Submission to Secondary Legislation Scrutiny Committee on the draft Statutory Instrument for the Genetic Technology (Precision Breeding) Regulations 2025 and the Explanatory Memorandum for the same

From Claire Robinson, Co-Director, GMWatch, and Prof Michael Antoniou, King's College London. 3 Mar 2025. Contact: Claire Robinson editor@gmwatch.org*

Abbreviations used:
GM = genetically modified
GMO = genetically modified organism
NGT = new genomic techniques – new genetic engineering/modification techniques
PB = precision bred
PBO = precision bred organism
WGS = whole genome sequencing

About the authors

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* This document represents the personal views of Prof Michael Antoniou and not the views of his employer.

Summary

This submission relates to the draft Statutory Instrument (SI) for the Genetic Technology (Precision Breeding) Regulations 2025[1] and the Explanatory Memorandum[2] (EM) for the same.

The scientific foundation of the Genetic Technology (Precision Breeding) Regulations 2025 is critical to its practical implementation, particularly regarding the verification of "precision bred" status. In this document, we demonstrate that this

[1] https://www.legislation.gov.uk/ukdsi/2025/9780348269123/introduction
[2] https://www.legislation.gov.uk/ukdsi/2025/9780348269123/memorandum/contents

scientific foundation is lacking. Therefore, we have serious concerns about how this policy will function in reality.

The draft Instrument currently lacks mandatory analytical processes, namely long-read deep whole genome sequencing and untargeted "omics" analyses, that would help to establish whether any given GMO qualifies as precision bred. Without the mandatory application of these scientific methods, the system relies heavily on self-declaration by applicants, creating significant regulatory uncertainty about whether genetic changes in supposedly precision bred organisms truly "could arise from traditional processes", as required by the legislation.

These scientific gaps have far-reaching implications across multiple sectors. The absence of mandatory detection methods prevents conventional and organic breeders from verifying and maintaining their non-GMO status, while also leaving them vulnerable to potential patent infringement claims. Meanwhile, the regulatory framework's assertion that precision bred organisms present "no greater risk to health or the environment than traditionally bred counterparts" lacks robust empirical evidence, contradicting scientific perspectives that emphasise the need for rigorous case-by-case analysis. These scientific considerations ultimately determine whether the regulations can achieve their intended balance between innovation and safety, transparency and practicality.

We elaborate on our concerns below.

False and misleading statement regarding GMO status of PBOs

The EM makes the false and misleading statement, "These new measures include a process for confirming that plants are precision bred, *not GMOs*, before they can be marketed" (EM, 5.6) (our emphasis).

In fact, the Genetic Technology Act 2023 makes clear that PBOs are GMOs, or products of "modern biotechnology" (Genetic Technology Act 2023, 1(2)), by cross-referencing the definition of a PBO to the Genetically Modified Organisms (Deliberate Release) Regulations 2002, 5(1)(a) and (b), "Techniques of genetic modification". These techniques of genetic modification, as defined in the Regulations, would include all gene editing techniques, including those defined as PB. Therefore, PBOs are indeed a subclass of GMOs under UK law. This accords with the general recognition in the scientific community that gene editing technologies are genetic modification/genetic engineering technologies.[3]

Suggestion: The committee may wish to suggest to DEFRA a rewording of the EM and remind them to word other relevant documents accurately. Because UK law already defines PB techniques as genetic modification techniques, the EM could be reworded along the lines of "These new measures include a process for confirming

[3] E.g. https://wp.lancs.ac.uk/futureofhumanreproduction/genome-editing/ ; https://www.technologynetworks.com/genomics/articles/genetic-modification-techniques-and-applications-382001#D2

that plants are **precision bred organisms** before they can be marketed".

Uncertain "precision bred" status

No analytical processes are mandated in the SI that the notifier/applicant is required to apply in order to prove that their genetically modified organism is PB in that it "only contains genetic sequences that could arise from traditional processes" (SI, 4(g); 9). Instead, the notifier/applicant only has to provide "a description of the analysis and procedures used to confirm" the PB designation (SI, 4(g); 9).

It is not scientifically justifiable to allow the notifier/applicant to self-declare PB status of their GMO without providing evidence. The lack of evidence-base in PB status leads to legal uncertainty and vulnerability for GMO developers and for non-GMO and organic sectors of the agriculture and food industries alike. In order to supply such evidence, the SI should mandate that the notifier/applicant perform long-read and deep whole genome sequencing (WGS) to search for unintended insertion of foreign DNA, deletions and rearrangements that have been caused by the genetic engineering gene editing process taken as a whole.

DEFRA recently wrote to Claire Robinson in response to this point: "Scientific advice is that WGS should not be mandatory and would be disproportionate given the specific, targeted nature, of the types of changes resulting from the application of precision breeding technologies. However, to accurately characterise their plants, we expect notifiers to collect sufficient data to ensure that plants qualify as precision bred."[4]

We respond that while gene editing and other GM "PB" technologies are intended to produce only "specific" and "targeted" changes, they will not necessarily do so in all cases. They may also produce many unintended changes, such as large-scale deletions and rearrangements of DNA, as well as unintended insertions, and even chromothripsis (catastrophic shattering and random reassembling of the chromosome).[5] Some such changes can be very different to those that could arise from traditional processes (including random mutagenesis induced by chemicals or radiation) and consequently will pose different risks.[6] The only "sufficient data" that could begin to prove that a self-declared PBO is indeed PB is long-read, deep WGS, as multiple scientific authorities confirm. Long-read and deep whole genome sequencing is generally seen as the best way of capturing unintended large-scale deletions and rearrangements, as well as unintended insertions of foreign DNA that can be, and regularly are, missed by the more frequently performed short-read DNA

[4] Email of 24 Feb 2025 from the Genetic Technology Policy and Regulation Team.
[5] https://doi.org/10.3389/fbioe.2023.1276226 ; https://pubmed.ncbi.nlm.nih.gov/36365450/ ; https://www.frontiersin.org/journals/bioengineering-and-biotechnology/articles/10.3389/fbioe.2023.1276226/full
[6] https://doi.org/10.3389/fbioe.2023.1276226 ; https://www.frontiersin.org/articles/10.3389/fpls.2019.00525/full

sequencing.[7] However, neither long-read nor short-read sequencing are required by the SI or the primary legislation it serves.

In addition, untargeted "omics" molecular characterisation – proteomics and metabolomics – should be mandatorily performed on every claimed PBO to check that no unexpected toxins or allergens (or other unintended compositional changes) have been created by the genetic technologies applied.[8]

It is not sufficient that an FSA Technical Guidance document mentions a limited targeted "omics" analyses as a non-mandatory/optional piece of information to be included in the FSA food and feed marketing authorisation application only in the specific case "Where the purpose of the genetic change(s) is to intentionally alter the composition of the PBO relevant to the safety/nutritional quality of food/feed made of it".[9] This is because composition may be affected in unexpected ways as a result of genetic changes that are not intended to alter the composition of the PBO relevant to the safety or nutritional quality of the food; unintended compositional changes unlike those that would occur through traditional processes are an intrinsic risk factor of "new genomic techniques" (NGTs)/PB techniques and are not restricted to intended altered-composition NGT-derived/PB organism.[10]

The FSA guidance document does concede that "intended genetic changes introduced through the application of modern biotechnology may also cause unintended characteristics in plants".[11] Yet for the Tier 1 safety assessment that decides if there are safety concerns that demand a more detailed Tier 2 safety assessment or whether the PBO can be exempted from further examination, "applicants must consider whether genetic changes ***may reasonably be anticipated*** (see Definitions) to unintentionally increase levels of potentially harmful components, or change in nutritional quality" (our emphasis).

The history of biotechnology is packed with examples in which effects of genetic changes have not been anticipated.[12] Yet in the SI, procedures that would identify a

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[7] https://plantmethods.biomedcentral.com/articles/10.1186/s13007-020-00661-x ; https://www.nature.com/articles/nbt.3680 ; https://pmc.ncbi.nlm.nih.gov/articles/PMC9655061/ ; https://www.sciencedirect.com/science/article/abs/pii/S246845112300034X

[8] https://www.frontiersin.org/journals/bioengineering-and-biotechnology/articles/10.3389/fbioe.2023.1276226/full ; https://enveurope.springeropen.com/articles/10.1186/s12302-023-00734-3 ; https://www.frontiersin.org/articles/10.3389/fpls.2018.01874/full

[9] https://www.food.gov.uk/sites/default/files/media/document/Edited%20DRAFT%20Technical%20guidance%20to%20applicants%20for%20the%20authorisation%20of%20Precision%20Bred%20Organisms%20for%20food%20and%20feed_0.pdf See section 16.3.3

[10] https://www.frontiersin.org/journals/bioengineering-and-biotechnology/articles/10.3389/fbioe.2023.1276226/full ; https://www.frontiersin.org/journals/bioengineering-and-biotechnology/articles/10.3389/fbioe.2019.00031/full

[11] https://www.food.gov.uk/sites/default/files/media/document/Edited%20DRAFT%20Technical%20guidance%20to%20applicants%20for%20the%20authorisation%20of%20Precision%20Bred%20Organisms%20for%20food%20and%20feed_0.pdf See p10.

[12] E.g. https://www.nature.com/articles/s41587-019-0394-6 ; https://www.nature.com/articles/nbt.3680 ; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9655061/

good proportion of such unanticipated changes are not mandated and will therefore likely not be carried out. The FSA's decision tree (Figure 1) of questions that guide notifiers/applicants to decide if their PBO falls under Tier 1 or Tier 2 amplifies this omission, focusing on intended changes at the expense of unintended changes. For example, the notifier/applicant is asked:

- "Is the PBO designed to introduce significant changes to the nutritional quality of the organism currently consumed that are likely to be disadvantageous to the consumer?"

- "Is the PBO designed to introduce changes that are expected to elevate significantly the toxicity of any food/feed derived from the organism?"

- "Does the PB introduce changes that are expected to alter the allergenicity of any food/feed derived from the organism?"

Clearly no GMO developer with a reputation to protect will intentionally introduce into the food supply a GMO that they believe to be nutritionally compromised, toxic, or allergenic. Bioterrorism apart, it is not *intentional* toxicity or allergenicity that is of concern; it is *unintentional* toxicity or allergenicity. Yet the analyses that are needed to establish whether such unintended harmful changes have occurred in the claimed PBO are not mandated.

In conclusion, both long-read, deep whole genome sequencing and untargeted "omics" analyses would contribute substantially to "sufficient data" to prove PB status. These methods form the sole basis on which the notifier/applicant can assert PB status and on which the regulator can assess whether a self-declared PBO is genuinely PB.

Suggestion: The committee may wish to ask DEFRA to resolve regulatory and legal uncertainties by requiring that the notifier/applicant perform long-read, deep whole genome sequencing and untargeted "omics" analyses on the potential PBO and submit the resulting data in their application, in order to demonstrate PB status.

Evidence base not provided

The EM states that various bodies have "concluded that precision bred organisms present no greater risk to health or the environment than traditionally bred counterparts. The Advisory Committee on Novel Foods and Processes reached the same conclusion, stating that there is no evidence that precision bred organisms are intrinsically more hazardous than traditionally bred organisms."

Note that hazard refers to the potential danger posed by an agent without taking into consideration real circumstances such as exposure frequency and amount, safety measures, etc. Risk refers to actual danger based on taking those real circumstances into consideration. By analogy, flying in an aircraft poses a high hazard (in that a crash would almost certainly prove fatal to those on board), but the risk is low (because crashes are rare, thanks to regulations enforcing safety measures).

However, there has been little or no scientific research on the level of hazard or risk posed by GMOs designated as PBOs – and absence of evidence is not evidence of absence (of hazard or risk).

Even in a hypothetical case in which the hazard posed by a given PBO is no greater than that posed by its traditionally bred counterpart because the genetic changes made are conventional-like and could have arisen by traditional processes, the actual risk may be far greater. This is because the difference between traditional breeding and gene technologies such as gene editing is the frequency/rate of creating a particular change, whether it be intended or unintended; beneficial or harmful. The journey to either a good or bad outcome is much shorter with targeted techniques. If the genetic change made creates a GMO that can be a hazard, that GMO is created at rates thousands of times faster, and in numbers, thousands of times larger, compared with a traditionally bred counterpart.[13]

We have repeatedly asked UK government agencies for primary experimental evidence that PBOs present no greater risk to health or the environment than traditionally bred counterparts and that precision bred organisms are not more intrinsically hazardous than traditionally bred organisms, but none has been forthcoming.

Because there is no research on the actual risk posed by PBOs/NGT-derived organisms, scientists have had to assess their risk potential based on the types of genetic changes that are possible with PB techniques.

The German Federal Agency for Nature Conservation (BfN) states that NGT-derived/gene-edited plants "have a similar if not greater risk potential compared to the plants produced by genetic engineering to date. Grouping certain NGTs depending on their risk profile has been discussed. In general, traits cannot be categorised and deemed less risky. From a scientific point of view, no criteria exist which would allow these NGTs to be grouped in a general manner. The size of the genetic modification – for example – cannot be regarded as a reliable denominator of risks and safety of the specific modifications in an individual plant. Only a case-by-case analysis as performed under the current legislation can ensure a high safety level."

According to the BfN, a high level of safety can only be ensured with a case-by-case analysis, as required in current GMO legislation, especially since there is no experience, or only very limited experience, with the deliberate release of these plants and their products. The BfN states that, in contrast to conventional breeding, "genome editing makes the whole genome accessible for changes. This indicates that directed mutagenesis increases the depth of intervention, and is thus not comparable to conventional breeding, including random mutagenesis."[14]

Similarly, the French food safety agency ANSES conducted around ten case studies of food crop plants produced with "new genomic techniques" (NGTs, equivalent to

[13] https://online.ucpress.edu/elementa/article/9/1/00086/116462/Differentiated-impacts-of-human-interventions-on
[14] https://www.bfn.de/sites/default/files/2021-10/Viewpoint-plant-genetic-engeneering_1.pdf

PB techniques) and considered the possible risks that these NGT plants pose to health and the environment. They wrote, "certain potential risks appear repeatedly in these case studies" and that "These include risks linked to unexpected changes in the composition of the plant, which could give rise to nutritional, allergenicity or toxicity problems, or medium- and long-term environmental risks, such as the risk of gene flow from edited plants to compatible wild or cultivated populations."[15]

A significant number of peer-reviewed scientific publications state that the risks of gene-edited plants are similar to, or greater than, those of older-style GM plants and that detailed risk assessment involving whole genome sequencing and detailed molecular "omics" analyses (proteomics, metabolomics) is needed for each NGT/PB plant, on a case-by-case basis.[16]

While DEFRA has cited the European Food Safety Authority (EFSA) as supporting its assertion that PB/NGT plants carry no greater risks than conventionally bred ones,[17] EFSA had to ignore a large number of recent relevant studies to reach that conclusion (80% of studies sent to EFSA by the research nonprofit Testbiotech[18]).

Regarding the independence of scientific advice on how to regulate GMOs, including PBOs, the UK government has relied on experts with conflicts of interest with the GMO development industry.[19] For example, Millstone and Lang examined UK food regulatory institutions for conflicts of interest, including the FSA, the ACNFP, and another GMO regulatory body, the Advisory Committee on Releases to the Environment (ACRE). They found that each included members declaring interests at some point, with some panels having more experts with conflicts of interest than without.[20] In the EU, EFSA is similarly compromised.[21]

Suggestions: The committee may wish to ask DEFRA to publish the evidence base in support of the view that PBOs present no greater risk to health or the environment than traditionally bred counterparts. This evidence should consist of robust analyses of actual organisms that could be asserted to be PBOs, for instance, via long-read deep WGS and/or "omics" analyses.

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[15] https://www.actu-environnement.com/media/pdf/news-43622-avis-anses-nouveaux-ogm.pdf ; English translation of parts of French language report provided by GMWatch: https://www.gmwatch.org/en/106-news/latest-news/20391

[16] E.g. https://enveurope.springeropen.com/articles/10.1186/s12302-023-00734-3 ; https://enveurope.springeropen.com/articles/10.1186/s12302-020-00361-2 ; https://www.sciencedirect.com/science/article/pii/S1673852720300916?via%3Dihub ; https://www.frontiersin.org/journals/bioengineering-and-biotechnology/articles/10.3389/fbioe.2023.1276226/full ; https://www.mdpi.com/2223-7747/11/21/2997 ; https://www.mdpi.com/2223-7747/10/11/2259/htm ; https://www.mdpi.com/2673-6284/10/3/10

[17] Email of 24 Feb 2025 from the Genetic Technology Policy and Regulation Team. EFSA's opinion is here https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2022.7618

[18] https://www.testbiotech.org/en/news/new-genomic-techniques-and-unintended-genetic-changes-efsa-overlooked-most-scientific-findings/

[19] https://www.gmwatch.org/en/106-news/latest-news/20157 ; https://www.nature.com/articles/s43016-022-00666-w ; https://www.gmwatch.org/en/106-news/latest-news/19999 ; https://www.gmwatch.org/en/106-news/latest-news/20373

[20] https://www.nature.com/articles/s43016-022-00666-w ; https://www.gmwatch.org/en/106-news/latest-news/20157

[21] https://www.gmwatch.org/en/106-news/latest-news/20454

Further, the committee may wish to ask the UK government to commission an independent review of the evidence on the comparative safety of PBOs and traditionally bred organisms, excluding experts with conflicts of interest and addressing all relevant studies that could be supplied by civil society organisations and concerned scientists.

In addition, given the lack of scientific consensus on the safety of PBOs/NGTs between the UK government's chosen advisors and other independent scientists, the committee may wish to ask DEFRA and the FSA to require mandatory labelling of these products from seed to fork.

Importance of WGS and publicly available detection methods

The SI fails to require not only that WGS is carried out, but also that a detection method for the PBO is made publicly available – something that is still required in the EU, pending any changes to the regulations for NGTs. According to the German Federal Agency for Nature Conservation, "Despite claims of challenges in identifying NGTs [equivalent to PBOs], so far there has been no known case where applicants failed to provide a method to detect or identify a plant derived by NGTs for which they are seeking approval."[22] It is obvious that every notifier/applicant will have in-house a detection method for their claimed PBO, or they would not be able to protect their patent from infringement.

If no detection method is made publicly available, breeders and farmers will not be able to maintain their non-GMO status, nor will they be able to protect themselves against allegations of patent infringement for using patented genetic sequences, as they will not be able to test for those sequences in the seeds or germplasm that they use for breeding or that they produce in their breeding programmes. This is already a real problem for plant breeders:

- A breeder that announced that they had produced a non-GMO purple tomato received a warning about patent infringement from Norfolk Plant Sciences, which has patented the GMO Purple Tomato, leading to the breeder having to withdraw their claimed non-GM tomato.[23]

- Certain patented traits (whether GM or not) are seen as off-limits to breeders because those traits, including plants expressing those traits, have been patented – creating a chilling climate for breeding innovation and resilience.[24] Since all GMOs, including PBOs, are patented, the UK government's deregulation of PBOs will increase the number of patented plants and traits. In such a climate, the very least that responsible legislation should provide is a detection method to enable plant breeders and farmers to protect themselves against inadvertently infringing patents.

[22] https://www.bfn.de/sites/default/files/2021-10/Viewpoint-plant-genetic-engeneering_1.pdf
[23] https://www.gmwatch.org/en/106-news/latest-news/20393
[24] https://www.theguardian.com/environment/2024/jan/25/plant-patents-large-companies-intellectual-property-small-breeders ; https://infogm.org/en/a-dutch-seed-company-faces-up-to-kws-patents/

DEFRA has justified the omission of mandatorily supplied whole genome sequencing data and detection method by stating, “Whilst prior knowledge of the altered genome and suitable reference materials may, in theory, assist in the detection of precision bred organisms, there would be no way of knowing whether the genetic change resulted from the application of precision breeding technology or traditional breeding practices due to the nature of the genetic changes permittable under precision breeding legislation.”[25]

In reality, however, this issue arises from only looking at the limited section of the genome that contains the intended genetic modification(s). Beyond this limited section of the genome, each PBO will have a unique whole genomic sequence, in the context of which the intended genetic modification(s) is/are placed.

If this were not the case, the PBO would not be worth developing or patentable, as a patent is awarded for an inventive step and not something that is already found in nature/conventional breeding. The PBO developer will possess this unique genetic sequence as its intellectual property. On the basis of this sequence, they will also have developed a detection method to protect their patent. There should therefore be no issues in making the detection method publicly available so that breeders and farmers can maintain their non-GMO status and protect themselves from allegations of patent infringement.

Suggestion: The committee may wish to ask DEFRA to require public disclosure of either (a) whole genome sequencing data and a detection method, or (b) at the bare minimum, a detection method, so that breeders and farmers can maintain their non-GMO status and protect themselves from allegations of patent infringement.

Who can initiate a review of a PB confirmation decision – and how?

The SI (section 8) mentions the potential for initiating a review of a PB confirmation or revocation decision. However, it does not mention who may call for such a review and what the process is.

Suggestion: The committee may wish to ask the UK government to clarify who may call for such a review and whom they should approach to set the process in motion.

[25] Email of 24 Feb 2025 from the Genetic Technology Policy and Regulation Team.