Regulating new GMOs responsibly

A briefing from GM Freeze

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GM FREEZE

Background

The 2023 Genetic Technology (Precision Breeding) Act created a new legal category for a subset of genetically modified organisms (GMOs) that were named Precision Bred Organisms (PBOs).*

These were defined as plants or animals that "could have resulted from traditional processes", but with changes to the genome having been made using modern biotechnology - techniques such as gene editing.

The Act paved the way for the removal of existing GMO regulations over these organisms. However, as of September 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 former government was on a path of reckless deregulation of new GMOs.† The new government has an opportunity to ensure that the forthcoming regulatory framework is:

- **environmentally and economically responsible**
- **proportionate to risks**
- **compliant with the country's international obligations**
- **in line with what the electorate want.**

This briefing provides recommendations for the appropriate regulation of this rapidly-developing technology. It is supported by the following civil society organisations and businesses: **Biodynamic Federation Demeter International, Civil Society Alliance, Compassion in World Farming, CSA Network UK, Ethical Consumer Research Association, GM Watch, Hodmedod, Landworkers' Alliance, Organic Farmers & Growers, Organic Research Centre, Permaculture Association Britain, Real Farming Trust, Real seeds, Soil Association, Sustainable Food Trust, Unchecked UK, Unicorn Grocery.**

* 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.

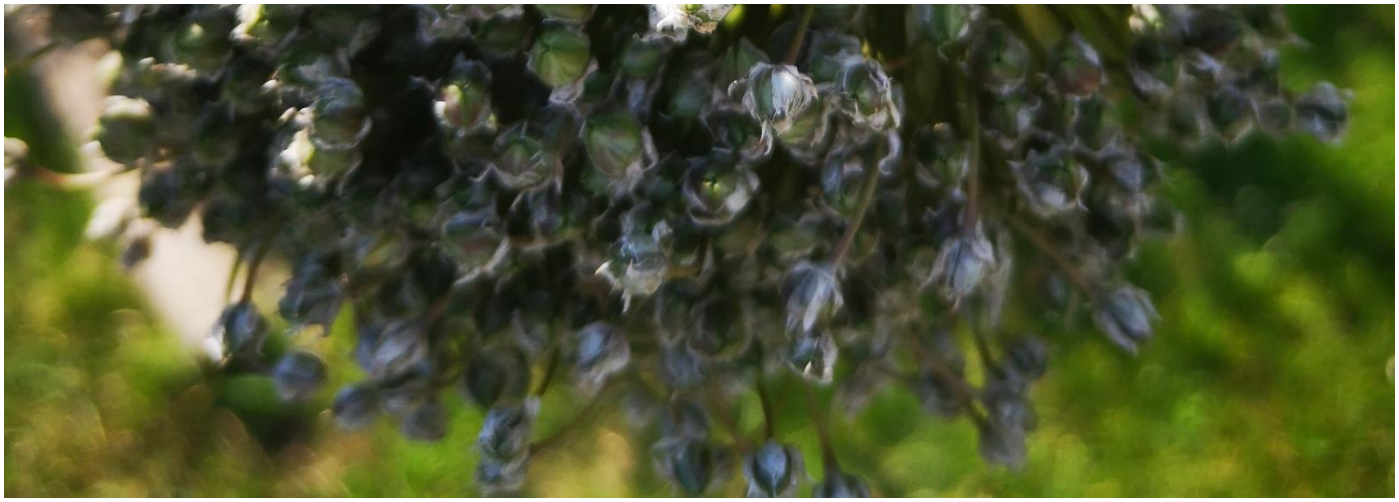
† For a full analysis, see the GM Freeze report 'Problems with the proposed regulatory framework for new GMOs under the Conservative government', 30th September 2024.

Recommendations

1. Mandate labelling, traceability and co-existence measures

This is crucial to:

- **Meet the intentions of the Genetic Technology (Precision Breeding) Act.**
  - The Act has a provision for traceability requirements.
- **Protect the UK's trade with Europe and internationally.**
  - £8.56 billion in trade with Europe a year could be negatively impacted by non-tariff barriers.[1]
  - Non PBO supplies to commodity and international markets could be at risk.
- **Respect the autonomy of the devolved nations.**
  - Neither the Scottish or Welsh governments have consented to the Act, and have said that a failure to label would obstruct devolutionary powers.[2,3]
- **Meet the electorate's demands for transparency and freedom of choice.**
  - Consumers want all GMOs - including those categorised as PBOs - to be labelled.[4]
- **Enable the of co-existence of organic and traditionally-bred sectors and ensure costs are appropriately apportioned.**
  - Failure to mandate coexistence will put organic supply chains at risk.
- **Effectively manage risks to the environment and health.**
  - No environmental risk assessments have been conducted on new GMOs.
  - The French national health and safety agency has found that potential risks include changes in the composition of the plant, which could lead to nutritional, allergenicity or toxicity problems.[5]
  - 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.



2. Exclude wild species and trees

The Act as it is currently written may apply to wild species, including forest trees. Given that the risks of unforeseen impacts and their consequences on the natural environment are high and wide-ranging,[6] and considering the lack of public engagement and expert input to date, secondary legislation should remove wild species and trees 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.

3. Require independent risk assessment and safety testing

Risk assessment and safety testing should be conducted for all PBOs destined for food and feed by independent third parties commissioned by government agencies. The costs of this analysis should be covered by the application for authorisation 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.

4. Address environmental risks and international obligations

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.[7] The previous government considered that the Protocol did not apply to PBOs and thereby dismissed all of its provisions, including case-by-case environmental risk assessment.

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.

5. Address impacts on 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.[8] They should publish data on the predicted procedures that will result from both the safety testing of PBOs and the development of PBO animals.

6. Devise 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.

7. Require sustainability outcomes

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.

8. Consider the international repercussions of the Act

What happens in the UK in terms of regulations, research and trade agreements has profound effects in other areas of the world, yet these effects may not be adequately scrutinised in Parliament. Debates and other forums such as hearings and inquiries are needed on the impact of UK policies on food security and Food Sovereignty at a global level.[9] The views of impacted communities must be considered. Food Sovereignty advocates should provide an analysis of both new and older forms of genetic modification.

Further, the potential international repercussions of the Act should be considered in a formal impact assessment process that is designed with the participation of civil society organisations. This should include an analysis of the combined effects of the Act and trade agreements, and how this could impact farmer livelihoods, communities and international food security and Food Sovereignty.

9. Future-proof for emerging technologies

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 and future Statutory Instruments. This may include but is not limited to gene drives,[10] gene-silencing pesticide sprays,[11] the genetic alteration of microorganisms,[12] and genetic modification combined with Artificial Intelligence.[13] The new government must ensure that such technologies are developed with transparency, public awareness, and regulatory oversight.

10. Address issue of 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.[14,15] Patents can also lead to economic hardship for food producers.[16]

The Act does not address the issue of patents. The new government should establish a mechanism to scrutinize 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.

11. Require monitoring and reporting of unintended 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 from DEFRA.

12. Scientifically define 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; this will mean the difference between virtually unregulated and lightly regulated products. 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.

13. Collect information to enable the development of 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]

14. Mandate post-market monitoring

The government should require post-market monitoring of precision bred plants as well as animals.[20] 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.

15. Agencies to conduct fit-for-purpose impact assessments

Given that the Regulatory Policy Committee rated DEFRA's Impact Assessment of the Act (then Bill) not fit for purpose,[21] 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.[22]

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 global impacts of changes in UK policy in this area, as well as the economic impacts that divergent regulatory approaches in other jurisdictions would have on the livelihoods of all British 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 in consideration of the wellbeing of all citizens and economic actors, rather than just those in the business of biotechnology.

Supported by

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