Genetic Technology (Precision Breeding) Bill

GM Freeze Briefing for Second Reading in the House of Lords



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 peers to raise key concerns at second reading and to discuss with us the kind of amendments that would allow the bill to better protect our food, our farms and the natural environment.

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 <u>not understood by citizens</u>. ¹ It is not scientifically defined and was not included in the International Organization for Standardization (ISO)'s <u>recently published guide to internationally agreed-upon terms relating to genome editing</u>. ² Its use in the context of this bill has been <u>criticized by over a hundred international scientists and policy experts</u>. 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. Worryingly, debate in the Commons revealed significant confusion among Parliamentarians (including Ministers) about the role of exogenous genetic material ("foreign DNA") in "precision breeding".

It is important for peers to understand that genome editing begins with the insertion of exogenous genetic material ["foreign" DNA and/or RNA] into a target organism's cells. Genome editing usually uses the inserted genetic material to alter the target organism's own genome, whereas more established GM techniques (often referred to as transgenesis) focus on deliberately integrating some of the inserted DNA into the genome of the target organism. However, technical detail in the bill is extremely light so it is likely that there will be future claims that a wide range of transgenic GMOs should qualify as "precision bred organisms".

In addition, the bill states [Part 1, 1 (6)] that "no account is to be taken of genetic material which does not result in a functional protein". Not all genes (or parts of genes) code directly for a protein – many are involved in regulating the expression of genes, often in complex and overlapping ways. This clause specifically allows a "precision bred organism" to include "foreign DNA" that can control and influence the expression of a wide range of genes with complex, and often unexpected, results.

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

The process by which a genetic change occurs has a huge influence on what can go wrong. New methods are more targeted than first generation GMOs, but <u>all genetic engineering techniques are prone to errors</u>⁵ and neither precision nor accuracy can be assumed. The genome functions more like an ecosystem than a codebook so small changes – even those that amend just one base pair in the DNA sequence – can have farreaching, even catastrophic, impacts.

Genome editing is often favourably compared with the random mutagenesis techniques that are exempted from genetic modification regulations but this is disingenuous. 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, mutations.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 and uptake of their patented inventions. Instead, we need to retain 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 all genetically engineered organisms is essential to support recall in the event that novel allergens, toxins and other safety issues emerge after release.

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 plans that formed the basis of the bill. As noted in Defra's own Summary of responses, "most individuals (88%) and businesses (64%) supported continuing to regulate such organisms [those in which it is deemed that the genetic changes "could have been produced through traditional breeding"] as GMOs.".

Research has shown consistently that there is <u>broad public support for strong environmental and food safety regulation</u>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, <u>published in July 2021</u>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 <u>first phase of the FSA's new and ongoing social research project</u> 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

The recently published Nuffield Council on Bioethics, BBSRC and Sciencewise <u>public dialogue on</u> <u>genome editing and farmed animals</u> found that consumers "wanted products from genome edited animals to be labelled as such"¹¹.

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 in England, 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 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' 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

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 can <u>viewed online</u> or requested by emailing <u>policy@ciwf.org</u>.

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 Stage¹⁴ 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 in a "precision bred organism".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 <u>an evidence session for the House of Commons Bill Committee</u>, 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.

Amending the bill

GM Freeze supported all of the amendments proposed in the House of Commons report stage and we are keen to work with peers to develop amendments that address any of the concerned raised within this briefing. In particular, we are already developing new amendments to recognise the importance of the DNA sequences that control genes and to protect choice through traceability and consumer labelling. Please contact us on the details below to find out more or ask for our help in developing amendments on any aspect of the bill.

Background to the GM debate

GM food, crops and animals (including those produced with newer genome editing techniques) are not banned in the UK, they are regulated. Those regulations are largely held in retained EU law, but Brexit has already given the UK (and its devolved nations) the power to decide which GMOs to approve for cultivation or entry into the food chain. This bill seeks to remove the checks and balances that currently protect our food, our farms and the environment through independent risk assessments, traceability and labelling.

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, but <u>around a third of it is wasted</u>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.

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 concerned citizens, 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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- ³ https://docs.google.com/document/d/1bTXTWZwwDHfReRaiA4Kt25Jfrgab4iNyAlLAsEGTPR4/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
- ⁷ Defra: Summary of responses to a consultation on the regulation of genetic technologies (September 2021) https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/10213
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- ¹² https://www.gov.uk/government/publications/the-genetic-technologies-precision-breeding-techniques-bill-rpc-opinion
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- 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

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