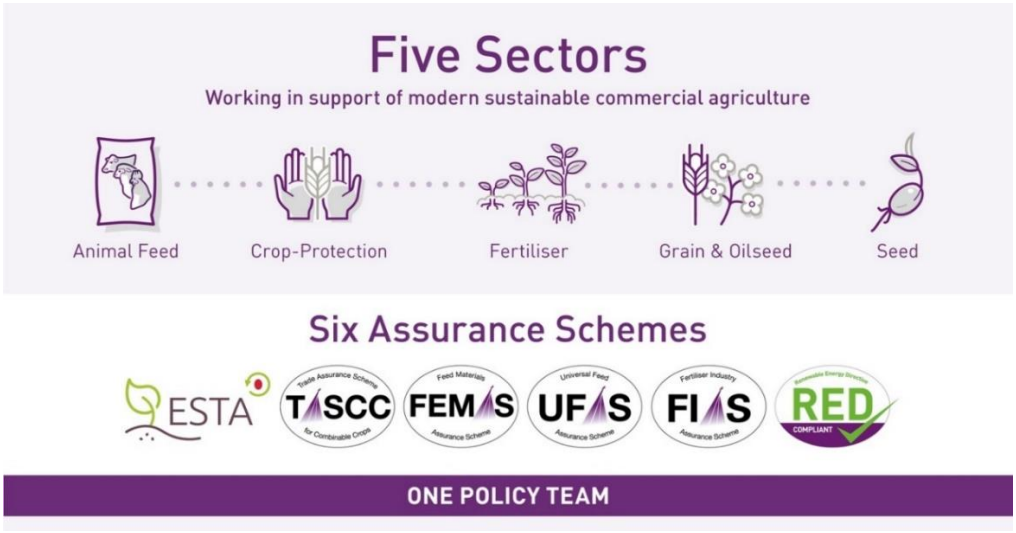
# The Genetic Technology (Precision Breeding) Act
## *Briefing from the AIC*

## About the AIC

The Agricultural Industries Confederation (AIC) is the agri-supply industry's leading trade association with over 230 Members in the agri-supply trade and represents over £15 billion turnover at farmgate. AIC represents several sectors within the agri-supply industry including: Animal Feed; Crop Protection and Agronomy; Fertilisers; Grain and Oilseed; Seed.




# Summary

- AIC supports Precision Breeding and welcomes its intent to deliver benefits to the environment, producers, supply chain and consumers.
- The legislation applies to England only. Scotland and Wales currently do not support the Act and consideration must be made of the UK internal market and how goods can be traded.
- The Act requires no mandatory labelling and traceability because precision breeding is comparable to conventional breeding. AIC supports this. It is also impossible to label goods without segregating supply chains, adding unnecessary costs to consumers.
- The EU is currently negotiating on its own precision breeding proposals (new Genomic Techniques) and could end up with a similar regulatory position as England.
- An FSA consultation on implementing the secondary legislation is live, closing on 8/1/24.

## 1. Background

The Genetic Technology (Precision Breeding) Act was granted Royal Assent in Spring 2023, following a consultation with industry in 2021, followed by the initiation of a Bill to Parliament in 2022. The Act seeks to 'encourage agricultural and scientific innovation at home.' Government has stated that: "legislation will unlock the potential of new technologies to promote sustainable and efficient farming and food production." The Act ensures plants, animals, and food and feed products developed using precision breeding technologies—those modified using technological methods such as gene editing to replicate changes which can occur naturally—are regulated "proportionately to risk". Consequently, its provisions remove these products from the regulatory system for genetically modified organisms (GMOs) in favour of a new regime.

## 2. AIC Position

AIC welcomes the Act. AIC supports the strategic approach taken by the Government to differentiate between precision breeding and GMOs, and more specifically to look at the possible benefits across a number of sectors, delivering a variety of beneficial outcomes.

With increasing challenges facing agriculture and environment, AIC is clear that more efficient breeding technologies could have an important role to play. We should by no means consider precision breeding as the only answer to challenges in our climate and food systems, however we cannot, and should not, overlook the possible opportunities that could be achieved across a variety of sectors. AIC has identified three broad themes for future applications in Precision Bred Organisms (PBOs):

1. **Environmental outcomes:** Precision breeding will allow researchers and AIC Members to explore techniques or applications in plant health, livestock feed and seed breeding that can minimise emissions and disease spread, while allowing for new varieties or breeds that can adapt to the real challenges of climate change.
2. **Meeting the needs of consumer and animal nutrition:** It is evident that dietary requirements and demands are changing in the UK and around the world. By harnessing innovation, we have an opportunity to address nutritional challenges in crops and livestock, as well as eliminating

allergens to consumers. The technology has great potential to minimise food waste, either in the growing stage of a crop, or at retail.

3. **Diversity:** There has been a growing concern across the UK agricultural sector that the nation's genetic diversity in crops and livestock is diminishing. We now have an opportunity to fundamentally readdress the possible availability of crop varieties and types available to farmers, which can help UK food and feed production whilst catering for the wide variety of products that UK consumers are demanding across the food chain. Having the means by which to offer farmers more choice in their cropping options would be of clear benefit.

## 3. The Act

The primary objective of the Act is to ensure that plants, animals, and food and feed products developed using precision breeding technologies are regulated proportionately to risk. It will introduce simpler regulatory measures to enable these products to be authorised and brought to market more easily.

The four key policy changes are to:

1. Remove plants and animals produced through precision breeding technologies from regulatory requirements applicable to the environmental release and marketing of GMOs (Genetically Modified Organisms).
2. Introduce two notification systems; one for precision bred organisms used for research purposes and the other for marketing purposes.
3. Establish a proportionate regulatory system for precision-bred animals to ensure animal welfare is safeguarded.
4. Establish a new science-based authorisation process for food and feed products developed using precision-bred organisms.

## 4. What is Precision Breeding (PB) Technology?

Precision breeding describes a range of breeding technologies, such as gene editing (GE), that enable DNA to be edited much more efficiently and precisely than current breeding techniques. Precision breeding technologies can make targeted genetic changes to produce beneficial traits that can also occur through traditional breeding and natural processes. This makes it different to genetic modification where modern techniques are used to insert functional DNA from an unrelated species into another species. Countries such as Argentina, Brazil, Australia, Canada, USA, Japan and Israel regard GE and GMO as different and they are therefore treated accordingly.

## 5. Opportunities and benefits

As a result of the legislation allowing research and market authorisations, nine field trial notifications for gene edited crops in England have been announced by Defra. These include:

- Pod shatter-resistant oilseed rape,
- Non-browning potatoes,
- Late blight resistance in potatoes
- Oleic oil rich, omega-3-enriched camelina,
- Tomatoes higher in provitamin B3,
- Low-asparagine wheat.

It was welcome that the Government, in setting out its rationale for the legislation, was explicit that precision breeding could help meet environmental and net zero outcomes. The overall lack of political disagreement surrounding the Bill during its legislative stages demonstrates how much this issue has become publicly acceptable.

## 6. Precision Breeding regulation and role of the FSA

### Public consultation

In November 2023, the FSA outlined its approach on how it will regulate and approve PBOs in England, with a public consultation open until 8th January 2024. Overall, it proposes a pragmatic and proportionate approach to regulating PBOs. Mirroring the regulatory approach already adopted in Canada, and the approach proposed in the EU, FSA is recommending a move away from the lengthy regulated products process currently applied to GMOs, novel foods and irradiated foods, opting instead for a more streamlined process for PBOs, more proportionate to the scientific evidence of risk.

This is also in line with the Advisory Committee on Novel Foods and Processes (ACNFP) advice that it has seen 'no evidence that PBOs are intrinsically more hazardous than traditionally bred organisms (TBOs)', and is also consistent with the definition set out in the Act that a confirmed PBO must contain genetic changes which could have occurred in nature or through conventional breeding.

## Tier 1 and Tier 2 Precision Bred Organisms

FSA is proposing a pre-market authorisation system designed around the classification of PBOs into two tiers, based on independent scientific advice relating to risk:

- Tier 1: PBOs that are very similar to TBOs for which potential safety risks are understood, do not warrant a bespoke safety assessment and for which there would be a simpler route to market.
- Tier 2: PBOs with traits where further analysis of the data is required. Specifically, this would include novelty or PBOs that have compositional changes which could affect toxicity, allergenicity, nutritional quality or other safety concerns where potential food and feed safety risks need further consideration. For these PBOs there will be a bespoke safety assessment process, including a more detailed examination of the characteristics of the PBO.

In order to assess which tier a PBO would fall into, a triage process has been suggested based on:

1. Novelty – whether the PBO would otherwise require assessment as a novel food;
2. Composition – whether there is a significant change in composition that impacts the food/feed safety risks in relation to toxicity, nutritional quality or allergenicity and;
3. Other safety concerns – whether it is intended to provide a route for further review in [rare] cases where there is significant uncertainty around the impact on safety for a PBO, outside the considerations around novelty and composition detailed above.

FSA is recommending that industry should have legal responsibility for undertaking initial triage and determining whether a PBO is Tier 1 or Tier 2, subject to technical guidance.

The vast majority of PBOs are expected to be classified as Tier 1. For these PBOs, applicants would be required to notify FSA of the Tier 1 determination, including a description of the nature and purposed of the genetic change(s) introduced using precision breeding. FSA would acknowledge receipt of the notification and confirm that the PBO can lawfully be placed on the market for use in food and feed. A public register would be maintained by FSA providing information about notified PBOs.

Once approved for food/feed marketing by FSA, however, precision bred plant varieties would continue to be subject to existing statutory variety testing/registration and seed certification requirements prior to marketing as seed or propagating material. Under the terms of the Act, a

separate animal welfare declaration process will also be developed by Defra for precision bred animals, overseen by a new animal welfare body.

## Pre-Market Authorisation

The proposed notification systems for Tier 1 and Tier 2 is as follows:

1. Tier 1 PBOs for food/feed would require notification to the FSA. At the triage stage, developers would apply the ACNFP criteria and notify the FSA of PBOs for food/feed falling within Tier 1 according to those criteria. The FSA would acknowledge receipt of the notification and recommend to the Secretary of State that the PBO be authorised for use in food and feed. Developers of a Tier 1 PBO granted a food/feed marketing authorisation would receive a communication from the FSA to that effect and the FSA would place the PBO on the public register.
2. Tier 2 PBOs for food/feed would require an application to the FSA as with other regulated products. At the triage stage, developers would apply the ACNFP criteria and in respect of PBOs for food/feed falling within Tier 2 would be required to submit an application with data as required by the ACNFP and any additionally identified data which may be required for bespoke risk assessment relevant to the factors in respect of which the PBO was determined as Tier 2 (i.e. novelty, composition or other concerns).

## Market transparency

*Applications*

As PBOs for food/feed will be a "regulated product", interested parties will be able to view notifications (Tier 1) and applications (Tier 2) on the public Register of Regulated Product Applications on the FSA website. Notifications / applications for PBOs for food/feed will be managed online, enabling the market to see what is progressing though the system at any given time.

*Public register to consumers*

PBOs for food and feed that have received marketing authorisations will be entered on a public register maintained by the FSA, available to any interested party including consumers, industry and enforcement authorities and that this should include all PBOs regardless of tier. The public register is proposed to contain the following for each PBO:

- Name of the PBO

- Authorisation holder
- Purpose of the edit
- Date of authorisation
- Any conditions of authorisation
- A unique reference number (URN) for each authorised PBO.
- A link to the relevant entry on the Defra register confirming PBO status
- Details of any bespoke safety assessment

This is consistent with other countries such as Canada that has a similar public register in place.

*Plant varieties to farmers and the supply chain*

The British Society of Plant Breeders (BSPB) has separately committed to establish and maintain a public register of all plant varieties approved for sale in the UK which have been developed using precision breeding techniques. The register will enable farmers and growers to identify which crop varieties have been developed using precision breeding techniques, and provide the basis for producers and their supply chains to provide information in response to market demand.

## Labelling considerations

AIC is of the opinion that because the legislation focuses on goods that could be produced by conventional means, mandatory labelling is unnecessary and costly. It is recognised that the supply chain and consumers may expect information where precision breeding has been used in producing a product, however AIC is firmly of the opinion that if the market wishes to provide information on PBOs, then it must bear the costs of the necessary segregation throughout the chain. Indeed this may be the case where food brands or retailers wish to positively label a product in order to provide its USP (longer shelf life, improved nutritional qualities) or where it would be required to do so under existing food and feed law (i.e allergen claims).

AS the FSA and Defra acknowledge, PB seeds, plants and food are chemically and molecularly indistinguishable from those of conventional breeding, meaning no tests are available today or envisaged in the future, making labelling extremely difficult to monitor or enforce in any case. Any requirements around labelling could create administrative burdens and reduce uptake of edited products.

## Traceability considerations

The AIC has made considerable representations over the past two years to Defra and FSA outlining that no new auditing or traceability are necessary for PBOs in grains or animal feed sectors. AIC assurance schemes such as UFAS, FEMAS and TASSC, awarded Earned Recognition status by the FSA, focus on safety, supply chain requirements on transparency and legality. In order to facilitate existing traceability throughout the supply chain, details such as supplying store/farm, through stores, quantity, description of goods, and supplier details must be made available to the competent authorities where it is believed a potential risk to food/feed safety exists. In addition, the *system* of documentation and records must ensure that food/feed is traceable and can be made available when requested.

The FSA has therefore, reassuringly, stated that existing General Food and Feed Law traceability requirements are proportionate and sufficient to support stated policy objectives. The FSA has noted that existing food and feed law and assurance schemes will allow business to work with existing familiar requirements without creating any further burden. The FSA therefore proposes that no traceability requirements for food/feed from PBOs beyond those in General Food Law are adopted at this time. The AIC supports this.

## Enforcement

The FSA proposes that enforcement authorities will use the same approaches for detecting and preventing fraud and minimising the risk of inaccurate information passed along the supply chain as they do for other products that cannot readily be identified through testing, such as organic food.

## ANNEX A: Pre-Market Authorisation Flowchart

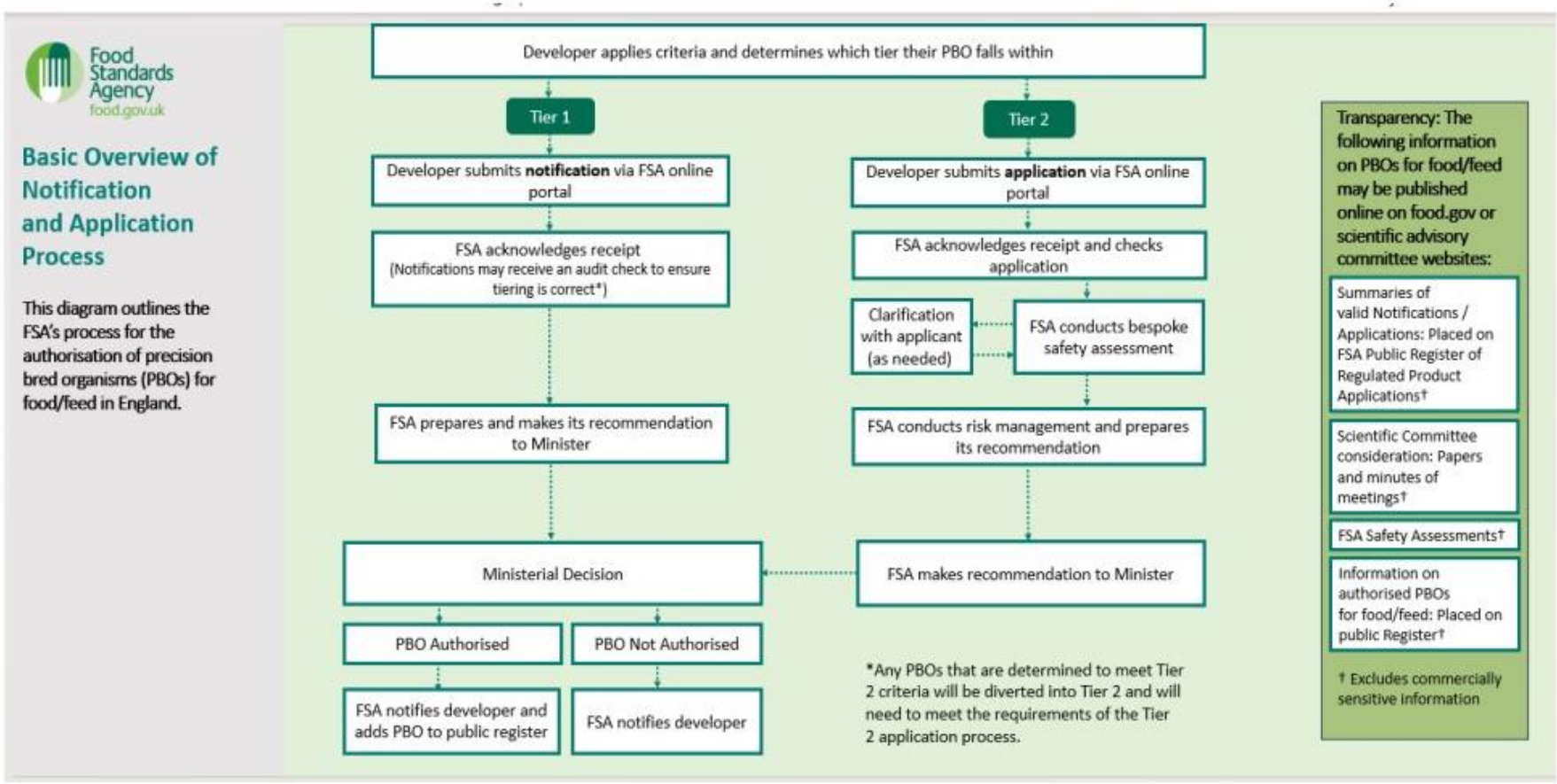



*Figure. 1 - Proposed market authorisation approach from the FSA*

## 7. Devolved and UK considerations

A key challenge of the Precision Breeding Act is that the territorial scope covers England only. The regulation of the production, release into the environment and marketing of precision bred plants and animals, and derived food and feed, is devolved. Currently, both the Scottish Government and Welsh Government oppose the legislation and have stated their intention to align with EU policy, where PBOs are currently regulated as GMOs (the EU is currently consulting on its own legislation as detailed in the next section).

As the regulation of genetic technologies is a devolved matter and the Act's provisions only apply to England, PBOs may only be grown in England and not Scotland or Wales. It is important to note however, that food produced through PB techniques in England may be legally marketed in Scotland and Wales, under the terms of the UK Internal Market Act (UKIMA). Under UKIMA market access principles, food/feed from PBOs which have a marketing authorisation in relation to England which has been produced in, or imported into, England could also be sold lawfully in Wales and Scotland. This would be the case even if the PBOs were not authorised for use in food and feed under existing GMO legislation relating to those countries which would continue to apply

AIC is clear that the legislation must be unambiguous on the legal position of the internal market, to ensure the supply chain has certainty over what is and is not permissible from a marketing perspective. Figure 2 provides a guide to the possible differences in approach of a PB milling wheat variety placed on the market, depending on the scale of the processing in the supply chain.

AIC continues to work with Defra, the FSA, the Office of the Internal Market (OIM) and Welsh and Scottish Governments to ensure market clarity of PBOs and provide clear information as to the impacts this could have on the production and sale of seed and 'mixed' commodities such as animal feeds, grains and oilseeds.

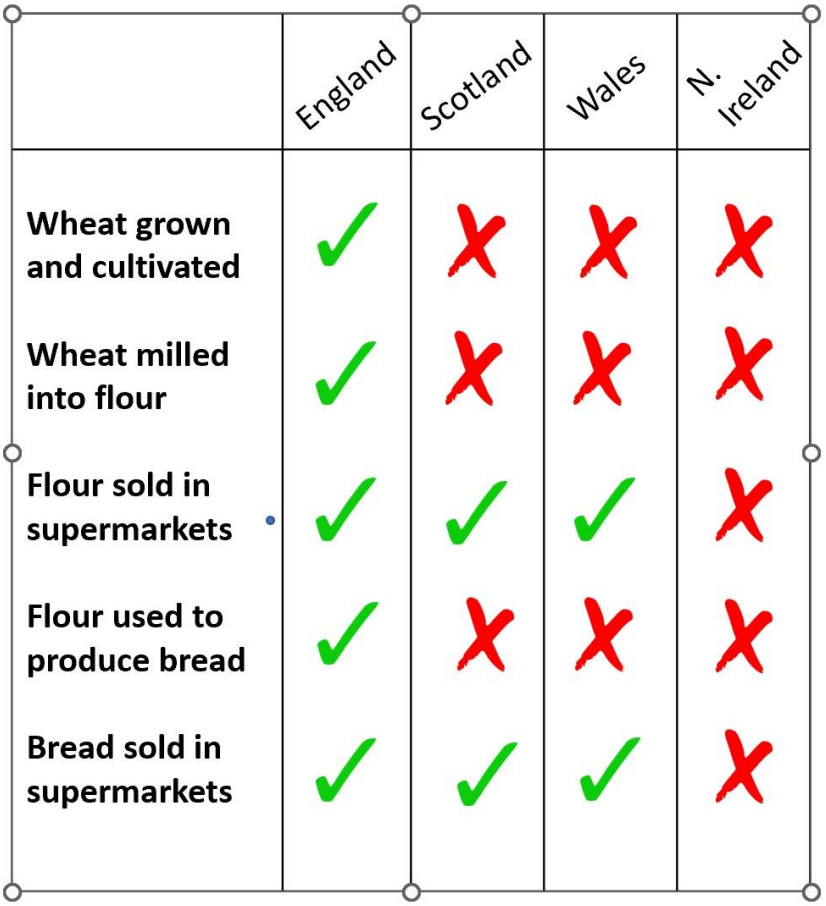



*Figure 2 - Proposed food product journey from Defra/FSA in GB*

## 8. Gene Editing in the EU: 'New Genomic Techniques' (NGTs)

In July 2023, European Commission published its legislative proposal on targeted mutagenesis and cisgenesis (including intragenesis), referred to them as New Genomic Techniques (NGTs). AIC has been aware that the EU has been considering its own NGT legislation after pressure was applied from farming and food groups as well as member states since the EU Court of Justice ruling in 2018 and the invasion of Ukraine. In addition, the Commission has recognised that in order to meet stated green aims in its Farm to Fork policy, it can not only focus on reduction goals but also needs to focus on productivity measures on farms.

The new legislation in the EU could be very significant for food production in the EU and UK for a number of reasons:

1. The change in the EU represents a big shift towards science based, objective policy in food production and agricultural productivity. In 2018, the European Court of Justice ruled that gene editing was equivalent to GMOs in Europe, a decision also conferred then on the UK. Since then, it has held back the development of gene editing in the EU and UK.
2. Alignment between the UK proposals and EU proposal could help facilitate the trade in precision bred/NGT products in both directions.
3. Scotland and Wales have a stated policy of alignment with the EU in this area. Now that the EU has proposed its own NGT legislation, it will mean both Scotland and Wales will have to decide whether or not to copy the EU proposal, the English proposals, or do neither.

## EU proposal vs England's proposals

According to the European Commission, the proposal is a lex specialis to the current GMO law and creates two distinct pathways for NGT plants to be placed on the market. This is similar to the UK proposals which also will have a two-tiered approach:

1. NGT plants will be subject to a verification procedure, based on so-called equivalence criteria (equivalent to conventional breeding) set. NGT plants that meet these criteria are treated like conventional plants and therefore exempted from the requirements of the GMO legislation. This means that for these plants no risk assessment has to be made. Nevertheless seeds need to be labelled as Category 1 NGT and these conventional-like NGT plants are prohibited for use in organic farming. This is similar to the UK's proposal for tier 1 products, however it should be noted that the EU proposals are seeking a limit of 20 genetic modifications and specific types, whereas no such arbitrary ceiling exists in England.

2. For all other NGT plants that do not meet the equivalence criteria, the requirements of the current GMO legislation would apply. This means that they are subject to an adapted risk assessments and can only be put on the market following an authorisation procedure. This is different to the UK proposals, whereby Tier 2 will be excluded from the scope of GMOs, however similar in that there is an enhanced application procedure.

However, the EU proposal also states that these Tier 2 NGTs will require GMO labelling, detection methods and tailored monitoring requirements. These measures are not supported by the UK Government or FSA proposals. AIC supports the UK Government and FSA in this.

### Transparency and public register of products

The Commission, like the UK, is proposing that NGT plants cannot be used in organic production. To exclude gene edited plants from organic production – even those that have been verified to be equivalent to conventional plants – farmers and the whole supply chain can consult a public register of all gene edited products and seed labelling in common catalogues of varieties in the EU and through a public register in the UK.

### Next Steps

In the EU, the proposal follows the regular legislative procedure with Member States (Council) and Parliament involved. As ever, it is difficult to gauge how long the legislative process will take in the EU as it may become quite politicised. AIC remains in close contact with our EU associations, notably Euroseeds, who are leading much of the technical and advocacy work in NGTs. We continue to work together to share the latest proposals in the respect English and EU legislation, learning from one another's experiences, and sharing information or data where required. Euroseeds has indicated that NGTs in the EU are unlikely to come to the market before 2026/2027, whereas the target for England is 2025.

## 9. Gene editing in the rest of the world

Countries such as Argentina, Brazil, Canada, Japan, and the US have all implemented their own gene editing legislation, underlining the need for both the UK and EU to follow suit. Each of those countries have largely committed to the same fundamental issues, such as not mandating labelling and providing either mandatory or voluntary public registers. The measures in the UK could help facilitate greater trade with countries that currently, or are planning to, make use of precision breeding technologies. As a result, Government believes that the Act could enable the creation of potential new export markets for UK-based producers.

The FSA has stated that imports, including from the EU, must continue to meet relevant GB standards to be lawfully placed on the GB market. PBOs from other countries must meet the regulatory requirements for PB food/feed to be imported into England. Food exported from the UK to other countries/blocs will need to continue to meet the rules of those countries/blocs. Because of the absence of testing, AIC will work closely with Government and other stakeholders to ensure there is consistency with other countries moving forwards with gene editing.

## Next Steps

The FSA consultation closes on 8th January 2024. AIC is encouraging members to respond to it, as it is vital that FSA and Defra hear from individual businesses who may be directly or indirectly involved in the supply or sale of PBOs.

Depending on the outcome of the consultation, it is hoped that the Secondary legislation, enabling the provisions described in Section 6, will be passed by Parliament in 2024. This is extremely important due to the fact that a General Election is certain to take place in 2024, and considerable delays could occur if it is not passed before then. It is also possible that a change of Government could revise the approach suggested in Section 6 and propose a less pragmatic approach.

In order to facilitate the whole supply chain working together on precision breeding, Defra has convened a high-level group of representatives from trade associations, researchers and food and retail businesses to address practical barriers to the uptake of PB goods in the supply chain, and for consumer facing businesses to articulate what they would like from PB as a technology. AIC is represented on the group.

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