Briefing:

Creating a robust regulatory framework for new-style GMOs

Prepared by GM Freeze on 21st August 2024

Background

The 2023 Genetic Technology (Precision Breeding) Act (hereafter the Act) created a new legal category for a subset of genetically modified organisms (GMOs) that were named "Precision Bred Organisms" (PBOs).* These are defined in the Act as those that "could have resulted from traditional processes", but with changes to the genome having been made using "modern biotechnology". This includes some but not all applications of gene editing. The Act paved the way for the removal of existing GMO regulations over these plants, animals and other organisms such as microbes. However, as of August 2024, much is yet to be determined as the rules will be laid out in secondary legislation named Statutory Instruments (SIs). When the 2024 general election was called, the Department for Food and Rural Affairs (DEFRA) and the Food Standards Agency (FSA) were working on these.

The plans being developed under the former government had multiple problems.† The new government has an opportunity to reimagine the secondary legislation and ensure that the regulatory framework for new-style GMOs is economically and environmentally responsible, proportionate to risks, compliant with the country's international obligations and in line with what the electorate want. This briefing provides a set of recommendations for the appropriate regulation of this rapidly-developing technology.

Recommendations

1. Labelling, traceability and co-existence

The new government must mandate the labelling, traceability and segregation of PBOs throughout supply chains. This is crucial to:

a) Meet the intentions of the Genetic Technology (Precision Breeding) Act.

- The Act contains a provision for regulations to impose traceability requirements. Traceability is defined as the ability to follow the organism and its products through all stages of production, processing and distribution.[1]

b) Protect the UK's trade with Europe and internationally.

- According to the Impact Assessment of the Act, £8.56 billion in trade a year could be impacted by non-tariff barriers in the event of the EU having a different regulatory system

* In this document the term PBO is used, however, it is noted that this is not a scientifically meaningful classification but rather a political construct that is not recognised by other jurisdictions, including within the United Kingdom.

† These are outlined in the GM Freeze report 'Problems with the proposed regulatory framework for new-style GMOs under the Conservative government', 21st August 2024.

to the UK.[2] In February the European Parliament voted to require labelling and traceability of products from "New Genomic Techniques" (NGTs).[3]

- Internationally, trade regimes differ with regard to products from newer forms of genetic modification, such as genome editing. It is unclear how British products with PBO varieties – such as wheat - could be traded on commodity markets if there is no segregation of PBOs.

c) Respect the autonomy of the devolved nations.

- Neither the Scottish or Welsh governments have consented to the Act, which the Scottish government has said "undermines devolution".[4] Nevertheless, it was the former government's position that, due to the Internal Markets Act, PBOs authorised in England could be sold in Wales or Scotland without the GMO controls that would otherwise apply there. Both the Scottish and Welsh parliaments have highlighted the fact that a failure to label would obstruct devolutionary powers.[5,6]

d) Meet the electorate's strong preference for transparency and freedom of choice.

- Public consultations have repeatedly found that consumers want all GMOs - including those categorised as PBOs - to be labelled.[7]

e) Protect the viability of co-existence for the organic and non-PBO sectors and ensure costs are appropriately apportioned.

- Organic producers and traders are required by law to exclude PBOs throughout supply chains. Without a requirement to label and trace these new-style GMOs, segregation will be costly, difficult and may reduce the availability of some organic products. Costs – that should be carried by the GM sector - will be passed on to consumers of organic and traditionally-bred produce.

f) Effectively manage risks to health.

- The FSA has recognised that 'precision breeding' technologies are "rapidly developing" and that in relation to risks, "a range of outcomes is possible".[8] If unlabelled and untraceable PBOs are permitted throughout food and farming systems, the costs and complications of dealing with any hazards that may be identified in future are difficult to estimate.
- An expert opinion on the risks of new GM plants published by the French National Agency for Food, Environmental and Occupational Health and Safety (ANSES), and supported by other governmental agencies such as the German Agency for Nature Conservation, states that potential risks include those "linked to unexpected changes in the composition of the plant, which could give rise to nutritional, allergenicity or toxicity problems."[9] Taking action on labelling now will prove decisive in the event of novel allergens being identified in the future.

2. Animal testing

DEFRA and the FSA should acknowledge the impact of the proposed regulatory framework for PBOs on the number and types of scientific procedures involving animals that will be conducted, as per

their responsibilities in this area.[10] They should publish data on the predicted procedures that will result from both the safety testing of PBOs and the development of PBO animals.

3. Ethical frameworks for PBO animals

The ethics of genetically altering animals are complex, and the Act is broad enough to encompass wild, companion and sporting animals as well as farmed animals. An Ethics Committee, which includes the participation of civil society and Non-Governmental Organisations (NGOs), should be established to assess the implications of the new regulations on different categories of animals and devise ethical frameworks or rules in relation to these. The traits being developed should be subject to an approval process before any scientific procedures commence.

4. Sustainability requirements

Whilst the former government promoted the potential for positive sustainability outcomes that could be achieved through the Act, there is nothing in the Act to require that the development of PBOs is for societal or environmental benefit, or how to assess this.

Secondary legislation should establish that each PBO is developed for the benefit of society. Technology assessments should be conducted to evaluate the specific traits developed, for example, in relation to sustainability goals or climate change adaptation strategies. This should include consideration of their environmental, socio-economic and ethical impacts, and encompass cumulative and long-term impacts. The actual performance of the organisms and any wider impacts they have should be monitored and evaluated.

5. Exclusion of wild species, trees and microorganisms

The Act as it is currently written may apply to wild species, including forest trees, and microorganisms. Given that the risks of unforeseen impacts and their consequences on the natural environment are high and wide-ranging,[11,12] and considering the lack of public engagement and expert input to date, secondary legislation should remove wild species, trees and microorganisms from the scope of the Act. In the event of them being included in future, the new government must develop a framework for civil society engagement, consultations with experts and NGOs, and appropriate, landscape-level environmental impact assessments.

6. Emerging technologies – future proofing

Additional secondary legislation is required to provide a framework for the government's approach to the application of emerging technologies that are within the scope of the Act. This may include but is not limited to gene drives, RNA "gene-silencing" sprays, the genetic alteration of microorganisms, and genetic modification combined with Artificial Intelligence. The new government must ensure that such technologies are developed with transparency, public awareness, and regulatory oversight.

7. Patents

The former government claimed that the Act could promote scientific innovation. However, experience in Europe has shown that patents on organisms developed using new genetic technologies can stifle innovations in traditional plant breeding.[13],[14] Patents can also lead to economic hardship for food producers.[15]

The Act does not address the issue of patents. The new government should establish a committee to evaluate the impact of relevant patent regimes on the development of both PBOs and traditionally bred organisms. Secondary legislation should address the issue of patents in order that plant breeders and food producers are not unjustifiably economically penalised, and research and development into traditionally bred plants and animals is not negatively impacted by the regime that will apply to PBOs.

8. Independent risk assessment and safety testing

Risk assessment and safety testing should be conducted for all PBOs by independent third parties commissioned by government agencies. The costs of this analysis should be covered by the application process and ultimately but indirectly paid for by PBO developers.

An example of a procedure that could provide important safety information is long-read whole genome sequencing, which can give accurate information about unintended as well as intended genetic changes. Other "omics" molecular analyses, such as those of transcriptomes, proteomes and metabolomes, can give crucial information relevant to safety, such as about compositional changes (quantitative as well as qualitative) that may affect toxicity or allergenicity.

9. Environmental risks and the Cartagena Protocol

Plans for the authorisation of PBOs, as they were due to be proposed by DEFRA, did not include any environmental risk assessments. The UK is a party to the Cartagena Protocol on Biosafety, a legally binding international agreement that addresses the risks posed by Living Modified Organisms (LMOs) to the world's biological diversity, with consideration given to human health.[16] The previous government considered that the Protocol did not apply to PBOs and thereby dismissed all of its provisions, including: conditions that should be met for transboundary movements of LMOS, case-by-case environmental risk assessment, and public awareness and participation.

The new government should commission and publish legal advice regarding the applicability of the Cartagena Protocol to the regulations under development for PBOs. It should also consider the Aarhus Convention with regard to citizen engagement. It should ensure that the country fulfils its international legal obligations.

10. Monitoring and reporting unintended genetic changes

There should be requirements within secondary legislation for the monitoring and reporting of unintended as well as intended genetic changes to PBOs.[17] Approved methods such as long-read whole genome sequencing should be specified as well as the use of specific omics to understand unintended changes at the transcription or metabolic level. Developers should be required to remove unintended genetic changes or investigate and report on their effects prior to seeking approval for release or marketing of a PBO.

11. Criteria for categorisation of PBOs

The FSA has stated that it will regulate on the basis of two categories of PBOs that have different risk profiles. It must provide clear, scientific guidance on what the difference is between these two categories and how this can be scientifically proven. The tier categorisation of organisms should be independently verifiable. The results of tests that indicate whether or not unintended changes have occurred should be included in the categorisation process.

12. Analytical detection methods

Developers must provide information regarding the genetic changes made and the methods used to make those changes in order for risks to be adequately assessed and to feed into the development of detection methods.[18] The government must adequately resource research into detection methods to ensure that the UK is ahead of the curve with regard to new genetic technologies, and will not be at a trade disadvantage in relation to other regions that are funding such research.[19]

13. Post-market monitoring

The government should require post-market monitoring of precision bred plants as well as animals. Traders along supply chains should be required to report issues including: any unintended genetic or epigenetic changes, or unintended trait changes that become apparent; the genetic stability of progeny, and the spread of precision bred traits into unintended populations.

14. Impact assessments

Given that the Regulatory Policy Committee rated DEFRA's Impact Assessment of the Act (then Bill) not fit for purpose,[20] DEFRA should publish a new Impact Assessment. The Food Standards Agency should reverse its decision not to conduct a full Impact Assessment of its proposals for secondary legislation.[21]

Conclusion

The new government is presented with an opportunity to forge a new approach to the regulation of new forms of genetic technologies and their applications. It should reject the cavalier approach of

the former government, pay due regard to its international obligations, and consider all of the potential health, environmental and socio-economic risks posed by PBOs. It should aim to build consumer trust through transparency and labelling, and protect the viability of non-PBO supply chains. It should take into consideration the economic impacts that divergent regulatory approaches in other jurisdictions would have on the livelihoods of all agricultural exporters.

The new government should make it clear to DEFRA, the FSA and the electorate that the irresponsible approach of the previous government will not be continued. It should instead act responsibly and in consideration of the wellbeing of all citizens and economic actors, rather than just those in the business of biotechnology.

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[21] In its 'Consultation pack on proposals for a new framework in England for the regulation of precision bred organisms used for food and animal feed,' (available from: https://www.food.gov.uk/our-work/consultation-pack-on-proposals-for-a-new-framework-in-england-for-the-regulation-of-precision-bred-organisms-used-for-food-and) the FSA stated that it had not conducted a full impact assessment.