**Gene technology media pack**

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# Overview

*New Zealand’s gene technology rules are changing.* Gene technology (also known as genetic engineering or genetic modification) is a powerful tool available to scientists that has the potential to deliver enormous benefits for New Zealand.

Recent improvements mean we can use it more precisely and safely than ever before and places like Australia, Japan, the EU and England have safely embraced gene technologies.

While gene technologies have been used in New Zealand for a long time, the current rules have not been updated to match the scientific advancements.

With updated rules our scientists can make advances in healthcare, adapt to climate change, protect our unique environment, lift our agricultural productivity and boost exports.­­

*The use of gene technology will be safe.* Like Australia, a regulator will be established to allow New Zealand to access the benefits and manage the risks of these technologies. The new rules and the regulator will ensure that human health and the environment are protected.

*Some examples that show what gene technology can do.*In healthcare, new rules will mean our doctors and scientists could more easily research, develop and manufacture innovative therapies in New Zealand such as using the patient’s own cells to help fight against cancer.

Or scientists could develop a new type of pine tree that meets our forestry needs but doesn’t spread. This will help to protect and preserve our natural environments.They could develop fresh fruit and vegetables that are more resilient to pests and diseases, meaning more food ends up on the table and less in the bin.

*How the new rules will be applied?* Like Australia, the regulator will use a hybrid approach, meaning specific gene technologies can be exempted from regulations. An activity will be exempted because it either involves minimal risks or it cannot be distinguished from those achievable by conventional breeding techniques.

The regulator is critical to gaining the confidence of both the public and the science sector, and ensuring that the whole regulatory system, not just the legislation, is fully fit for purpose.

*The public has an opportunity to have their say.* The Government welcomes feedback on changes to these rules and encourages you to have your say at Select Committee. Keep an eye on the MBIE website for details, and check out an explainer video here: [https://youtu.be/I\_O9DGT\_jy4](https://aus01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fyoutu.be%2FI_O9DGT_jy4&data=05%7C02%7CMary.Direen%40mbie.govt.nz%7C5fed0b79e18f4eb9eb5508dcba6451cc%7C78b2bd11e42b47eab0112e04c3af5ec1%7C0%7C0%7C638590187241028184%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=JBU0%2B5d9PmmjsqAefioAA%2FhZp6cjPVxeYcOW9QCRl7w%3D&reserved=0)

# Q+As

**Why do we need to change the rules?**

* New Zealand’s biotech sector, of which gene technology is a part, generated $2.7 billion in revenue in 2020.
* As well as economic benefits, gene technology can help solve some of the major challenges our country is facing.

**What problems are these reforms aiming to address?**

* We are not benefiting from potential gene tech-related research, innovation and applications that can be done safely.
* The risks of gene technology and genetically modified organisms (GMOs), and how best to manage those risks, are better understood now than they were when the Hazardous Substances and New Organisms Act 1996 (HSNO) Act came into force.

**What are the key features of the new law?**

The legislation is intended to enable New Zealand to safely benefit from gene technologies by managing risks to the health and safety of people and the environment.

The new law:

* Allows for greater use of gene editing
* Is risk-proportionate and evidence-based
* Internationally aligned
* Retains public participation
* Focuses on the management of risks
* Leverages overseas expertise
* Has streamlined, efficient and transparent processes

**What will the proposed legislation be based on?**

The proposed legislation will be closely based on Australia’s Gene Technology Act 2000 and, like Australia, we will take a ‘hybrid approach’ to regulation, with applications assessed under a risk framework. This means we will regulate higher risk activities and exclude some low-risk gene editing activities from regulation.

**How will the regulator make decisions?**

A hybrid approach means specific, low-risk and well-understood gene technologies can be exempted from regulations. An initial list of non-regulated activities will be communicated to provide certainty to researchers, assist the transition from the HSNO Act and enable relevant research to begin as soon as the regime comes into effect.

**Is gene technology being safely used in other countries?**

* 29 countries have planted GM crops so have a more permissive regime than New Zealand including USA, Canada and Argentina.
* The EU is looking to liberalise its rules to exempt gene edited plants from regulation, and England and Australia have already done this.

**Will the new legislation cover all biotechnology?**

* The new legislation will only apply to gene technologies, which include GMOs.

# Examples of gene technology

Under the proposed regulations, the regulator will assign activities to non-notifiable and notifiable risk tiers, the requirements of which will be graduated based on risk. Categories will be tailored for contained activities (e.g., undertaken in a laboratory), environmental release and medical use.

Since the HSNO Act came into force for new organisms, only three unconditional releases of GMOs into the environment have been approved. All three approvals were for medical uses.

**Medical / Health examples**

* **Engineering a patient’s own cells to fight cancer (CAR T-cell cancer therapies)**
	+ Wellington’s Malaghan Institute is developing next-generation CAR T- cell cancer therapies. The therapy involves collecting a patient’s immune cells, genetically modifying the cells to recognise and kill their cancer and returning the cells to the patient as treatment. It’s proved effective against B-cell non-Hodgkin lymphomas.
	+ Current restrictions are challenging for scientists to work with.
	+ Proposed regulations: Regulated, non-notifiable. Under the new rules, CAR T- cells will still be regulated, but we expect they will go into the non-notifiable category, which will mean that they will be authorised under the gene technology legislation without requiring an assessment and approval by the regulator. This will be technical decision for the regulator.
* **Combatting blood disorders**
	+ Modifying genes to repair genetic blood disorders will be less restrictive under the new rules. Clinical trials will be assessed for risk by the regulator, and a licence issued.
	+ Other example where gene-editing can make a difference is in the treatment for hepatitis B, haemophilia, cataracts, cystic fibrosis.
	+ Proposed regulatory status: Regulated. Notifiable.

**Environmental / Agriculture examples**

* **Wilding pines**
	+ Wilding conifers (also known as wilding pines) are introduced conifers and are invasive weeds. They threaten to permanently affect and alter New Zealand’s unique landscapes.
	+ To address the wilding pine problem, Scion is developing gene-edited sterile Douglas Fir and would be able to successfully field trial these plants right here in New Zealand if it wasn’t for overly stringent conditions they currently would have to follow.
	+ Proposed regulations: Non-regulated/Exempt. This work would be non-regulated/exempt from regulation, meaning that field trials could take place in New Zealand and any eventual release into the environment wouldn’t need the regulator’s approval.
* **White clover**
	+ To help lower agricultural methane emissions, AgResearch is developing a range of applications for our pasture-based agricultural system.
	+ By using a gene taken from another species of clover, AgResearch’s innovative white clover technology can deliver both reductions in methane and improved animal welfare benefits.
	+ The current regulatory settings make it incredibly challenging to field trial this innovative solution in New Zealand, so it is being trialled across the Tasman.
	+ Proposed regulations: The new regulations will enable applications like AgResearch’s white clover to be assessed under an expedited assessment pathway. Under the new rules, a trial like this will be able take place on New Zealand soil, under New Zealand’s unique conditions.
* **Modifying kauri to reduce chances of disease**
	+ Modifying the DNA structure of kauri to protect it against disease or kauri die-back.
	+ Proposed regulations**:** We cannot say how this would be dealt with under the new legislation as nothing has been developed yet. This is an example where a Māori Advisory Committee could provide guidance on an application for modifying the DNA structure of kauri to strengthen it against disease. As kauri is a taonga, the committee’s views will be invaluable for the regulator. The committee will also issue engagement guidelines and provide advice to applicants and Māori on the application process.

 **Non-browning mushrooms**

* + Gene-editing is conducted to keep mushrooms fresh and white much longer than other mushrooms.
	+ Proposed regulations:Unregulated

# Myth busters

**Myth:** Enabling more gene technology will mean genetically modified food that is unsafe for humans.

**Fact:** Genetically modified vegetables, fruit or meat can be sold now in New Zealand and are already regulated under the Food Safety Act and labelled as GM. Food Standards Australia and New Zealand set the standards for safe food in Australia and New Zealand. They also regulate the code for the use of, among other things, food ingredients, composition and food technologies like genetic modification. There are currently nine GMO crops approved by FSANZ for use as an ingredient in food sold in New Zealand, including varieties of soy, wheat, potatoes, corn, and rice.

**Myth:** Genetic modification in agriculture is unsafe.

**Fact:** In Australia modified crops including canola, cotton and safflower are approved for use and undergo stringent assessments including for health effects and environmental impacts, before being approved for commercial use. Safflower crops produce a higher level of oleic acid in their oil, and reduce the need for petroleum-based products to be used in materials such as plastics, lubricants or cosmetics. <https://www.ogtr.gov.au/sites/default/files/202304/genetically_modified_gm_crops_in_australia.pdf>

In 2016, the US National Academies of Science released a comprehensive report on genetically modified crops (GM crops). It concluded that GM soybean, cotton, and maize had generally favourable economic outcomes for producers who adopted those crops through decreased yield losses and decreased use of insecticides. Environmentally, these crops were also found to result in higher insect biodiversity. In addition, the National Academies of Science found no effects on human health resulting from the cultivation of GM crops or the consumption of GM food. Available at [Genetically Engineered Crops: Experiences and Prospects | The National Academies Press](https://nap.nationalacademies.org/catalog/23395/genetically-engineered-crops-experiences-and-prospects)

**Myth:** Animals such as cows that are fed genetically modified food will produce genetically modified milk and meat.

**Fact:** Cows, and other animals fed with supplementary feed that has been produced using gene technology will not be genetically modified or produce genetically modified milk or meat.

**Myth:** A genetic change to human DNA means the person’s subsequent children will be genetically modified.

**Fact:** Genetic changes to human DNA will not be carried through to children unless changes are made to a person’s gametes. The ethics committee would have to approve any genetic change that affects gametes (sperm or eggs) or embryos.

For example, gene technology can be potentially used on human cells to prevent sickle cell anaemia or Huntington’s Disease. If a person gets this treatment, the genetic change to their cells will not be passed onto children.

**Myth:** Enabling more gene technology means people will create super humans.

**Fact:** The only use for this gene technology regime is for medical purposes not “enhancement” to create super humans.

Implantation of genetically modified gametes and embryos is prohibited by the Human Assisted Reproductive Technologies Act 2004.

For the use of genetic technology in human clinical trials and research, scientific assessment is provided by the Gene Technology Advisory Committee, with ethics review undertaken by the Health and Disability Ethics Committees.

**Myth:** We will have genetically modified humans and animals under a looser gene technology regime.

**Fact:** There are already controls in place in related regulatory systems for this type of science and under the new rules, humans cannot be deemed genetically modified.

Implantation of genetically modified gametes and embryos is prohibited by the Human Assisted Reproductive Technologies Act 2004 and these will not change.

The use of genetic technology in human clinical trials and research, scientific assessment is provided by the Gene Technology Advisory Committee, with ethics review undertaken by the Health and Disability Ethics Committees. The National Animal Ethics Committee considers the ethics of genetically modifying animals under the Animal Welfare Act.

**Myth:** Genetically modified crops will be allowed outside the laboratory so crops growing around them (such as organic crops) will be contaminated.

**Fact:** It is expected that GM crops for environmental release will be assessed for risk and if they require a full assessment then there will be a public consultation before the regulator is satisfied the risks can be managed and the regulator can issue the licence.

The gene technology regulator can apply conditions to the licence to manage the risks. In this example the regulator may require a boundary or a particular distance to be applied to the perimeter of the GM crop (similar to conditions currently imposed on use of sprays). Industry bodies will ensure they have suitable assurance programmes (which will not be overseen/regulated by the gene technology regulator).

# Definitions and glossary

**What is gene technology?**

* Gene technology is any modern technique used for modifying genes. Products of gene technologies can be used in areas such as human and animal health, medicines, and food production.

**What is biotechnology?**

* Biotechnology is the use of biology to develop new products, methods and organisms intended to improve human health, the environment and society.

**What’s the difference between GMO and gene editing?**

* Gene editing is generally regarded as a type of genetic modification that involves targeted changes to an organism's genome.
* More traditional genetic modification involves untargeted insertion of genetic material into an organism's genome (because of the untargeted nature of these older techniques, whole genes have to be inserted in order to produce intended changes).

**Glossary of terms**

|  |  |
| --- | --- |
| Bioeconomy | Bioeconomy describes the parts of the economy that use renewable biological resources to produce food, products and energy. |
| Biotechnology | Biotechnology is the use of biology to develop new products, methods and organisms intended to improve human health, the environment and society. |
| Conventional breeding or traditional breeding | Choosing parent organisms with desirable traits and breeding these to produce offspring with the same desirable traits. Results can be variable, and the trait is not always passed from parent to offspring. Also sometimes called Traditional Breeding. Tools and techniques in this category do not fall under genetic modification regulations. |
| CRISPR | Clustered Regularly Interspaced Short Palindromic Repeats, which are the hallmark of a bacterial defence system that forms the basis for CRISPR-Cas9 gene editing technology. |
| DNA | Deoxyribonucleic acid, the hereditary material in humans and almost all other organisms. |
| Gene | A gene is the basic physical and functional unit of heredity. Genes are made up of DNA. |
| Gene editing | A technique to induce specific targeted changes in an organism’s existing genome to achieve a specific desired outcome. Transgenic modification, often crossing species boundaries, is typically excluded from this definition (see definition below for transgenic). What technology and resultant organisms are encompassed under this definition varies by country. Gene edited organisms can be indistinguishable from conventionally bred counterparts and this is dependent on a number of factors including the change made, the size of the change and how much is already known about the genome and genetic variation of the organism and species. |
| Genetic engineering | Synonymous with genetic modification |
| Genetic modification  | A technique to change the characteristics of an organism by modifying its genome. What technology and resultant organisms are encompassed under this definition varies by country.  |
| Genetic technology  | Gene technology is any modern technique used for modifying genes. Products of gene technologies can be used in areas such as human and animal health, medicines, and food production. |
| Genome | All the genetic information of an organism or species. |
| In vitro  | (meaning in glass, or in the glass) studies or treatments that are performed with microorganisms, cells, or biological molecules outside their normal biological context. |
| In vivo  | Studies or treatments that are performed within the body of a living organism. |
| Mutagenesis | Process by which DNA of an organism is changed due to a mutation. Can occur spontaneously in nature or via exposure to mutagens such as chemicals or radiation. |
| RNA | Ribonucleic acid. Can have multiple functions within an organism, including being the intermediate product between a gene (encoded by DNA) and a protein. |
| Selective breeding | The controlled breeding of organisms by human intervention to selectively produce traits. |
| Synthetic biology  | A subset of biotechnology which includes the design and construction of biological systems and devices, as well as the redesign of existing biological systems for useful purposes.  |
| Synthetic nucleic acid | Nucleic acid molecules (DNA or RNA) that are chemically synthesized or amplified but can base pair with naturally occurring nucleic acid molecules. |
| Trait | A genetically determined characteristic, sometimes called a phenotype. |
| Transgenic | Introducing specific genetic material from one donor organism to another host organism to produce a desired trait, where the two organisms are not sexually compatible species. |

# Graphics

Comparison between HSNO and proposed Gene Technology Bill



Overview of the proposed Gene Technology regulatory regime

