



Business and Trade Issues Arising from The Genetic Technology (Precision Breeding) Bill

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The Genetic Technology (Precision Breeding) Bill¹ is advancing through Westminster. It is set to have its Report stage in the House of Commons when parliament returns after the conference recess (11 October). To date, despite a range of critics, the bill has advanced unamended.

There is concern from a wide range of bodies – scientific communities, businesses and economists, NGOs and environmental campaigners – regarding the principles of the Bill, and its impacts. This is also a vacuum in terms of meaningful, informed debate.

In particular, there has been very little scrutiny, including in the media, of the business case for the bill and its potential impacts on business and trade. Given that this is a bill intended to stimulate business and thereby the economy, this is a serious omission.

A BILL FOR INDUSTRY NOT FOR FARMING

Although the PR around the bill suggests it is a bill to make farming more efficient and climate friendly, this bill does not mention farming and food is only mentioned in the context of marketing.

The Genetic Technology (Precision Breeding) Bill is a bill for industry. Specifically, it details what government believes is a plan for growing the agricultural biotech sector in the UK. In the context of growing concern about the government's overall deregulation agenda and the furore over the ill-judged 'mini budget'², it may come as no surprise that the independent regulatory watchdog the Regulatory Policy Committee has judged the business case for the bill to be "weak".

¹ <https://publications.parliament.uk/pa/bills/cbill/58-03/0011/220011.pdf>

² <https://www.chathamhouse.org/2022/09/uk-mini-budget-stark-warning-policymakers>

In June, the RPC (which is made up of economists not activists) rejected – for the second time – the government’s business case for the bill, as laid out in its impact assessment (IA), deeming it ‘not fit for purpose’³ and noting that government:

- has not adequately considered the full range of potential impacts arising from its invention of a new kind of GMO – the so-called “precision bred organism”
- has not sufficiently considered the full range of impacts upon small and medium businesses
- has not made a detailed assessment of the competition, innovation, consumer and environmental impacts
- needs to be clearer about the impact of removing labelling and traceability requirements
- needs to revisit assumptions relating to the impact on devolved administrations

The RPC also cautions that most of the evidence regarding risk “is drawn from interested parties, or based on scientific trials, that do not replicate real-world conditions”. Such a narrative could, it says, “impede research, development and evaluation of an important new technology.”

MAKING IT UP AS THEY GO ALONG

With this Bill the government has made up an entirely new category of GMO that does not exist anywhere else in the world and is not referred to any regulation anywhere else in the world. The so-called “precision bred organism”, or PBO, is a GMO that could have, according to the Bill’s authors, occurred naturally or been produced through ‘traditional’ breeding.

This, as an open letter from more than 90 international scientists and policy makers protests, is scientifically implausible⁴ and, as several learned organisations pointed out to Defra during the 2021 public consultation⁵, unworkable as a basis for regulation. It also opens the door for patent disputes – see [below](#).

GAINS FOR BUSINESS WILL LIKELY BE SLOW TO COME, SMALL AND SHORT TERM

Since the 2018 European Court of Justice ruling, regulation has been represented by the government and the biotechnology industry as an insurmountable hurdle to innovation and a barrier to market for smaller companies. This view is too simplistic because:

Biotech breeding is not speedy or cheap. The cost, but also the complexity of the process, means that development of a single GMO plant can take decades. Indeed, we are still waiting for the drought resistant, salt tolerant, flood resistant, high yielding, higher nutrition crops promised 25 years ago. That time lag is not due to regulation. Even in countries where regulation is lax these promised innovations have not come to fruition. The average cost of bringing a new trait to market is around \$136 million⁶. At most 25% of this is related to regulation with the remaining 75% attributed to research and development and commercialisation costs.

³ [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1085223/2022-06-16-RPC-DEFRA-5170_1 - Genetic Technologies Precision Breeding Bill f .pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1085223/2022-06-16-RPC-DEFRA-5170_1_-_Genetic_Technologies_Precision_Breeding_Bill_f.pdf)

⁴ <https://docs.google.com/document/d/1bTWTWZwwDHfReRaiA4Kt25Jfrqab4iNyAILAsEGTPR4/edit>

⁵ https://abiggerconversation.org/wp-content/uploads/2022/01/Filling-in-the-Blanks_Defra-Consultation_ABC_Jan2022.pdf, Chapter 3

⁶ <https://croplife.org/wp-content/uploads/2014/04/Getting-a-Biotech-Crop-to-Market-Phillips-McDougall-Study.pdf>

The business model of biotech favours global corporations The suggestion that small and medium sized enterprises (SMEs) will benefit from a lower regulatory burden is simply not borne out by the reality of the global marketplace and the way that business is conducted within it. Patents on GM technologies are, in the main, owned by a few large global corporations. These large corporations are happy for SMEs to take on the work – and the risk (see next point) – of using their patented technologies to try and make something new, which is why licenses to use gene editing technologies in R&D are arguably the least costly part of the whole R&D process⁷.

The real cost is at the commercialisation stage where that same handful of very large companies that own the patents can demand crippling high payments, in the form of commercial licence fees and royalty payments on product sales, for the use of their technology.

From boom to bust In truth, most SMEs do not have sufficient resources to gain access to the global market. The best many can hope for is to hype up their discoveries then be bought up by larger companies in order to recoup investment and make a profit. This boom-and-bust mentality is not a recipe for sustainable growth.

It should also be noted that SMEs that fail to develop a viable product bear the cost of their failure alone. The current R&D business model for genome editing allows large companies to outsource a significant part of the research to SMEs but still take advantage⁸ of the profits from commercialisation while, at the same time, offloading some or all of the risk.

PATENTS COULD BE PROBLEMATIC

In industries where patents and proprietary information technology is in the hands of a few large corporations, there seems to be a trend towards a slowing down of innovation⁹ and a diminishing ability for innovation to deliver economic benefit and social good. It's worth considering whether this effect is also being felt in the plant breeding sector. Lack of regulation or the removal of regulation could simply open the door for larger companies to capitalise on the technologies that they already have, and for a further slowing of innovation. In addition:

Patents don't equal profits While the UK sees an increasing number of patents in biotechnology as a 'win' for business, patents are not a useful indicator of business potential. Most patents, even in plant breeding, sit on a shelf gathering dust. Since liberalising its regulatory regime Argentina has seen growth in the number of patents filed but almost none have found a route to market.

Could have occurred naturally? The claim that so-called precision bred organisms could have occurred naturally leaves the door wide open for legal challenges, given that the organisms being deregulated have patents attached to them and in order to gain a patent the researcher must prove the organism is not natural and that its creation involved an inventive man-made step and that it is intended for industrial use. A question, which goes to the heart of the deregulation legislation is how could that same patented organism have "occurred naturally"? And if the patent is achieved, are there circumstances under which that patent could extend to any genuinely naturally occurring organism found to mimic the GMO organism?"

⁷ <https://www.gmwatch.org/en/news/latest-news/19239>

⁸ <https://www.euractiv.com/section/agriculture-food/news/gene-editing-regulation-not-the-biggest-hurdle-for-smes-in-eu-says-academic/>

⁹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8024784>

Bad actors ‘exploiting uncertainty’ In his oral testimony to the public bill committee in June¹⁰, Dr Michael Edenborough KC (a recognised expert in patent law with a background in biology) notes:

“The simple point is that clause 1, as drafted, is quite imprecise. For example, if I may refer to the detail, there is the way in which subsection (2)(c) says, “every feature of its genome could have resulted from...traditional processes...or...natural transformation.” First, “could have resulted from” is staggeringly imprecise. Is that “likely”? Is that “very possible”? What level of probability is it? Then “traditional processes” is actually defined further in subsection (7), but it is still incredibly wide.

“At the moment, there are no bars within the intellectual property regime to doing this sort of work. So, the hesitation comes not from the IP regime but from commercial factors: in essence, whether or not you are going to make money at the end of it. The Bill, though, could introduce greater uncertainty into the commercial field, which would arise because of the unclear way in which “precision bred” is defined. That could lead to people, in some senses, exploiting that uncertainty. Now, there are a number of ways in which that could happen, but one is that you could have a big entity with a lot of muscle, and therefore a lot of money, which might want to push all the boundaries and cause confusion in the marketplace. That could have a dampening effect on other, smaller people who do not have the financial muscle to challenge the legal parameters.”

MOST OF THE WORLD IS NOT DEREGULATING GMOs...

This includes all of Europe, the whole of Africa, Russia, India, New Zealand, Southeast Asia. Only 16 have drawn up regulations to treat gene editing differently to GMOs. All other countries regulate gene-edited organisms as GMOs. Perhaps unsurprisingly, it is the [top biotech producer and exporter countries](#) such as the USA, Canada, Brazil and Argentina which are leading the drive to reduce the regulation on gene-edited crops. Eight of the 16 countries that have passed laws exempting some gene-edited crops from existing GMO legislation are based in the Americas: USA, Canada, Argentina, Brazil, Colombia, Chile, Honduras and Paraguay. Even so, many of these countries are taking a more measured and cautious approach. Government claims that we will be left behind are simply not true – but we may find ourselves with trade problems if we are out of step with other countries. See the 2022 report [Modifying the Rules](#) which provides an overview of the divisions and inconsistencies in the global regulation of agricultural gene editing.

TRADE ISSUES

Government says it wants to support British business and British farming, but once this Bill is passed, before the first GMOs are even in the ground here, we are likely to see a rise in cheap GMO food imports from places like the USA where deregulation is already fairly-advanced.

These will be highly processed foods and foods produced to lower safety, environmental, or animal welfare standards, which could weaken the domestic market, driving prices down for UK farmers who simply cannot compete.

¹⁰ [https://hansard.parliament.uk/Commons/2022-06-30/debates/1b4c41e7-8027-43e0-9408-94a552313da1/GeneticTechnology\(PrecisionBreeding\)Bill\(FourthSitting\)](https://hansard.parliament.uk/Commons/2022-06-30/debates/1b4c41e7-8027-43e0-9408-94a552313da1/GeneticTechnology(PrecisionBreeding)Bill(FourthSitting))

Note that the Trade and Agriculture Commission (TAC) report¹¹ on the UK-Australia Free Trade Agreement found that: *“It is possible that GM canola oil (from rape oilseed) from Australia will be imported in increased quantities under the FTA.”*

It is also interesting and eye opening to read what the TAC chair told EFRA¹² in May of this year when asked how much attention the commission had paid to pesticide and GMO issues. In essence, he conceded they hadn't given pesticides and GMOs the same level of scrutiny as other issues and was unaware of what was in place in terms of border checks for unauthorised pesticides or organisms or that, post-Brexit, we just don't have the resources to do such checks.

For the moment, at the very least, the goal of creating and growing more GMO crops puts us at odds with the EU – our largest trading partner – where there are more robust regulations and a thriving and rapidly growing GMO-free market.

- This month, a coalition of 23 UK and EU civil society groups wrote to Executive Vice-President of the European Commission Franz Timmermans and other key political leaders in the EU (and UK), with raising the possibility that the current deregulatory agenda is in breach of the non-regression clause of the UK-EU Trade and Cooperation Agreement.¹³
- The Environment Act 2021 states that environmental principles must be taken into account when making future government policy. The Genetic Technology Bill explicitly states that no environmental assessment is necessary for gene edited organisms grown in open fields in England. Removing the requirement for environmental assessment could leave developers open to legal challenge and complicates relationships with trading partners.

Closer to home

- Echoing the RPC's concerns, the organic sector published a joint letter¹⁴ to Environment Secretary, Ranil Jayawardena, raising the as yet unaddressed issues of co-existence and traceability throughout the food chain to ensure organic non-GM farms and businesses can maintain their values-based and commercially valuable 'GMO free' status.
- The Westminster government disputes that Scotland and Wales have the legal authority to ban the sale of English gene edited products. However, Scotland and Wales' alignment with EU rules on single-use plastics, recently led to the first exception under the UK Internal Market Act to restrict the free flow of goods within it: from 1 June 2022, the supply and manufacture a range of single-use plastic items¹⁵ has been banned in Scotland. Strength of feeling on the GMO issue is high and the plastics ban is unlikely to remain an isolated case.
- The situation in Northern Ireland is equally complex. Although Northern Ireland is a part of the UK, under the terms of the Northern Ireland Protocol it remains aligned to the EU. Thus, currently, English genetically engineered organisms cannot be grown and would not be allowed for import or sale without approval and labelling.

¹¹ <https://www.gov.uk/government/publications/uk-australia-fta-advice-from-trade-and-agriculture-commission/trade-and-agriculture-commission-advice-to-the-secretary-of-state-for-international-trade-on-the-uk-australia-free-trade-agreement-web-version>

¹² <https://committees.parliament.uk/oralevidence/10191/pdf>

¹³ <https://beyond-gm.org/wp-content/uploads/2022/09/20220913-NGO-Letter-on-UK-non-regression.pdf>

¹⁴ <https://ofgorganic.org/news/letter-to-defra-the-genetic-technology-precision-breeding-bill-2022>

¹⁵ <https://www.gov.scot/publications/single-use-plastics-regulations-draft-guidance-document>

REAL INNOVATION INVOLVES REAL RISK

We accept this principle in every other type of disruptive technological innovation; AI, the internet and social media, facial recognition software, cryptocurrency, driverless cars and **crucially** the concerns expressed around human and animal genetic engineering. If agricultural innovation in the form of genetic technologies is the government's goal, it must be prepared to acknowledge and deal properly with risk and the potential for damage and unintended consequences, environmentally and economically. That's what regulation is for: to manage consequences and risk. Instead, the Bill appears to have no provisions for foresight, mitigation, precaution or remediation.

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