Beyond GM/A Bigger Conversation Response

Genetic Technology (Precision Breeding) Bill

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 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 same old arguments and impasses of the past.

Unfortunately, the Bill amounts to an opportunity missed (or perhaps forsaken). Instead, we have been presented with proposals that are unlikely to lead to either effective regulation or the kind of socially responsive and responsible innovation we need in the 21st century.

QUICK TAKES:

- 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. There are very few things the government "must" do.
- The Bill, for the most part, leaves further regulation to undebated secondary legislation.
- It replaces the words gene editing and GMO with Precision Breeding. This is a marketing term rather than a scientific one. Precision Breeding is not commonly understood, poorly defined and misleads on what the Bill is about.
- It does not differentiate between processes – almost every type of GMO including those made using transgenes (foreign genes) can come under the heading of precision breeding.
- There is no delay in the implementation of gene edited animals in spite of the fact there are considerable implications for animal welfare with this technology.
- There is no provision for co-existence – neither on the farm nor through the entire food chain – for non-GM and organic crops/foods.
- There are no provisions for labelling of genetically engineered foods (labelling isn't mentioned at all).
- 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 one for crops, the FSA is under no obligation to make one for novel foods.
- Indeed, it is not clear if gene edited/GMO products will be novel foods under this legislation.
- For commercial products (plants and animals) it appears there will be a similar kind of notification system as for SI 2022, no. 347 (developers self-declaring) though these declarations will be reviewed by advisory panels/committees. But, how these committees are constructed is crucial. The conflicts of interest on the ACRE panel, for example, calls its trustworthiness into question (see below).

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.

Regulation and innovation need not be at odds. We believe that all products of agricultural genetic engineering (including newer genome 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 which we are willing to suggest or collaborate on.

FURTHER CONTEXT/CONSIDERATIONS

It uses 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.

It lacks 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).

Government is 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 '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 contained provisions to bring gene edited animals into the marketplace immediately.

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.

The government's intention to establish "a new science-based authorisation process for food and feed products developed using precision bred organisms" explicitly precludes any and all options for meaningful citizen input and engagement.

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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