Beyond GM/A Bigger Conversation Brief

Genetic Technology (Precision Breeding) Bill
Second Reading

The need for innovation that contributes to sustainable development goals is unarguable. The rapid development of agricultural genetic science and technologies means the time is right to review regulatory provisions for these technologies. The Government's Genetic Technology (Precision Breeding) Bill, therefore, should provide an opportunity for a comprehensive, society-wide discussion on how we should regulate genetic technologies in the UK. It should be a chance to avoid the ideology, arguments and impasses of the past.

Instead, we have been presented with proposals that mislead in language and scientific fact; lack transparency and accountability; fail to protect consumers, farmers and animals; ignore environmental protection. In our view, the Bill fails on its own terms by generating confusion and mistrust and undermines the relationship between innovation, consumers, business and the market.

We urge parliamentarians to raise the concerns detailed below during the Second Reading debate and, in the later stages, support amendments that will ensure that gene editing benefits from clear robust regulation.

QUICK TAKES

The Bill and its accompanying documents are misleading

- It replaces the words gene editing and GMO with 'Precision Breeding'. Yet, in scientific and legal terms (and buried in the Bill's text) precision breeding is genetic engineering and the new category of 'Precision Bred Organisms' ('PBOs') created for the purposes of the Bill are GMOs.
- 'Precision breeding' is a marketing term, rather than a scientific one, which has been used to rebrand gene editing. However, this term is not commonly understood, poorly defined and its use obscures the full scope of the proposed deregulation.
- 'Precision breeding' has been promoted using a false narrative – specifically that the process is just a simple "cut" or "tweak" that might have occurred "naturally" and that it does not involve the insertion of transgenes (so-called 'foreign' DNA). These misperceptions affect the clarity and robustness of the Parliamentary debate. *See further context section below.*

The Bill lacks transparency and accountability

- Almost every type of GMO, including those made using transgenes (foreign DNA) can come under the heading of precision breeding.
- Far too much in the Bill depends on what the Government "may" (and therefore may not) do in the future. We are expected to trust it will make the right choices around *e.g.,* risk assessment and environmental management. There are very few things the Government "must" do.

- The Bill, for the most part, leaves further regulation to undebated secondary legislation.
- There is mention of various registers of 'precision-bred' organisms and products, but it is unclear how these will function and while there must be a register for crops, the FSA is under no obligation to make one for food and feed.
- For commercial products (plants and animals) careful assessment has been replaced with a notification system based on self-declaration by developers with no external risk (or benefit) assessment.
- Declarations will be "reviewed" not assessed by advisory panels/committees based on the ACRE model which has endemic, built-in conflicts of interest. The focus of these reviews will be narrowly science-based, excluding ethical and social impact assessments and citizen participation.

The Bill fails to protect consumers, farmers and animals

- There are no provisions for labelling of genetically engineered/'precision-bred' food. This omission removes all consumer and farmer choice and transparency in the supply chain.
- There is no provision for mechanisms of coexistence between conventional/non-GM, organic/agroecological or local artisanal production systems and supply chains.
- There is no recognition of the considerable implications for animal welfare of this technology and no binding provision for delay or amendment in the deregulation of gene edited animals.

The Bill does not fulfil the obligations of the Environment Act

- The environmental statement on the front page of the Bill, required by section 20 of the Environment Act 2021 states that "the Bill will not have the effect of reducing the level of environmental protection provided for by any existing environmental law".
- However, no environmental impact assessment has been performed, and the entire Bill was drafted without reference to the environmental principles which the Environment Act says should inform the development of government policy going forward.

The Bill generates confusion and mistrust in the market, thereby undermining its own aims

- It creates confusion and conflict within the UK internal market by failing to address the views of the devolved administrations
- It runs counter to the "non-regression" terms of the Brexit agreement.
- It pays no attention to trade and regulation alignment with the EU and other parts of the world.
- The impact assessment fails to provide evidence of benefit to the diversity of SMEs throughout the UK farming and food supply chain.
- As drafted, the Bill risks damaging the UK's reputation for sound and robust science and ethical regulation.

- Through its lack of transparency, it undermines citizen and consumer trust in scientific and technological innovation by putting corporate interests first and last.

WHAT BEYOND GM/A BIGGER CONVERSATION IS CALLING FOR

Innovation in agriculture, including genetic engineering, may have a role in responding to challenges such as feeding a growing world population, adapting to climate change and protecting natural resources. But based on what the Government has put forward, it is difficult to see how these poorly conceived proposals for regulatory reform will lead to either effective regulation or the kind of food, farmer, citizen and environment focused, socially-responsible innovation that we so desperately need in the 21st century.

Regulation and innovation need not be at odds. We believe that all products of agricultural genetic engineering (including newer gene editing techniques) should be regulated and that a robust regulatory framework should:

- Be subject to independent and transparent risk/benefit assessments involving civil society bodies and citizens as well as stakeholders and researchers representing ethical, social and environmental perspectives.

- Be subject to a transparent, proportional approach involving timely reviews of current evidence, experience and circumstance.

- Ensure effective traceability to allow monitoring of impacts and to facilitate recall.

- Guarantee the right to choose for consumers, processors and producers through clear labelling and traceability at all stages of the supply chain.

- Ensure equitable co-existence between conventional (non-GMO), agroecological and organic and genetic engineering-based farming systems and supply chains.

- Devise and maintain a more comprehensive public register of all genetic engineering events/organisms used in UK agriculture.

For these provisions to be met the Bill will require extensive revisions (and potentially deletions) which we are willing to suggest or collaborate on.

FURTHER CONTEXT/CONSIDERATIONS

Poorly defined criteria

The criteria for reduced regulation – genetic changes that could have arisen through traditional breeding or “natural transformation" – is questionable.

There is no clear definition of these terms backed by convincing scientific evidence (actual or theoretical), nor is there clarity on how they can be consistently applied in robust regulation of genome-edited organisms in the environment or the marketplace.

In response to last year’s public consultation, several learned organisations such as the FSA’s Advisory Committee on Novel Foods and Processes, the Royal Society, the Microbiology Society, the

Royal Society of Biology, the Institute of Food Science & Technology, Fera Science, Wildlife and Countryside Link and the Organic Research Centre challenged the Government's creation of a hypothetical class of GMOs that could have "occurred naturally" or could have been created using traditional breeding.

Their view was that this is a fundamentally flawed and unscientific basis for regulation. The Defra report on the consultation and the new Bill ignore these concerns (see *Filling in the Blanks – What Defra Didn't Say*, A Bigger Conversation, 2022).

The implications of this are far-reaching:

- As there is no agreed international consensus on the scientific definition of the terms used in the proposed Bill, any regulation based on them will not be aligned with those of the UK's trading partners.
- In addition, as it applies to England only, it will lead to confused and dysfunctional regulations and confused markets within the UK for both domestically grown crops and imported food and feed.

Lack of scientific coherence and clarity

In its title and text, the Bill uses the term "precision breeding". However, "precision breeding" is not a specific technology nor a scientific discipline; it is a colloquialism for genome editing, and an umbrella term for a number of recently developed genetic engineering technologies which do not form a coherent group of methods and do not justify being called "precise". The scientific literature is full of reports of genetic technologies such as gene editing creating unexpected and unwanted mutations, genetic errors, altered proteins, and extensive deletions and complex rearrangements of DNA in plants (and in animals, see below).

Misleading about the nature of gene editing

The popular narrative around gene editing is that it is different from genetic modification in that it does not insert foreign genes into an organism. This is simply not the case. Gene editing can and does use the insertion of foreign genes and in fact the more complex the goal (such as drought resistance or disease resistance) the greater the likelihood that foreign genes must be used. Promoting this falsehood in the media makes an honest debate about gene editing impossible and fosters public mistrust.

A "science-based authorisation process" – means what?

The Government has said it wants a 'science based' authorisation process. Often this phrase is used as proxy language for trait or end-product assessment which is demonstrably inadequate in assessing complex genetic changes and for revealing unintended errors (see above). It is also shorthand for assessments made under controlled conditions, bound by confidentiality rules and undertaken by a narrow group of specialists, often with vested interests.

A recent investigation, for example, found that 100% of the scientists at ACRE – which has produced the current guidance on GMOs that could have "occurred naturally" – have conflicts of interest and none have any expertise in environmental toxicology. This kind of process is a major factor in continuing public mistrust over genetic technologies.

The notion of "science-based" regulation has become popular in government and amongst those with a narrow technological focus and vested interests. This is at odds with the socio-economic and values-based considerations which are integral to the Sustainable Development Goals to which the UK is signed up.

The impact of genetic technologies in agriculture cuts across multiple areas of concern. Therefore, robust and meaningful regulation must be based not just on evidence from laboratory science but also from the social sciences, environmental science, ecology, ethics, consumer preference and the concerns of farmers and food businesses.

Exaggerated promises of what gene editing can do

The Government has consistently said it wants to liberalise GMO regulations in order to fight climate change, feed the hungry and improve biodiversity. The urgency of these issues is being used to justify the haste with which this Bill is being pushed through. However, the industry has been using this same justification for 25 years and still no genetically engineered crop can do these things.

The two recent approvals under new UK field trial rules are instructive. In the two months since the UK removed restrictions from field trials of GMOs that could have "occurred naturally" or been created through traditional breeding, researchers have put forward:

- A camelina (false flax) engineered to have an altered fatty acid profile. The camelina has been the subject of several trials in the UK already.

- A vitamin D-containing tomato. This trial seems very small and informal; the notification describes tomatoes "grown in pots on the research centre grounds". The variety being used, "Moneymaker", is popular with home gardeners.

Neither of these crops addresses these pressing global issues. The camelina is intended for farmed fish feed and the nutraceutical industry. The vitamin D tomato also appears to be the subject of pharmaceutical rather than agricultural/environmental interest. Tomato fruits do not naturally contain vitamin D.

Speeding genetically engineered animals into the marketplace

The Defra 'Lobby Pack' for the Bill stated: "No changes will be made to the regulation of animals until animal welfare is safeguarded". This promise was open to wide interpretation and, indeed, the Government's view of what is needed to safeguard animal welfare can be relatively undemanding.

It was also a tacit acknowledgement of the significant animal welfare implications of unintended and unexpected genetic errors (see here and here) which have been documented in genetically engineered animals.

On publication, it was clear the Bill's provisions could be used to bring gene edited animals into the marketplace at any time.

Ignoring public views

Last year the Government asked the public if it supported the planned changes in regulation of genetic technologies. The overwhelming majority said no; 85% expressed the view that genetic technologies used in farming should continue to be regulated in the same way as other GMOs.

This result was not unexpected. Recent public polls by the Economic and Social Research Council and UK Research and Innovation, the Lloyd's Register, the National Centre for Social Research, Food Standards Scotland and the Pew Research Center have all shown little public appetite for genetically engineered crops and foods.

A recent survey by the Food Standards Agency found that *"consumers wanted thorough regulation and transparent labelling if GE foods reach the UK market*".

The Nuffield Council on Bioethics public dialogue on genome-edited animals found, amongst other things, that participants had a strong interest and desire to influence the way in which the food they consume is grown and reared and that they expressed significant concerns over the commercial drivers of genome editing in farmed animals, as well as the ability of governance and regulatory systems to control the technology in a way that meets public aspirations for the UK's future food system.

Nevertheless, citizens are major stakeholders in the food and farming discussion and their input on matters of how taxpayer money is spent, the needs for and appropriateness of specific genetically engineered crops and animals and on the roll out into the food chain and environment – including the necessity of labelling – is crucial. A failure to address these issues will result in a lack of trust and the collapse of both citizen and market "buy-in" to any new regulatory regime.

The proposal for a public register is welcome but…

…only if it is accessible, comprehensive and transparent enough in scope and detail to facilitate effective audit and provenance trails through the supply chain and, where necessary, post-release food safety and environmental monitoring. Since it is the stated intention of the Government to eventually deregulate all forms of agricultural genetic engineering, the public register should be forward looking and include all GMO 'events' used in plants and animals in the UK and not just those which are genome-edited. All of this is necessary to ensure citizen and stakeholder trust and confidence in the regulatory process.

In addition, the Bill, as currently drafted. does not require the FSA to make a register for gene edited foods in our food system. This is an impediment to transparency and citizen choice.

For more information:

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