Open Response to

Genetic Technology (Precision Breeding) Bill – Committee stage follow up Lord Benyon's Letter to All Peers, 13 January 2023

Prepared by Beyond GM/A Bigger Conversation and GMWatch

The Genetic Technology (Precision Breeding) Bill was subjected to deep and thoughtful critique during Committee stage in the House of Lords. A raft of necessary and, in some cases crucial, amendments were put forward and several fundamental questions were put to the Defra Minister, Lord Benyon, which he was unable to answer at the time.

In a recent letter to all peers, dated 13 January 2023, he has attempted to answer some of these questions.
His answers selectively omit some important points raised in the House, while the answers to those he does address are generally inadequate and, in some cases, cause more confusion. Given the importance of this Bill and the upcoming Report stage, we address some of these below.

We urge peers to continue to press the government for the necessary amendments to a bill that has been described by three government agencies (the Regulatory Policy Committee, the Delegated Powers and Regulatory Reform Committee and the Constitution Committee) as "not fit for purpose", "unclear" and as failing to provide "adequate justification" for delegated powers that the Bill confers. The Bill has also been widely criticised by stakeholder groups on scientific, legal and conceptual grounds and for its potential to strain the operation of the UK's internal market and future trading with markets in the EU and Asia.

As such, it is incautious and, in addition to any risks it poses to the UK's farming and food system and its environment, may well damage the prospects and public perception of the technologies it claims to support.

Public Good

In addressing questions raised by Baroness Hayman and others, Lord Benyon inexplicably describes public good as a hindrance:

> *"We want to be at the forefront of research in this area and imposing public good restrictions at this stage may drive research towards other countries".*

He further suggests that any definition would be difficult to produce and subjective.

This is a bizarre statement coming from a Minister in a department which has made the delivery of "public goods" a keystone of a recent major policy. Defra's 25 Year Plan to Improve the Environment and the Agriculture Act 2020 define environmental and social public goods and the whole of the Environment Land Management (ELM) scheme is built around those definitions.

Furthermore, Lord Benyon is clearly unaware that most countries (including the EU) reviewing their regulation of genetic technologies are also discussing a public goods or wider sustainability criteria.

The Minister attempts to make a link between existing plant variety regulations and public good when he says,

> *"Existing legislation (The Seeds (National List of Varieties) Regulations 2001) regulating the marketing of seed and propagating material requires new varieties of most major agricultural and horticultural crops to meet certain criteria before they can be placed on the market. This includes sustainability and quality targets such as disease resistance, stability and in some cases value for cultivation. This regulatory regime has worked effectively for many years for new plant varieties, and we consider that this is the best approach for setting standards rather than introducing them separately for different breeding methods."*

This is disingenuous. There is no public good or sustainability requirement in the Seeds (National List of Varieties) Regulations 2001, and crucially, no health or environmental risk assessment is required. Value for Cultivation and Use (VCU) – the mandatory variety testing system for agricultural crops in the European Union (EU) – focuses on ensuring that new varieties are an improvement on existing varieties. But that improvement is usually demonstrated by a range of cultivation characteristics and not a coherent consideration of public goods or sustainability criteria.

It is notable, also, that the Bill imposes no requirement for sustainability, health or environmental benefit for so-called precision bred plants and animals.

Intellectual Property

Lord Benyon is correct in his response to Baroness Bennett that plants and animals produced using technical processes such as precision breeding may be granted a patent. However, this does not answer Baroness Bennett's important question, which he misquotes/misrepresents, and which was:

> *"how, where a genetic technology breeding process for any living organism has been granted a patent under international or national law, it can be the result of a traditional process or a natural transformation since novelty is required for granting such a patent."*

National intellectual property law in the United Kingdom is determined by the European Patent Convention (EPC) and governed by the European Patent Office (EPO) which the United Kingdom became a signatory member of in 1977. The EPO is separate from the EU. When the United Kingdom left the European Union in 2020 it did not leave the EPO. As a result, national intellectual property law relating to all patents, including modern biotechnology patents, continue to abide by the rules, regulations, principles, conditionality, criteria and judicial findings of the European Patent Organisation (EPOrg).

Lord Benyon states:

> *"The Bill does not make provision in relation to intellectual property rights in precision bred organisms or the technologies used to produce them."*

Whilst it is true that the Bill does not seek to regulate IPR law, it does seek to regulate modern biotechnologies for environmental, agricultural and rural purposes.

In his letter, Lord Benyon echoes the central thesis of the Bill, that precision breeding technologies produce *"plants or animals with similar genetic changes as can occur naturally and by traditional breeding methods"*.

Baroness Bennett is right to question the veracity and legality of this. It is true that any end products (plants or animals) produced by novel, invented and engineered processes may look "similar" to end products that could have arisen through natural processes. But their genetic makeup and composition can be very different.

As a matter of legal fact, it is precisely the difference between an applied, genetically engineered novelty and a natural process which entitles the patentee to a market monopoly.

As such, any end product developed by life science engineers using modern biotechnology cannot be the same as could have been achieved by a natural process, described in patent law as an "essentially biological process".

Were a patentee unable to describe the genetic differences between a natural product and their invented, engineered product, they would fail to meet the EPC patent criteria of novelty, manmade inventiveness and industrialisation.

By continuing to pursue the line that genetic technologies produce end products that are the same as could be achieved through natural or traditional transformations, Defra leaves the use of modern biotechnology breeding processes and any commercialisation of end products highly vulnerable to legal actions. These include, but are not limited to:

- Patentees that claim their modern biotechnological breeding process produces end products that are the same as can be achieved through "essentially biological", natural and traditional transformation risk having their patents revoked for failure to meet the EPC criteria of novelty, manmade inventiveness and industrial applicability.

- Any commercial operator (patentee, farmer, company, retailer) seeking to license, sell, market or brand either the breeding process and/or the end product derived from modern genetic biotechnology as "essentially biological" or as the same as can be achieved through natural and/or traditional processes (e.g. with a label claim of '100% natural', 'natural origin' or 'naturally good for you') could face prosecution under British consumer law for misleading and fraudulent claims to end consumers.

Furthermore, according to the Retained EU Law Dashboard, several pieces of retained EU legislation relevant to plant breeding and biotechnology are due for review. These include:

- Patents and Plant Variety Rights (Compulsory Licensing) Regulation 2002

- Patent rules 2007, Schedule 1

- Regulation 1610/96 on supplementary protection certificates for plant protection products

- The Intellectual Property (Enforcement etc) Regulations 2006 amending the Registered Designs Act 1949, the Patents Act 1977, the Copyright Designs and Patents Act 1988, the Trade Mark Act 1994, the Duration of Copyright and Rights in Performances Regulations 1995, the Copyright and Related Rights Regulations 1996, the Copyright and Rights in Databases Regulations 1997 and the Community Design Regulations 2005.

We have no idea what the government has in mind or whether it intends to widen or limit the opportunity to patent plants, animals and other living organisms, nor how the interaction between PVRs and patent rights will function in relation to gene-edited (precision bred) plants. This means

Lord Benyon is currently in no position to make reassurances in this regard.

Given this, the reasoning behind the amendment tabled by Lord Krebs, Baroness Hayman of Ullock and Lord Patel at Committee seems sound:

> *"Within three months of the day on which this Act is passed, and before the Secretary of State makes any regulations under Parts 2 to 4 of this Act, the Secretary of State must review and publish guidance on the implications of this Act for the law of intellectual property."*

This speaks directly to the uncertainties of how retained EU patent law may be treated in the near future, as well as to the lingering questions of licensing, scope of existing patents and liability, all of which are inadequately addressed in Lord Benyon's letter.

Environmental protection

Concerning Baroness Jones of Whitchurch's question on the role of the Advisory Committee on Releases to the Environment (ACRE) in advising on environmental risk, Lord Benyon states that ACRE:

> *"have released several papers on this and have since advised that organisms produced by modern biotechnologies, such as gene editing, pose no greater risk to the environment than traditionally bred organisms, when these techniques are used to produce. Qualifying plants and animals are known as precision bred organisms."*

Although the 2022 Statutory Instrument on field trials of gene edited plants will be subsumed into the current bill, nowhere is there text which says that the Qualifying Higher Plants (QHP) described in that regulation, or the subsequent guidance issued by ACRE on these, are the same as so-called precision bred organisms.

Furthermore, the criteria used by ACRE to determine which organisms (plants and animals) could have been produced by natural transformation or by traditional breeding have not been published, let alone subjected to peer review or any type of outside scrutiny.

Where ACRE has cited references in its QHP guidance, they are limited and do not contain nearly enough information about evaluation criteria, such as how natural transformation or application of traditional breeding will be judged and over what time period. Equally, the assessment of transgenic techniques (the insertion of "exogenous DNA") in the production of PBOs or QHPs remains poorly articulated.

Consequently, neither the public, the FSA nor developers can have confidence in the robustness and consistency of ACRE's assessments.

The failure of Defra and ACRE to bring forward the criteria and protocols fundamental to their proposed new regulatory framework contrasts starkly with their aggressive rejection of the existing framework.

Lord Benyon states confidently that:

> *"It is the characteristics of the organism that determines its risks and benefits. Therefore, continuing to regulate qualifying precision bred organisms under the genetically modified organisms deliberate release regulations, simply because they were developed using particular techniques, does not follow current scientific rationale…ACRE's view is consistent*

with the opinions of other expert bodies such as our Royal Society, the European Academies' Science Advisory Council, and the EU's Scientific Advice Mechanism."

In stating that only the "characteristics of the organism" determine its risks and benefits, he ignores the fact that the process by which a gene-edited/precision bred (or other type of GMO) is generated determines the characteristics of the organism and its risks and benefits.

Many scientists and expert scientific groups emphasise that process must be considered, as well as the intended characteristics of the final product. These include:

- The European Network of Scientists for Social and Environmental Responsibility (ENSSER).
- The German Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection (see here and here).
- The Environment Agency Austria.
- Several peer-reviewed scientific papers (e.g. here; here; here; and here)
- The over 100 signatories to the scientists' and policy experts ' joint statement disputing the use of the term "precision breeding" to describe gene editing.
- The German independent research institute, Testbiotech.

Only risk assessment methods that take process into consideration can evaluate the unintended effects as well as the intended effects of genomic transformation and associated processes.

The European Commission study on New Genomic Techniques (NGTs) stated that it is widely recognised that "molecular characterisation" would be needed to demonstrate the absence of transgenic DNA. It also stated that: *"NGTs and NGT products vary considerably (the same technique can be used in various ways to achieve various results and products), so it is not possible to draw generalised conclusions as to their safety"*.

Analysis of data from the European Food Safety Agency (EFSA) shows that even gene editing can give rise to complex patterns of genetic change that go beyond what has been achieved in genetic engineering and conventional breeding thus far. Its February 2021 opinion on NGTs suggests that risk assessment should take issues such as molecular changes, gene expression and the potential impact on health and the environment into account.

In addition, it is recognised that different processes lead to different types of risk. For instance, a review of the scientific evidence concluded that genome editing makes the whole genome, including parts that would normally be protected from mutation, accessible for changes, illustrating that the types of changes possible from gene editing are different from, and can go far beyond, those occurring through natural breeding or chemical/radiation-induced mutagenesis breeding.

At Committee Lord Winston drew attention to this complexity and questioned Defra's apparent unwillingness to recognise this in the Bill's proposals.

This omission leads to a consideration of ACRE and the advice it is giving.

The Role of ACRE

Analysis shows that 100% of ACRE committee members have actual or potential conflicts of interest and, further, that no committee member has expertise in environmental toxicology. This is not to suggest any individual impropriety – rather the danger of "groupthink" and overly narrow perspectives.

A recent paper in *Nature Food* found conflicts of interest are common in food regulating institutions in the UK and proposes that this situation should be avoided, not managed. Thus, there is a need for a genuinely independent, more diverse and widely qualified authority to help assess the appropriateness and need for individual precision bred organisms on a case-by-case basis. Such an authority was proposed in an amendment tabled by Baroness Jones of Whitchurch and the composition of its members was suggested by Baroness Bennett in separate amendments at Committee.

Existing plant testing regulations

Lord Benyon notes that so-called precision breeding may shorten the pre-breeding (research) phase of the plant breeding process but does not shorten any other stage. Elsewhere in his letter, he says that, with so-called precision breeding technologies*, "Results observed under controlled conditions do not necessarily translate under field conditions."*

These are interesting concessions, given that Defra has consistently promoted this bill as a way of making plant breeding more precise and speeding up nature to achieve new traits in plants at warp speed. Indeed, Defra Minister Mark Spencer recently stated, *"What we're doing is just speeding up the process of natural breeding."*

Evidence suggests that genetic engineering (including so-called precision breeding) is not much faster than conventional breeding, in part because while genetic technologies have advanced rapidly in recent years, so have conventional breeding techniques. For example, marker assisted selection, a biotechnological method to identify and map desirable genes, can speed up conventional breeding, but does not produce GMOs.

Further, a range of factors affect the duration of breeding, making it hard to put a figure on the time gains from gene editing (or any other technology). These include:

- The lifecycle of the species; annuals take a shorter time to breed than tree crops.
- Whether the gene of interest exists in the wild gene pool; if not, the time for pre-breeding to introduce it into the domesticated pool is lengthened.
- Qualitative traits (those governed by a small number of genes) are easier to breed than quantitative traits (those governed by a larger number of genes).
- If the trait is recessive, an additional step of selfing (self-pollination) would be required during each cycle for selection purposes.
- Breeding for abiotic or biotic stress resistance may require ideal environmental conditions for optimal selection for rapid genetic gains.
- Breeding for resistance to airborne diseases and improved above ground traits are much easier than addressing soil-borne diseases or underground traits.

- If high uniformity of the final product is needed, breeders may need additional cycles of selfing, thus prolonging the program.

Lord Benyon states:

> *"removing precision bred plants and animals from genetically modified organism legislation does not mean that other existing regulations, that apply to plants and animals however they are produced, will be removed."*

It would be useful if he could provide a list of the "other existing regulations" that will apply to precision bred organisms and outline how these link-up with the provisions in the bill, for consideration in the ongoing debate.

Environmental Principles

In response to Baroness Hayman of Ullock's question about whether the Bill meets provisions in the Environment Act 2021, in particular Section 19 which provides that Ministers must have due regard to the policy statement on environmental principles, Lord Benyon admits that the government has still not managed to produce, in time to contribute to informed debate, a policy statement on the Environmental Principles of the Bill. That this was not a priority in drafting the Bill speaks for itself and is an example of the lack of foresight that has come to define the Bill.

Update from the Food Standards Agency on the number of environmental health officers and trade standards officers

Lord Benyon briefly addresses Lord Rooker's question on the number of Environmental Health Officers and Trading Standard Officers but doesn't get to the heart of the issue.

The government's common law approach to regulation, as laid out in the May 2021 Taskforce on Innovation, Growth and Regulatory Reform (TIGRR) report, has inevitable consequences; for the Food Standards Agency and its mantra of "food you can trust" – which the Minister does not address in his response – but also for other government agencies, such as the Genetic Modification Inspectorate, tasked with ensuring field trials meet agreed standards of environmental safety. The strain on these local and government agencies' (and, potentially, their counterparts in devolved nations) resources will likely increase as the number of precision bred field trials, crops and foods increases.

Lord Benyon does not mention at all another critical point raised by Lord Rooker – namely, the clear public wish that robust traceability and labelling should be part of this Bill. It is arguable, though not convincingly so, that the bones of a traceability system are contained in the Bill. But there is no provision for this new category of GMOs to be labelled and Defra has repeatedly rejected the idea.

It is indefensible that the right of consumers to choose to buy or not – and of farmers to use or not – the products of genetic technologies, is being denied.

The failure to include statutory provision for labelling can only deepen the mistrust that citizens already feel towards these controversial technologies and the government's ability to regulate them properly.

Regulatory Horizon Council report recommendations in relation to the proposed genetic technology authority

In response to the request for further information on recommendations made by the Regulatory Horizons Council on wider reform of genetic technology regulation and the establishment of an organisation (referred to as ACRE2) that would take on and add to ACRE's current role, Lord Benyon suggests that this is a discussion that can happen at some indeterminate time in the future.

This is careless. The questions of assessment and regulatory process are fundamental to this Bill.

Furthermore, and importantly, the Bill is clearly paving the way for the adoption of a whole new range of genetic technologies, not limited to agriculture, such as synthetic biology and gene drives, which will sit under the vague, catch-all marketing slogan of 'precision breeding'. These technologies bring with them an increased number and variety of claims for public good and other benefits that are beyond the competence of ACRE, as it is currently constituted, to assess.

It should be noted, however, that the Regulatory Horizon Council's vision of ACRE2 still focuses on end products rather than process, supports the deregulation of transgenics, does not include assessment of public good or actual, proven need or benefits and is grounded in the same old inadequate risk/safety paradigm.

Left unamended, this Bill is not, as Lord Benyon suggests, a cautious stepwise change in regulation. It is a hijack, with all the implications for uncertainty and instability that implies. In its current form, the Bill exercises far too little precaution, demonstrates far too little understanding of science and public sensibilities, relies too heavily on an 'honours system' amongst biotech developers and grants far too much power to Ministers to create future regulations at will, to be the basis of the coherent and trustworthy regulation of genetic technologies.

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