



# Briefing Note

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## The Genetic Technology (Precision Breeding) Bill 2022

### Introduction

On 25 May 2022 DEFRA, the UK government's Department for Environment, Food and Rural Affairs, introduced the Genetic Technology (Precision Breeding) Bill.

The Bill aims to change regulations concerning genetically modified gene edited organisms.

Defra's intention is to amend the Environmental Protection Act 1990 to exempt these new GMOs as if the CRISPR gene modification tool and process are akin to 'traditional' or 'natural' breeding.

OF&G's concerns are that this proposed change in UK law is unnecessary and appears to be based on a flawed understanding of plant breeding and environmental risk assessments and is likely to lead to harmful outcomes for plant breeders, farmers and for the environment.

### Strong or Weak

- The Bill creates a subcategory of genetically engineered organism which could cause a "precision bred organism", or 'PBO'.
- When used in this Bill the term 'PBO' is an organism that "could have occurred naturally or been created through traditional methods". There is no scientific evidence for this contention.
- The new Bill only requires breeders to self-declare the status and safety of their environmental releases.
- Jennifer Doudna, co-ordinator of the CRISPR/Cas technique for "editing" in the genome has called for stronger regulation. <https://www.technologyreview.com/2019/11/15/102457/crispr-has-made-jennifer-doudna-rich-now-she-says-it-must-be-controlled/>

### What's in a name?

- The term "Precision Breeding" is entirely inaccurate - it is not breeding; it is genetic engineering.
- Genetic engineering can be a very powerful tool but the outcomes are not always reliable.
- The intention here with plant material is a form of trait tweaking performed in isolation leaving plants divorced from the ecosystems in which they must grow.
- Integrating genomics and genetic mapping with breeding is non-invasive and has much greater potential for real success than focusing on individual traits.

The need for this Bill is not clear. We do not accept the government's arguments that traditional plant breeding is too slow and not powerful enough to address current challenges such as climate change and loss of biodiversity.

Whole system agro-ecological approaches are proven to be more resilient to climatic shock than their mono-cultural cousins and still produce good yields, enhance biodiversity, and potentially store more carbon.

This Bill and the technology it seeks to promote looks set to keep the food supply chain working as it is, to hold farmers to the yoke of artificial inputs, and will maintain a business-as-usual approach at a time when we know massive change is inevitable.

If we really do want to build resilience into our food system we must be clear about our goals, and honest and transparent about the methods we choose to achieve them. See *The facts about CRISPR-Cas on page 4*.

It is clear that for food systems to function well, they must conform to comprehensible standards that are applied consistently.

This offers protection to everybody involved and ensures people and businesses can be held to account.

### Consultation

Early in 2021 Defra ran a public consultation on the regulation of genetic technologies. Responses to the consultation, from the public, academia and from the business community showed a great deal of concern over Defra's language in the drafting of the consultation.

Scientists from the Science Policy Research Unit at the University of Sussex, described their reservations with Defra's methodology in drafting such a consultation:

*...the consultation was framed in such a way as to not allow robust scientific engagement.*

Following the close of the consultation Defra published a press release that appeared to conclude that the majority of responses were favourable to reducing the regulatory burden on material produced by genetic technology.

However, in contradiction with Defra's conclusion the summary of responses ([https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/1021309/genetic-technologies-regulation-summary-of-responses.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1021309/genetic-technologies-regulation-summary-of-responses.pdf)) carried statistics that painted a very different picture:

*The majority of individuals (88%) and businesses (64%) supported continuing the regulation of GEOs as GMOs.*

From the section 'The risk of harm to human health or the environment':

*The majority of individuals (87%) and businesses (64%) stated that there was a greater risk. The majority of academics (63%)*



OF&G  
Old Estate Yard  
Shrewsbury Road | Albrighton  
Shrewsbury | Shropshire  
SY4 3AG



01939 291 800



info@ofgorganic.org



ofgorganic.org



@ofgorganic



/organicfarmers

and public sector bodies (82%) stated that there was a similar risk. Responses amongst NGOs were mainly split across greater risk (45%) and similar risk (38%). Those that stated there was a lesser risk were in the minority across all groups.

The independent group, Beyond GM put it another way - Defra noted in its official response to the consultation that: "Most individuals (88%) and businesses (64%) supported continuing to regulate such organisms as GMOs. Non-governmental organisations (NGOs) were evenly split (50%). A slightly higher proportion of public sector bodies (55%) and academic institutions (58%) did not support continuing to regulate such organisms as GMOs."

But stated this way, these figures are disingenuous. Public sector bodies and academic institutions, for instance, made up only around 1% of the responses. Defra says each response was treated equally (i.e., not weighted) but given its decision to press ahead with deregulation, these minority views, which support the government's plans, as stated prior to the consultation, do appear to have carried disproportionate weight.

## Public scrutiny

As part of the process of introducing a new Bill to parliament, the opportunity to give evidence is made available with the aim of helping the Bill committee to seek clarity and gain better understanding of the Bill and even to discuss possible amendments where such may be seen as strengthening a new piece of legislation.



A Public Bill Committee is set up by the House of Commons to examine the details of a particular Bill. All Bills, other than Money Bills, are automatically sent in a Public Bill Committee following their second reading unless they are committed to a Committee of the whole House. The composition of the committees must match the size of the parties in the House.

Public Bill Committees have the power to receive written evidence from outside organisations and members of the public, and to take oral evidence from interested parties, in the same way as Select Committees do, as part of their consideration of the Bill.

On 28 June 2022 OF&G's chief executive Roger Kerr, and business development manager Steven Jacobs, attended a session of parliament's Genetic Technologies (Precision Breeding) Bill Committee. (<https://parliamentlive.tv/Event/Index/bdbdbc74-fb6d-43d2-bec6-fb376f8fd74a>)

Roger and Steven went to Portcullis House, opposite the House of Commons, along with Jo Lewis and Chris Atkinson from the Soil Association, to give oral evidence to the Bill Committee.

## Clear Rules and Strong Definitions

OF&G are calling for clear rules and strong definitions to provide robust protection for everybody in the food system, from farmers to shoppers.

OF&G have raised concerns with how implementation of the Bill may impact people and businesses particularly with reference to Intellectual Property and commercial liability.

When a product defined in law as a 'Precision Bred Organism' comes to market it is not clear what impact this would have

on supply chains, especially those choosing not to work with genetic technologies as described in the Bill.

What responsibilities and liabilities would be placed on people and businesses in the supply chain? What are the levels of commercial and environmental risk of serious negative outcomes?

Containment breaches can occur, during transportation, or when outcrossing occurs across field scale commercial cropping. Plant variety traits may transfer to other crops and farmers and growers affected could unwittingly be liable for financial penalties and may be the subject of potentially costly litigation.

Such legal aspects were discussed in fine detail at the Bill Committee session, 30 June 2022, when Dr Michael Edenborough gave evidence. (<https://parliamentlive.tv/Event/Index/d22f9fd2-6fd2-4cee-9411-4aff8b1c00fa>)

Dr Edenborough is a barrister specialising in Intellectual Property law. In his professional opinion the Bill used terms that were ill-defined, and would therefore cause legal uncertainty. Such terms include 'Precision Bred', 'traditional process' and 'natural transformation'.

He also criticised some of Defra's phrasing in the Bill. For instance, the use of a particular phrase, 'could have resulted from..', is "staggeringly imprecise". Michael posed the question, "How likely is this 'could have resulted from'? Very possible? What level of probability?"

He told the committee that, "...the way things are being defined in a cascading way you have uncertainty built upon uncertainty."

"This could introduce greater uncertainty into the commercial field and that would arise because of the unclear way Precision Bred is defined. **That would lead people to exploiting that uncertainty. Now, there's a number of ways in which that could happen. One of the ways is you could have a very big entity with a lot of muscle and therefore a lot of money and they might want to push all of the boundaries and cause confusion in the marketplace. And that could be a dampening effect on smaller people who don't have the financial muscle to challenge the legal parameters.**"

## A system to be based on the principle of best practice

- OF&G does not believe there should necessarily be a ban on products resulting from the use of genetic technology.
- However, we are certain that strong regulatory frameworks are an efficient approach to safeguarding commercial and public interests.
- When robust standards are rigorously and consistently applied, we know this to be a highly effective method of ensuring commercial longevity while protecting supply chain integrity.

This is how organic has been working, quite successfully, and for quite a while.

### Best practice

- Safety – environmental & societal
- Monitoring & evaluation
- Transparency
- Co-existence
- Choice - business & domestic customer
- Liability & insurance

## Regulatory Policy Committee

The Regulatory Policy Committee is parliament's 'independent better regulation' watchdog sponsored by the Department for Business, Energy and Industrial Strategy (BEIS): <https://www.gov.uk/government/organisations/regulatory-policy-committee/about>



On 23 June 2022 the UK parliament's Regulatory Policy Committee published a report on the Impact Assessment Defra had submitted in support of the Genetic Technologies Bill.

*The Impact Assessment (IA) for the proposals has been rated NOT FIT FOR PURPOSE (red-rated), on both the assessment of the equivalent annual net direct costs to business (EANDCB) and the small and micro-business assessment (SaMBA).*

The following are extracts from the RPC report —

### Equivalent Annual Net Direct Cost to Business (EANDCB) — Identification of impact(s)

*The Department has not sufficiently considered and discussed what additional impacts may arise as a result of the creation of a new category. The creation of the PBO [Precision Bred Organism] category would mean that businesses, research firms and other interested parties, would have three distinct classifications to be aware of and use, as opposed to simply two (i.e. GMO and non-GMO) as is currently the case.*

*This will add further complexity to the market and potentially lead [to] further costs, such as additional transitional costs to establish new systems, as well as those for new processes to handle this new category.*

*In particular the IA needs to have considered whether:*

- this will create potential burdens and risks for businesses, and farmers, in cases where an organism turns out not to qualify for this new category or, leads to adverse effects that could be said not to be plausible from traditionally bred organisms;*
- activities for organisms and businesses in the new category are the same as those in the 'traditional' or unregulated category; and*
- the category does not create new markets, where different organisations have significant power, or where existing organisations gain or lose significant market power.*

### Cost-benefit analysis - Assumptions, risk and uncertainty

*The IA uses a range of assumptions that are now given appropriate justification and are supported by evidence.*

*The IA notes that "Whilst this legislative change will only take effect in England, the mutual recognition element of the United Kingdom Internal Market (UKIM) Act means that products entering the market in England would also be marketable in both Scotland and Wales. Thus, there would be no tangible barrier to PBOs entering the market across GB. However, in the unlikely event that this does become a barrier to market, we have captured the Net Present Value of such a scenario in our overall "low estimate" with 0 trials per year." However, the Department needs to address whether this is an accurate assumption to be made and whether the Bill may create an*

*internal market barrier, e.g., given that PBOs will still be able to be sold in the English market, it does not seem reasonable to treat this as '0 trials'.*

In summary, based on the quality of Defra's evidence the judgement of the Regulatory Policy Committee is that the Impact Assessment for the Genetic Technology (Precision Breeding) Bill 'is not fit for purpose'.

OF&G's opinion is that while we can discuss the science, and debate the rhetoric, however, we must find a way to do so with transparency and with honesty.

## Reference Material

**The Bill** - <https://bills.parliament.uk/bills/3167>

**The RPC report** - <https://www.gov.uk/government/publications/the-genetic-technologies-precision-breeding-techniques-bill-rpc-opinion>

**Agrobacterium-mediated plant transformation** - <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6501860/>

**Precaution, Risk, & the Need to Develop Prior Societal Technology Assessment** - [https://econexus.info/files/Steinbrecher\\_%26\\_Paul\\_Precaution-and-NGETs\\_Environment\\_AM\\_2017.pdf](https://econexus.info/files/Steinbrecher_%26_Paul_Precaution-and-NGETs_Environment_AM_2017.pdf)

**Why New Genetic Engineering needs to be regulated** - <https://www.testbiotech.org/en/news/why-new-genetic-engineering-needs-be-regulated>

**Broadening the GMO risk assessment in the EU for genome editing technologies in agriculture** - <https://enveurope.springeropen.com/articles/10.1186/s12302-020-00361-2>

**GM FREEZE** - <https://www.gmfreeze.org/>

**BEYOND GM** - <https://beyond-gm.org/>

**Agroecology and the design of climate change-resilient farming systems** : <https://link.springer.com/article/10.1007/s13593-015-0285-2>

## The Devolved Nations of Scotland and Wales

**The Scottish Agriculture Minister published a letter, 10 June 2022.**

An excerpt from that letter:

"My officials continue to scrutinise the details of this legislation. While the intended scope of the Bill

may be England-only, the Bill documentation itself is clear that it will have significant impacts on areas devolved to the Scottish Parliament. I note in particular that the Impact Assessment for the Bill states that "whilst this legislative change will only take effect in England, the mutual recognition element of the United Kingdom Internal Market (UKIM) Act means that products entering the market in England would also be marketable in both Scotland and Wales." Such an outcome is unacceptable."

Full letter available online:

<https://www.gov.scot/publications/genetic-technologies-precision-breeding-bill-letter-to-uk-government/>



Scottish Government  
Riaghaltas na h-Alba  
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**Part of a statement from the Welsh Government given to the Welsh Organic Forum 30 June 2022:**



“The new genetic techniques available are powerful tools, but this power must be used responsibly. The Welsh Government’s approach to genetic modification, including gene editing, is one of precaution.

Gene edited plants and animals, which would be released into the wider

environment, present a much greater risk than in a contained use environment. The issue of gene editing in animals raises serious ethical and welfare issues.

The Welsh Government’s policy position remains that GE plants and animals should be subject to a full risk assessment. They should be able to demonstrate their sustainability and environmental benefits rather than focus on just the potential claims of what the GE technology could deliver”.

## The facts about CRISPR-Cas

- A genetically modified gene edited plant is usually made via the insertion of foreign genes into the target organism.
- The inserted genes, such as CRISPR/Cas, are commonly removed after the “editing” has been performed, although parts of these genes can stay behind undetected:

‘Plant genetic transformation heavily relies on the bacterial pathogen *Agrobacterium tumefaciens* as a powerful tool to deliver genes of interest into a host plant’ <https://doi.org/10.1199/tab.0186>

Once inserted CRISPR/Cas components have enacted a change in the organism’s genomic material (usually DNA), their transgenes can be removed from plants by backcrossing with parental lines - <https://doi.org/10.1186/s12302-020-00361-2>
- The scientific community define “precise” where it is used to describe the relationship between measurements, and to a degree of repeatability.
- In relation to CRISPR-Cas following the “cut” or “edit” the repair to DNA and subsequent consequences are neither precise nor predictable.
- Off-target mutations, where changes occur away from what is intended, are likely. Some are predictable and some off-target mutations will be unpredictable, and some can be highly unpredictable.
- “Precision Breeding” as used in this Bill is not a functional term. The technology that it aims to refer to is neither breeding nor precise. This leads to a sharp discrepancy between a term employed by government and anything recognised by those in the scientific and plant breeding communities. This leads to uncertainty, causes confusion and will increase the risk of negative outcomes. The term should be removed from the Bill and associated documents.

### Further Reading

OF&G response to the UK government’s public consultation on the regulation of genetic technologies  
<https://ofgorganic.org/news/of-g-response-to-govt-consultation-on-regulation-of-genetic-technologies>

Genome Editing – Sensible fail safes and regulatory safeguards  
<https://ofgorganic.org/news/genome-editing-sensible-fail-safes-and-regulatory-safeguards>

IFOAM Organics Europe - GMOs  
<https://www.organicseurope.bio/what-we-do/gmos/>

<https://ofgorganic.org/news/of-g-briefing-note-the-genetic-technology-precision-breeding-bill-2022>

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