

NEW ZEALAND FOREIGN AFFAIRS & TRADE Manatū Aorere

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### New Approach to Gene Editing in England

MARKET INTELLIGENCE REPORT

## Summary

- The UK is changing its legislative approach to gene editing technologies in England. The changes are designed to grow the UK's biotechnology and agriculture sectors and enable the development of crops and livestock with improved environmental, nutritional, and economic characteristics. Gene editing involves making precise changes to an organism's DNA to enhance certain characteristics.
- The primary legislation for the regulatory changes has been passed. However, the changes will not come into effect until two separate pieces of secondary legislation, governing the use of gene editing technologies in plant and animal settings, are passed. To date, only the secondary legislation governing gene editing in plants has been lodged. The secondary legislation applying to animals is more controversial and has not been lodged. The Bill did not receive legislative consent from the Scottish and Welsh Parliaments, so the changes will only apply to England.
- Northern Ireland is required to follow the <u>Windsor Framework</u> negotiated with the EU following Brexit, which requires that it follows EU rules regarding the definition of GM crops in Europe, which cover gene edited crops, whereas Brexit <u>enabled the UK to relax its rules</u> for the new technology.
- The UK is also at the forefront of liberalising the use of gene technologies in healthcare. A therapy derived from gene editing technology has now been approved for the treatment of two blood disorders in England – <u>a world first</u>.
- As the New Zealand government <u>liberalises its gene editing</u> regulations, there will likely be opportunities for researchers and businesses operating in both jurisdictions to trial, commercialise and scale-up existing technologies, and invest in their further development.

# Report

The UK is establishing itself as a leader in gene editing research and technology. It has passed legislation to encourage precision breeding research and commercialisation in the agriculture sector, and is at the cutting edge of gene therapy use in healthcare.

#### Genetic Technology (Precision Breeding) Bill

In 2023, Westminster passed the <u>Genetic Technology (Precision Breeding) Bill</u> with the aim of unlocking the potential uses of gene editing technologies for plants and vertebrate animals (excluding humans). The Bill defines precision breeding as gene editing to elicit genetic changes that could have emerged through traditional processes or natural transformation. It differs from genetic modification, which involves the insertion of DNA from one species to another unrelated species, which cannot occur in traditional breeding methods or natural processes. The latter will continue to be regulated as genetically modified organisms (GMOs).

Proponents say the new Act will enable the development of crops and livestock that have more nutritional value; use fewer pesticides; and are more resistant to drought and disease – potentially safeguarding global food security as the climate warms and weather systems become less predictable.

The Act removes plants and non-human animals produced through precision breeding technologies from regulatory requirements previously applicable to genetically modified organisms (GMOs). Precision-bred organisms (PBOs) would instead be subject to a two-tiered regulatory approach ahead of being authorised for market:

- Tier 1: Lower risk PBOs that are very similar to traditionally bred varieties which consumers are already familiar with. PBOs in this category would just need to notify the Food Standards Agency (FSA).
- Tier 2: PBOs with traits where the risks are not fully understood, particularly those that involve compositional changes that could affect toxicity or allergenicity. PBOs in this category would be subject to a bespoke <u>safety assessment</u> from the FSA.

To be activated, the Act requires two separate sets of secondary legislation to be enacted, one for the development of precision bred plants and crops, and one for the development of precision bred animals. The secondary legislation for plant PBOs was lodged in February 2025 and will be debated during the year. The secondary legislation applying to animals is more controversial and is expected later. The Act also establishes a regulatory system to safeguard the welfare of precision-bred animals. Changes to the regulations for animals will not be introduced until this welfare system is in place.

Agriculture is a devolved matter in the UK (meaning Scotland, Wales and Northern Ireland have responsibility for shaping their own agricultural policies since the UK left the European Union), and the Bill did not receive legislative consent from the Scottish and Welsh Parliaments. Both have no plans to change their regulation of gene editing technologies. This means that if/when the secondary legislation is passed, the changes will only apply to England. Nonetheless, precision-bred products from England would hypothetically be available in the Scottish and Welsh markets, although this remains controversial.

Northern Ireland complies with European Union (EU) regulations on gene editing under the Windsor Framework. The EU is considering reform to its own gene editing regulations but at a slower pace.

Alongside the legislation, the <u>Department for Environment, Food & Rural Affairs (DEFRA)</u> is funding the <u>British On-Farm Innovation Network (BOFIN)</u> to run a three-year £2.2m project to trial the cultivation of precision bred crops on UK farms. The project is trialling three precision-bred cereals: a higher productivity wheat crop; a higher energy barley crop for livestock feed; and a wheat crop with improved processing and cooking properties. These crops will be available for farmers to trial non-commercially as part of the project from 2026. The trial results will then be assessed by scientists and food manufacturers.

#### Healthcare applications

The UK is at the cutting edge of employing gene editing technology in healthcare. In November 2023, <u>the UK became the first country to approve gene editing as a medical</u> <u>treatment</u> – signing off on Casgevy, a treatment for two rare blood disorders that uses CRISPR technology – a technology that led its inventors to win a Nobel prize in 2020. As of January 2025, patients with beta thalassaemia and sickle cell disease in England are eligible for the treatment, which offers a potential cure for both diseases.

#### **Opportunities**

New Zealand is exploring a similar pathway to that of the UK on gene editing. In August 2024, the New Zealand Government announced that it would seek to end a nearly 30year ban on gene technology outside of laboratory settings. Legislation will be introduced to allow gene technologies in healthcare and agriculture to be developed and commercialised, overseen by a dedicated regulator. The Government plans to pass the legislation and set up the regulator by the end of 2025.

New Zealand and the UK simultaneously liberalising their regulatory regimes for gene technology presents opportunities for researchers and companies operating in both jurisdictions to trial, commercialise, and scale-up existing technologies, and also provides investment opportunities for further development.

UK farmers see New Zealand as a <u>trusted partner</u> on agricultural technology, suggesting that New Zealand businesses interested in exporting precision-bred crops and other agricultural gene technologies to the UK will have good foundations to build upon.

#### **External links**

- <u>UK Government press release on precision breeding legislation</u>
- DEFRA-funded BOFIN PROBITY project
- <u>UK Parliament legislation tracker: Genetic Technology (Precision Breeding)</u> <u>Regulations 2025 secondary legislation</u>
- New Zealand Government press release on reversing gene technology ban
- Gene technology regulation in New Zealand MBIE

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