Gene Editing (Precision Breeding) Techniques as Defined in the

Genetic Technology (Precision Breeding) Bill

The Genetic Technology Bill[1] introduces a new and controversial category of GMO – the so-called 'precision bred' organism.

To get to grips with why this is controversial, it may help to understand a bit more about gene editing.

Gene editing technologies like CRISPR do not, in themselves, create new organisms. In most instances, these genome editing tools, which are sometimes described as 'genetic scissors', are used to cut both strands of the DNA helix at a pre-determined location. This cut then activates the cell's DNA repair mechanism. This combination of events allows genetic engineers to introduce a genetic modification at a specific location on the genome.

Currently there are three types of procedures that can be used following the 'cut'. In the simplest possible terms these are:

- **SDN-1** the cut is made, and the organism's normal cellular repair mechanisms are left to make the repair;
- **SDN-2** the cut is made, and a template is provided to instruct the organism how to repair itself;
- **SDN-3** the cut – and sometimes multiple cuts – are made and both a template for repair and the simultaneous insertion of transgenes are applied.

It is argued by proponents of genetic engineering that SDN-1 and possibly SDN-2, are close to what could happen in nature. Governments in the US, Australia and Japan have partially accepted this argument and have deregulated SDN-1 techniques.

The counter argument is that there is rapidly mounting evidence that even a 'simple' cut and repair can produce the intended mutation at the target site (intended on-target effect), but also unintended mutations at the target site (unintended on-target effect) or at other locations (off-target effect).

Other countries, including Australia, New Zealand, China, many European Countries and the EU are looking at establishing proportionate regulations of this technology based on these distinctions.

This Bill ignores all of this and is built on a narrative of deregulation because the technology is simple, mimics nature and is more or less the same as "traditional breeding".

It is important to reiterate that, despite the government's narrative which is based around terminology ("precision breeding" and "precision bred organisms") co-opted from marketing and PR,

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

this Bill concerns genetically modified organisms (GMOs) and their release into the environment, the farmed environment, the market and the food system.

PBOs are GMOs

Its starting point in defining a precision bred organism (PBO) is regulation 5(1)(a) and (b) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (S.I. 2002/2443).[2]

There the techniques of genetic modification used to produce GMOs are set out as:

> (a) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;
>
> (b) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;
>
> (c) cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

The Bill's baseline is that a PBO is the product of a) and/or b). Techniques included in c) are excluded from this point in the Bill but are included elsewhere (in the definition of 'traditional breeding' – see below).

The Regulatory Get Out Clauses

To avoid PBOs being regulated as GMOs, as the terms of SI 2002/2443[3] and the Environmental Protection Act 1990 requires them to be, a qualification is introduced whereby:

> 2) For the purposes of this Act an organism is "precision bred" if—
>
> a) any feature of its genome results from the application of modern biotechnology,
> b) every feature of its genome that results from the application of modern biotechnology is stable, and
> c) every feature of its genome could have resulted from—
> i. traditional processes, whether or not in conjunction with selection techniques, or
> ii. natural transformation.

This sounds reasonable until the caveats are considered.

Firstly, in clause 6(a) "natural transformation" is only determined by taking into account genetic material which results in functional protein, this ignores[4]:

> *"…introduced genetic elements that can markedly alter multiple gene functions, with dramatic changes in the characteristics of the organism. This includes the production of RNA molecules that alter gene expression, which has been flagged by scientists as posing a risk of silencing the*

[2] https://www.legislation.gov.uk/uksi/2002/2443/contents/made
[3] *ibid*
[4] Robinson and Antoniou, Scientific Brief on the Genetic Technologies (Precision Breeding) Bill and accompanying Impact Assessment, 2022, https://gmwatch.org/en/uncategorised/20051

genes of animal or human consumers of the GMO or of unintendedly silencing genes in the organism itself."

Secondly, clause 5 states:

> 5) In determining whether a feature of an organism's genome could have resulted from traditional processes, no account is to be taken of—
>
> a) the copy number of the feature,
> b) its epigenetic status, or
> c) its location in the genome.

Excluding consideration of these elements, according to Robinson and Antoniou[5], means that critical assessments of gene function and the impacts of changes in the genome and possible implications on public health and environment:

> *"All these elements will not only impact the function of the newly introduced genetic feature, but also the modified organism's host genes.*
>
> *"Copy number of genes: In the field of human medical genetics, which appears to be far more safety-conscious than the field of agricultural genetic engineering, the copy number of genes is acknowledged to be "pivotal in biological pathways" and to play an important role in susceptibility to major common diseases.[34]*
>
> *In livestock animals, the copy number of genes is known to "alter the gene expression and change the phenotype of an individual"[35] – factors that could make the difference between health and severe disease, abnormalities, or premature death.*
>
> *In plants, the copy number of specific genes has been linked to important traits such as flowering time, plant height and resistance to environmental stressors.[36] The copy number of genes has also been found to be linked to evolutionary adaptation in plants and to affect defences against diseases.[37]*
>
> *In transgenic plants, the copy number of the transgene(s) can affect the stability of the desired GM trait.[38] Stability of the GM trait is one of the criteria named in the Bill for determining whether a GMO is a "precision bred organism.[39]*
>
> *While the Bill may assume that GMO developers will ensure the stability and phenotypic normality of their product, this is likely to be restricted to aspects such as whether the plant or animal looks normal and grows acceptably. Less obvious aspects at the level of the organism's biochemistry, including unexpected toxicity or allergenicity, or altered nutritional value, will easily pass unidentified into our fields and onto our dinner plates, without strict regulatory requirements for testing and independent assessment."*

Rationale behind these exclusions

The effect of these exclusion is to focus all assessments of genetically engineered PBOs on the final product and to ignore any changes or impact within the function of the genome.

This is a significant weakening – to the point of non-existence – of risk assessment for a complex and rapidly changing technology which does not have a history of safe use and where new findings which challenge existing knowledge and assumptions are regularly appearing in the scientific literature.

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[5] Robinson and Antoniou, *ibid*

(For more information, see the full scientific brief prepared by Robinson and Antoniou[6], from which we have drawn in this document).

Critically, by excluding these considerations, the Bill effectively rules out any proportionate regulatory risk assessment based on case-by-case consideration and differentiation based on comprehensive scientific knowledge.

The misuse of the "traditional" terminology

We have prepared a separate note on the breeding processes listed in the Bill. What we did not identify in that note is the following change: as mentioned above, in SI 2002/2443[7], the third category of GMO techniques is set out as:

> (c) cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

In clause 7 of the Bill this has been removed from the list of GMO techniques and a version of it has been placed as "traditional process":

> Somatic Hybridisation or cell fusion of plant cells of organisms which are capable of exchanging genetic material by a process within sub-paragraphs (i) to (vii).

The disingenuousness of this is breathtaking. Critically, taken with the points made above, it opens up almost all types of GMOs to release with no effective risk assessment or regulation.

whether or not this is a desirable thing to do is open to ongoing debate. But it is not desirable to do it in such a disguised and opaque way.

Our view is that the Genetic Technology Bill dresses deregulation up as regulation in a way that may be difficult for busy MPs to really get to grips with. Under its provisions, nearly all types of genetic engineering, including organisms created with transgenes can be exempted.

It is, therefore, not simply 'light touch', and it is misleading to say it is 'step-by-step' since no provisions in the bill (other than those for future regulations, most of which can be enacted immediately by undebated secondary legislation) exist to explain any particular or well defined timetable or 'steps'.

More information
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[6] Robinson and Antoniou, *ibid*
[7] *Op cit*, 2