there will not be any risk assessment, authorisation, additional traceability, or labelling of food or feed products. It is important to note that both Tier 1 and Tier 2 PBOs could fall under Category 1 and would therefore be treated as conventionally bred organisms. Category 1 products may require no further regulation, or they could be subject to other existing food regulations, such as novel food law. We expect the EU to have data requirements for their notification system. In Canada, there is no legal requirement for pre-market authorisation, but developers are encouraged to voluntarily notify Health Canada and a register (footnote 6) of those doing so is maintained. Those notifying can use whatever data is necessary to support their determination. Whilst the notification option we are recommending is more regulatory than some international comparators, the FSA is committed to considering the interests of consumers and our proposal reflects the feedback we have received from them, for example with regard to the register.

Decision-making and Coming-Into-Force

3.12 The process of incorporating EU Law into domestic legislation has added several additional steps to the authorisation process that were not present when the UK was a Member of the European Union. This includes a requirement for Ministers to make individual decisions on all authorisations and for these to come into force through secondary legislation, which may not be proportionate for PBOs.

3.13 A more streamlined process where some or all PB authorisations would not be made by individual secondary legislation, with authorisation taking place through an administrative process could significantly reduce the authorisation timeline, compared to other regulated product authorisations. **We intend to explore the options for streamlined decision-making with Ministers when providing our advice on the authorisation process.**

3.14 The Board is asked to **decide** whether industry should be legally responsible for completing triage and how this should be implemented, noting that Notification is our recommended option.

4. Maintaining Consumer Confidence In the Food System

4.1 The Board has previously discussed the importance of ensuring that consumers have the right information about PBOs to maintain confidence in the food system and to be able to make informed choices about the food they buy. The UK Government has confirmed there are no plans to require labelling of products on the basis that they have been produced using PB techniques; this policy is the responsibility of Defra in England. However, food businesses will be able to provide relevant information to consumers to inform purchasing decisions.

4.2 FSA will continue to make full use of safety labelling where it is appropriate for particular consumers. In the case of PBOs, this might include, for example, information about changes in allergens or information for people with certain health conditions.

Recommendation

4.3 Our consumer research indicated that visible regulation of PBOs used in food/feed would help ensure consumer confidence, and the proposal of a public register was welcomed. **We intend to provide an enhanced register that will go further than the basic information required by industry and enforcement officers and will include information requested by consumers** such as the purpose of the edit and any relevant safety assessment. More details about the proposed public register are in Annex 2.

Rationale

4.4 We have ruled out a register of individual consumer products that contain PBOs as the resources required to provide this would be disproportionate to the benefits. It would incur significant costs for businesses and for the FSA and, given the dynamic nature of modern food production, the register would be very difficult to keep up-to-date, undermining transparency and reducing consumer confidence, rather than promoting it.

4.5 If the Exemption option is chosen (as outlined in para 3.3 above) and developers are not required to notify the FSA about Tier 1 determinations, it would be difficult for the FSA to ensure all Tier 1 products are included on the public register. In this case, it may be more appropriate to focus the register on Tier 2 products, which had been identified as requiring more scrutiny. Consumers would be able to access the ACRE and the planned British Society of Plant Breeders registers containing details of all PBOs. However, a more limited register may not meet consumer expectations and could risk undermining trust in regulation. This potential approach would need to be carefully tested during public consultation.

4.6 The Board is asked to **agree** that the public register outlined in para 4.3 and Annex 2, which includes data fields specifically requested by consumers, provides sufficient information to meet consumers' needs.

5. UK Internal Market Act, Windsor Framework and International Trade

5.1 We have previously advised the Board about the implications of the UK Internal Market Act (UKIMA), where products lawfully produced in one part of the UK can be placed on sale in another. We have now considered the implications of the Windsor Framework, which establishes a new way to move prepacked goods from Great Britain (England, Scotland, and Wales) into Northern Ireland, known as the Northern Ireland Retail Movement Scheme, planned from 1 October 2023, and our basic position has not changed.

5.2 UK public health and consumer protection standards will apply for all retail food and drink moving to Northern Ireland through the scheme. PB food and feed legally on the market in GB will be able to move from GB into NI via the scheme's green lane; this aims to ensure that consumers in Northern Ireland will have access to the same goods as the rest of the UK. The UK Government has published guidance setting out further details on the Northern Ireland Retail Movement Scheme. (footnote 7)

5.3 Pre-packed retail goods moved from GB into NI, which are destined to move onwards into the EU single market, will need to enter via the red lane and continue to meet all EU rules. NI will continue to have unfettered market access to GB.

5.4 The UKIMAcontinues to operate as described in the MarchBoard paper. Under the UKIMA market access principles, PBO food and feed authorised in England (produced in or imported into England) can be sold lawfully in Wales and Scotland. The scope of the UKIMA does not, however, extend to processing after sale. If the PBO is subject to a final significant and regulated production step in Scotland or Wales, under UKIMA it would be considered to be produced in that nation and relevant domestic regulations would apply. In this scenario, currently, the final product can only be placed on the local market if it is authorised as a genetically modified organism (GMO) in that nation and satisfies the conditions of authorisation applicable to its placing on the market.

5.5 Imports, including from the EU, must meet relevant GB standards to be lawfully placed on our market. PBOs from other countries must meet the regulatory requirements for PB food/feed when imported into England. Goods imported directly into Wales or Scotland would need to comply with relevant legislation in those countries (currently GMO regulations apply). Imports of food from third countries directly into NI must continue to meet EU rules. Food exported from the UK to third countries will need to continue to meet the rules of that third country.

5.6 We have previously advised the Board that we do not propose to impose additional traceability requirements for PB food and feed above that in place in General Food Law. FBOs must be able to identify their immediate suppliers as well as the businesses to which their products are supplied (a "one up, one down" approach). This information must be provided to competent authorities, if requested. We have reviewed this in the light of the Windsor Framework, and we are content that no additional requirements are needed.

5.7 The Board is asked to **agree** that additional traceability requirements do not need to be implemented, as General Food Law is sufficient for managing food safety incidents.

6. Enforcement

6.1 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.

6.2 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).

Requiring the Payment of Fees In Respect Of the Exercise Of Any Function Conferred On the FSA By the Act.

6.3 The Act specifies that criminal sanctions are not permitted, but civil sanctions can be used, as these are considered proportionate to the safety risk posed by potential breaches. The table in Annex 3 summarises how new powers will work alongside existing powers available to enforcement officers. A more detailed breakdown of the enforcement process and different scenarios is also provided.

6.4 Genetically Modified Organism (GMO) regulations remain in place in Wales, Scotland and Northern Ireland. Local authority officers in these nations will be able to use GMO legislation to enforce any breaches as unauthorised GMOs as necessary. In addition, enforcement officials in those nations will be able to engage with the relevant local authority in England, as needed. If officials have safety concerns about PB products that are not related to their PBO status, they can use other relevant legislation (for example, relating to safety), as appropriate.

6.5 Ahead of the implementation of new enforcement measures, the FSA will provide guidance for local authorities, including guidance that is tailored to the scenarios that enforcement officers in Wales and Northern Ireland are likely to face. We will continue to engage with Food Standards Scotland to ensure enforcement officers in Scotland also have appropriate guidance. The FSA expects there to be one-off costs to familiarise local authorities with the new SI legislation and accompanying guidance, with minimal ongoing annual enforcement costs. In line with Government requirements in England, a New Burdens assessment determining the impact on local authorities will need to be completed, and the Government will be required to fund any associated financial burden.

6.6 The Board is asked to **agree** that the proposals for enforcement outlined here and in Annex 3 are sufficient for enforcing the new regulatory regime for PBOs.

7. Conclusion

7.1 In designing our recommended approach, officials have been mindful of the need for proportionality, taking into account scientific advice that there is no evidence that these food and feed products are inherently riskier than those produced by traditional breeding. We have considered the need to: maintain public confidence in the food system; help consumers make informed choices without creating undue concern; ensure that industry requirements build on existing responsibilities in General Food Law; and provide enforcement officers with the information and powers they need to protect public health and uphold the integrity of our regulatory system.

7.2 The key choices are about the extent to which the FSA will specify and require evidence to support an understanding of safety risk (ACNFP Model 1 or 2), who will be responsible for making an assessment about whether a product is Tier 1 or Tier 2 (industry or the FSA), and the process through which PBO products will be lawfully placed on the market in England (and, subject to UKIM provisions, in Scotland, Wales and Northern Ireland).

7.3 The Board is invited to:

- **decide** the preferred model for data requirements as part of the application and authorisation process;
- **decide** the preferred option for implementation of the pre-market assessment process and legal route to authorisation;
- **agree** the approach to provide an enhanced register of PBOs authorised for use in food/feed;
- **agree** the proposals for enforcement and traceability; and,
- **note** the implications of the UK Internal Market Act (2020) and the Windsor Framework.

Annex 1 – ACNFP Models Annex

ACNFP has developed two potential models outlining the data requirements needed to determine whether PBOs fall into Tier 1 or Tier 2. Both approaches laid out in the models are scientifically valid for a premarket authorisation approach.

This is a summary of the ACNFP statement, produced by the FSA, to support the Board paper. The full ACNFP statement can be found here.

The scope of each Tier can be summarised as follows:

Tier 1: PBOs that are very similar to traditionally bred varieties, which consumers are familiar with and for which potential safety risks are understood. There would be a simpler route to market.

Tier 2: PBOs with traits where the risks are not fully understood. Specifically, this would include novelty or PBOs that have compositional changes which could affect toxicity or allergenicity, or other safety concerns where potential food and feed safety risks need further consideration. There would be a bespoke safety assessment process, including a more detailed examination of the characteristics of the PBO. Details about the tiered approach and the triage questions have been published in previous ACNFP statements.

Evidence requirements

ACNFP has presented two possible approaches (Model 1 and 2 listed below) that outline the data requirements to support a decision about whether a PBO should be considered Tier 1 or Tier 2. The Committee has noted that the possible models are ‘intermediate points’ on a sliding scale of possible evidence requirements, from very extensive to very limited, and that a final decision about which model to adopt will rest with the FSA Board, taking into account what is considered proportionate to manage any risk, alongside consideration of other factors.

For all PBOs, descriptive information will be required at the outset about:

- the nature and purpose of the genetic change.
- the methods used to make the change.
- the analysis or procedures undertaken to minimise the potential for unintended alteration of the organism’s genetic material (so-called ‘off-target effects’).
- identification of parts intended for use as food and feed and intended uses.
- the history of safe use for food and feed of the relevant species.
- the predicted impact of change on composition and allergenicity.
- consideration of known hazards for the species that are managed by developers as part of due diligence; for example, antinutritional factors, toxins, and allergens.

The main difference between the two models is in the amount of compositional data considered at the triage stage to determine Tier status:

Model 1: A description confirming how the intended change has occurred and the likely occurrence of food/feed safety concerns. Initial data requirements would be lighter touch, with

only **limited compositional data** (see below) considered at the outset, to verify the desired change in the organism's physical characteristics where the quality of food and feed is impacted.

Note: if the triage step (based on limited compositional data) determines that the application was for a Tier 2 PBO (which requires a further safety assessment), then additional, bespoke compositional data relevant to the Tier 2 assessment would be requested.

Model 2: Provision of additional compositional data in order to allow screening for wider phenotypic changes. **Extra compositional data** (see below) would be considered at the outset for all PBOs to capture any wider consequences of the genetic change.

Compositional data requirements

The data requirements set out above outline the need for two levels of compositional data:

In Model 1, **limited compositional data** is used to verify that an intended change in composition of the edible part of a PBO has been achieved.

For example, in the case of an apple where the intended change concerns the nutritional quality of the edible apple, composition data on the apple would be required. In contrast, where the intended change improves the leaves of the apple tree, and there is no intended change to the composition of the edible apple, no compositional data would be required. Similarly, in the case of cattle bred without horns (targeting a non-edible part of the PBO), no compositional data would be required.

In Model 2, in addition to the data required for Model 1, **extra compositional data** is requested at the outset in order to assess wider compositional changes of the food or feed, taking into consideration indirect consequences of the targeted change.

For example, compositional data would be considered for an apple even if the intended change was to improve the non-edible leaves of the apple tree. Compositional data would also be considered for all edible products derived from an animal PBO (tissues and by-products such as eggs or milk) even where the intended change does not target edible parts of the animal, such as in cattle bred without horns.

Annex 2 – Public Register Annex

The proposed register would contain the following entry fields:

- the name of the authorised PBO;
- the details of the authorisation holder;
- the purpose of the edit – why the organism was precision bred;
- the date of the authorisation and link to any relevant legislation;
- any conditions of authorisation. For example, this could specify any mandatory product-level information that should be displayed; and,
- a unique reference number (URN) for each authorised PBO. This could both assist search functionality and enable businesses to include this URN on commercial documentation, should they wish to do so.
- a link to the relevant entry on the Defra register confirming the status of a PBO and so providing a picture of the individual regulatory route;
- details of the relevant safety assessment for each authorised PBO, if relevant.

Annex 3 – Enforcement Annex

Table 1 – How enforcement will happen throughout the authorisation and marketing of PBOs.

Enforcement in England

Step	Description	Who enforces?	How enforcement will occur	Powers
Step 1	Notification sent to Defra of intent to undertake field trials of a PBO.	Enforcement is carried out by APHA.	Defra's remit	Genetic Technology (Precision Breeding) Act 2023 and Statutory Instrument (Defra's remit)
Step 2	Marketing of a PBO for cultivation in England. Farmers produce either: Plant food PBO Plant feed PBO Animal food PBO	Enforcement is carried out by APHA.	Defra's remit.	Genetic Technology (Precision Breeding) Act 2023 and Statutory Instrument (Defra's remit)
Step 3	Application for marketing PBO for sale as food or feed required before being sold to food businesses. Authorisation done by FSA.	N/A	N/A	Genetic Technology (Precision Breeding) Act 2023 and Statutory Instrument Powers of entry, inspection, examination, search and seizure; Powers to take copies of documents, photographs and samples; Powers to impose requirements; Powers to require the provision of information. Compliance, stop and monetary notices. Powers for treating matters as relevant breaches, including—obstructing an inspector; providing false information to an inspector; impersonating an inspector;
Step 4 (a) Food	If products authorised for food use, both PBO animal and plant food products can be sold to food businesses for direct sale. or as an ingredient for further production.	Enforcement action will be required if a PBO product is marketed as food without authorisation by the FSA. Enforcement carried out by local authorities in England.	If local authorities suspect a breach, they will be able to trace the PBO status through a product's paperwork from the business right back to the original supplier to check whether the correct authorisation has been granted.	As above.
Step 4 (b) Feed	If a PBO is authorised for feed use for animals, then these products can be sold to farmers in England, Scotland Wales and Northern Ireland.These animal food products can then be sold to any UK food businesses. Paperwork is not required to state that animals were fed PBO feed.	Enforcement action will be required if a PBO product is marketed as feed without authorisation by the FSA. Enforcement carried out by local authorities in England.	If local authorities suspect a breach, they will be able to trace the PBO status through a products paperwork from the business right back to the original supplier to check whether the correct authorisations has been granted.	As above.

Enforcement in the other UK Nations

Step	Description	Who enforces?	How enforcement will occur	Powers
Step 1 (a)	If PBOs are authorised for food or feed use, they can then be sold to businesses in Scotland or Wales under the mutual recognition UKIM principle. The scope of the UKIMA does not, however, extend to processing after sale (see paragraph 5.4 in main text)	Local Authorities in the other UK nations.	If a breach is identified in Wales, Scotland or Northern Ireland, LA s will use existing GMO legislation for enforcement. The GMO regulations are already in place in those nations and LA officers have the powers to enforce them where appropriate. LAs in the other UK nations can contact the relevant LA in England to report any breaches, if required.	Existing GMO powers as per Regulation 1829/2003 on Genetically Modified Food and Feed.

Step	Description	Who enforces?	How enforcement will occur	Powers
Step 1 (b)	If PBO retail goods moving to NI through the Green Lane, they can then be sold in NI.	As above.	As above.	As above.

Table 2 – Scenarios Where Enforcement Action Will Be Required

Situation	Breach that could occur	Method for enforcement
PBO grown or imported for food or feed use and being marketed as food or feed.	Not approved as a PBO	Defra's enforcement regime targeting initial PBO production
PBO grown or imported for food or feed use and being marketed as food or feed.	PBO authorised by Defra, but not approved by the FSA for food or feed use	Local authority can trace PBO back to suppliers to determine if authorisation has been granted or not. If a breach has occurred, then enforcement action takes place.
PBO grown or imported for food or feed use and being marketed as food or feed.	PBO authorised by Defra and approved by the FSA for food or feed use, with conditions of use (s only for animal feed) but is being marketed outside of this condition of use.	Local authority can trace PBO back to suppliers to determine what conditions, if any, have been given alongside the authorisation. If a breach has occurred, then enforcement action takes place.
PBO grown or imported for food or feed use and being marketed as food or feed in Wales, Scotland or Northern Ireland.	PBO authorised by Defra, but not approved by the FSA for food or feed use. Or PBO authorised by Defra and approved by the FSA for food or feed use, with conditions of use (such as only for animal feed) but is being marketed outside of this condition of use. Or PBO authorised in England and sold legitimately into Wales, Scotland or Northern Ireland, but is thenfurther processed and sold in those nations without a GMO authorisation, which is not permitted under UKIM (see paragraph 5.4 in main text)	Local authority in Wales, Scotland or Northern Ireland will enforce this breach as an unauthorised GMO and use existing GMO legislation to take enforcement action.

1. FAO. 2023. Gene editing and food safety – Technical considerations and potential relevance to the work of Codex Alimentarius. Rome.

2. Statement of (ACNFP) on Precision Bred Organisms (PBOs) - January 2023 | Advisory Committee on Novel Foods and Processes

3. Consumer perceptions of precision breeding: Executive summary | Food Standards Agency

4. General food law | Food Standards Agency

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