Genetic Technology (Precision Breeding) Bill

GM Freeze Briefing for House of Commons Report Stage and Third Reading - UPDATED

for a responsible, fair and sustainable food system

Introduction

The premise and framing of the Genetic Technology Bill are both deeply flawed. "Precision breeding" is genetic modification and needs to be subjected to both independent safety checks and full traceability to protect our food, our farms and the natural environment. Citizens want strong regulation and clear labelling of genetically engineered foods but this bill removes their right to choose while threatening food and farming businesses, devolution and international trade. It also falls far short of fulfilling the Government's stated commitment to protecting animal welfare. The bill text is poorly drafted and introduces significant legal ambiguity just as the Government departments that will need to put its provisions into practice are also tasked with delivering the extensive impacts of the Retained EU Law (Revocation and Reform) Bill and significant changes to agricultural policy.

The Genetic Technology Bill is the wrong bill at the wrong time. GM Freeze urges MPs to vote against the Report Stage and Third Reading while also supporting amendments that will help mitigate some of its most damaging impacts.

Please SUPPORT the following report stage amendments:

- New Clauses 1, 2, 3, 4, 5 and 6 plus New Schedule 1 – establishing a Genetic Technology Authority.
- New Clause 7 – requiring labelling of food and feed produced from "precision bred organisms".
- New Clause 8 – requiring labelling of food and feed produced from "precision bred animals" [particularly if there is no vote on New Clause 7].
- New Clause 9 – preventing the Internal Market Act from overriding the Scottish Parliament's decision making about "precision bred" organisms, food and feed.
- Amendments 1 and 2 – removing animals from the scope of the bill.
- Amendment 3 – requiring that "precision bred" organisms must provide a public benefit.
- Amendment 4 – expanding the factors to be considered before the issuing of a "precision bred" animal marketing authorisation.
- Amendment 5 – requiring that regulations are made in accordance with the environmental principles (as set out in the Environment Act 2021) and the non-regression clause in the UK/EU Trade and Cooperation Agreement.
- Amendments 6, 7, 9 and 10 – changing powers created by the bill into obligations.
- Amendment 8 – specifying that traceability should occur through supply chain auditing.
- Amendment 11 – excluding the use of exogenous genetic material (often described as "foreign DNA") in the creation of "precision bred" organisms.
- Amendment 12 – preventing the issue of a "precision bred" animal marketing authorisation if traits are likely to adversely affect animal health or welfare.
- Amendment 13 – requiring that a Common Framework Agreement is in place before the creation of new regulations on "precision bred" organisms, food and feed.

Regardless of amendments, please vote AGAINST the Genetic Technology Bill.

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Precision breeding is genetic modification.

The bill will create a new class of genetically modified organism (GMO), the "precision bred organism". The term "precision breeding" is not widely used in the UK and is not understood by citizens.[1] It is not scientifically defined and is not included in the International Organization for Standardization (ISO)'s recently published guide to internationally agreed-upon terms relating to genome editing.[2] Its use in the context of this bill has been criticized by over a hundred international scientists and policy experts.[3]

The bill defines a "precision bred organism" [Part 1, 1 (2) (c)] as a product of genetic engineering in which the genetic changes made in the laboratory could – theoretically – have instead occurred as a result of "traditional processes" or natural transformation. This wording is chosen to sound reassuring but it is meaningless, especially as no limit is given for the period of time or number of generations over which such a hypothetical event "could have" occurred. Debate on the bill so far has revealed significant confusion about the role of exogenous genetic material ("foreign DNA") in "precision breeding".

It is important for Members of Parliament to understand that genome editing ALWAYS involves the insertion of exogenous genetic material into a target organism's cells. The genetic material that is added includes the genome editing tool, marker genes and, often, a genetic template or guide.[4] Genome editing uses the inserted exogenous genetic material to alter the target organism's own genome, whereas more established transgenesis techniques focus on deliberately integrating some of the inserted exogenous genetic material into the genome of the target organism. However, the definitions in the bill do not cover any technical detail. This could well lead to developers claiming that transgenic GMOs are "precision bred organisms".

Please support:

- **Amendment 3 requiring that "precision bred" organisms must provide a public benefit.**
- **Amendment 11 which excludes the use of exogenous genetic material in the creation of "precision bred" organisms.**

Independent safety checks and full traceability are essential to protect our food, our farms and the natural environment.

Regardless of the intended outcome, the process by which genetic changes occur has a huge influence on what can go wrong. New techniques are more targeted than first generation GMOs, but all genetic engineering techniques are prone to errors[5] and neither precision nor accuracy can be assumed. Human understanding of the genome is developing all the time but do now understand that it functions more like an ecosystem than a codebook. That means that small changes – even those that amend just one base pair in the DNA sequence – can have catastrophic impacts. The invasive power of new genetic engineering techniques means they can access and amend parts of the genome that are protected from naturally occurring (or induced) mutation.[6]

The bill proposes significant discretion for the developers of genetically engineered organisms, allowing them to, effectively, check their own homework. This is not adequate as developers have a significant financial interest in the release of their patented inventions. Instead, the bill should require independent safety checks to ensure that the only genetic changes that have occurred are those that were planned *and* that these changes have only resulted in the intended outcomes. In addition, traceability of genetically engineered organisms (whatever you choose to call them) is essential to support recall in the event that novel allergens, toxins and other safety issues emerge after release.

Please support New Clauses 1-6 and New Schedule 1 to create a Genetic Technology Authority as this would help address some concerns around safety checks.

Citizens want strong regulation and clear labelling of genetically engineered foods.

The public, and businesses, have already rejected the measures in this bill. The overwhelming majority of responses to Defra's 2021 Consultation on the Regulation of Genetic Technologies were opposed to the proposal to regulate on the basis of hypothetical judgements that X or Y "could have occurred" in another way. As noted in Defra's own *Summary of responses, "most individuals (88%) and businesses (64%) supported continuing to regulate such organisms* [those in which genetic changes could have been produced through traditional breeding] *as GMOs.".*[7]

Research has shown consistently that there is broad public support for strong environmental and food safety regulation[8] and that consumers want robust regulation of all forms of genetic engineering including clear labelling at the point of purchase. The Food Standards Agency's (FSA) *Consumer perceptions of genome edited food* study, published in July 2021[9] found that *"Consumers wanted transparent labelling, and reassurance about the thoroughness of regulation and safety assessments, if genome edited foods reach the UK market."* This finding applied even when consumers felt it would be appropriate to regulate what the study described as "GE food" separately from GM food, in which case "*Most consumers felt labelling should always inform the consumer of the presence of GE ingredients*". In the first phase of the FSA's new and ongoing social research project 77% of those questioned said "*it would be important when buying a food item to know that it had been precision bred"*. Notably, a majority of these (45% of total respondents) felt it was *"very important"* to have this knowledge in advance of purchase.[10] Similarly, the recently published Nuffield Council on Bioethics, BBSRC and Sciencewise public dialogue on genome editing and farmed animals found that consumers "*wanted products from genome edited animals to be labelled as such*"[11].

Please support:

- **New Clause 7 to require "precision bred" food and feed labelling.** New Clause 8 is also helpful, but only requires labelling of food and feed from "precision bred" animals. We encourage you to support New Clause 8 if there is no vote on New Clause 7.
- **Amendment 5 to require that regulations relating to "precision breeding" are made in accordance with the environmental principles set out in the Environment Act.**

Provisions in the bill threaten food and farming businesses, devolution and international trade.

Changes in the regulation of genetic engineering will significantly affect a wide range of food and farming businesses. However, Defra has repeatedly failed to properly identify the business sectors impacted by this bill, focusing instead on the handful of genetic engineering companies that have a direct financial interest in the uptake of their patented inventions. This is one of many concerns that led the Regulatory Policy Committee to issue an Opinion that the Impact Assessment for this bill is "NOT FIT FOR PURPOSE"[12].

By redefining what constitutes a GMO, the bill will remove any requirement for those who grow or process certain genetically engineered organisms in England to notify their neighbours or prevent supply chain contamination. This will directly threaten the viability of all GM-free food and farming businesses, including those that are certified organic. "Precision bred" organisms should not be released without effective coexistence measures, supported by full traceability and clear allocation of liability.

"Precision bred organisms" will retain their GMO status in all three of the UK's devolved nations, the European Union and many other territories. The changes proposed in this bill are likely to disrupt trade with the European Union and could constitute a breach of the UK/EU Trade and Cooperation Agreement commitment to non-regression from levels of protection. For Scotland and Wales, the impact of the Internal Market Act means that, as noted in a recent FSA board paper, the bill will undermine the devolved nations' legitimate authority as "*It is likely that it will not be possible to prevent the sale of genome edited products authorised in England from being sold elsewhere in Great Britain, irrespective of the regulatory regimes in place in any of the devolved nations."*[13]

Please support:

- **New Clause 9 requiring an amendment to the Internal Market Act to protect the Scottish Parliament's decision making about the marketing of "precision bred" organisms, food and feed.**
- **Amendment 5 requiring that regulations are made in accordance with the non-regression clause in the UK/EU Trade and Cooperation Agreement (and with the environmental principles set out in the Environment Act 2021).**
- **Amendment 8 supporting traceability through supply chain auditing.**
- **Amendment 13 delaying the creation of the new regulations set out by the bill until a common framework has been agreed between the UK, Scottish and Welsh Governments.**

The bill does not fulfil the Government's commitment to protecting animal welfare.

Despite Government assurances that the genetic engineering of animals would not be allowed until proper welfare protections had been put in place, the provision for such protections in the bill is wholly inadequate. GM Freeze recommends the briefing from animal welfare charities, which you can view online or request by emailing policy@ciwf.org.

Please support:

- **Amendments 1 and 2 removing animals from the scope of the bill.**
- **Amendment 4 expanding the factors to be considered before the issuing of a "precision bred" animal marketing authorisation.**
- **Amendment 12 preventing the issue of a "precision bred" animal marketing authorisation if traits are likely to adversely affect animal health or welfare.**

The bill is poorly drafted and introduces significant ambiguity.

Parliamentary debate and consideration of the bill to date has revealed significant confusion over the exact nature of the genetic changes that will be removed from the protection of GMO regulations. Ministers were unable to clarify the status of exogenous genetic material in the bill when questioned directly in the Committee Stage[14] and one speech during the House of Commons Second Reading erroneously described techniques that are central to genome editing as an example of what would **not** be allowed under the Bill.[15]

From a legal perspective, the definitions provided by the bill introduce significant ambiguity. Intellectual property law specialist Dr Michael Edenborough KC was asked, in an evidence session for the House of Commons bill committee, if he was confident that lawyers would find the bill straightforward to interpret. He responded "*I am confident that it would **not** be straightforward*" elaborating that clause 1 is "*staggeringly imprecise".*[16]

With an issue as technically complex as genetic engineering, the devil is very much in the detail. However, the vast majority of the regulatory detail relating to this this bill will be provided later through statutory instruments (SIs) which will not be subjected to adequate scrutiny. The bill grants significant powers but creates few obligations for Ministers and others (such as the FSA). In addition, detail on the role and make up of the advisory bodies established by this bill is very limited and the Secretary of State is not required to follow their advice.

Please support:

- **New Clauses 1-6 and New Schedule 1 establishing a Genetic Technology Authority as this would help address some concerns around safety checks.**
- **Amendments 6, 7, 9 and 10 converting bill powers (what authorities "may" do) into obligations (what they "must" do).**

Background to the GM debate

GM food, crops and animals are not currently banned, they are regulated. Those regulations are largely held in retained EU law, but the UK already has the power to make its own decisions and approve GMOs for use in the food chain if it wishes to do so. This bill seeks to remove the checks and balances that currently protect our food, our farms and the environment.

The vast majority of example applications used to demonstrate the potential benefits of new GMOs are either entirely hypothetical or at an early 'proof of concept' stage of development. The proposed applications largely mirror the unfulfilled promises made about first generation GMOs 20+ years ago. They also often miss the point entirely. For example, we already produce enough food globally to feed at least 10 billion people – the predicted 2050 peak world population – but around a third of it is wasted[17]. Food poverty and malnutrition are problems of economics and access which will not be solved by increasing production or boosting levels of individual micronutrients.

More about GM Freeze

GM Freeze is the UK umbrella campaign for a responsible, fair and sustainable food system, focused on concerns around the use of genetic engineering in food and farming. We are a non-profit organisation with a turnover of less than £100,000 a year, two staff members and a voluntary management committee that operates as our board of directors. GM Freeze member organisations include large NGOs, scientists, farmers, retailers and community groups.

We are aware of many misconceptions around the role of single-issue campaigns and would like to stress that we exist because we are needed. GM Freeze member organisations and the thousands of individuals who support and follow our work, tell us that they find it difficult to engage in political and policy discussion about the use of genetic engineering in food and farming. They ask us to follow the fine detail of technical and political developments on their behalf and help them to articulate their concerns. That is why we produce briefings such as this one and why constituents, our member organisations and others may have sent this briefing to you, rather than producing one of their own.

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References

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[2] ISO 5058-1:2021(en) biotechnology – Genome Editing – Part 1: Vocabulary https://www.iso.org/obp/ui/#iso:std:iso:5058:-1:ed-1:v1:en

[3] https://docs.google.com/document/d/1bTXTWZwwDHfReRaiA4Kt25Jfrqab4iNyAlLAsEGTPR4/edit

[4] See our briefing, *Why Gene Editing is GM with Better PR:* https://www.gmfreeze.org/publications/gm-with-better-pr/

[5] https://ensser.org/publications/ngmt-statement European Network of Scientists for Social and Environmental Responsibility Statement on New Genetic Modification Techniques, 2017

[6] https://www.testbiotech.org/en/node/2901 or see short article "Nature protects key parts of the genome" on page 2 of this GM Freeze newsletter: https://www.gmfreeze.org/wp-content/uploads/2022/04/GMF-Thin-Ice-Issue-61-REFERENCED.pdf

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[8] Unchecked UK, September 2022, *Protect or deregulate? A review of public attitudes to regulation* https://unchecked.uk/research/protect-or-deregulate-a-review-of-public-attitudes-to-regulation/ and additional polling (October 2022) https://unchecked.uk/wp-content/uploads/2022/10/Poll_Unchecked_Deregulation_03102022.pdf

[9] https://www.food.gov.uk/research/behaviour-and-perception/consumer-perceptions-of-genome-edited-food

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[11] Public Dialogue on genome editing and farmed animals, October 2022, Executive Summary, downloaded from https://www.nuffieldbioethics.org/publications/public-dialogue-on-genome-editing-and-farmed-animals-2

[12] https://www.gov.uk/government/publications/the-genetic-technologies-precision-breeding-techniques-bill-rpc-opinion

[13] FSA 22-06-08 – The Genetic Technology (Precision Breeding) Bill https://www.food.gov.uk/about-us/fsa-22-06-08-the-genetic-technology-precision-breeding-bill

[14] Genetic Technology (Precision Breeding) Bill (Eighth sitting), 7 July 2022, Hansard column 242 https://hansard.parliament.uk/commons/2022-07-07/debates/123e4aec-4744-4709-b8ab-06cf337ed9e2/GeneticTechnology(PrecisionBreeding)Bill(EighthSitting)

[15] In the House of Commons on 15 June 2022, Katherine Fletcher MP described the process of "taking DNA material in vectors such as plasmid, and pebbledashing a target DNA area." She presented this as an old fashioned and outdated approach, contrasting it with the new gene editing techniques that the bill sets out to enable. However, what Fletcher described was the process of microparticle bombardment (also known as "gene gun") which is still very widely used in genetic manipulation techniques variously described as gene or genome editing and/or or precision breeding. [HC Deb, 15 June 2022, c383 https://www.theyworkforyou.com/debates/?id=2022-06-15b.374.0&s=katherine+fletcher+pebbledash#g383.1]

[16] Genetic Technology (Precision Breeding) Bill Public Bill Committee, fourth sitting, 30 June 2022, Hansard column 125 https://hansard.parliament.uk/commons/2022-06-30/debates/1b4c41e7-8027-43e0-9408-94a552313da1/GeneticTechnology(PrecisionBreeding)Bill(FourthSitting)

[17] World Food Programme https://www.wfp.org/stories/5-facts-about-food-waste-and-hunger