Submission to Secondary Legislation Scrutiny Committee on the draft Genetic Technology (Precision Breeding) Regulations 2025 and Explanatory Note

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Contents

Abbreviations

The Act = The Genetic Technology (Precision Breeding) Act 2023
DEFRA = Department for Environment, Food, And Rural Affairs
DMA = *De Minimis* Assessment
FSA = Food Standards Agency
GM = Genetically Modified
GMO = Genetically Modified Organism
NGT = New Genomic Techniques
PB = Precision Bred
PBO = Precision Bred Organism
RPC = Regulatory Policy Committee
The Regulations = the draft Genetic Technology (Precision Breeding) Regulations 2025
SLSC = Secondary Legislation Scrutiny Committee

An intervention from civil society

GM Freeze would like to place on record serious concerns about the draft Genetic Technology (Precision Breeding) Regulations 2025 and urges the SLSC to draw deficiencies in the legislation to the special attention of the House of Lords.

A reckless approach

The problems with the Regulations are centred not on the provisions they contain, but those they do not contain. There are no requirements for:

- environmental risk assessments;
- health-related risk assessments;
- labelling;
- traceability;
- the provision of information that would enable detection methods to be developed;
- the specification of certain scientific tests to confirm PB status and check for unintended genetic changes;
- the genetic changes made to be for the purpose of achieving sustainability outcomes.

Also of concern is the failure of the Act, Regulations or the government more widely to address the issue of patents and how these may affect producers and manufacturers in the future. This has emerged as a major issue for the European Union, where it is blocking the adoption of similar legislation.[1]

More information on these issues is provided in the GM Freeze report "Problems with the planned regulatory framework for new GMOs under the Conservative Government," published in September 2024.[2] The change of government has led to no changes which alter

the concerns raised in the report other than introducing a delay for the Regulations that will apply to PB animals.

The consequences

The overarching outcome of the deregulation of PBOS/certain GMOs set out in the Regulations and outlined briefly above is that producers and consumers will not be able to select products that are PBO-free, or GMO-free as far as the legal duty of organic producers is concerned.

This is a policy issue of public interest given that successive consultations have shown that consumers overwhelmingly want labelling and the freedom of choice that this would allow.[3]

Example 1: Consumer wishing to choose PBO/GMO-free food and body care products

The only source of information available to consumers regarding food which contains PBOs will be the FSA's food and feed register. The only piece of information that the food and feed register will contain that will help consumers to identify products that contain PBOs/GMOs will be the name of the precision bred organism. The only scenario in which a consumer is likely to be provided with the name of the precision bred organism is if that consumer is buying fresh fruit or vegetables and if the seller provides the name of the varieties on sale. In this instance they would need to check the varieties of all the fruit and vegetables they buy against entries in the food and feed register.

In all other circumstances in which a consumer buys food they will not be able to access the information that would enable them to check whether what they were buying was or contained a PBO. This includes any food that has undergone any type of processing, such as tomatoes in a sandwich or tomato puree, or purchasing food in a restaurant.

The Regulations do not provide information regarding whether organisms that have been allocated PB confirmations will be permitted in other supply chains, such as body care. There is insufficient explanatory material in this regard. It is therefore unclear what position consumers who wish to avoid PBOs in body care products will be in.

It may be that in some cases consumers that wish to avoid PBOs will be able to select organic alternatives, however, as highlighted below, this is far from certain.

Organic producers

The Regulations do not contain any references to organic and there is insufficient explanatory material in this regard. The organic sector is under threat from these Regulations and DEFRA's failure to acknowledge or address this is both unethical and, given that it is a market worth £3.7 billion,[4] economically reckless.

There is currently a great deal of uncertainty regarding how organic operators will be able to maintain their legal duty to remain PBO/GMO free. Pages 17 and 18 of the unpublished DEFRA DMA of the Regulations highlight the following areas of uncertainty:

- How organic farmers will be able to check whether the material they source is not PB.
- What or whether "options" to make required information accessible for organic producers will be put in place.
- What evidence organic farmers will need to obtain, what records they will need to keep and how they will have to demonstrate that they have avoided PB crops or contamination by PB crops.

Additional uncertainties include:

- Who would be liable in the event of an organic farmer's crop being contaminated with PB material from a nearby farm.
- Who would be liable for the financial and reputational losses caused by the organic farmer's loss of certification in the event of contamination.
- What measures will or could be put in place by organic control bodies to ensure that organic produce does not contain GMOs.
- How it will be possible to detect food ingredients such as lecithin derived from GMO soya in food supply chains, and how this will affect organic operators.
- How segregation will be maintained throughout supply chains to consumers.

Example 2: Organic farmers attempting to avoid contamination of their crops with GMOs

If the Regulations are enacted as they are proposed, and if PB crops are grown widely, it will be almost impossible for organic farmers to avoid their crops becoming contaminated with GMOs and thereby to meet their legal obligations.

The DMA suggests that organic producers will be able to put in place "protective buffers". It is here assumed that this means areas within organic farms where no organic-certified crops are grown. However, bees can travel up to approximately 5 kilometres in any direction, so such a buffer would need to be 10 kilometres in order to be effective; this is not feasible for individual farms.

Organic and other non-GMO producers are unlikely to be informed as to whether there are any PBOs being grown in the surrounding areas or neighbouring farms. If they do establish that PBOs are grown on a neighbouring farm, and would like to put in place buffer zones that may be suitable to avoid contamination via crawling insects (rather than flying insects, or walking or flying mammals), it is far from certain that they would have the space on their farms to do so, or that their farms would remain economically viable with the loss of that growing space.

A legal contradiction

The organic sector highlights a significant legal problem with these Regulations: That PBOs will have two legal statuses at the same time and in the same jurisdiction, being considered both GMOs under organic regulations and not GMOs elsewhere.

Trade problems

The Act and Regulations have major implications for the UK's trade, both internationally and internally with the devolved nations.

Devolved nations

The Act only applies to England, but it is the government's position that PBO products placed on the market in England would be saleable in Scotland and Wales without GMO regulations applying as a result of the Internal Market (UKIM) Act. However, Wales and Scotland have not agreed to the Genetic Technology Act and therefore the use of the UKIM Act to force unlabelled PBOs onto devolved nation markets represents a threat to those nations' sovereignty in a devolved policy area. Furthermore, they may fall foul of their existing trade agreements due to the preferential terms of trade afforded to PBOs originating in England.

A further complication is that the UKIM Act only applies to the product as it is first put on the market. If PBOs undergo a "significant production step" in Wales or Scotland they would fall under the existing GMO legislation there. However, if there is no segregation or labelling of PBOs, it could be impossible to identify those products sold from England that would need to be labelled post-processing. This situation will make it almost impossible for the devolved nations to uphold their legal responsibilities with regard to their own regulations.

Example 3: A Welsh sandwich maker

It is unclear where legal responsibility would lie for labelling a product as a GMO if a PBO is sold into Wales and undergoes some form of processing there. In order to ensure compliance, a sandwich maker using multiple inputs in his or her business would need to only buy fresh products which were labelled with the name of the variety. They would need to check each variety name against the FSA's food and feed register and only include PBOs in their products if they also labelled them as being GMOs. If a processed tomato product containing a PBO was used by the sandwich maker, they would need to label it as a GMO if it had been manufactured in Wales but not if it had been manufactured in England.

In the event of the sandwich maker inadvertently not complying with the law, would they be responsible for placing an unlabelled GMO on the market? Could they challenge this on the basis that they had not been responsible for the initial release of the GMO? There will be significant legal uncertainty in such a case.

The European Union

It is acknowledged in the DMA that, prior to an anticipated change in European regulations, PBOs will be considered GMOs and will therefore need to be authorised and labelled before being placed on the European market. However, the DMA fails to state the potentially extreme ramifications of divergent regulatory systems, specifically the fact that different labelling and traceability requirements for PBOs in the UK and organisms produced using New Genomic Techniques (NGTs) in Europe could spell disaster for *all* British agricultural producers.

For British products to be placed on the market in Europe, customs officials would need to differentiate between PBOs and traditionally bred organisms. Without labels, this would require the development of a system which DEFRA has predicted would involve "checks and certification requirements,"[5] though may in future also include testing.[6] DEFRA's Impact Assessment of the Genetic Technology (Precision Breeding) Act, which was rated not fit for purpose by the RPC,[7] estimates the value of exports that could be impacted to be £8.56 billion.[8]

It must also be noted that PBOs and NGTs are not the same and it may be unlikely that they could in the future be considered equivalent.

International trade and commodity markets

Trade regimes differ with regard to products from newer forms of genetic modification. If the UK fails to segregate PBOs it is unclear how British products for which there are PBO varieties could be traded with countries that require additional controls for PBO products. This is particularly relevant for products that are sold on to commodity markets, as the basis of trade in these products is that they are homogenous.

International obligations

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 also given to risks to human health.[9] An area of concern is that the UK may not meet its obligations with regard to the Cartagena Protocol, an issue which will be compounded by a failure to mandate the identification of PBOs in the environment and when they are moved across borders. The Explanatory Notes for the Act state that the Cartagena Protocol "does not apply to organisms produced using modern biotechnologies if those organisms could have occurred naturally or been produced by traditional methods."[10] This position is highly questionable and could be subject to legal challenge.

Consultations and a survey

There were a number of consultations conducted with regard to the Act and secondary legislation, two by the FSA and one by DEFRA. The government and these agencies have

refused to incorporate the findings of the consultations in the Regulations. For example, in all three cases it was found that the public overwhelmingly wanted labelling, but there are no provisions for labelling in the Regulations. The DMA refers to an unpublished DEFRA YouGov survey from 2022; it is unclear why this publicly-funded agency has not published a survey it has commissioned, what the majority of findings were or why they are undisclosed.

Grossly inadequate assessment of impacts

The Explanatory Note for the Regulations states:

> "A full impact assessment has not been produced for this instrument as no, or no significant impact on the private, voluntary or public sector is foreseen. A de minimis assessment of the effect that this instrument will have on the cost of business has been prepared".

The lack of a full impact assessment is reckless. A number of potential impacts of the Regulation have varying degrees of probability and probable severity. DEFRA should have formally assessed these, as the risks – particularly to non-GMO sectors and international trade – are large.

DEFRA's Impact Assessment of the then Genetic Technology (Precision Breeding) Bill, printed in March 2022, was found to not be fit for purpose by the Regulatory Policy Committee.[11] This undermines confidence in DEFRA's ability to make an adequate assessment with regard to this instrument, especially if robust procedures are not in place; that is, if a full impact assessment is not undertaken.

Some of the problems with the DMA produced by DEFRA are outlined in the Appendix to this submission.

Conclusion

The Regulations have been written such that it will not be possible to identify PBOs in the UK's food and farming systems. This was not prescribed by the Act, on the contrary, it contains a provision for traceability and defines this as "the ability to trace and follow the organism and the food or feed through all stages of production, processing and distribution."[12]

Labelling, traceability, risk assessments and the means of detection would not have weakened legislation on PBOs, rather, they would engender the confidence of consumers and provided producers with a system by which they could demonstrate not only safety but the demand for their products.

As it stands, the legislation will create market failures, as consumers, suppliers, manufacturers and producers will be unable to choose PBO-free products, even where they are legally obliged to do so.

Appendix: DEFRA's *de minimis* assessment

The DMA that DEFRA has produced is grossly inadequate and in areas may be factually incorrect. For example:

1. It states that consumers who wish to avoid PBOs are a minority. This statement is not supported the results of successive consultations that are in the public domain.[13] The DMA refers to one survey that it is claimed shows something marginally different, however, it is impossible to ascertain the veracity of this claim as the document is unpublished.
2. The DMA indicates that consumers will still be able to select PBO-free products should they wish to.
3. It states that organic operators will be able to maintain segregated supply chains.
4. It fails to recognise or incorporate the financial implications of an inability to maintain organic status by operators.
5. It fails to recognise or take into account that segregation is required for organic produce beyond the farm level.
6. It states that the public register of PBOs will provide consumers with information that will allow them to assess the benefits and risks of the organisms.
7. Though the DMA acknowledges that PBOs will need to authorised and labelled as GMOs when exported to Europe, it does not take into account the cost of maintaining separate exporting processes for PBO and non-PBO varieties. It is unclear what processes could be implemented that enable labelling at the border when there is no labelling throughout supply chains.
8. It fails to incorporate the increased costs of non-PBO products for consumers that will inevitably result in the absorption of segregation costs by these sectors.
9. The Theory of Change does not consider any negative consequences, including on trade, consumer choice or undermining devolved nation sovereignty.
10. It does not consider the impacts of an increase in patents in the plant breeding sector that may result from the Act and Regulations.
11. It does not consider any potential risks arising from challenges to the UK's refusal to recognise the applicability of the Cartagena protocol.
12. It does not recognise the possibility of safety-related product recalls, or recalls in the event of revocations of PBO status, or state where liability would fall for these.

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