The UK Genetic Technology (Precision Breeding) Act 2023: Summary and commentary

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The UK Genetic Technology (Precision Breeding) Act [1] applies to plants (including algae) and vertebrate animals – both wild and cultivated. The Act defines a new subclass of genetically modified organisms (GMOs) – "precision bred organisms" or PBOs, called in this document PB-GMOs – that are exempted from the requirements of the GMO regulations. The requirements that formerly applied to all GMOs – risk assessment for health and the environment, traceability throughout the farm and food chain, and labelling from seed to fork – will not apply to PB-GMOs.

The government's briefing on the Act says it "removes plants and animals produced using modern biotechnologies, and the food and feed derived from them, from Genetically Modified Organisms (GMO) regulation if those organisms could have occurred naturally or been produced by traditional methods".[2]

In the summary and commentary below, substantial quotes from the Act are in blue type. Our explanations, interpretations, and comments are in black type.

Part 1

Part 1 of the Act defines key terms. Key points are as follows.

According to the Act, PBOs are GMOs.

The Act says (1, 1-4):
"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,
(c) every feature of its genome that results from the application of modern biotechnology could have resulted from traditional processes, whether or not in conjunction with selection techniques, alone, and
(d) its genome does not contain any feature that results from the application of any artificial modification technique other than modern biotechnology.

To be deemed "stable", the genomic feature must be "capable of being propagated whenever the organism is reproduced, whether by sexual or asexual reproduction".

The Act continues:

[1] The Act is here: https://www.legislation.gov.uk/ukpga/2023/6/enacted
[2] Summaries of the Act by the government are in this research briefing: (https://researchbriefings.files.parliament.uk/documents/CBP-9557/CBP-9557.pdf), pages 39-40 (short) and 42–53 (detailed).

"In this Act 'modern biotechnology' means any technique mentioned in… the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (S.I. 2002/2443)."

According to the Genetically Modified Organisms (Deliberate Release) Regulations 2002, these GMO techniques are:
"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;

And/or:
"techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation".

And/or:

"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 above definitions include gene-editing techniques.

According to the Act, crucial information must be omitted when considering if an organism is PBO – thereby allowing almost anything to be a PBO.

Namely: In determining if an organism is a PBO, no account is to be taken of the copy number of the (genetic) feature, its epigenetic status, or its location in the genome (1.5).

This is of course nonsense, as the genetic feature's copy number, epigenetic status, and location in the genome can affect its properties profoundly, including whether it is toxic or allergenic or otherwise dangerous. And *genetic regulatory elements* that do not encode for a functional protein can nevertheless alter patterns of gene function, altering a plant's biochemistry and composition with unknown consequences to health and environment.

Part 2

Part 2 contains main elements of the new regulatory framework and prescribes processes for the authorisation of the release of PBOs, their marketing and risk assessments on animal health and welfare.

Marketing a PBO

A person with a PBO under their control must not release the organism outside of their control or into the environment until they have satisfied the notification requirements. A person (the "notifier") may apply for a precision bred confirmation in relation to an organism by giving a notice (a "marketing notice") to the Secretary of State. The Secretary of State must refer the marketing notice to the advisory committee by sending the committee the marketing notice and any required information accompanying it. The advisory committee must report back within 90 days. If the Secretary of State is satisfied, he issues a "precision bred confirmation".

A person must not market a PBO unless a "precision bred confirmation" has first been obtained from the Secretary of State. If the PBO is an animal, a PB marketing

authorisation from the Secretary of State must be in force (see “PB animals” section, below).

Note: Under the Act, marketing of the PBO is only allowed in England, but the UK Internal Market Act 2020 (UKIMA) allows PB food and feed that are legally marketed in England to also be marketed in other parts of the UK. This means that PB food and feed authorised in England can be sold in Wales and Scotland. However, the UKIMA doesn’t extend to further processing in Wales or Scotland, which would require authorisation under the separate GMO regulations.

PB animals

For PB animals, an application under this section must include a (self-)declaration that the notifier does not expect the health or welfare of the relevant animal or its qualifying progeny to be adversely affected by any PB trait (note: this only considers intended traits!).

An application must be accompanied by an assessment of the risks to the health or welfare of the relevant animal or its PB progeny which could reasonably be expected to result from any PB trait (11.4(a)), and an explanation of the steps that the notifier has taken to identify the traits and risks (11.4(b)).

The Secretary of State must refer applications for marketing a PB animal to a welfare advisory body, which must reply within a set time period, stating whether the applicant has addressed the traits and their risks to health and welfare. If the Secretary of State is satisfied, the applicant gets their marketing authorisation.

The Secretary of State can rescind the authorisation if he considers the animal’s health or welfare is being harmed by the PB traits. However, there is no mandate in the Act to check for any unintended or unforeseen impacts of the genetic modification processes applied on animal health or welfare. The applicant can appeal against the decision.

In case of “adverse effects” of the PB trait, the decision whether to authorise a PB animal, or to rescind authorisation on health or welfare grounds, can be made subject to future, as yet unwritten, “regulations”, which can define “circumstances” in which health and welfare can be regarded, or not (25)!

Risk assessments

Regulations may (or may not) make provision for requiring a person to carry out an environmental risk assessment before importing a PBO where its destination is in England, or acquiring a precision bred organism which is in England (17.1(a) and (b)). However, the secondary legislation only requires environmental risk assessment when the PB-GMO is in contained use (Part 5, 12).[3]

Contained use means “an activity in which organisms are genetically modified or in which genetically modified organisms are cultured, stored, transported, destroyed, disposed of or used in any other way and for which physical, chemical or biological barriers, or any combination of such barriers, are used to limit their contact with, and to provide a high level of protection for, humans and the environment.”[4] Work carried out in laboratories,

[3] https://www.legislation.gov.uk/ukdsi/2025/9780348269123
[4] https://www.hse.gov.uk/pubns/priced/l29.pdf

glass houses or which is otherwise contained, where there is no release into the environment, is considered “contained use” work.[5]

Precision breeding register

The Secretary of State must establish and maintain a public register containing information about the PBO (18). However, it is unclear exactly what information this register will contain and how user-friendly it will be for the public. Providing it contains complete information on individual PBOs, a register maintained on a government website might assist farmers/growers who wish to avoid growing PBOs, but it is unlikely to be useful to consumers who wish to avoid purchasing or consuming PBOs. Commenting on the proposed government register in lieu of labelling, the Secondary Legislation Scrutiny Committee 20th report noted that “it is neither realistic nor reasonable to expect consumers to carry out their own research using what are likely to be highly technical public registers”.[6] Also, some information may remain “commercially confidential” and doesn’t have to be placed on the register.

Inspectors

The Secretary of State may appoint inspectors to monitor compliance with Part 2 of the Act (19.1).

Part 3

Part 3 sets out regulations for the marketing of food and feed produced from PBOs and makes provisions for monitoring and inspection of Part 3 obligations, including powers to make regulations for designating enforcement bodies with various functions.

Clause 26, 1 grants the general power to introduce a regulatory framework governing the placing on the market of food and feed from PBOs – namely to:

- prohibit the placing on the market of a PBO without authorisation from the Secretary of State.
- impose requirements for securing traceability of food or feed produced from PBOs that is placed on the market in England.

The regulatory framework “may” require that to get a marketing authorisation:

- any food or feed produced from the organism and covered by the authorisation will not have adverse effects on human or animal health;
- the way in which any such food or feed will be placed on the market will not mislead consumers;
- the production of any such food or feed will not have adverse effects on the environment;
- consuming any such food or feed in place of other food or feed that it might reasonably be expected to replace will not be nutritionally disadvantageous to humans or animals. (26.3(b))

Secondary legislation blindfolds the regulator to risks and harms

[5] https://www.sasa.gov.uk/wildlife-environment/gm-services/gm-regulatory-framework
[6] https://publications.parliament.uk/pa/ld5901/ldselect/ldsecleg/98/98.pdf

At first glance it may appear impressive that the above proposal ("any food or feed produced from the organism… humans or animals", (26.3(b)) was taken up in the draft secondary legislation[7] relating to the Precision Breeding Act 2023 (30.3).

But the language is weak – it states that the Secretary of State may issue a marketing authorisation "if it appears to [him]" that these conditions are in place. If these conditions "appear" to him to be in place, but are not – a likely scenario, if he is wearing the usual rose-tinted spectacles with which UK government officials tend to view GMOs – then PB-GMOs that damage human or animal health or the environment or which are nutritionally harmful can be marketed without restriction. This language ("appear") is unacceptably subjective for a law that is supposed to protect health and the environment.

What is even more unacceptable is that when considering whether these conditions are in place, according to the secondary legislation, the Secretary of State "must... not apply any test in connection with these requirements which would not otherwise be applicable in relation to any food or feed produced from organisms which are not produced from the application of modern biotechnology".[8]

This is an extraordinary stipulation. It assumes, without requiring confirmatory testing, that PB-GMOs are completely equivalent to traditionally bred organisms. And worryingly, it bans the regulator from ever finding out that the genetic engineering processes used to create the PB-GMO have caused unintended changes that could endanger human or animal health or the environment. Among the tests that could begin to identify risks of PB-GMOs are long-read ultra-deep whole genome sequencing, "omics" analyses (transcriptomics, proteomics, and metabolomics), and long-term animal feeding studies.

Yet not only will these tests not be required by the regulator, but the government is banning them from ever being performed, simply because they are not required with traditionally bred foods. The government regulator is telling the industry, "Not only do I not see any risks from PB-GMOs at the moment (because the right tests have not been done), but I promise I will never see any risks or identify any actual harms in the future (because those tests will never be done)."

This clause is so contrary to the public interest that only the GMO industry and/or its closely allied scientists and lawyers could have written it. In effect, the regulator is wilfully blindfolding himself and tying his own hands behind his back in a determination NOT to identify any risk pre-commercialisation, or the cause of any harm that occurs to health or the environment post-commercialisation.

As for the clause in the Act saying that future regulations may "impose requirements for securing traceability in relation to food or feed produced from PBOs that is placed on the market in England" (26.2(b)), the secondary legislation only mentions traceability to say that the EU law requiring that GMOs are traceable and labelled does not apply to PB-GMOs in England (Schedule 5, Part 1; 2).[9] A complete ban on government safety testing combined with a complete lack of traceability means that it is highly unlikely that any problems caused by a PB-GMO will ever be traced.

[7] https://www.legislation.gov.uk/ukdsi/2025/9780348269123
[8] https://www.legislation.gov.uk/ukdsi/2025/9780348269123
[9] https://www.legislation.gov.uk/ukdsi/2025/9780348269123

It is almost beyond belief that a regulator would voluntarily promise that he "won't look, won't find" any problem that the PB-GMO might cause, now or in the future. But this is the strange new world that the GMO industry and its allies have imposed upon us.

As an example of the kind of oversight that will occur from such self-blinding, in the US, gene-edited cattle were claimed by the developers and allied scientists to be free from unintended effects of the genetic modification and natural-like. However, a voluntary (not mandated by the weak US regulations) analysis by US FDA scientists found that the cattle unexpectedly contained antibiotic resistance genes and bacterial DNA, all inserted during the gene-editing processes used and not removed by the developers. As commentators noted, "The presence of the previously undetected antibiotic resistance genes in gene-edited cattle raises issues of biosafety given that there is a strong global push to limit the spread of genes conferring antibiotic resistance. This is because every cell of the gene-edited cattle with the polled locus will also contain the resistance genes, allowing them to easily be transferred to bacteria."[10]

Revoking authorisations, enforcing compliance

To return to the Act, the regulatory framework "may" make provision for

- revoking marketing authorisations
- conferring powers on the UK Food Standards Agency to perform risk assessments (26.6(a)) and to establish a public "food and feed" register (27.1).[11] It is unclear what information will be in the register.

The regulatory framework "may" make provision for designating a body or bodies to enforce compliance with Part 3 obligations. Compliance violations "may" include making false or misleading statements or providing false or misleading information.

Part 4

Part 4 relates to enforcement.

The government's summary says:

"Clause 31 relates to 'relevant breach'. Clause 31 (3) grants powers to create regulations that may outline certain circumstances where a failure to comply with a Part 3 obligation will not be deemed to constitute a relevant breach. Examples included where the breach was someone else's fault or where a person can demonstrate that they took all reasonable precautions and exercised due diligence to avoid the breach in question. It also provides a power for regulations to enable the transfer of liability to another person in circumstances where the commission of the relevant breach was due to the fault of that other person."

… "Clause 32 enables the Secretary of State to make regulations on the issuing of compliance notices, stop notices, and monetary penalty notices, as well as on legal enforcement in the courts by way of an application for an injunction

[10] https://www.independentsciencenews.org/news/fda-finds-unexpected-antibiotic-resistance-genes-in-gene-edited-dehorned-cattle/ This article contains references to the relevant peer-reviewed studies.
[11] https://publications.parliament.uk/pa/bills/cbill/58-03/0011/220011.pdf

by the Secretary of State."[12]

A person who is issued an enforcement notice can appeal.

Part 5

Part 5 sets out provisions on fees.

[12] https://researchbriefings.files.parliament.uk/documents/CBP-9557/CBP-9557.pdf