



Department
for Environment
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Dear Adrian and Christopher et al.,

Thank you for your letter of 8th September to the Secretary of State about the Genetic Technology (Precision Breeding) Bill. I am replying as the Minister responsible for this policy area. I am hugely privileged to have been appointed to this post and I know the Secretary of State feels the same.

The Genetic Technology (Precision Breeding) Bill offers great potential to help us improve food security, enhance investment, stimulate growth in our science capability, and strengthen the sustainability and resilience of agricultural systems. I know that Defra colleagues have been engaging with representatives from the United Kingdom organic sector regarding the Bill and we will continue to do so as it moves through parliament.

I want to assure you that HM Government is taking a stepwise approach, supported by sound science, to realising the potential benefits of precision breeding technologies, such as gene editing.

Impact on Businesses

Existing genetically modified organism (GMO) legislation, which is now more than 30 years old, was developed in response to the development of new genetic technologies that enabled scientists to transfer sections of genetic material from one species to another. While this can occur in nature, it is not typical in traditional breeding. Therefore, as a precautionary measure, the law requires that every GMO must be assessed and authorised before it can be released into the environment for research and development purposes or placed on the market. This situation has not catered well for some of the more recent technological breakthroughs, leaving British and EU innovators trailing behind their international competitors. Since 2018, around 40% of small and medium enterprises (SMEs) and 33% of large companies have stopped or reduced their precision breeding research and development activities in the EU.

HM Government recognises that innovation through technology, such as precision breeding, can help to create new markets, support a sustainable economy and help United Kingdom businesses to compete globally. We expect the Bill will unlock future private investment in the sector and attract international developers.

The key benefits of the Bill to businesses will be reduced regulatory costs and greater certainty on regulatory outcomes compared to the current GMO process. These savings will primarily benefit the plant and animal breeding sector, but ultimately consumers and other businesses engaged in food and feed production.

Adrian Steele and Christopher Stopes
Co-Chairs of the English Organic Forum

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More widely, the Bill will encourage greater research and use of precision breeding, which will in turn drive innovation and result in potentially significant economic, environmental, climate and health benefits for society.

Impact Assessment

The Regulatory Policy Committee's (RPC) opinion on the Bill's Impact Assessment (IA) is not a reflection of the quality or the ambition of the Bill. HM Government is committed to proportionate, science-based regulations and we have carefully considered all views and evidence in establishing our approach.

The main criticism from the RPC is that the description of the policy differed between initial review notice and the IA's final submission. The RPC's view is that the Bill now requires businesses to familiarise themselves with three distinct classifications of organisms instead of two. Our position is that stakeholders were engaged on the premise that this Bill would be creating a new 'third' path by which qualifying organisms could be used in research trials and marketed. At no stage has this changed during drafting of the IA.

Defra has agreed to work with the RPC and its secretariat to address the comments raised and we are currently working closely with stakeholders and economists to update the IA to address these concerns. This work will continue and will take into account any amendments made as the Bill completes its passage through parliament. Defra will submit an Enactment IA to coincide with the Bill's Royal Assent.

The scientific advice from our independent Advisory Committee on Releases to the Environment, supported by the Royal Society, the Royal Society of Biology and the Roslin Institute, is that precision bred organisms pose no greater risk to the environment and health than their traditionally bred counterparts.

Precision bred organisms only contain genetic changes that could have occurred through natural or traditional breeding processes. In addition, the Food Standards Agency (FSA) will only authorise products for sale in the first place if they are judged to present no risk to health, do not mislead consumers and do not have lower nutritional value than traditionally bred counterparts. Defra do not believe mandatory labelling to indicate the technology used (precision breeding) would be appropriate and may incorrectly imply that precision bred products are unsafe.

However, traceability is an essential element of enforcement at all stages of production processing and distribution. The FSA is working to ensure that this can be achieved through other means, such as documentary checks, in accordance with the general requirements of food law.

Legal Definitions

Precision breeding describes a range of technologies, such as gene editing, that enables DNA to be edited much more efficiently and precisely than current breeding techniques, that can take decades to produce the same changes. These technologies can make targeted genetic changes to produce beneficial traits that can also occur through traditional breeding and natural processes.

The definition of precision breeding, as written, aims to cover all organisms produced by modern biotechnology that could have occurred through traditional processes and natural

transformation, without being prescriptive of a specific type of technology that researchers and developers must use. This approach to carving out precision bred plants and animals from GMO legislation is in line with scientific evidence and advice because it focuses on the end product rather than the technology used to produce it.

Our approach will align us with many other countries, such as Canada, the USA and Japan, that have already established a more proportionate regulatory framework for products developed using precision breeding. In addition, the European Union has recently opened a public consultation and intends to have a new regulatory framework in place by 2023 for the future regulation of plants and food and feed products obtained using 'New Genomic Techniques'. This indicates the European Union may take a similar approach to that of the United Kingdom.

Commercial Sensitivities

The United Kingdom is at the forefront of genetics and genomics, and we host leading agricultural research founded on scientific excellence. HM Government wants to foster an environment that incentivises innovation and captures the benefits of genetic technologies for all, while managing any risks in a way that is supported by sound science.

On genetic diversity, in countries that already regulate precision bred organisms more proportionately there has been a diversification in the traits being investigated - moving from productivity traits to traits governing improved nutrition, disease resistance and resilience to the impacts of climate change. Overall, this suggests that altering the regulations may improve genetic diversity by moving away from the increasingly restricted gene pool available to breeders using traditional methods.

Likewise, on intellectual property, in those countries that have chosen to regulate precision bred products differently from GMOs there is evidence of a 'democratisation' of the technology, with an increasing proportion of patents being held by SMEs and local businesses.

While there is great potential for increasing innovation, HM Government recognises that there is a need to safeguard animal welfare in the new regulatory regime. We are therefore taking a step-by-step approach with regulatory changes applicable to plants being introduced first. We will not be introducing changes to the regulations for animals until the system for plants is in place and the system for safeguarding animal welfare has been developed.

I hope that these explanations provide adequate responses to your concerns and an explanation of the steps we are taking. We feel that these actions, alongside the secondary powers in the Bill, mitigate the need for further amendments at this time.

Please do not hesitate to get in touch if you need further information.

Yours sincerely,



Rt. Hon. Mark Spencer MP