Submission from GM Watch and Professor Michael Antoniou

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

Claire Robinson is Co-Director of GMWatch, a nonprofit civil society organisation that provides the public with news and evidence-based critical comment on genetically modified (GM) crops and their associated pesticides.

Michael Antoniou is Professor of Molecular Genetics and Toxicology at King's College London. He is a molecular biologist who has made seminal contributions to the field of gene structure and regulation. His discoveries have led to various biotechnological applications, including in the fields of gene therapy and the industrial manufacture of therapeutic proteins. He holds inventor status on patents covering gene expression platforms (expired, with others pending). He has first-hand experience of all genetic modification technologies, including gene editing technologies. He has over 160 publications in the peer-reviewed literature.
* 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.

3 March 2025

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

Response from Defra and the FSA

GM Watch Submission

(Refer to attachment for full submission)

1. *'False and misleading statement regarding GMO Status of PBOs'*

GM Watch assertions:

- *"...PBOs are indeed a subclass of GMOs under UK law"*.

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

Defra Response:

- The Genetic Technology (Precision Breeding) Act 2023 (The Act) establishes precision bred organisms as a class of regulated organisms that are distinct from genetically modified organisms (GMOs).
- The Act refers to techniques of 'modern biotechnology'. These can result in genetically modified organisms or in precision bred organisms. There is no definition of 'PB techniques' in the legislation. We have used 'precision breeding techniques' in the EM instead of using a longer phrase i.e. 'techniques of modern biotechnology that would result in precision bred organisms'. We do not consider that using the term precision breeding techniques is inaccurate or misleading.

2. *'Uncertain "precision bred" status'*

GM Watch assertions:

- *"No analytical processes are mandated in the SI"*
- *"It is not scientifically justifiable to allow the notifier/applicant to self-declare PB status of their GMO without providing evidence.*
- *"The SI should mandate that the notifier/application 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"*

GM Watch 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."

Defra Response:

- Defra's position, based on independent scientific advice, is that Whole genome sequencing (WGS) is not necessarily required to demonstrate the precision bred status of an organism. Developers may choose to include sequencing data when submitting their marketing notices, however this is not a requirement.
- Schedules in the regulations set out a series of questions that must be answered in marketing notices. These are questions that our scientific advisors have asked for in order to be able to determine whether a plant has been precision bred. They include questions about the methods used to develop the plants, which will inform what needs to be checked. There are also questions about how these checks were carried out by the notifier. The regulations are not prescriptive about the analytical techniques that need to be used, particularly in the light of technical advances. But they must demonstrate that the notifier has addressed the question satisfactorily. WGS may be used to address questions in the regulations, but more information will also be required.
- For example, those submitting precision bred organism marketing notifications must include descriptions of how any transgenic DNA has been removed and describe the analysis which has been undertaken to confirm removal of these sequences. As part of this, rationale for the depth of analysis undertaken must also be provided.
- We do not agree with GM Watch that the process to obtain confirmation of PBO status, which involves an assessment by a scientific advisory committee, constitutes a self-declaration by notifiers.

FSA Response:

- Based on their review of case studies (published in the ACNFP Statement July 2023, Annex A) and their knowledge of the wider literature, ACNFP members did not find evidence that PBOs are intrinsically more hazardous than traditionally bred organisms; they concluded that it was the alteration in trait that could lead to phenotypes of concern regarding the safety of the food or feed, rather than specifically the technology used to achieve the trait. The ACNFP recognised that most organisms produced by PB will be similar in risk profile to their traditionally bred counterparts where the same change has been achieved and a risk assessment is not required. By definition, the spectrum of genetic changes introduced by precision breeding techniques are identical to those that could occur through traditional breeding. A requirement of the PBO marketing notice is to provide information on checks for unintended genetic changes..
- It is possible that in some instances unintended compositional effects may occur during development of a PBO. However, this is also the case with organisms produced through traditional breeding. If an applicant cannot demonstrate that the application of modern biotechnology does not introduce genetic changes to the organism that are expected to lead to significant compositional changes, the PBO must be assessed by the FSA. Applicants are required to provide experimental data to evidence their conclusions, where

necessary, to facilitate this assessment. To request omics data of all PBOs where not required of traditionally bred organisms would be disproportionate. During the planning and production of PBOs, developers are expected to take all reasonable measures to identify and limit any such unintended effects.

3. *<u>'Evidence base not provided'</u>*

GM Watch assertions:

- "*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.*"
-"*actual risk may be far greater...*"

GM Watch 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.
- "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".

Defra Response:

- The issue of mandatory labelling was a feature of debates in both houses of Parliament during the passage of the Act. In both houses, amendments to require mandatory labelling of PBOs failed to gain sufficient support.
- The scientific advice from the Advisory Committee on Releases to the Environment (ACRE) is that precision bred organisms do not confer a greater risk than their traditionally bred counterparts. This advice is built on a wealth of peer reviewed literature, and it is consistent with statements from The Royal Society, the Food Standards Agency (FSA)'s Committee on Novel Foods and Processes, the European Academies of Science Advisory Council and the Scientific Advice Mechanism (to the EU Commission) amongst others.
- We do not consider that it is necessary to commission an additional review given the existing body of evidence.

- Based on the scientific advice that the risk associated with precision bred plants is no greater than for traditionally bred counterparts, we do not consider that mandatory labelling focused on the breeding technology or process used is appropriate.
- However, the UK maintains high standards on the information that is provided on food labels, whether that be mandatory or voluntary, so that consumers can have confidence in the food that they buy.
- All food and drink sold on the UK market must comply with food labelling rules. The fundamental principle of food labelling rules is that information provided to the consumer must not mislead and must enable the safe use of food.
- Registers published by Defra and FSA will contain information about precision bred plants, including those approved for use in food and feed.
- Businesses may choose to label their products as being from precision bred plants.

FSA Response:

- There is no justification for the provision of labelling distinguishing all PB food as such on grounds of consumer safety. Based on their review of case studies (published in the ACNFP Statement July 2023) and their knowledge of the wider literature, ACNFP members did not find evidence that PBOs are intrinsically more hazardous than traditionally bred organisms.
- As with any food, if there is a need to provide safety information for a particular population group, (for example, hypersensitive consumers or people with certain health conditions) this can be required as appropriate. The UK Government has been clear that there are no plans to require labelling of products to indicate they have been produced using PB techniques.
- Th FSA has conducted consumer research which told us that consumers saw a range of risks and benefits to PB food but on balance consumers thought the benefits outweighed the risks if properly regulated; they trust the FSA to regulate PB food; the public register builds towards confidence and reassurance; more proactive information provision (public education campaign, education in school curriculum, labelling, for example) would reassure them that regulation was happening; they wanted labelling to enable them to make choices at the point of purchase.

- The FSA Board considered this issue at Board meeting in 2023 and 2024. The Board has actively discussed the views of consumers throughout the development of the proposals and recognises the importance of these views. This was a key focus of the Board's discussion and associated Board paper at the March 2023 Board meeting.
- The power to decide on the mandatory labelling of PBOs for non-safety related purposes in England sits with the Secretary of State for Defra. FSA officials have shared results of the consumer research and public consultation with Defra.

- The ACNFP is an independent Scientific Advisory Committee (SAC) that provides scientific insight, advice and the technical knowledge needed to evaluate the safety of PBOs for use in food and feed. It is established under Article 5(3) the Food Standards Act 1999. Members are recruited in line with the Code of Practice for Scientific Advisory Committees (CoPSAC). The ACNFP Code of Practice requires all members to provide clear declarations of interests which are then made publicly available on the ACNFP website. The Code of Practice outlines how conflicts of interests are managed within meetings of the Committee.

- We consider the independent advice provided by the ACNFP on precision breeding to be the best available scientific advice. ACNFP meeting agendas, papers, minutes and reports are published in a timely manner and open to scrutiny.

- The FSA strives to be an open and transparent organisation. We want to hear the views and perspectives from all those with an interest in food including academia, industry, civil society groups and members of the public. This is reflected in the range of viewpoints amongst members on the Scientific Advisory Committees. Recruiting people to our Advisory Committees who have experience and insights from across the food system, including as individual citizens, is essential in helping the FSA deliver its mission to keep food safe. We have no evidence to suggest that any bias from any committee member has influenced the work of the FSA.
- The Food Standards Act 1999 safeguards our political independence and ensures we are accountable to Parliament. It sets out our main goal to protect public health in relation to food. It gives us the power to act in the consumer's interest at any stage in the food production and supply chain.
- The Food Standards Act 1999 also establishes how Board members are appointed and how advisory committees are established. In the case of FSA Board members, all appointments are ultimately made by UK Ministers. Appointments to SACs are made by the Chair.
- Our Board works to the Cabinet Office Code of Conduct for Board members of Public Bodies and FSA Code of Conduct. Likewise, the ACNFP works accordingly to the Good Practice Guidelines for Scientific Advisory Committees.

4. *'Importance of WGS and publicly available detection methods'*

GM Watch assertions:

- *"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."
- "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"

GM Watch 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.'

Defra Response:

- As previously mentioned, there is no legislative requirement for notifiers to submit whole genome sequencing data as part of a release or marketing notice for the reasons previously outlined.
- To our knowledge, there are currently no scientific methods that provide unequivocal identification of genetic changes associated with precision bred plants without prior knowledge of the altered genome and suitable reference materials. If these data were available, there would be no way of knowing whether the genetic change resulted from the application of precision breeding technology or traditional breeding practices.
- In order to help those breeders and farmers who wish to grow non-precision bred plant varieties only, the government wants to ensure that there is accessible marketing information to enable this. The government is exploring a variety of methods and tools to communicate information on the precision bred status of plant varieties.
- To facilitate the marketing of precision bred varieties of the main agricultural and vegetable species, a Precision Bred Plant Variety List for England is proposed in addition to the existing GB and NI variety lists. Information regarding applications made and varieties accepted onto the list, including variety name, will be published in the Plant Varieties and Seeds Gazette. The Animal and Plant Health Agency through their Delivering Sustainable Futures project are looking to improve the accessibility and usability of the Gazette.
- Views on the proposed Precision Bred Plant Variety List for England are being sought through the public consultation on Plant Varieties and Seeds Framework for Precision Bred Plant Varieties (17 Feb – 14 Apr 2025) which also seeks feedback on the provision of information on precision bred seed and other plant reproductive material.

FSA Response:

- LGC Ltd.'s Literature review on analytical methods for the detection of precision bred products highlights that there are no methods of providing unequivocal detection of the genetic change in most PBOs defined by the Genetic Technology (Precision Breeding) Act, without prior knowledge of the altered genome sequence and suitable reference materials. For those PBOs where detection may be possible, it is not currently feasible to distinguish whether the genetic changes are the result of genome editing, natural variation, or traditional breeding methods. In cases where detection was possible, this is likely to be lost in subsequent generations.
- In our response to this report, we concluded that due to proportionality and feasibility reasons we did not plan to take forward the recommendations in the report to aid ongoing policy development on precision breeding, we welcomed further research in this area to ensure we have the most up to date scientific information available when reviewing policy and/or developing new policies related to genetic technologies.
- The FSA is science and evidence led. We regularly conduct horizon scanning and independently review new evidence that becomes available that is relevant to food and feed safety. In the case of detection, we will continue to monitor new developments in this area.
- The consensus is that currently there are no methods that provide unequivocal detection of PBOs

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

GM Watch 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'

Defra Response:

- 7 (1) of the regulations state that the Secretary of State may revoke a precision bred confirmation relating to an organism if the Secretary of State is no longer satisfied that an organism is precision bred in any of the following circumstances:
    - (a) the notifier or other person named in the marketing notice notifies the Secretary of State directly or indirectly that the organism is not precision bred;
    - (b) the Secretary of State reasonably suspects that a notifier or other person named in a marketing notice has provided false or misleading information in the marketing notice;

    - (c) the Secretary of State is provided with new genetic information about an organism with a precision bred confirmation.
- In practice this means that the revocation process can be initiated by the notifier or other person named in the marketing notice, the Secretary of State or a person not named in the marketing notice that provides credible genomic information indicating that the organism is not precision bred. Defra should be approached by email to genetictechnologies@defra.gov.uk.

6 March 2025

Submission from Beyond GM

Submission from Beyond GM on
The Genetic Technology (Precision Breeding) Regulations 2025

Beyond GM is a UK-based civil society organisation. We engage with and present the perspectives of a wide range of citizens and stakeholders, organisations and individuals – including farmers and growers, consumers, seed producers, artisanal processors and retailers and civil society groups – on genetic engineering technologies in farming and food. We regularly engage with policymakers and the political process, advocate for higher standards of evidence and aim to raise the level of the discussion around genetic engineering and other novel approaches in food and farming to make it more thoughtful and inclusive.

We submit, below, general comments and recommendations related to the above Instrument and its explanatory materials.

Note: Legally and scientifically so-called "precision-bred organisms" (PBOs) are genetically modified organisms (GMOs). The Genetic Technology Act defines them as such and then creates a series of regulatory exemptions (deregulation) for these organisms. For accuracy, we will refer to PBOs as "precision-bred GMOs" throughout this submission.

1. Context and general comments

This Instrument spans over 40 pages with 55 Regulations across 11 Parts, including amendments to 14 different pieces of legislation. It is accompanied by a 7-page explanatory memorandum, a 37-page de minimis assessment (DMA), 32 pages of ACRE guidance and 135 pages of FSA guidance (with further promised FSA enforcement guidance still unpublished).

It creates entirely new regulatory frameworks for notification requirements, marketing authorisations, safety assessments, public registers and enforcement regimes. Given this breadth and significance, these provisions would typically warrant the scrutiny of primary legislation. The Secondary Legislation Scrutiny Committee has previously raised concerns about this approach.

a) Presumption of approval

The government has described this Act as based on self-certification (Defra impact Assessment) or self-determination/self-assessment (FSA consultation pack).

The regulatory structure operates with an apparent presumption of approval. Regulation 30(5), for example, describes specific circumstances where authorisation "must not" be issued, implying that authorisation is the default position.

While the Instrument includes verification requirements (Regulation 23), it has limited assessment obligations and explicitly prohibits the application of tests or stricter standards than what would normally apply to food or feed made from conventionally bred organisms (Regulation 30(4)(b)) – an irrational approach given the novel nature of precision breeding and incomplete understanding of its impacts.

This approach places the burden on regulators to raise concerns, but the Instrument lacks prescribed processes for how concerns are identified or addressed. It also disproportionately burdens businesses and consumers wishing to avoid precision-bred GMOs, by failing to provide clear and readily accessible information at point-of-sale. Instead, it leaves them to navigate a complex set of electronic registers that provide technical detail about precision-bred GMOs but no information about the foods or products that contain them.

b) Missing guidance

Critical aspects such as technical criteria, public register content and procedures for notices are deferred to guidance documents. At the time of this submission, important guidance listed under 8.2 remains unpublished, including:

- Administrative guidance on food and feed marketing authorisation applications
- Enforcement guidance for enforcement authorities and their officers involved in the enforcement of the Instrument, e.g. local authorities and port health authorities in England.
- Enforcement guidance for authorities in England, Wales and Northern Ireland

It is unacceptable that these have not been published in time for scrutiny in this submission. We suggest that the Committee calls for accelerated development and publication of the remaining guidance to ensure smooth implementation and minimise transitional uncertainty.

c) Lack of impact assessment and statutory review clause

Despite establishing an entirely new regulatory framework with cross-cutting impacts, the Instrument lacks a full Impact Assessment (EM 9.1) and asks those scrutinising it to apply to Defra in writing for a copy of an inadequate DMA. A full impact assessment was

not produced for the parent Act and what was produced was deemed “not fit for purpose” by the Regulatory Policy Committee (RPC). A full impact assessment was also not produced by the FSA for its consultation recommendations. This means no full impact assessment has been produced for either the parent Act or the Instrument. This:

- Prevents proper evaluation of claims that the regulations in the Instrument "*will have a low level of impact on businesses*"
- Ignores acknowledged concerns about impacts on organic producers (EM 9.3) as well as those of provenance-based artisanal produces and conventional non-GMO farmers and food producers
- Fails to quantify costs and difficulties for consumers seeking to avoid precision-bred GMO products (EM 9.5)
- Fails to account for the costs of a PBO recall from environmental or supply chain/market releases

This omission undermines the concept of evidence-based policy and fails to address significant economic questions raised by stakeholders during consultations and meetings.

The decision not to include a statutory review clause (EM 10.2) limits opportunities for oversight of a fast-changing technology. In situations where enforcement actions or administrative decisions under this Instrument are later viewed as disproportionate or arbitrary, the absence of a built-in review mechanism might strengthen future challenges to the legislation.

2. Ambiguities in Definitions and Criteria

a) Definition of ‘traditional’

The EM outlines that precision-bred GMOs are “*plants produced by modern biotechnology, but which only contain genetic features that could have resulted from traditional processes*” (EM 5.4). Likewise, the Instrument repeatedly references genetic changes that "*could arise by traditional processes*" (e.g., Regulations 9 and 10(4)(g)).

This is the core definitional boundary of the entire regulatory system and yet:

- The criteria for what an allowable “traditional” change is not fully elaborated in the Instrument. Instead, the fundamental scope of the Instrument – which organisms are included or excluded – is relegated to guidance documents (EM 8.1). This guidance, produced by ACRE, is presented as opinion rather than a scientifically credible proposition, e.g. with references and arguments that can be scrutinised

- Guidance should not be confused with legislation. The legal standing of guidance offered by ACRE in the SI's accompanying documents is unclear. This is problematic as the guidance is crucial to the regulatory functioning of the Act and SI.

This lack of information may lead to uncertainty about which genetic changes qualify as "traditional" and which do not, potentially causing inconsistent applications in practice and, consequently, undermining consumer trust in regulation and the technology itself.

This information deficit has impacts on how the Instrument will function in practice in other areas. The lack of detection requirements, which stems from the central premise that precision-bred organisms are equivalent to those produced through traditional breeding, will further undermine fair competition and coherence in the marketplace, as well as farmer and consumer uncertainty and trust in products and technology.

Inconsistencies which arise from trying to equate a high-tech, laboratory-based process with a traditional one will only grow as the number of different techniques for genetic modification grows (see also *Lack of provisions for assessing future technology* below).

The Committee may wish to seek greater clarity on which specific genetic changes are acceptable as 'traditional? How will borderline cases be adjudicated?

b) Patent confusion

Although it is a live discussion in Europe, the UK has failed to address the legal implications of defining precision-bred GMOs as "traditional", the definition of which covers naturally occurring genetic changes (as specifically confirmed to us in an email from Defra dated 5/2/25). Developers wishing to enjoy patent protection will be aware that such protection hinges on, amongst other criteria, their inventions being new/novel (i.e. it must not exist or be part of traditional knowledge anywhere else in the world) and anthropogenic (i.e. man-made and involving a technical process or "inventive step"). If an invention fails either of these criteria, it will fail the patent application. If, due to legal challenge, a patent is revoked, this could have a negative financial impact for developers.

The Committee may wish to seek greater clarity from the government on excluding patented precision-bred GMOs from this Instrument and, instead, continuing to regulate them as GMOs. We suggest a full investigation into this legal issue.

c) The potential for unregulated market entry of precision-bred GMOs

The light touch approach to regulation in the Instrument creates artificial distinctions between what is an environmental release and what is a marketing release. These will become more apparent and more difficult to negotiate as more notifications such as the recently announced PROBITY trials come on stream. The Probity Project, approved

under the Deliberate Release Amendment 2022 (which will transition into the Act with this Instrument) will be staging experimental trials on 25 farms in England these trials perform several functions: to test how the precision-bred GMOs performs in the field, to function as demonstration fields to interest other farmers in growing PBO crops and to multiply seeds for marketing purposes.

As a result of this uncertainty, there is a significant risk that precision-bred GMOs which have been notified to Defra and entered the environment through the 'release' section of these regulations will end up in the food and feed supply chain.

The Committee may wish to question how the person responsible for overseeing such trials will straddle these different responsibilities of public relations, scientific evaluation and biosecurity? What criteria should the person responsible for preventing material from trials being marketed use? Can the job be left to just anyone? It may also wish to highlight the lack of transparency as to the several types of environmental release allowed in the Act – i.e. research, demonstration/public relations, seed multiplication or 'other' purposes.

3. Transparency and Public Accountability

a) Assessment of safety and risk

In summary, the Instrument does not require detailed safety or risk assessments from developers, either as part of Defra's environmental release process or Defra's precision-bred confirmation process. FSA's food and feed marketing authorisation process does require the developer to demonstrate that food safety is not affected, but the process is solely reliant on developer declaration in the form of a narrative statement. An application may be accompanied by "*any other information the applicant considers relevant*" but leaves it entirely up to the applicant to decide the meaning of "relevant". (For relevant sections see e.g. Regulations 12 and 20 and Schedules 1-3)

There is only one category of precision-bred GMO which must undergo a safety assessment by regulators and that is foods or feeds which fall into Tier 2 of the FSA's process. Given the majority of organisms – 94% according to one assessment – are expected to meet the Tier 1 criteria, the result is that the majority of precision-bred GMOs will be released into the environment and/or the food chain with very little consideration for safety or risk – and none at all when it comes to environmental risk – either by developers or by regulators.

The Committee may wish to question how the government will ensure adequate safety evaluation in the absence of mandatory risk assessments. The Committee should also seek clarification on what specific criteria will be used to identify potential risks when applicants are not required to provide comprehensive safety data and examples of other "relevant" information.

b) Advisory bodies' decision-making process

The Act and this Instrument require that advisory committee reports be sought before precision-bred confirmation can be given (6(c)). Other processes also involve advisory committee advice. However, as mentioned above in 'Definition of 'traditional', the scientific basis upon which advisory committee advice and reports are based is not disclosed and the Instrument does not mandate full disclosure. Consequently, the rationale behind key decisions may not be fully available to stakeholders or the public.

The Committee may wish to seek assurances that reports from advisory bodies will include full disclosure of the evidence considered and the weight given to different sources and that this be put on the public registers.

c) Lack of specific detection mechanisms

Whilst we are encouraged to see the emphasis on case-by-case assessment of precision-bred GMOs, the lack of interest or investment in such mechanisms will make this less process rigorous> it may also make assessment more prone to the potential bias of interested parties which make up both ACRE and the Food Standards Agency's Advisory Committee on Novel Foods and Processes (ACNFP) on Precision-bred Organisms have demonstrated.

We note that, in 2023, the Food Standards Agency commissioned a literature review, undertaken by eminent scientists with links to government. The review highlighted the need for a robust, science-based framework to detect precision-bred GMO products, emphasising that such products often display subtle genetic modifications which are "*very challenging to distinguish*" from those produced by traditional breeding. This ambiguity presents significant challenges for regulatory bodies and enforcement, making it essential to adopt advanced analytical methods that incorporate multiple lines of evidence. The FSA rejected these findings.

The review recommended a multifactorial detection approach using advanced molecular techniques, specialist review processes and centralised reference databases. Regarding the Genetic Technology Act, it noted "*There does not appear to be a definitive requirement for traceability and labelling of PBOs*" and concluded that without traceability requirements, "*it will be very challenging to prevent food and feed containing a precision-bred organism from being subject to fraud and adulteration*."

Considering these findings, the Committee may wish to ask the government and the FSA how the rigour of individual assessments can be ensured without investment in such methods and whether they will commit to infrastructure and allocate funding for the necessary laboratory upgrades and research?

d) Labelling as the basis of transparency

The Instrument fails to include point-of-sale labelling of precision-bred GMOs despite overwhelming evidence of public support. FSA's own research, along with studies by Beyond GM and the Nuffield Council on Bioethics, consistently show approximately 80% of UK consumers want labelling. During parliamentary debates on the Draft Genetic Technology Bill, Labour emphasised that "*Clear labelling is a sensible way forward*."

FSA's 2024 consultation (see main report and the summary of responses) revealed that most respondents rejected electronic registers as an adequate substitute for labelling, noting they would have little motivation to use such registers without point-of-sale information.

Labelling concerns extend beyond consumer choice to supply chain integrity. Without clear labelling throughout the food chain, businesses dependent on non-GMO supply chains (organic, artisanal, craft and Geographical Indication [GI] enterprises) will have no means to identify or avoid contamination. By removing requirements for unique identifiers, labelling and detection methods, the Instrument makes contamination inevitable while making detection impossible.

While the explanatory memorandum (9.3) and DMA (pages 17-18) acknowledge that organic systems will continue to exclude precision-bred GMOs, they offer no mechanisms to support this exclusion. This represents an unprecedented shift of responsibility – sectors choosing not to adopt the technology bear all costs of avoiding it, while those deploying it have no obligation to contain it. The DMA fails to quantify these potential impacts on small- and medium-sized enterprises.

The organic – and indeed the non-GMO, artisanal, craft and GI food sectors – have an established relationship with consumers built on transparency and trust. This Instrument, which seeks to hide genetically engineered PBOs in the food chain to foster growth in the market, will undermine the trust in the biotech sector and cast doubt on the integrity of genetic engineering technologies on the basis of 'if they won't label it, what are they hiding?'.

The Committee may wish to ask the government and the FSA: 1) why potential impacts on organic SMEs were not quantified in the DMA; 2) what specific financial support will help smaller organic businesses implement necessary testing measures; and 3) how the government will protect UK organic exports to markets where precision-bred GMOs are still regulated as GMOs.

It might also consider asking the government to add a new part establishing a coexistence framework for both environmental and food chain releases.

e) Lack of provisions for assessing future technology

The Act specifies that an organism can be precision-bred if "*any feature of its genome results from the application of modern biotechnology*" [2(a)] It further states that "*modern biotechnology*" means any technique mentioned in Regulation 5(1)(a) or (b) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002 [3].

The Act describes these techniques as:

> "*(a) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;*
>
> *(b) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation*"

As the Committee will no doubt be aware, developments in genetic technologies are happening very quickly. It is therefore likely that before too long Defra will receive PBO confirmation applications from developers who have engineered organisms using technologies which do not currently exist.

However, the permitted scope of future technologies is unclear. These Instruments do not set out a process for determining whether a new technology meets the criteria listed above.

The Committee may wish to ask Defra, what will be the situations in which a technology will be rejected for departing from the definition of 'modern biotechnology'? Which department will be responsible for this and how will it work in practice? These questions are unanswered or poorly answered in the Instrument and its accompanying document.

4. Legal Obligations

The regulatory approach taken in this Instrument raises serious questions about compliance with the UK's legal obligations.

a) Aarhus Convention compliance

The Almaty (or "GMO") Amendment to the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, to which the UK is a signatory, was ratified on 20 January 2025 and comes into force on 20 April 2025. It requires parties to establish arrangements for public participation prior

to decisions on whether to permit the deliberate release or market placement of genetically modified organisms.

The Convention specifically requires:

- Publication of information relating to proposed releases including environmental risk assessments
- Opportunity for public comment
- Evidence that public comments are taken into account in permitting decisions
- Publication of decisions with reasons

The current Instrument fails to meet these requirements in multiple areas, with no provisions for public participation in:

- The notification process for environmental release (Regulation 3)
- The application process for precision-bred confirmation (Regulation 5)
- The review process (Regulation 8)
- The appeal process (Regulation 9)
- The food and feed marketing authorisation process (Regulations 20, 22 and 30)

The Committee may wish to question whether the Instrument, as drafted, satisfies the UK's obligations under the Aarhus Convention and whether it intends to make appropriate amendments before the instrument comes into force.

b) Human Rights Act considerations

The Human Rights Act 1998 requires public authorities to act compatibly with Convention rights, which include providing sufficient information to enable the public to assess health and safety risks to which they are exposed. In the context of this Instrument, this applies to:

- Consumer information about precision-bred GMOs when placed on the market
- Information enabling food producers to reassure consumers about their products
- Protection of property rights to enable farmers and landowners to prevent contamination of their land and crops by precision-bred GMOs grown nearby

Despite these requirements, the Instrument fails to include:

- Detailed release location information in the notification requirements (Regulation 3) release notice (Regulation 10(3)) sufficient for farmers and landowners to assess potential impacts

- Requirements for full DNA sequencing to verify that precision-bred GMOs only include permitted genetic sequences (Regulation 10(4)(g))

The Committee may wish to ask the government if it will amend the Instrument to ensure that it properly safeguards property rights and provides sufficient information to the public, in line with the UK's obligations under the Human Rights Act.

In consideration of the legal obligations above **we further urge the Committee to recommend the following amendments**:

- Regulation 30(3)(b) needs to make clear that the misleading of consumers includes misleading by omission including omitting information which would allow them readily to identify that the product is a precision-bred GMO, as well as information that would allow them to locate information relating to the organism on all the registers maintained for the purposes of the Act.
- Regulation 30(4)(b) needs to make clear that the words "*otherwise be applicable*" should not be taken to mean that the test in question is one which is, in practice, applied to other foods.
- Regulation 30(5) needs to make clear that the results of full sequence DNA testing referred to above is not to be treated as confidential; likewise all risk assessments considered by the FSA and/or Secretary of State for the purposes of the regulation and the Act.
- Regulation 35(1)(g) should omit the words "*a summary of*" because full publication of any risk assessment is required

5. Administrative Complexity and Enforcement Challenges

a) Register management and information access

The Instrument establishes multiple registers (the precision breeding register in Part 4 and the food and feed marketing authorisations register in Part 8) but timelines for updating these registers are vague. Delays or inconsistencies in updating these registers could undermine transparency and lead to enforcement challenges.

The Committee may wish to suggest the government review the lack of clear timelines that would ensure that marketing information for the registers is added within a prescribed timeframe.

In addition, the Instrument allows for developers to volunteer extra information in their notifications/applications which is not necessarily required in the schedules. Will this extra information appear in the registers?

The Committee may wish to clarify if all information submitted by notifiers/applicants will be included on the register, even if it falls outside the required information.

b) Enforcement mechanisms

Throughout the FSA consultation process, serious concerns about traceability and enforcement have been repeatedly raised. In September 2023, one board member, a Chartered Trading Standards Practitioner, commented: "*If I were designing a system where I wanted to ensure there would be no enforcement, this is what I would design*".

The enforcement system relies on inspectors working with/for Defra and the FSA – both chronically underfunded agencies facing uncertain futures with potential staff reductions. The DMA (page 22) notes there is no longer a requirement for post-market monitoring, presenting this as a cost-saving opportunity "*assuming full compliance*."

This creates a fundamental disconnect: the Instrument acknowledges potential non-compliance risks and prescribes enforcement measures, yet these measures depend on traceability and information that the Instrument no longer requires for precision-bred GMOs. Moreover, unlike the Genetically Modified Organisms (Deliberate Release) Regulations 2002, which establish clear processes and timelines for application information and objections, this Instrument lacks transparent processes for raising concerns to the Secretary of State.

The absence of traceability provisions will particularly impact sectors required (organic) or choosing (premium, artisanal and GI sectors) to remain PBO-free. These sectors must now develop or use private verification schemes at their own expense, yet the Instrument provides no mechanism for how the Secretary of State will work with these schemes.

The Committee may wish to question this disconnect between enforcement assurances in the EM and the lack of clear enforcement provisions in the Instrument and ask how this gap will be addressed to ensure environmental and public safety.

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4 March 2025

Response by Defra and the FSA

Defra SLSC response - Beyond GM Submission– 07/03/2025

Beyond GM assertions to address:

"Legally and scientifically so-called "precision-bred organisms" (PBOs) are genetically modified organisms (GMOs). The Genetic Technology Act defines them as such and then creates a series of regulatory exemptions (deregulation) for these organisms. For accuracy, we will refer to PBOs as "precision-bred GMOs" throughout this submission".

Defra response:

The Genetic Technology (Precision Breeding) Act 2023 establishes precision bred organisms as a class of regulated organisms that are distinct from genetically modified organisms (GMOs).

1. **Context and General comments (*Presumption of approval and Missing Guidance)***

Beyond GM assertions:

- *The length and complexity of the instrument and supporting guidance is better suited to the kind of oversight given to primary legislation.*
- *The new framework operates with a presumption of approval for precision-bred plans but with limited assessment obligations*
- *Critical guidance documents remain unpublished, including enforcement guidance*
- *No full IA has been conducted, despite the RPC deeming the previous assessment for the Bill "not fit for purpose". – Why has the DMA not been published given the significance of the instrument and the level of public interest? It should be readily available.*
- *No statutory review clause is included, limiting oversight of fast-changing technology*

Beyond GM suggestion: "Critical aspects such as technical criteria, public register content and procedures for notices are deferred to guidance documents. At the time of this submission, important guidance listed under 8.2 remains unpublished, including:

• Administrative guidance on food and feed marketing authorisation applications

• Enforcement guidance for enforcement authorities and their officers involved in the enforcement of the Instrument, e.g. local authorities and port health authorities in England.

• Enforcement guidance for authorities in England, Wales and Northern Ireland

It is unacceptable that these have not been published in time for scrutiny in this submission. We suggest that the Committee calls for accelerated development and

publication of the remaining guidance to ensure smooth implementation and minimise transitional uncertainty".

Defra Response:

- This statutory instrument has been laid before Parliament as it provides the detail and practical measures necessary to bring The Genetic Technology (Precision Breeding) Act 2023 into effect. It's complexity and length are commensurate, and in proportion to the measures contained within the Act.
- Neither the Act nor the regulations operate on a 'presumption of approval'. A decision on whether a plant is precision bred and authorised for marketing is only made by Secretary of State following submission of a marketing notice and receipt of advice from the Advisory Committee on Releases to the Environment (ACRE) on whether that organism should be classed as precision bred.
- It is not mandatory to submit an impact assessment for measures with impacts below £10m Equivalent Annual Net Direct Costs on Business; however, a de minimis assessment of the estimated impacts has still been prepared, of which a summary is provided in the Explanatory Memorandum (EM). This considers the issues listed by Beyond GM as far as possible within a 10-year period of the Regulations coming into force.
- In line with the requirements of the Small Business, Enterprise and Employment Act 2015, the provisions of the Genetic Technology (Precision Breeding) Regulations 2025 are such that a statutory review clause would be inappropriate, for proportionality reasons, given the costs associated with such a review and the nature of the industry.

FSA Response

- Regulations place a duty on the FSA to report information to the Secretary of State, who has discretion on decision making. The Secretary of State can only authorise a PBO for food and feed uses where satisfied that the food or feed would not:
    - Have adverse effects on animal or human health;
    - Would not mislead consumers;
    - Would not have adverse effects on the environment and
    - Would not be nutritionally disadvantageous.
- The processes for the FSA reporting to the SoS on such matters are required to ensure decisions are made based on advice and are completed for all applications. This is in line with the FSA's statutory duty for providing advice to Ministers on matters of food and feed safety.
- PBOs used in food and feed must meet the same safety standards that a conventionally bred alternative would otherwise have to meet. Food and feed safety is not absolute, and all foods and feed carry some level of inherent risk

that is either tolerated or managed through other means and legislative provisions. This provision ensures that a PBO can be authorised for food and feed uses if it meets the same standards as a conventionally bred alternative.

- **The FSA has published draft administrative and technical guidance documents for applicants on its website.** The administrative guidance explains the mechanisms and legislative requirements that applicants need to understand to make an application once the new regulatory service is live. This guidance links to the FSA draft technical guidance, which provides comprehensive support to applicants on:
    - Completing the Tier 1 safety assessment for each assessment criterion;
    - The information to include in all applications;
    - The additional supporting evidence required to facilitate a Tier 2 safety assessment.
- To ensure that the guidance for the safety assessment of precision bred organisms works effectively, the FSA will undergo a period of user testing to allow businesses and researchers as potential applicants to take time to review it and provide feedback on the clarity of the document.
- The FSA's technical guidance has been subject to strict governance, including independent scientific peer review by the ACNFP and approval by the FSA's Chief Scientific Advisor, Professor Robin May. FSA science officials have collaborated with policy officials in both the FSA and Defra throughout the development of the guidance and the FSA's Board has been regularly kept up to date on progress. Defra officials supporting the development of the Advisory Committee on Releases to the Environment's technical guidance have been regularly consulted in the development of the FSA guidance.
- Establishing and maintaining technical guidance will give the FSA flexibility and adaptability with the most technical elements of assessment, given the nascent nature of the technology and pace of innovation in the applications of precision breeding techniques in the agri-food system. This means the FSA can ensure that the evidence collected and submitted by applicants continues to be sufficient and appropriate.
- This approach is in line with the FSA's statutory remit for providing advice and information on matters related to food and feed safety and public health. The FSA is the independent government department responsible for food and feed safety and best placed to provide advice on such matters, based on independent scientific advice provided by our Advisory Committees and our Science, Evidence and Research Division.

- Taking this regulatory approach will allow the FSA to monitor the types of products that are being brought to market using precision bred organisms and whether the technical guidance is providing adequate support to applicants considering the potential impacts on food and feed safety.
- Matters of food and feed safety and public health require a rapid response from the FSA and therefore it is important that guidance can be adjusted swiftly to address any emergent safety issues. This agile approach will allow the FSA to learn as PBOs develop and tailor advice, where required, to trends in products (such as biofortification), resulting in better guidance for developers.
- The FSA's draft enforcement guidance is not being published but is being shared directly with enforcement authorities for their input and we will publish final versions once we have concluded our engagement with these authorities. The finalised guidance documents will be made available at least four weeks before the coming into force of the regulations.
- The FSA conducted an assessment of the impact of the proposed regulatory framework for PBOs as part of its consultation process. This assessment estimated an impact below the **minimum threshold of +/- £10m.**
- In line with the obligation to provide a proportionate assessment of the impacts of policy proposals, we included our findings from this assessment in the consultation document. The impact was assessed against the status quo - a baseline of the existing GMO legislation under which PBOs would currently require pre-market authorisation.
- The consultation also sought feedback from stakeholders on these impacts and asked respondents if they were aware of any impacts that had not been identified. Feedback on this aspect of the consultation, and the FSA's formal response, was included in the **FSA's summary of consultation responses.**

2. **Ambiguities in Definitions and Criteria (*Definition of 'traditional'; patent confusion; possible unregulated market entry of 'precision-bred gmos')***

Beyond GM assertions:

- *The core definition of what constitutes "traditional" genetic changes (and thus qualifies for the new policy) is unclear and delegated to guidance documents whose legal status is unclear rather than legislation*
- *Legal contradictions exist between defining these organisms as "traditional" while developers may seek patent protection (which requires novelty and a man-made*

"inventive step"). Revocation of a patent could have a negative financial impact for developers.

- *Artificial distinctions between the presumed safety of environmental releases and marketing releases create regulatory gaps and a risk that precision-bred plants which have been notified to Defra and entered the environment through release will end up in the food and feed supply chain*

Beyond GM suggestions:

- The Committee may wish to seek greater clarity on which specific genetic changes are acceptable as 'traditional? How will borderline cases be adjudicated?
- The Committee may wish to seek greater clarity from the government on excluding patented precision-bred GMOs from this Instrument and, instead, continuing to regulate them as GMOs. We suggest a full investigation into this legal issue.
- The Committee may wish to question how the person responsible for overseeing such trials will straddle these different responsibilities of public relations, scientific evaluation and biosecurity? What criteria should the person responsible for preventing material from trials being marketed use? Can the job be left to just anyone? It may also wish to highlight the lack of transparency as to the several types of environmental release allowed in the Act – i.e. research, demonstration/public relations, seed multiplication or 'other' purposes.

Defra Response:

- Beyond GM suggest that allowable 'traditional changes' are not fully elaborated in the SI. The Act establishes that these changes are those that could result from the use of traditional processes; these processes are listed in Part 1(6) of the Act. The list of possible traditional changes is vast and too long to include in regulations or in guidance. The guidance produced by our advisory committee (producing precision bred organisms) covers genetic changes produced by techniques of modern biotechnology, used currently, and clarifies whether they would result in precision bred plants. The guidance will be updated as necessary, in line with advances in technology.
- Defra is not equating the process of traditional breeding with that of precision breeding, as suggested. Instead, the precision breeding legislation focuses on the end product, in accordance with the scientific advice. This means we are assessing whether the genetic changes resulting from precision breeding could have resulted from traditional breeding i.e. whether the risk is equivalent.
- The suggestion that precision bred plants cannot be protected by patents is incorrect. Precision bred plants may be protected by patents if they meet the necessary criteria of a technical innovation that is novel, inventive and has utility.

- There is not a regulatory gap between what constitutes marketing and what constitutes a release for non-marketing purposes. The definition of marketing is included in the Act (5 (3)(a) and (b) and Schedule 1 of the regulations requires those submitting release notices to confirm that they will put in place appropriate measures, as necessary, to prevent material from the precision bred plants being marketed until such time as a precision bred confirmation is issued in respect of those plants. Defra has published draft guidance alongside the regulations to support those submitting release notices: releasing precision bred plants into the environment in research and development trials . The guidance recommends submitting a marketing notice and an application for authorising the plant's use in food and feed if there is a risk that material could be marketed inadvertently.
- As long as precision bred plant material is not marketed, it may be released under a release notice. This may include in displays/ demonstrations.

3. **Transparency & Public Accountability (*Assessment of safety & risk; advisory bodies' decision-making process; lack of specific detection mechanisms; labelling as the basis of transparency; provisions for assessing future technology*)**

Beyond GM assertions:

- *No detailed safety or risk assessments are required from developers for the majority of precision-bred organisms*
- *The scientific basis for advisory committee decisions is not fully disclosed*
- *No specific detection mechanisms are required, making enforcement problematic*
- *No point-of-sale labelling is required despite approximately 80% of UK consumers wanting this, undermining supply chain integrity, transparency and public trust*
- *Need for a coexistence framework for precision-bred and non-precision bred plants*
- *No provisions exist for assessing future genetic technologies against current definitions; this is a safety as well as a cost issue.*

Beyond GM suggestions:

- The Committee may wish to question how the government will ensure adequate safety evaluation in the absence of mandatory risk assessments. The Committee should also seek clarification on what specific criteria will be used to identify potential risks when applicants are not required to provide comprehensive safety data and examples of other "relevant" information.

- The Committee may wish to seek assurances that reports from advisory bodies will include full disclosure of the evidence considered and the weight given to different sources and that this be put on the public registers.
- Considering these findings, the Committee may wish to ask the government and the FSA how the rigour of individual assessments can be ensured without investment in such methods and whether they will commit to infrastructure and allocate funding for the necessary laboratory upgrades and research?
- The Committee may wish to ask the government and the FSA: 1) why potential impacts on organic SMEs were not quantified in the DMA; 2) what specific financial support will help smaller organic businesses implement necessary testing measures; and 3) how the government will protect UK organic exports to markets where precision-bred GMOs are still regulated as GMOs. It might also consider asking the government to add a new part establishing a coexistence framework for both environmental and food chain releases.
- The Committee may wish to ask Defra, what will be the situations in which a technology will be rejected for departing from the definition of 'modern biotechnology'? Which department will be responsible for this and how will it work in practice? These questions are unanswered or poorly answered in the Instrument and its accompanying document.

Defra Response:

- The scientific advice is that precision bred plants do not pose a greater risk than their traditionally bred counterparts. As such, there are no provisions in the Act for case-by-case environmental risk assessments comparing precision bred plants with traditionally bred plants.
- The reports from ACRE will be published in full on the publicly available precision breeding register to ensure transparency.
- Independent scientific rigour on assessments about whether plants meet the criteria for being precision bred is provided by ACRE. ACRE members are appointed in accordance with the requirements of the Office of the Commissioner for Public Appointments. ACRE's framework agreement outlines their commitments to openness and transparency, including recording any actual or potential conflicts of interest and the action taken to handle them (in accordance with the Nolan principles).
- To our knowledge, there are currently no scientific methods that provide unequivocal identification of genetic changes associated with precision bred plants without prior knowledge of the altered genome and suitable reference materials. If these data were available, there would be no way of knowing whether the genetic change resulted from the application of precision breeding technology or traditional breeding practices.

- The issue of mandatory labelling was a feature of debates in both houses of Parliament during the passage of the Act. In both houses, amendments to require mandatory labelling of PBOs failed to gain sufficient support.
- Based on the scientific advice that the risk associated with precision bred plants is no greater than for traditionally bred counterparts, we do not consider that mandatory labelling focused on the breeding technology or process used is appropriate.
- However, the UK maintains high standards on the information that is provided on food labels, whether that be mandatory or voluntary, so that consumers can have confidence in the food that they buy.
- All food and drink sold on the UK market must comply with food labelling rules. The fundamental principle of food labelling rules is that information provided to the consumer must not mislead and must enable the safe use of food.
- All food and drink sold on the UK market must comply with food labelling rules. The fundamental principle of food labelling rules is that information provided to the consumer must not mislead and must enable the safe use of food.
- Registers published by Defra and FSA will contain information about precision bred plants, including those approved for use in food and feed. Businesses may choose to label their products as being from precision bred plants.
- The impact on organics was considered in the DMA, but this did not include a separate assessment for organic SMEs. The impact was predicted over a 10-year period, starting from when the regulations come into force. The expectation is that the industry will maintain the identity of precision bred crops and keep them separate from traditionally bred material until uncertainty about international regulations and other measures are resolved. This means that exposure of organic production to precision bred material will be limited in this period.
- However, we are preparing for the medium/ longer term when precision bred commodity crops are marketed outside of identity preservation schemes by discussing non-legislative options for supply chain coexistence with the organic sector.
- Defra are facilitating discussions between organic and conventional farmers to develop industry-led coexistence measures between precision bred and non-precision bred plants. This is in line with approaches taken internationally. As part of this process, industry have committed to maintaining a register of precision bred varieties to complement the statutory Defra and FSA registers.
- Defra will determine whether 'modern biotechnology' has been used. We have been responsible for making this determination since 1990 when the first iteration of the Genetically Modified Organisms (Deliberate Release) legislation first came into effect. This is because the definition of techniques of modern biotechnology has the same meaning as techniques in regulation 5(1)(a) or (b) of the Genetically

Modified Organisms (Deliberate Release) Regulations 2002. As the competent authority for both sets of legislation in England, we would seek legal and scientific advise (from our statutory advisory committee - the Advisory Committee on Releases to the Environment) if necessary.

- With respect to the comment that there is no mechanism for amending the definition of modern biotechnology in line with scientific advances, the Act makes provision to amend the definition of modern biotechnology in line with any changes to regulation 5(1) of the GMO Regulations, 2002.

FSA Response:

- The FSA has published draft guidance which sets out the expectations on applicants for meeting their statutory duties in the regulations. If an applicant cannot demonstrate that the application of modern biotechnology does not introduce genetic changes to the organism that are expected to lead to significant compositional changes, the PBO must be assessed by the FSA. The applicant must also be able to demonstrate a relevant history of safe food use and that there are no other safety concerns. Where these criteria are not met or the applicant is unsure, the PBO must be assessed by the FSA.

- This approach will ensure that all PBOs that pose risks beyond those understood and accepted in traditional breeding will be subject to assessment by the FSA.

- LGC Ltd.'s Literature review on analytical methods for the detection of precision bred products highlights that there are no methods of providing unequivocal detection of the genetic change in most PBOs defined by the Genetic Technology (Precision Breeding) Act, without prior knowledge of the altered genome sequence and suitable reference materials. For those PBOs where detection may be possible, it is not currently feasible to distinguish whether the genetic changes are the result of genome editing, natural variation, or traditional breeding methods. In cases where detection was possible, this is likely to be lost in subsequent generations.

- In our response to this report, we concluded that due to proportionality and feasibility reasons we did not plan to take forward the recommendations in the report to aid ongoing policy development on precision breeding, we welcomed further research in this area to ensure we have the most up to date scientific information available when reviewing policy and/or developing new policies related to genetic technologies.

- The FSA is science and evidence led. We regularly conduct horizon scanning and independently review new evidence that becomes available that is relevant to food and feed safety. In the case of detection, we will continue to monitor new developments in this area.

- The consensus is that currently there are no methods that provide unequivocal detection of precision bred products.
- There is no justification for the provision of labelling distinguishing all PB food as such on grounds of consumer safety. Based on their review of case studies (published in the ACNFP Statement July 2023) and their knowledge of the wider literature, ACNFP members did not find evidence that PBOs are intrinsically more hazardous than traditionally bred organisms.
- As with any food, if there is a need to provide safety information for a particular population group, (for example, hypersensitive consumers or people with certain health conditions) this can be required as appropriate.
- The FSA has conducted consumer research which told us that consumers saw a range of risks and benefits to PB food but on balance consumers thought the benefits outweighed the risks if properly regulated; they trust the FSA to regulate PB food; the public register builds towards confidence and reassurance; more proactive information provision (public education campaign, education in school curriculum, labelling, for example) would reassure them that regulation was happening; they wanted labelling to enable them to make choices at the point of purchase.
- The FSA Board considered this issue at Board meeting in 2023 and 2024. The Board has actively discussed the views of consumers throughout the development of the proposals and recognises the importance of these views. This was a key focus of the Board's discussion and associated Board paper at the March 2023 Board meeting.
- The power to decide on the mandatory labelling of PBOs for non-safety related purposes in England sits with Defra. FSA officials have shared results of the consumer research and public consultation with Defra.

4. **Legal Obligations (*Aarhus Convention compliance; Human Rights Act considerations)***

Beyond GM assertions:

- *The instrument may be non-compliant with the Aarhus Convention (effective April 2025), which requires public participation in decisions on GMO releases*
- *Potential Human Rights Act violations regarding public access to information and protection of property rights*

Beyond GM suggestions:

- The Committee may wish to question whether the Instrument, as drafted, satisfies the UK's obligations under the Aarhus Convention and whether it intends to make appropriate amendments before the instrument comes into force.
- The Committee may wish to ask the government if it will amend the Instrument to ensure that it properly safeguards property rights and provides sufficient information to the public, in line with the UK's obligations under the Human Rights Act.
- In consideration of the legal obligations above we further urge the Committee to recommend the following amendments:
    - Regulation 30(3)(b) needs to make clear that the misleading of consumers includes misleading by omission including omitting information which would allow them readily to identify that the product is a precision-bred GMO, as well as information that would allow them to locate information relating to the organism on all the registers maintained for the purposes of the Act.
    - Regulation 30(4)(b) needs to make clear that the words "otherwise be applicable" should not be taken to mean that the test in question is one which is, in practice, applied to other foods.
    - Regulation 30(5) needs to make clear that the results of full sequence DNA testing referred to above is not to be treated as confidential; likewise, all risk assessments considered by the FSA and/or Secretary of State for the purposes of the regulation and the Act.
    - Regulation 35(1)(g) should omit the words "a summary of" because full publication of any risk assessment is required

Defra Response:

- The Genetic Technologies (Precision Breeding) Act 2023 carves precision bred organisms out of GMO legislation. We therefore consider that the Aarhus Convention on GMOs does not apply to precision bred organisms.
- The Government considers that the regulations and Act are compatible with the European Convention on Human Rights. The registers provided for in both the regulations and the Act and published by Defra and the FSA will contain publicly available information about precision bred plants, including those approved for use in food and feed.

5. **Administrative Complexity and Enforcement Challenges (*Register management and information access; enforcement mechanisms)***

Beyond GM assertions:

- *Multiple registers are established but with vague timelines for updates*

- *Enforcement depends on traceability and information that the instrument does not require for precision-bred plants*
- *Sectors choosing to remain precision bred plant-free (organic, artisanal, etc.) must develop verification schemes at their own expense.*

Beyond GM suggestions:

- The Committee may wish to suggest the government review the lack of clear timelines that would ensure that marketing information for the registers is added within a prescribed timeframe.
- The Committee may wish to clarify if all information submitted by notifiers/applicants will be included on the register, even if it falls outside the required information.
- The Committee may wish to question this disconnect between enforcement assurances in the EM and the lack of clear enforcement provisions in the Instrument and ask how this gap will be addressed to ensure environmental and public safety.

Defra Response:

- The regulations and the Act require the keeping of a precision breeding register to be maintained by Defra and a food and feed register to be maintained by the FSA. For the precision breeding register, the requirements around its maintenance are described at section 11 and the food and feed marketing authorisations register at section 35. While information around release notifications must be added to the precision breeding register before the end of the 20-day period beginning when the Secretary of State received the release notice. Information about marketing notices must be added as soon as reasonably practicable after the Secretary of State has made a decision on whether to issue precision bred confirmation. As for the food and feed register, this must also be updated with the required information in the regulations (section 35) as soon as reasonably practicable after a food and feed marketing authorisation has been issued. All required information under the legislation will be added to the register and we do not expect there to be any undue delays or inconsistencies in this process.
- There is a suite of enforcement provisions established in the Act and details around their use are included in the regulations.

FSA Response:

- The FSA's aim has been to develop a proportionate enforcement regime which will enable enforcement authorities to take effective action against non-compliance.

- Enforcement authorities will use the same approaches for detecting and preventing non-compliance 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.
- Under General Food/Feed Law traceability requirements, food business operators will be required to be able to identify their immediate suppliers, as well as the businesses to which their products are supplied (a “one up, one down” approach). This information must be provided to competent authorities, if requested. This will also be the case for food and feed produced from PBOs.
- Enforcement authorities will be able to use information obtained from the audit of systems, records and paperwork, in addition to the FSA’s Public Register of PBOs authorised for use in food and feed, to ensure that only food and feed produced from authorised PBOs is marketed for sale.
- Further information on traceability can be found within the following web pages Food incidents, product withdrawals and recalls | Food Standards Agency and Guidance on Food Traceability, Withdrawals and Recalls within the UK Food Industry

7 March 2025

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

Prepared by: GM Freeze
Date: 6th March 2025

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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Response from Defra and the FSA

SLSC Question responses – 07/03/2025- GM FREEZE Submission

1. **The lack of any labelling requirement, so that consumers will not be able to select products that PBO free.**

Defra response:

- The issue of mandatory labelling was a feature of debates in both houses of Parliament during the passage of the Act. In both houses, amendments to require mandatory labelling of PBOs failed to gain sufficient support.
- Based on the scientific advice that the risk associated with precision bred plants is no greater than for traditionally bred counterparts, we do not consider that mandatory labelling focused on the breeding technology or process used is appropriate.
- However, the UK maintains high standards on the information that is provided on food labels, whether that be mandatory or voluntary, so that consumers can have confidence in the food that they buy.
- All food and drink sold on the UK market must comply with food labelling rules. The fundamental principle of food labelling rules is that information provided to the consumer must not mislead and must enable the safe use of food.
- Registers published by Defra and FSA will contain information about precision bred plants, including those approved for use in food and feed.
- Businesses may choose to label their products as being from precision bred plants.
- We will ensure that food and feed produced from precision bred organisms is considered in any future work to ensure that labelling remains fit for purpose, maintains consumer confidence and provides a level playing field.

FSA Response:

- There is no justification for the provision of labelling distinguishing all PB food as such on grounds of consumer safety. Based on their review of case studies (**published in the ACNFP Statement July 2023**) and their knowledge of the wider literature, ACNFP members did not find evidence that PBOs are intrinsically more hazardous than traditionally bred organisms.
- As with any food, if there is a need to provide safety information for a particular population group, (for example, hypersensitive consumers or people with certain health conditions) this can be required as appropriate.
- The FSA has conducted consumer research which told us that consumers saw a range of risks and benefits to PB food but on balance consumers thought the benefits outweighed the risks if properly regulated; they trust the FSA to regulate PB food; the public register builds towards confidence and reassurance; more

proactive information provision (public education campaign, education in school curriculum, labelling, for example) would reassure them that regulation was happening; they wanted labelling to enable them to make choices at the point of purchase.

- The FSA Board considered this issue at Board meeting in 2023 and 2024. The Board has actively discussed the views of consumers throughout the development of the proposals and recognises the importance of these views. This was a key focus of the Board's discussion and **associated Board paper at the March 2023 Board meeting**.
- The power to decide on the mandatory labelling of PBOs for non-safety related purposes in England sits with Defra. FSA officials have shared results of the consumer research and public consultation with Defra.

2. **The lack of traceability, risk assessments and detection methods.**

Defra response:

- *Risk assessment*. The scientific advice from the Advisory Committee on Releases to the Environment is that precision bred organisms do not confer a greater risk than their traditionally bred counterparts. This advice is built on a wealth of peer reviewed literature, and it is consistent with statements from The Royal Society, the FSA's Advisory Committee on Novel Foods and Processes, the European Academies of Science Advisory Council and the Scientific Advice Mechanism (to the EU Commission) amongst others. As such, there are no provisions in the Act for case-by-case environmental risk assessments comparing precision bred plants with traditionally bred plants.

- *Detection*. To our knowledge, there are currently no scientific methods that provide unequivocal identification of genetic changes associated with precision bred plants without prior knowledge of the altered genome and suitable reference materials. If these data were available, there would be no way of knowing whether the genetic change resulted from the application of precision breeding technology or traditional breeding practices. For those PBOs where detection may be possible, it is not currently feasible to distinguish whether the genetic changes are the result of genome editing, natural variation, or traditional breeding methods. In cases where detection was possible, this is likely to be lost in subsequent generations.

FSA Response

- The FSA's aim has been to develop a proportionate enforcement regime which will enable enforcement authorities to take effective action against non-compliance.
- Enforcement authorities will use the same approaches for detecting and preventing non-compliance 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.
- Under General Food/Feed Law traceability requirements, food business operators will be required to be able to identify their immediate suppliers, as well as the businesses to which their products are supplied (a "one up, one down" approach). This information must be provided to competent authorities, if requested. This will also be the case for food and feed produced from PBOs.
- Enforcement authorities will be able to use information obtained from the audit of systems, records and paperwork, in addition to the FSA's Public Register of PBOs authorised for use in food and feed, to ensure that only food and feed produced from authorised PBOs is marketed for sale.
- Further information on traceability can be found within the following web pages Food incidents, product withdrawals and recalls | Food Standards Agency and Guidance on Food Traceability, Withdrawals and Recalls within the UK Food Industry
- LGC Ltd.'s Literature review on analytical methods for the detection of precision bred products highlights that there are no methods of providing unequivocal detection of the genetic change in most PBOs defined by the Genetic Technology (Precision Breeding) Act, without prior knowledge of the altered genome sequence and suitable reference materials. For those PBOs where detection may be possible, it is not currently feasible to distinguish whether the genetic changes are the result of genome editing, natural variation, or traditional breeding methods. In cases where detection was possible, this is likely to be lost in subsequent generations.
- In our response to this report, we concluded that due to proportionality and feasibility reasons we did not plan to take forward the recommendations in the report to aid ongoing policy development on precision breeding, we welcomed further research in this area to ensure we have the most up to date scientific information available when reviewing policy and/or developing new policies related to genetic technologies.
- The FSA is science and evidence led. We regularly conduct horizon scanning and independently review new evidence that becomes available that is relevant to food and feed safety. In the case of detection, we will continue to monitor new developments in this area.
- The consensus is that currently there are no methods that provide unequivocal detection of PBOs

3. **The particular uncertainties for organic producers – how they will be able to check that material they source is PBO free and how they will they be able to demonstrate that their products are PBO free; as well as the unclear legal status of PBOs which will be considered GMO under organic regulations.**

Defra response:

- The impact on organics was considered in the DMA. The impact was predicted over a 10-year period, starting from when the regulations come into force. The expectation is that the identity of precision bred crops will be maintained and they will be separated from traditionally bred material until uncertainty about international regulations and other measures are resolved. This means that exposure of organic production to precision bred material will be limited in this period.
- However, we are preparing for the medium/ longer term when precision bred commodity crops are marketed outside of identity preservation schemes and there is ongoing dialogue between Defra and the organic sector on non-legislative options for supply chain coexistence.
- In order to help those breeders and farmers who wish to grow non-precision bred plant varieties only, the government wants to ensure that there is accessible marketing information to enable this. The government is exploring a variety of methods and tools to communicate information on the precision bred status of plant varieties.
- To facilitate the marketing of precision bred varieties of the main agricultural and vegetable species, a Precision Bred Plant Variety List for England is proposed in addition to the existing GB and NI variety lists. Information regarding applications made and varieties accepted onto the list, including variety name, will be published in the Plant Varieties and Seeds Gazette. The Animal and Plant Health Agency through their Delivering Sustainable Futures project are looking to improve the accessibility and usability of the Gazette.
- Views on the proposed Precision Bred Plant Variety List for England are being sought through the public consultation on Plant Varieties and Seeds Framework for Precision Bred Plant Varieties (17 Feb – 14 Apr 2025) which also seeks feedback on the provision of information on precision bred seed and other plant reproductive material.

4. **The impact on trade, including unlabelled PBOs being forced onto devolved nations under the UK internal market and the impact of post-processed products; the impact on trade with the EU**

Defra response:

- The Government is engaging and will continue to engage with the Scottish and Welsh Governments to understand the specific impacts on businesses in Scotland and Wales.
- Information on precision bred seed of the main agricultural and vegetable species will be available on the Precision Bred Variety List for England. Farmers, agronomists and seed merchants, including in the devolved nations, will be able to access information about precision breeding in crop varieties to inform purchasing decisions.
- We are engaging with the EU and closely following their development of any new regulatory approaches to plants produced by new genomic techniques (NGTs).

5. **Doubts whether the Regulations meet the obligations of the Cartagena Protocol**

Defra response:

- The Act removes precision bred organisms from genetically modified organism (GMO) legislation. Therefore, as the GMO elements of the Aarhus Convention and Cartagena Protocol do not apply to precision bred organisms, the government considers that the approach being taken is consistent with the UK's international obligations in respect of these.

6. **Lack of transparency – not publishing the findings of Defra's YouGov poll.**

Defra response:

- Defra has aimed to be as transparent as possible in sharing information. But there may have been situations when we haven't been able to publish data owned by others.

7. **The failure to conduct a full IA and to publish the DMA and errors and omissions in the DMA**

Defra response:

- It is not mandatory to submit an impact assessment for measures with impacts below £10m Equivalent Annual Net Direct Costs on Business; however, a de minimis assessment of the estimated impacts has still been prepared, of which a summary is provided in the Explanatory Memorandum (EM).

- The De Minimis Assessment (DMA) has been compiled by Defra economists and reviewed by Defra Chief Economist.

Defra response to content included within GM Freeze's submission 'Example 1: Consumer wishing to choose PBO/GMO-free food and body care products' :

The precision breeding Act and regulations apply an additional layer of controls when organisms produced by particular techniques are deliberately released into the environment and/or material from them is used in food and/ or animal feed. Neither the GMO legislation nor the legislation on precision bred organisms cover the use of material derived from precision bred organisms in body care products.

7 March 2025

Joint submission from the Soil Association, Organic Farmers and Growers and the English Organic Forum

Dear Committee Members,

The Genetic Technology (Precision Breeding) Regulations 2025

On behalf of the organic sector, we wish to raise our serious concerns regarding the Statutory Instruments (SIs) proposed for the implementation of the Genetic Technology (Precision Breeding) Act 2023. The signatories of this letter include organisations responsible for certifying the majority of the UK's organic land, approximately half a million hectares and most of organic products on retailer shelves.

We strongly recommend that these concerns, outlined below, are considered for parliamentary debate, under the terms laid out with an 'affirmative' procedure.

These build on our ongoing concerns with the parliamentary process in the development of the Genetic Technology (Precision Breeding) Act 2023, the Impact Assessment for which was rated red by the Regulatory Policy Committee back in 2022, i.e. 'unfit for purpose'. This signified a failure to fully consider the economic impact of the Bill, and was the first 'unfit for purpose' rating for the Department for Environment, Food and Rural Affairs since at least 2015.

While others may highlight broader concerns, the primary purpose of this submission is to outline the urgent risks posed to the organic sector, both for domestic markets and regarding the very real risk of these SIs present for UK organic exports.

The organic market is experiencing significant growth in the UK, worth £3.7 billion at the end of 2024 - double what it was 10 years ago. Organic unit sales grew four times more than non-organic in major retail last year, indicating that consumer support for organic has remained strong despite the cost-of-living crisis, with shoppers looking for certified sustainable, high-quality products. At a time when changes in consumption patterns are needed to support the country's climate and nature targets, this market increase highlights the value of the organic sector in driving best practice in food and farming.

However, we are concerned that the Genetic Technology (Precision Breeding) Regulations 2025 put the future of UK organic businesses at risk, as they contain many inconsistencies and contradictions which threaten the production, consumption and trade of both UK organic and UK non-organic products. These include the following areas:

- The organic legislation (UK primary legislation) prohibits the use of Genetically Modified Organisms (GMOs). Although the Genetic Technology (Precision Breeding) Act categorises Precision Bred Organisms (PBOs) differently to other GMOs, they are the result of genetic engineering and are therefore prohibited from use in organic production. This approach to prohibiting the use of products made from or by any form of GMOs, including all new genomic techniques, is one that is also reflected in similar organic legislation in other territories e.g. in the EU. The Genetic Technology Act and the proposed SIs don't contain provisions that sufficiently take account of the requirement that organic supply chains must avoid PBOs - such measures would include labelling and full traceability - nor do they provide us with any assurance that the information we need to perform our duties as Organic Control Bodies, under UK organic legislation, would be made available to us.
- The De Minimis Assessment (DMA) published with the secondary legislation is clearly written in full knowledge of the concerns that we have raised about the uncertainty this legislation poses for organic supply chains yet fails to identify any tangible solutions. On

page 18, it states: '*As a result of concerns expressed about the impact of the cultivation of Precision Bred crops, we have contracted an organisation to facilitate discussions between stakeholders on coexistence measures required to segregate the different production systems at the farm level. […] During these discussions, stakeholders have acknowledged that existing mechanisms can enable segregation, but* ***they have not reached a consensus on the details of these measures****. This is exacerbated by uncertainty around what will be expected of organic producers to demonstrate how they have avoided Precision Bred crops. Therefore, it will be hard to establish quantitative costs at this stage*.' (p18)

- A similar level of uncertainty is anticipated for consumers wishing to avoid products containing PBOs. The DMA acknowledges that '*there may be a minority of consumers who may wish to buy non-Precision Bred food products so may have to spend time researching which brands do not contain Precision Bred ingredients or switching to buying organic food'* (p18). This is problematic on several levels: as described above, we are yet to understand in detail how organic supply chains will be able to avoid PBOs; secondly, there is a lack of information around the public register of PBO events, and how such a register would allow consumers to join the dots between existing PBOs and products/brands that would be using them. Placing the emphasis on consumer research therefore offers an unreasonable and unrealistic pathway to granting members of the public an informed choice should they wish to avoid those products.
- Finally, we would ask the Committee to examine the core issue – the lack of requirements for labelling products containing PBOs. Not only does this overlook the fact that the Food Standards Agency (FSA) has consistently reported the public expectation for gene edited products to be clearly labelled, but it also presents us all with a major barrier to international trade. Indeed, as the DMA points out: '*In the meantime, Precision Bred Organisms would still be GMO under EU regulations and would therefore need to be authorised and labelled as GM before being placed on the EU market*.' (p28) The lack of requirements for labelling therefore goes beyond the issue of consumer trust, and raises fundamental questions about this country's ability to trade with our EU neighbours. We would draw the Committee's attention to the fact that under the Northern Ireland Protocol and the Windsor Framework all organic operators in Northern Ireland are legally obliged to work under EU organic regulations.

We are grateful to the Committee for taking the time to consider these concerns, and would welcome an opportunity to discuss these in more detail. For further information, our joint position on the Genetic Technologies Act is set out here and our response to the consultation on the Statutory Instruments is here.

Yours sincerely,

Dominic Robinson, CEO, Soil Association Certification

Sarah Compson, Director of Standards Innovation, Soil Association

Steven Jacobs, Business Development Manager, Organic Farmers and Growers

Adrian Steele and Christopher Stopes, co-chairs, English Organic Forum

7 March 2025

Response from Defra and the FSA

1. **The fact that UK organic legislation prohibits the use of GMOs and PBOs but the draft Regulations does not enable full traceability or require labelling, so how can Organic Control Bodies carry out their function?**

Defra response:

- As mentioned in the submission, the impact on organics was considered in the *de minimis* assessment. The impact was predicted over a 10-year period, starting from when the regulations come into force. The expectation is that the identity of precision bred crops will be maintained and they will be separated from traditionally bred material until uncertainty about international regulations and other measures are resolved. This means that exposure of organic production to precision bred material will be limited in this period.
- We are however preparing for the medium/ longer term when precision bred commodity crops are marketed outside of identity preservation schemes and there is ongoing dialogue between Defra and the organic sector on non-legislative options for supply chain coexistence between precision bred and non-precision bred plants and on-farm practical measures to ensure coexistence. This is in line with approaches taken internationally. As part of this process, the British Society of Plant Breeders, representing the plant breeding industry, have committed to maintaining a register of precision bred varieties to complement the statutory Defra and FSA registers.
- In order to help those breeders and farmers who wish to grow non-precision bred plant varieties only (e.g. the organic sector), the government wants to ensure that there is accessible marketing information to enable this. The government is exploring a variety of methods and tools to communicate information on the precision bred status of plant varieties.
- To facilitate the marketing of precision bred varieties of the main agricultural and vegetable species, a Precision Bred Plant Variety List for England is proposed in addition to the existing GB and NI variety lists. Information regarding applications made and varieties accepted onto the list, including variety name, will be published in the Plant Varieties and Seeds Gazette. The Animal and Plant Health Agency through their Delivering Sustainable Futures project are looking to improve the accessibility and usability of the Gazette.
- Views on the proposed Precision Bred Plant Variety List for England are being sought through the public consultation on Plant Varieties and Seeds Framework for Precision Bred Plant Varieties (17 Feb – 14 Apr 2025) which also seeks feedback on the provision of information on precision bred seed and other plant reproductive material.

FSA Response:

- The FSA's aim has been to develop a proportionate enforcement regime which will enable enforcement authorities to take effective action against non-compliance.
- Enforcement authorities will use the same approaches for detecting and preventing non-compliance 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.
- Under General Food/Feed Law traceability requirements, food business operators will be required to be able to identify their immediate suppliers, as well as the businesses to which their products are supplied (a "one up, one down" approach). This information must be provided to competent authorities, if requested. This will also be the case for food and feed produced from PBOs and ensures that food can be traced.
- Further information on traceability can be found within the following web pages Food incidents, product withdrawals and recalls | Food Standards Agency and Guidance on Food Traceability, Withdrawals and Recalls within the UK Food Industry

2. **Despite discussions with relevant stakeholders, there is no agreement yet on co-existence measures. (In this context, it would be helpful to understand, when the Department expects the new framework for PBOs to go live and whether it expects to have agreed coexistence measures with stakeholder by then.)**

Defra response:

- The Genetic Technology (Precision Breeding) Act (the Act) does not contain powers to legislate for coexistence measures between PB and non-PB crops. As such, coexistence measures will be developed and implemented by industry.
- We have worked closely with the sector to identify ways to mitigate the unintentional inclusion of precision bred inputs in organic production. We expect industry to build on upon previously agreed coexistence measures, such as the industry-led precision breeding register, to enable successful coexistence between PB and non-PB crops.

3. **How can organic supply chains and consumers avoid PBOs without labelling?**

Defra response

- Based on the scientific advice that the risk associated with precision bred plants is no greater than for traditionally bred counterparts, we do not consider

that mandatory labelling focused on the breeding technology or process used is appropriate. Indeed, the issue of mandatory labelling was a feature of debates in both houses of Parliament during the passage of the Act. In both houses, amendments to require mandatory labelling of PBOs failed to gain sufficient support.

- All food and drink sold on the UK market must comply with food labelling rules. The fundamental principle of food labelling rules is that information provided to the consumer must not mislead and must enable the safe use of food. Additionally, the UK maintains high standards on the information that is provided on food labels, whether that be mandatory or voluntary, so that consumers can have confidence in the food that they buy.
- Registers published by Defra and FSA will contain information about precision bred plants, including those approved for use in food and feed.
- Businesses may choose to label their products as being from precision bred plants.
- We will ensure that food and feed produced from precision bred organisms is considered in any future work to ensure that labelling remains fit for purpose, maintains consumer confidence and provides a level playing field.

FSA response:

- There is no justification for the provision of labelling distinguishing all PB food as such on grounds of consumer safety. Based on their review of case studies (published in the ACNFP Statement July 2023) and their knowledge of the wider literature, ACNFP members did not find evidence that PBOs are intrinsically more hazardous than traditionally bred organisms.
- As with any food, if there is a need to provide safety information for a particular population group, (for example, hypersensitive consumers or people with certain health conditions) this can be required as appropriate.
- The FSA has conducted consumer research which told us that consumers saw a range of risks and benefits to PB food but on balance consumers thought the benefits outweighed the risks if properly regulated; they trust the FSA to regulate PB food; the public register builds towards confidence and reassurance; more proactive information provision (public education campaign, education in school curriculum, labelling, for example) would reassure them that regulation was happening; they wanted labelling to enable them to make choices at the point of purchase.
- The FSA Board considered this issue at Board meeting in 2023 and 2024. The Board has actively discussed the views of consumers throughout the development of the proposals and recognises the importance of these views. This was a key focus of the Board's discussion and associated Board paper at the March 2023 Board meeting.
- The power to decide on the mandatory labelling of PBOs for non-safety related purposes in England sits with Defra. FSA officials have shared results of the consumer research and public consultation with Defra.

What is Defra's view on the impact of the absence of any labelling requirement on international trade, the need for PBO products to be labelled GMO for exports to the EU and the impact of trade between England and Northern Ireland where EU law continues to apply with regard to organic products.

Defra response

- The expectation is that the identity of precision bred crops will be maintained and they will be separated from traditionally bred material until uncertainty about international regulations and other measures are resolved. This means that exposure of organic production to precision bred material will be limited in this period.

- However, we are preparing for the medium/ longer term when precision bred commodity crops are marketed outside of identity preservation schemes and there is ongoing dialogue between Defra and the organic sector on non-legislative options for supply chain coexistence.

- Defra Secretary of State recently announced the reinstatement of the Precision Breeding Industry Working Group. The Working Group's remit includes addressing some of the challenges outlined in this submission, with members working to:
  - identify the challenges and opportunities for precision breeding
  - discuss how to facilitate a route to market
  - get initial products on retail shelves for consumers.

- The EU is considering a proposal that is similar in aim to the Precision Breeding Act. Until new rules for plants produced by new genomic techniques (NGTs) are in force in the EU, precision bred organisms will be regulated as GMOs in the EU and exports must meet all relevant requirements for GMOs, including labelling.

- Precision bred organisms will also need to comply with EU GM law to be sold in Northern Ireland.

10 March 2025

Submission from Slow Food in the UK

Slow Food in the UK

Submission from Slow Food UK on

The Genetic Technology (Precision Breeding) Regulations 2025

Slow Food in the UK is the UK office by reach. We have offices in 150 countries, and work in excess of 160.

We support quality food and agriculture production and consumption globally; and do this via a number of distinct but interlinked ways. We inform consumers of how their choices benefit the environment and the communities that they are purchasing food from; we support producers to produce high quality food which adds value, but also protects the environment and provides for a genuinely sustainable food system, and lastly we work with retailers to understand the issues they face, encourage sustainable procurement and act as a trusted advisor to those wanting impartial advice.

We are partnered with UN FAO, and work with local and national governments, as well as other NGOS, producer groups, consumer groups and trade bodies.

The value of food and drink exports was £24.4 Billion (Defra, 2023 using ONS and HMRC data), a large proportion of these exports coming from SMEs. 98.8% of all food manufacturing and production within the UK are SME producers (Defra, Overseas Trade July 2024).

Over 80% of food and drink exports are to countries which prohibit Gene Editing/GMO (or both)

Food and drink exports are dominated by the quality sector, with substantial efforts to sell food and drink based on craft, tradition and provenance. Frequently protected status indicators are used/sought, and the value of these exports is significant. For example, the value of Scotch Whisky Association put values of exports at £5.6 Billion (2023), the AHDB (2023) show £800 million of quality cheese exports.

Loss of consumer confidence, and/or availability to export due lack of transparency of ingredients within the supply chain and whether they have been gene edited (“precision-bred”) risks a significant reduction in our balance of payments, alongside thousands of jobs, and billions of pounds in our most deprived communities which are disproportionate areas of food production.

General comments

It has long been accepted that UK farming and food policy encourages a range of production methods and the marketing of products from a variety of production systems, thus providing choice for producers and consumers.

The government has consistently framed the Genetic Technology Act as a way of increasing agricultural possibilities and enhancing innovation.

However, examining the systemic implications of these new regulations reveals an approach that threatens to reduce the diversity of the UK food system in profound ways.

The new Genetic Technology (Precision Breeding) Regulations as drafted, present significant challenges for non-GMO food producers who wish to exclude "precision-bred organisms" (PBOs) from their farming and supply chains by creating a streamlined regulatory pathway for the marketing of food and feed created using so-called "precision breeding".

In doing so, it creates extra obstacles and burdens for businesses committed to non-GMO, organic and traditional production methods. This sector, which predominantly comprises SMEs, is significant and is growing as consumers increasingly seek provenance information.

In its desire to promote precision-bred GMOs, the government has prioritised one approach to food production over others and created new burdens that threaten the operations and markets of the non-GMO sector in a number of ways outlined below.

In considering the real-world impact of these regulations for good or for ill, the Committee should note that the 'choice', as implied in the Instrument, explanatory memorandum and the de minimis assessment is not a binary choice between PBOs and organic. The UK has a large and thriving non-GMO market, which reaches far beyond just organic, which will also be affected by these regulations.

It should also consider that true food system diversity isn't merely about the number of plant varieties or novel food types available but encompasses diversity of:

- Production methods
- Business scales and models
- Genetic resources
- Market segments
- Consumer choices

Finally, we would like it noted that precision-bred organisms are defined in the Genetic Technology Act as GMOs. We reject, in the strongest terms, the idea of equivalence between genetically modified precision-bred crops and foods and those produced by traditional means.

Whilst this notion is a convenient, if scientifically flawed 'hook' to justify this legislation, it will cause endless difficulties down the line as, for example, producers of geographical indication foods grapple with the concept of 'traditional' as defined in the Genetic Technology Act – a definition that contains processes that are far from traditional such as polyploidy induction, embryo rescue and cell fusion and the market and consumer expectation of what 'traditional' means. The gap is so large it cannot help but foster legal disputes.

With these thoughts in mind, we would like to raise the following issues with the statutory Instrument, its explanatory memorandum (EM) and the de minimis assessment (DMA):

1. Lack of full impact assessment

The EM (9.1) states:

"*A full Impact Assessment has not been prepared as this instrument will have a low level of impact on businesses and will not introduce new costs or benefits above the threshold required for a full Impact Assessment*."

However, the assertion of a low level of impact seems questionable given that the memorandum (9.3) acknowledges: "*The issue of ensuring precision-bred material does not enter organic supply chains* ***has been raised as a practical concern by some stakeholders*** *[our emphasis] and Defra is continuing to run a series of engagements with stakeholders to explore this further*."

- The memorandum admits there is an ongoing concern but doesn't provide evidence that these concerns have been quantitatively assessed.

The memorandum 9.5 states: "*There may be consumers wishing to buy food that does not contain precision-bred organisms who may have to research suitable products such as organic food. This may incur additional cost with less choice or availability. It was* ***not raised as an issue in either Defra or Food Standards Agency consultations*** *[our emphasis], however, and has not been quantified*."

- Our engagement on this issue and discussions with others who have been similarly engaged suggest this last statement is not true. While the costs to consumers were not raised by either Defra or the FSA in their consultation document, the costs to consumers, both direct and indirect, have repeatedly been raised in stakeholder meetings. They have simply been ignored.

The Committee may wish to question Defra and the FSA's clear prioritisation of one part of the food system – the biotech industry – over many others and why, in so doing, they have not sought to understand or quantify the impacts on artisanal, craft, GI, organic and other non-GMO businesses.

2. Traceability and Coexistence Measures

The legislation does not establish clear, legally binding coexistence measures to protect non-GMO supply chains from contamination with PBOs. Stakeholder discussions on segregation options appear to have been initiated, but these appear to involve only the organic sector and there is no consensus yet on practical measures, and existing mechanisms may be insufficient. (DMA, page 18; EM 9.3)

The explanatory memorandum (9.5) suggests "this legislation is unlikely to result in higher costs to businesses." But farmers may need to adopt additional practices at their own expense to maintain PBO-free supply chains, without regulatory or financial support. (DMA, page 2).

Food businesses in the non-GMO sector rely on labelling transparency to maintain consumer trust. Without labelling, businesses that wish to remain PBO-free may need to develop costly private certification schemes.

- In the US, the Non-GMO Project offers a voluntary certification scheme for producers who wish to demonstrate that their product is free of GMOs. This includes a yearly fee for use of the Non-GMO Project logo and access to a number of different testing laboratories or 'technical partners'. On average this amounts to around $2000 per year for 1-5 products, plus $50-$100 for each high-risk ingredient such as corn, and $150 non-GMO Project fee per product. For some businesses, an additional annual inspection fee will incur a charge of $1000+. The cost to producers in the case of PBOs in the UK is likely to be even higher due to detection challenges and the costs involved in setting up a scheme in the first place. This is likely to be simply unaffordable to many small-scale producers.

While this may not result in direct costs to consumers (EM 9.5) it will result in indirect costs to them in terms of rising cost of non-PBO foods. The language of the EM suggests this is a problem consumers have brought on themselves by rejecting PBOs. However, consumers who wish to avoid PBOs – and to see them labelled so that they can do so – are in the majority – 8 in 10 according to surveys by the FSA, and Beyond GM. The register is unlikely to help these consumers since it will provide information only on the PBO crop/ingredient, not on foods containing PBOs or PBO ingredients. Therefore, these consumers will be solely reliant on voluntary measures the non-GMO sector takes to guarantee their products are free of PBOs.

The Committee may wish to raise the issue of why the cost of voluntary detection/verification schemes was not included as a significant impact on non-GMO sector businesses.

It may also wish to enquire how the government proposes to support the non-GMO sector in preventing contamination on-farm or throughout the supply chain, in the absence of any mandatory traceability or coexistence measures. Will the government provide financial support for non-GMO businesses to develop their own laboratory-based traceability schemes or to help them opt in to existing verification laboratory-based schemes to maintain market integrity?

3. Increased Burden on Non-GMO Producers

The Instrument shifts the burden of detection and prevention onto the non-GMO and organic sector. Whilst precision-bred organisms will continue to be regulated as GMOs for the purposes of organic certification, the supply chain still bears the burden to detect and identify organisms for which the EM states (5.8) that "*developers of precision-bred plants will not be required to provide scientific detection methods as part of the authorisation process*".

The DMA (page 21) also notes that, unlike other GMOs, precision-bred GMOs will "no longer require a unique identifier (UI)" which assists with traceability through the food system.

This means that non-GMO food producers and processors will bear the cost of ensuring their supply chains remain free from PBOs, including testing, certification, and potentially segregating supply chains. (DMA, page 18)

- The cost of this is difficult to quantify at present as it is not clear from the SIs exactly what information will appear in the various precision breeding registers. For example, it is unclear how much of the information listed in the SIs will be redacted on the public register due to commercial confidentiality (SI 34 and Act 18(2)). Therefore, it is unclear how the information on the register will be matched to the ingredient available to producers, and how that will be traced through supply chains.

- Organic farmers are explicitly recognised in the legislation as requiring additional due diligence when sourcing non-organic materials, suggesting that the same issue will affect non-GMO producers. (DMA, page 17-18)

The Committee may wish to ask why developers are not required to make their detection methods available to businesses or to provide whole genome sequencing information to allow the non-GMO sector to develop its own lab-based detection systems.

4. Regulatory Uncertainty and Market Impact

The legislation only applies in England, whereas Scotland and Wales have not adopted similar deregulation. This could create internal market challenges if, for instance, non-GMO products are required to meet stricter GMO standards in these regions (DMA, page 27). Despite this, the 'risk' in the DMA is framed as a risk for devolved nations rather than the English PBO market.

The Committee may wish to ask why the DMA does not fully acknowledge the evolving and complex nature of legal issues around devolved nations and the impact of this on government plans for a growing PBO market?

The EU still considers PBOs as GMOs, meaning exports to the EU will require GMO authorisation and labelling, leading to potential market access issues for businesses dealing in non-GMO products. The DMA acknowledges (page 28) that this is another fluid area and one that will also have an impact on Northern Ireland should the EU regulations ultimately not align with those in England.

It is clear from newspaper reports and ongoing discussions within the EU that there are ongoing concerns about removing border checks on food and plant products. If English PBO products remain unlabelled and untraceable, the risk of unauthorised GMO products entering the EU food chain increases. No labelling means potential breach of the EU-UK Trade and Cooperation Agreement (TCA). The fact that the Act requires no environmental assessment (e.g. Regulations 12 and 20 and Schedules 1-3 and part 3 of Schedule 5 which amends the 2015 Environmental Damage Regulations) is also a clear breach of the TCA's principle of non-regression and the EU is entitled to deal with this breach in accordance with the non-regression clause of the agreement.

The Committee may wish to ask why there has not been a more thorough examination of trade issues in the DMA (pages 27-28) and what guarantees can be given to non-GMO businesses that they will not face trade restrictions or loss of business due lack of detection, traceability and labelling provisions in this Instrument.

Slow Food in the UK

Part 1 of schedule 5 excludes precision-bred plants from the scope of Regulation (EC) No 1946/2003 of the European Parliament and of the Council on transboundary movements of genetically modified organisms as they relate to The Cartagena Protocol on Biosafety to the Convention on Biological Diversity. However, this exclusion applies to England only.

The Committee may wish to enquire how a regulation related to moving goods across national borders can be disapplied for a single country and whether this indicates that devolved nation competency extends to deciding for themselves whether to opt in or out of Cartagena Protocol obligations around transboundary movements.

7 March 2025

Response from Defra

Defra response – Slow Food UK submission – 10/03/2025

Points from Slow Food UK to address

General Comments

- *The government has consistently framed the Genetic Technology Act as a way of increasing agricultural possibilities and enhancing innovation. However, examining the systemic implications of these new regulations reveals an approach that threatens to reduce the diversity of the UK food system in profound ways.*
- *In its desire to promote precision-bred GMOs, the government has prioritised one approach to food production over others and created new burdens that threaten the operations and markets of the non-GMO sector in a number of ways*

Defra Response:

- We do not agree with the view that the Genetic Technology (Precision Breeding) Act 2023 (the Act) or the Genetic Technology (Precision Breeding) Regulations 2025 threaten to reduce the diversity of the UK food system. Both the Act and the regulations will enable the use of precision breeding in plants to develop a variety of innovative products that may be brought to market much more quickly. These legislative pieces present the opportunity to increase diversity in the UK food system.
- As mentioned in our responses to other received submissions, Defra are facilitating discussions between organic and conventional farmers to develop industry-led coexistence measures between precision bred and non-precision bred plants. This is in line with approaches taken internationally. As part of this process, the British Society of Plant Breeders, representing the plant breeding industry, have committed to maintaining a register of precision bred varieties to complement the statutory Defra and FSA registers.
- Additionally, in order to help those breeders and farmers who wish to grow non-precision bred plant varieties only, the government wants to ensure that there is accessible marketing information to enable this. The government is exploring a variety of methods and tools to communicate information on the precision bred status of plant varieties.
- To facilitate the marketing of precision bred varieties of the main agricultural and vegetable species, a Precision Bred Plant Variety List for England is proposed in addition to the existing GB and NI variety lists. Information regarding applications made and varieties accepted onto the list, including variety name, will be published in the Plant Varieties and Seeds Gazette. The Animal and Plant Health Agency through their Delivering Sustainable Futures project are looking to improve the accessibility and usability of the Gazette.

- Views on the proposed Precision Bred Plant Variety List for England are being sought through the public consultation on **Plant Varieties and Seeds Framework for Precision Bred Plant Varieties** (17 Feb – 14 Apr 2025) which also seeks feedback on the provision of information on precision bred seed and other plant reproductive material.

1. Lack of full impact assessment

- *The Committee may wish to question Defra and the FSA's clear prioritisation of one part of the food system – the biotech industry – over many others and why, in so doing, they have not sought to understand or quantify the impacts on artisanal, craft, GI, organic and other non-GMO businesses.*

Defra Response:

- The interests of no one sector or industry have been prioritised during the development of the Act or the regulations. The more proportionate and science based regulatory system created by the Act and these regulations will save businesses developing precision bred foods and feed, time and money whilst creating a more dynamic, competitive and responsive industry. This will be favourable for businesses of all sizes.
- Precision breeding offers great potential in making plant breeding more efficient. The legislation would allow plant breeders to add precision breeding to their toolkit alongside other techniques. We recognise that it is not a silver bullet and that breeders need access to a range of techniques.
- As mentioned in our responses to other submissions, it is not mandatory to submit an impact assessment for measures with impacts below £10m Equivalent Annual Net Direct Costs on Business; however, the de minimis assessment of the estimated impacts prepared, considers impacts as far as possible within a 10-year period of the Regulations coming into force.
- The impact on organics was considered in the *de minimis* assessment (DMA), but this did not include a separate assessment for organic SMEs. The impact was predicted over a 10-year period, starting from when the regulations come into force. The expectation is that the identity of precision bred crops will be maintained they will be separated from traditionally bred material until uncertainty about international regulations and other measures are resolved. This means that exposure of organic production to precision bred material will be limited in this period.

- However, we are preparing for the medium/ longer term when precision bred commodity crops are marketed outside of identity preservation schemes by discussing non-legislative options for supply chain coexistence with the organic sector.

2. Traceability and Coexistence Measures

- *The Committee may wish to raise the issue of why the cost of voluntary detection/verification schemes was not included as a significant impact on non-GMO sector businesses.*
- *It may also wish to enquire how the government proposes to support the non-GMO sector in preventing contamination on-farm or throughout the supply chain, in the absence of any mandatory traceability or coexistence measures. Will the government provide financial support for non-GMO businesses to develop their own laboratory-based traceability schemes or to help them opt in to existing verification laboratory-based schemes to maintain market integrity?*

Defra Response:

- To our knowledge, there are currently no scientific methods that provide unequivocal identification of genetic changes associated with precision bred plants without prior knowledge of the altered genome and suitable reference materials. If these data were available, there would be no way of knowing whether the genetic change resulted from the application of precision breeding technology or traditional breeding practices. Therefore, the associated cost of any possible detection schemes have not been considered as part of the DMA.
- There are established methods for enabling different supply chains to coexist in agriculture. We have engaged with the sector, and we are currently working towards implementing industry-led coexistence measures to assist those who wish to produce non-precision bred plants or their products only.
- There are no plans to provide financial support for laboratory-based traceability or verification schemes.

3. Increased Burden on Non-GMO Producers

- *The Committee may wish to ask why developers are not required to make their detection methods available to businesses or to provide whole genome sequencing information to allow the non-GMO sector to develop its own lab-based detection systems.*

Defra Response:

- Defra's position, based on independent scientific advice, is that Whole genome sequencing (WGS) is not necessarily required to demonstrate the precision bred status of an organism and therefore there is no legislative requirement for developers to provide this. Developers may choose to include sequencing data when submitting their marketing notices, although if requested and agreed by Secretary of State to be deemed as commercially confidential (as per Section 18

(2) of the Act), this information will not be present on the publicly available precision breeding register.

- As mentioned above, to our knowledge, there are currently no scientific methods that provide unequivocal identification of genetic changes associated with precision bred plants without prior knowledge of the altered genome and suitable reference materials.

4. Regulatory uncertainty and market impact

- *The Committee may wish to ask why the DMA does not fully acknowledge the evolving and complex nature of legal issues around devolved nations and the impact of this on government plans for a growing PBO market?*
- *The Committee may wish to ask why there has not been a more thorough examination of trade issues in the DMA (pages 27-28) and what guarantees can be given to non-GMO businesses that they will not face trade restrictions or loss of business due lack of detection, traceability and labelling provisions in this Instrument.*

Defra Response:

- The DMA has been compiled by Defra economists and reviewed by the Defra Chief Economist. The purpose of the DMA is to outline economic impacts of the regulations based on reasoned assumptions. As the question notes, the nature of interactions between the Precision Breeding Act and other pieces of legislation with impact on the devolved nations, including the UK Internal Market Act, and the Windsor Framework, is complex and evolving. It would not be practicable to economically assess or analyse all possible outcomes in a DMA.
- The development of the DMA also involved discussions with trade officials on the likely effects of this legislation on UK exports to the EU but similarly to the above, any assessment would have been based on an evolving set of legal and political issues, the effects of which are yet to be determined. Therefore, detailed economic analysis on this issue was not amenable to include in the DMA.
- Defra and the Food Standards Agency are continuing to engage with the devolved governments and with the Department for Business and Trade on internal market implications of the Precision Breeding Act.
- Our approach to labelling and traceability is aligned with several other countries that have implemented similar regulations for precision bred organisms, including Japan, Argentina, Canada and the USA.

10 March 2025