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(DMA), 32 pages of ACRE guidance and 135 pages of FSA guidance (with further promised FSA enforcement guidance still unpublished).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.