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To: All Peers

13th January 2023

My Lords,

Genetic Technology (Precision Breeding) Bill - Committee stage follow up

I would like to thank your Lordships for the robust and constructive debate at Committee stage on 12th and 14th December. I greatly appreciated the carefully considered and well-natured deliberations over the two days. During the debate I committed to providing written responses to a number of issues that were raised.

Public Good

A key concern of some Noble Lords, in particular the noble Baroness, Lady Hayman of Ullock, was the issue of public good.

Public good is at the heart of Government policy and the Bill is consistent with this. I believe that, by facilitating greater use and innovation of precision breeding technologies, this Bill will enhance our ability to harness the genetic potential of plants and animals to make them more resilient and healthier. The exciting research taking place across this country is testament to the benefits that these technologies offer to the environment and to our food system.

Reaching consensus on what constitutes public good is not straightforward as demonstrated by the debate in both Houses. The noble Baroness, Lady Bennett of Manor Castle raised both herbicide tolerant plants and disease resistant sugar beet as applications of precision breeding that, in her opinion, may not qualify as delivering public good. I am aware, however, that some of our stakeholders suggest that disease resistant sugar beet and herbicide tolerant crops may offer advantages over conventional crops in terms of environmental impact, for example by enabling the adoption of no tillage or reduced tillage systems to protect soils and by reducing the need for pesticides.

Subjectivity in legislation should be avoided as it raises the risk of legal challenge, which would place unnecessary burden on the courts and create uncertainty within the regulatory system. Certainty and predictability in the regulatory regime are vital to encourage innovation and increase investment. The definition of public good is also likely to evolve over time as circumstances and the science develop. This could make any tests we establish now not fit for purpose in the future.

Precision breeding technologies, particularly gene editing, are valuable tools used by researchers to understand the relationship between specific DNA sequences in an organism and its physical characteristics. Results observed under controlled conditions do not necessarily translate under field conditions. Consequently, field trials can be important at a very early stage in research before it is clear if and how the research will be applied. 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.

The final issue to address is the rationale for setting criteria for products produced by particular technologies rather than overarching policies that establish consistent goals for all products. For example, herbicide tolerant and disease resistant plants can be developed using traditional breeding methods as well as by precision breeding. 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.

While I understand the sentiment behind public good amendments to the Bill, I hope that Noble Lords can see that the public good is already very much at the heart of the Bill and aligned with the interests of our researchers in the UK.

Environmental Protection

Ensuring environmental protection is a key priority of this Government, and the Bill. I welcome the contribution of Noble Lords regarding this, in particular the valuable points raised by the noble Baroness, Lady Jones of Whitchurch and the noble Baroness, Lady Hayman of Ullock.

<u>The Role of ACRE</u>

Concerning the noble Baroness, Lady Jones' question on the role of the Advisory Committee on Releases to the Environment (ACRE) in advising on environmental risk, ACRE's existing statutory functions include advising the Secretary of State and the devolved administrations on potential risk posed by the environmental release of genetically modified organisms.

ACRE began consideration of alternatives to current regulatory systems for certain kinds of genetically modified organisms in 2013. They 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 plants or animals with similar genetic changes as can occur naturally and by traditional breeding methods. Qualifying plants and animals are known as precision bred organisms.

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.

The Bill introduces a new category of organism made using modern biotechnology, the precision bred organism. It also includes provisions for the advisory Committee appointed under section 124 of the Environmental Protection Act 1990 to advise the Secretary of State on genetically modified organisms, to advise on whether particular plants and animals that have been altered using modern biotechnology qualify as precision bred. The committee will either confirm that it considers the organism to be a precision bred organism, or report that it considers the organism to be a genetically modified organism. As ACRE is currently the advisory committee appointed under section 124 of the Environmental Protection Act 1990, it will advise the Secretary of State, on a case-by-case basis, whether the plants and animals developed using modern biotechnologies such as gene editing, could have occurred naturally or through traditional breeding processes. If they could, there is no scientific basis for requiring onerous environmental risk assessments on them, which do not apply to their traditionally bred counterparts – as ACRE's scientific advice is that they do not pose an increased environmental risk compared to their traditionally bred counterparts as a result of having been produced using a modern biotechnology.

Existing Plant Testing Regulations

It has been suggested that the shorter timeframes involved for precision breeding in plants make the end results more hazardous to the environment. As we heard at Committee, plant breeding is a lengthy process, even when it involves precision breeding. Precision breeding will make the pre-breeding phase of this process more efficient, but the subsequent field testing and multiplication stages - taking many years - will not be shortened. For most agricultural and horticultural crops, years of additional mandatory field tests are required. This process has ensured that plant breeding has an excellent safety record and will continue to do so.

It is also important to emphasise that 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. Therefore, the risk posed by precision bred organisms to the environment, including to the climate are no greater than traditionally bred organisms and as such, additional requirements should not be placed on them because particular technologies were used in their development.

Environmental Principles

The noble Baroness, Lady Hayman of Ullock also raised the 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. As mentioned during the debate, we are making good progress with the policy statement. We have considered the feedback from Parliamentary scrutiny, and we intend to agree the final statement in the coming weeks. Once the final policy statement is laid before Parliament and published there will be an implementation period to allow departments to prepare for the duty before it comes into force.

I hope that this reassures the Noble Lords that this Government has a strong record of commitment to the environment, and with this Bill we are continuing to uphold this tradition.

Intellectual Property

This Bill does not make provision in relation to intellectual property rights in precision bred organisms or the technologies used to produce them, which will continue to be regulated under existing intellectual property law. Nonetheless, during the debate several of your Lordships expressed a desire to better understand how intellectual property rights would interact with the subject matter of this Bill, and I hope my response will assist your Lordships' understanding.

Patents

The primary concern of the noble Baroness, Lady Bennett of Manor Castle in relation to intellectual property was how a precision bred organism, as defined under this Bill, could be patentable. In particular, how could an organism that only contains genetic changes that could have arisen naturally, be granted a patent.

This Bill regulates organisms produced by modern biotechnology using a 'product-based' approach. In essence, these plants and animals are regulated based upon their final characteristics rather than the process used to create them. This is in contrast to patent law practice which determines patentability of an invention based on both the end product and the method used to create it. Your Lordships are correct that patent law excludes plants and animals from patent protection if they were developed using essentially biological processes such as crossing and selection, but there is no such exemption for plants and animals produced using technical processes, such as precision breeding, therefore, patents may be granted to precision bred plants and animals which have arisen from patentable methods despite the end product having genetic changes which are similar to those that could arise naturally.

Liabilities

The noble Baroness, Lady Bennett also raised a question about who would be liable for any environmental damage or cross contamination caused by patented plants. I would first like to reiterate the advice that the risk profile for precision bred plants is no different to

conventional plants. This being the case, any damage or contamination caused by precision bred plants would be dealt with in the same manner as cases where a conventional plant has resulted in similar damage. Whether or not a patent protects the plants in question does not alter the legal position regarding liability for any damage that may be caused by the plant.

In cases where patented seed is found to be growing in fields by someone that does not hold a licence to do so, the patent holder may choose to take legal action. The success of this action will depend on proving that patent infringing acts have taken place and this, in turn, will depend on the circumstances of the case, including any defence of growing patented seeds by accident.

Licensing

I was also asked about farm animals produced as a result of precision breeding techniques and whether such animals come under the licence. I can say that whether patented precision breeding techniques extend to protect animals produced by these techniques will depend on the scope of protection defined in the patents and any separate contractual arrangement agreed between the patent holder and the animal breeder.

Scope of Existing Patents

There was a further question from the noble Lord, Lord Winston about whether improvements to existing precision breeding technologies would fall within the scope of any patent that protected the existing technologies. Whether the use of the improved technology would infringe any patented methods would need to be determined on a case-by-case basis. Even if use of new methods would infringe existing patented methods, it is possible that patent holders may agree to license as there may be benefits for both parties to do so.

Why can Clause 1(6) not state that exogenous DNA should have no effect on the phenotype of the precision-bred organism?

I thank the noble Lord, Lord Krebs for his comments in Committee stage regarding potential changes to the wording in Clause 1(6). ACRE has also asked similar questions and queried whether “Natural Transformation” could be misinterpreted to include the stable integration of functional transgenic DNA as well as non-functional fragments.

During Committee stage it became clear that this was a source of confusion or contention for a number of Peers, with some feeling that this would allow precision bred organisms to contain transgenic DNA similar to that seen in classical genetically modified organisms. This is not in line with our policy intention, which is to allow DNA that is similar to that which can arise through “Natural Transformation” so long as this does not affect the physical characteristics of the organism and we are working with ACRE to see how this can be addressed.

How would we classify a plant organism treated by both gene editing and radiation?

The noble Lord, Lord Winston raised a valuable point regarding the joint use of radiation and gene editing to perform a genetic change during the debate. Plants made using random mutagenesis techniques are considered 'traditionally bred' and therefore not subject to any additional regulations. If a plant were to be made with a combination of both radiation and gene editing, developers would have to show that any changes made using the gene editing technology were the type of changes that could have arisen through traditional breeding or natural transformation. This could create enforcement difficulties, since the changes made using gene editing would be indistinguishable from those arising as a result of radiation techniques. In these cases, we believe that ACRE would most likely require developers to have performed a full genome sequence against reference material, as this direct comparison would be the only way of accurately predicting which changes are likely to have occurred by what method.

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

I thank the noble Baroness, Lady Bennett of Manor Castle for her comments in Committee stage regarding the Regulatory Horizon Council ('the Council') report recommendations. In its report[1] on Genetic Technologies, the Council has proposed a new regulatory system, which would apply to plants, animals and micro-organisms obtained using genetic technologies (including organisms that would be regulated as genetically modified organisms currently) that are intended for use in agriculture, food production and other uncontained conditions. One of the Council's recommendations for wider regulatory reform in this area is the establishment of an organisation that would take on, and add to, ACRE's current role.

In our 2021 public consultation on genetic technologies, we took the opportunity to begin gathering evidence on the wider regulatory framework governing genetically modified organisms. We set out our plans for wider reform of genetic technologies regulation in the subsequent Government response. We are taking a stepwise approach to developing a more proportionate governance framework in this area. As part of this, we intend to review how we regulate a wider range of genetic technologies and applications.

This wider review is a more appropriate context for discussions on an over-arching body such as a Genetic Technologies Authority and it is consistent with the recommendation made by the Council.

Home Office licensing and the Animals (Scientific Procedures) Act 1986

I thank the noble Lord, Lord Winston for his comments in Committee stage regarding the Animals (Scientific Procedures) Act 1986 ('the Act') and its relationship with the Bill. I would

[1]https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1089198/regulatory_horizons_council_report_on_genetic_technologies_july_2022.pdf

like to reassure Noble Lords that the Act will apply during the first stages of developing a breeding line using precision breeding techniques in animals in England. The Act enables the use of animals in research for limited purposes, including for human and animal health and welfare, and the protection of the natural environment. The Act rightly places rigorous requirements on the use of animals in scientific procedures, including precision breeding.

Under the Act, animals may only ever be used in science where there are no alternatives, where the number of animals used is the minimum needed to achieve the scientific benefit, and where the potential harm to animals is limited to that needed to achieve that benefit. Three licences are required under this legislation: a personal licence for each person carrying out the procedures on animals; a project licence for the programme of work; and an establishment licence for the place in which the work is carried out. An Animals (Scientific Procedures) Act licence will be needed for all new scientific research involving precision breeding in animals. The use of animals in science is regulated by the Home Office and all establishments that undertake licensed work are subject to a regime of inspections.

We will, of course, continue to work closely with the Home Office as we develop guidance on the relationship between the Act and this Bill.

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

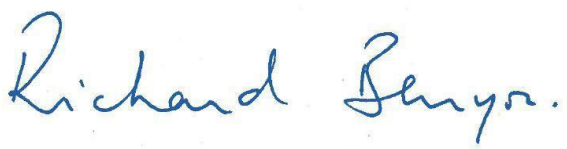
Finally in relation to the noble Lord, Lord Rooker's question on the number of Environmental Health Officers and Trading Standard Officers.

The latest data provided to the Food Standards Agency by local authorities, in October 2022, indicates that there are 1,578 full time equivalent professional posts allocated to delivery of food hygiene official controls, of which 1,462 posts are occupied and 376 full time equivalent professional posts allocated to delivery of food standards controls, of which 357 are occupied. Whilst the majority of these professional posts will be occupied by Environmental Health Officers and Trading Standards Officers, they will also include other officials involved in delivering food law official controls, such as Regulatory Support Officers and trainee officers working towards a suitable qualification.

I would like to reiterate my thanks to your noble Lordships for the constructive debate at Committee and I hope that my responses in this letter have clarified and addressed the concerns raised.

Please do not hesitate to get in touch at ps.lord.benyon@defra.gov.uk if you have any questions in the meantime.

Yours sincerely,



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Response draft

To All Peers
Response to **Genetic Technology (Precision Breeding) Bill - Committee stage follow up,** Lord Benyon's letter to All Peers, dated 13 January 2023

The Genetic Technology (Precision Breeding) Bill has a single beneficiary - the biotechnology industry. By removing regulatory control from this sector the government is, as Science Minister George Freeman has stated, looking to turn Britain into a "global testbed" for, amongst other things, agritech and gene editing of crops and synthetic biology.

Although the bill itself does not mention agriculture, farming or food, its clear intent is the widespread application of biotechnology in the agricultural sector.

Left undebated and unchallenged – and, crucially, unamended – the bill's emphasis on high tech, industrial farming and food production fundamentally changes our approach to food production and farming. Absent any other official or well-articulated vision for food and farming in the UK, this reimagining of an already failing industrial food system is a business-as-usual plan that will direct where our thinking, our actions and the flow of our resources in regard to agriculture will go in the future.

The bill benefited from almost no debate in the Commons but was subjected to deep and thoughtful criticism during Committee stage in the House of Lords. A raft of necessary and urgent 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 Peers, dated 13 January 2023, Lord Benyon has attempted to answer some of these questions.

This letter demonstrates Lord Benyon's understanding of the issues to be poor and his answers to be selective to the point of being misleading. Given the importance of this Bill and the upcoming Report stage, we address these inadequacies below and 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, in addition, been widely criticised by stakeholder groups as incautious, scientifically, legally and conceptually unsound, damaging to relationships with devolved nations and without a public mandate.

We address some of Lord Benyon's comments below.

Public good

Lord Benyon states: "*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.*
The two main criteria that distinguish a public good are not in dispute. A public good must be non-rivalrous and non-excludable. Non-rivalrous means that the goods do not dwindle in supply as more people consume them; non-excludable means that the good is available to all citizens.Given that this bill has a single beneficiary - the biotech industry - it already fails the public good test.

Further, given that public good can only be determined with the participation of the public, by ignoring the 85% of respondents to its public consultation on this issue, who expressed a desire to see precision bred organisms robustly regulated, the government compounds this failure.

The Minister suggests in his response that that defining public good is difficult, but the government's 25 Year Plan to Improve the Environment, the Agriculture Act 2020 define environmental public goods some of which were summed up simply in the and by extension in the Environment Land Management (ELM) scheme. e.g.:

- clean and plentiful water
- clean air
- protection from and mitigation of environmental hazards
- mitigation of and adaptation to climate change
- thriving plants and wildlife
- beauty, heritage and engagement

The Minister also suggests that any definition would be subjective and inexplicably describes public good as a hindrance which may encourage researchers to take their business to other countries, where presumably public good considerations are not important.

We are not aware of any data to suggest that research is hindered by public good considerations. We would ask the minister to provide his source for this statement and further ask what is research for, ultimately, if not to contribute to public good?

Science and technological advances may serve private profit, public good, or both. However, when public money is involved, as is often the case with the UK biotech sector, the public has a right to expect that research it has funded will serve the public good. Moreover, when private interests may result in public harm, the government has a duty to support public good over private interests.

Determining public good requires a careful weighing of risks and benefits. It also requires precaution where risks are unknown or where science does not yet have the capability to adequately determine risk. The public good criteria proposed by Baroness Hayman and the question raised by Baroness Bennett speak to the heart of the government's duty in this regard and amendments which propose a public good test should be accepted into the bill.

In this section the minister also appears to suggest that setting criteria for products according to the technology used to produce them is unnecessary. This reasoning, which has become endemic in the genetic technologies debate, would not be applied to any other technological innovation. We would not, for instance, set the same criteria for a driverless car as we would for one intended to be driven by a human being. E-cigarettes pose unique risks over and above regular cigarettes and therefore require their own risk/benefit assessment. The internet, as we now know, is not the same as a newspaper and presents unique risks that must be regulated differently.

The Minister notes (misleadingly) "*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.*"

There is no sustainability requirement in the Seeds (National List of Varieties) Regulations 2001, and crucially, no health or environmental risk assessment is required. The seeds regulations only require that the registered plant should be distinct, uniform and stable. We note, also, that the Bill imposes no requirement for sustainability, health or environmental benefit for so-called precision bred plants and animals.

Further, it is yet to be determined whether so-called precision bred plants are appropriate for inclusion on the National List of Plant Varieties. Aligned to this, it has been suggested that so-called precision bred plants could be subject to Plant Variety Rights (PVR) instead of the more common patent protection. But because the patent provides a much more effective monopoly and control mechanism (as patented germplasm cannot be used by other breeders), we suggest that most biotech developers would resist this.

Patents

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, will 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 look to regulate modern biotechnologies for environmental, agricultural and rural purposes. Defra is aware that the vast majority of modern biotechnology methods and processes have monopolistic patent rights or are in the process of acquiring this. It is disingenuous and misleading to suggest that the proposed Bill can act in isolation from and be free of long-established, existing and well transposed national and international IPR law.

In his letter Lord Benyon echoes the central thesis of the bill, that precision breeding produces "*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 outwardly resemble and 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.

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

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".

If Defra fails to amend the Bill and drop all references to modern precision and genetic breeding processes, methods, techniques and end products being the same as those achieved through traditional or natural transformations, any commercialisation of modern biotechnology breeding processes and end products are highly vulnerable to legal actions. These include but are not limited to:

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

- 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 traditional and/or natural processes (for example with a label claim of '100% natural' or 'natural origin' or 'naturally good for you') can face claims under British consumer law for misleading and fraudulent claims to end consumers.

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 in this context or how the interaction between PVRs and patent rights will function in relation to gene-edited plants. This means Lord Benyon is currently in no position to make reassurances in this regard.

For this reason we agree with the reasoning behind,amendment 74 in the marshalled list for Committee, tabled by Lord Krebs, Baroness Hayman of Ullock and Lord Patel which required:

> *"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 amendment 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 the noble 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 described in that regulation, or the subsequent guidance issued by ACRE on these, are the same as so-called precision bred organisms.

We reiterate that precision breeding is a colloquialism and a marketing term that has no

place in bona fide legislation, as raised by Baroness Bennett in the Second Reading and in Committee and in her amendment under clause 48.

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. Conflicts of interest, as a recent paper in *Nature Food* suggests, should be avoided, not managed, thus the need for an 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.

Product- versus process- and product-based regulation and risk assessment

Lord Benyon states, "*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."

- 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 this and this)
- Environment Agency Austria
- Several peer-reviewed scientific papers (e.g. this ; this ; this ; and this)
- Over 100 signatories to the scientists' and policy experts' statement disputing the use of the term "precision breeding" to describe gene editing.

There is a pronounced lack of consensus on the safety and risk profile of organisms produced using new GM techniques and a lack of empirical research on their effects on human and animal health and the environment. Therefore the precautionary principle must be applied and both process and product must be considered in evaluating risks. Knowledge of processes used will make regulators' jobs far easier in terms of enabling them to identify the source of any problems with a GMO that emerge post-commercialisation and will avoid the danger of blanket bans or public mistrust applying to all GMOs or even the whole food and feed system.

Existing plant testing regulations

Lord Benyon states 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 Lord Benyon concedes that with so-called precision breeding technologies, "*Results observed under controlled conditions do not necessarily translate under field conditions*." These are interesting admissions since Defra has consistently promoted this bill as a way of making plant breeding more precise and speeding up nature and achieving new traits in plants

at warp speed. Indeed Defra Minister Mark Spencer has recently stated, "What we're doing is just speeding up the process of natural breeding."

All 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. 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.
- The increased use of marker assisted selection, a biotechnological method to identify and map desirable genes, can speed up conventional breeding, without in itself producing a GMO.
- 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.

Lords 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."*

Can he please 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?

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.

Why can Clause 1(6) not state that exogenous DNA should have no effect on the phenotype of the precision-bred organism?

Ministers have suggested that the ACRE guidance on Qualifying Higher Plants offers a framework for interpreting the definition of a Precision Bred Organism but the definitions included in Clause 1 of the bill do not align with this guidance. To do so, amendments will need to be made to specify the terms under which the insertion of exogenous genetic material might be disregarded.

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

Although he credits the question to Baroness Bennett, 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 that would take on and add to ACRE's current role, came from Baroness Jones of Whitchurch.

Lord Benyon suggests that this is a discussion that can happen at some indeterminate time in the future. We disagree. The question of process is fundamental to the efficient execution of the provisions in this 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 has inevitable consequences for the Food Standards Agency – which by the minister's figures seems woefully understaffed for the workload ahead – but also for other government agencies, such as the Genetic Modification Inspectorate (tasked with ensuring field trials meet agreed standards of environmental safety), as well as local agencies that are expected to 'pick up the slack' where government has abandoned its responsibilities. This question inevitably links back to the question of public good.

The UK government's shift to a common law approach to regulation, as laid out in the May 2021 Taskforce on Innovation, Growth and Regulatory Reform (TIGRR) report is arguably the greatest indication of its unwillingness to provide public good, to pay for the provision of that public good and to ensure that this is a foundational concept locked in to this country's vision of an equitable future.

In its response to the government consultation on a common law approach to regulation, the Chartered Trading Standards Institute (CTSI) has warned that the adoption of a less-codified, common law approach to regulation would add burdens to local authority regulators to provide advice and expose them to a greater risk of legal challenge, increase burdens on micro-businesses and SMEs which have fewer available resources for ongoing advice, support and legal interpretation and representation, and would, in addition, threaten consumer confidence in the regulatory system.

The TUC has suggested that would create great uncertainty for workers and, moreover, is potentially a breach of the EU/UK Trade and Cooperation Agreement.

These are serious considerations which should be explored.

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