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To: All Peers

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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.

The Role of ACRE

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 report¹ 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

¹https://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,

A handwritten signature in blue ink that reads "Richard Benyon". The signature is written in a cursive, flowing style.

THE RT HON LORD BENYON