Ministry for the Environment
Manatū Mō Te Taiao

Genetic Modification
The New Zealand Approach

www.gm.govt.nz

Tihei Mauriora.

Ngā whakāro, kōrero kei roto i tenei pukapuka he kōrero noaiho.
Ko te ngako o ngā kōrero nei, no te Ao putaiao tauiwi, engari,
ngētehi o ngā tikanga, e orite ana ki te tikanga Māori.
No reira e ngā reo e ngā Mana, kei a koutou o koutou whakāro
kōrero mo tēnei kaupapa ātahanga ira.
Noho ora mai I te wa kainga.

This booklet aims to answer some of the basic questions you might have about what genetic modification is, how applications to use it can be made, and how they are controlled and managed in New Zealand. It will also point you to sources of further information.

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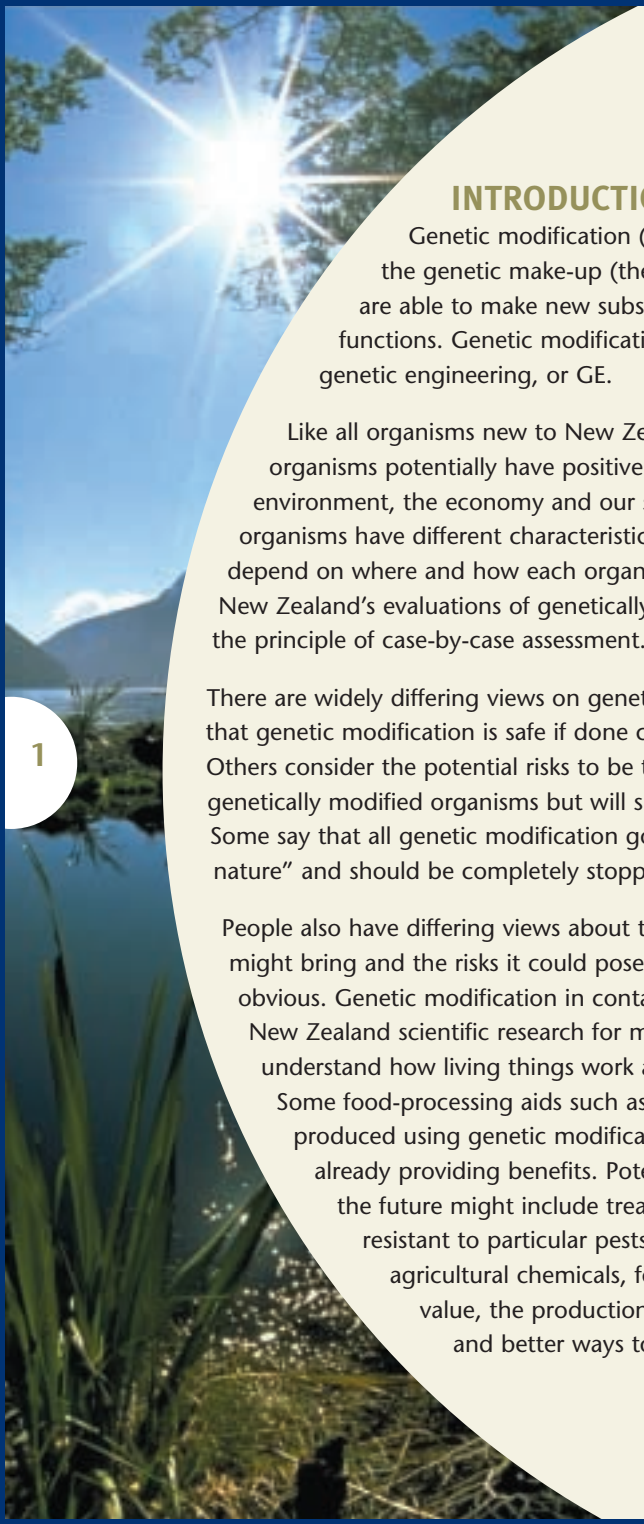


INTRODUCTION

Genetic modification (GM) is a technology for altering the genetic make-up (the DNA) of living organisms so they are able to make new substances or perform new or different functions. Genetic modification is sometimes referred to as genetic engineering, or GE.

Like all organisms new to New Zealand, genetically modified organisms potentially have positive or negative effects on the environment, the economy and our society. This is because different organisms have different characteristics, and their risks and benefits will depend on where and how each organism is used. For this reason, New Zealand's evaluations of genetically modified organisms are based on the principle of case-by-case assessment.

There are widely differing views on genetic modification. Many people insist that genetic modification is safe if done carefully and monitored closely. Others consider the potential risks to be too great to allow the release of genetically modified organisms but will support laboratory research. Some say that all genetic modification goes too far in "tampering with nature" and should be completely stopped.

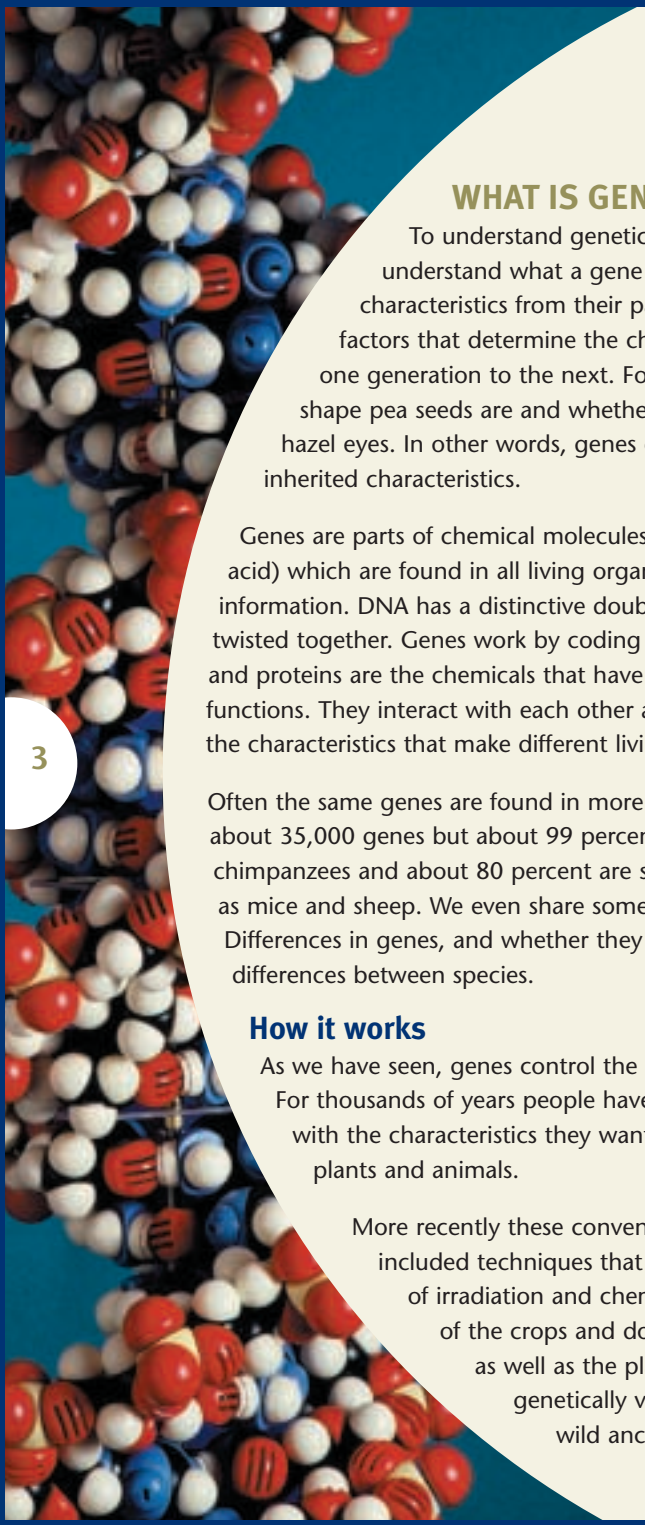
People also have differing views about the benefits genetic modification might bring and the risks it could pose. Some of the potential benefits are obvious. Genetic modification in containment has been used in New Zealand scientific research for more than 20 years to better understand how living things work and to produce certain medicines. Some food-processing aids such as rennet for cheeses are also produced using genetic modification technology. In these ways it is already providing benefits. Potential benefits for New Zealand in the future might include treatments for diseases, crops that are resistant to particular pests and diseases and require fewer agricultural chemicals, food that has greater nutritional value, the production of pharmaceuticals from plants, and better ways to control pests such as possums.

On the other hand, we can't always be certain about the effects of modifying living organisms in this way. For example, if released some of these organisms, like other new organisms, could have characteristics that may be undesirable in New Zealand. Some farmers worry that the inadvertent presence of genetically modified material in their products could damage their sales and affect markets. Some New Zealanders are uncertain about the safety of genetically modified food.

That is why New Zealand has implemented a strict system for controlling genetic modification. This looks at each case on its own merits to manage potential risks and maximise potential benefits.

Did you know?

New Zealand has a strict system for controlling genetic modification and managing potential risks.



WHAT IS GENETIC MODIFICATION?

To understand genetic modification it helps to understand what a gene is. Living organisms inherit characteristics from their parents and genes are one of the factors that determine the characteristics that are passed from one generation to the next. For example, they control what shape pea seeds are and whether a person has brown, blue or hazel eyes. In other words, genes contain information about inherited characteristics.

Genes are parts of chemical molecules called DNA (deoxyribonucleic acid) which are found in all living organisms and carry this genetic information. DNA has a distinctive double helix structure of two strands twisted together. Genes work by coding instructions for making proteins, and proteins are the chemicals that have a strong influence on biological functions. They interact with each other and the environment to produce the characteristics that make different living organisms.

Often the same genes are found in more than one species. Humans have about 35,000 genes but about 99 percent of our genes are shared with chimpanzees and about 80 percent are shared with other mammals such as mice and sheep. We even share some genes with plants and bacteria. Differences in genes, and whether they are turned on or off, create the differences between species.

How it works

As we have seen, genes control the characteristics of living organisms. For thousands of years people have developed plants and animals with the characteristics they want by selectively breeding the best plants and animals.

More recently these conventional breeding methods have included techniques that artificially alter genes (eg, the use of irradiation and chemicals to cause mutations). Most of the crops and domesticated animals on our farms, as well as the plants in our gardens today, are genetically very different from their wild ancestors.

One drawback of trying to improve plants and animals in the conventional way is that it takes a long time, and traditional breeding can never guarantee the presence of a desired characteristic — or the absence of an unwanted characteristic — in the resulting offspring. Genetic modification allows scientists to change genes in a more specific or controlled way. Genes can be switched on or off or their sequences can be altered. By using genetic modification it is possible to introduce new characteristics more quickly. Because all organisms use the same chemical building blocks, copies of genes can be moved between totally unrelated species, making it possible to introduce characteristics that would not be possible through conventional breeding. For example, corn has been genetically modified to produce an insecticide that is made naturally by soil bacteria.

Some people argue that genetic modification is just an extension of the breeding processes we already use to create new varieties. Others believe it is unnatural or inherently unstable, and so completely different from other breeding processes that it raises new ethical, environmental and safety concerns.

What is a genetically modified organism?

A 'genetically modified organism' is a plant, animal, insect or micro-organism whose genetic make-up has been changed using modern laboratory techniques. For example, new genes might have been added or the function of genes already present might have been altered. New genes may contain sequences found in the same or different species or they may be synthetic. A genetically modified organism is a living thing that can grow and reproduce and can pass on its genes (including its modified genes) to its offspring. A living genetically modified corn seed or potato is a genetically modified organism as well as a food. But not all the products we get from genetic modification are living organisms. For example, the flour ground from genetically modified corn seeds is not a living thing, nor is the oil extracted from genetically modified soybeans.

What is biotechnology and how does it differ from genetic modification?

'Biotechnology' refers to any technology that uses living organisms or their products for medical, commercial or industrial purposes. It includes ancient technologies such as using yeast to brew beer as well as modern technologies such as genetic modification.

Genetic modification is just one kind of biotechnology. For example, the following biotechnologies do not generally involve genetic modification:

- tissue culture, used to help grow plant or animal tissues in test tubes for industrial uses and medical research
- bioremediation, where organisms are used to clean up contaminated sites (eg, cleaning up contaminated soils through the use of trees that absorb heavy metals)
- cloning, which creates a genetic copy of something such as a plant (by taking a cutting) or animal (by transferring a copy of its genes into an egg)
- cross-species tissue transplants, or xenotransplantation (eg, using heart valves from pigs for transplantation into humans, a technique that was developed because human tissues or organs for transplant are in relatively short supply).

What can be genetically modified?

Bacteria. Genetically modified bacteria are widely used in research and to produce substances for food and pharmaceutical drugs. When the modified bacteria have produced a desired substance (eg, insulin or enzymes used in food production), that product is separated from the bacteria, purified and processed into its final form. Other micro-organisms such as yeast are also commonly genetically modified for similar purposes.

Did you know?

Genetic modification has a variety of uses – pure science, research, medicine, food production, agricultural innovation.

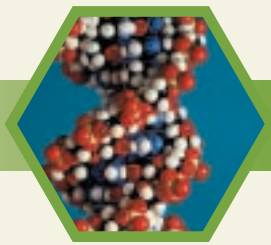
Plants. Plants have been modified for a number of purposes, mostly to make them resistant to pests and diseases, to extend their growing season, or to increase crop yields. Other plants are being modified to increase their nutritional value, to grow in difficult environments or to carry vaccines against diseases. Ornamental plants have been genetically modified to produce new colours or to extend vase life.

Animals. Animals have been used mainly for medical research. For example, mice have been genetically modified to help with cancer research. Genetic modification

could also potentially be used to improve breeding techniques or to induce cows to produce medical compounds in their milk. Some animals, such as salmon, have been genetically modified to enhance their utility as a farmable food source.

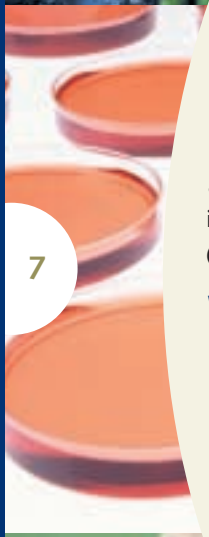
Humans. Genetic modification of human cells has the potential for treating diseases. One approach, gene therapy, delivers 'corrected' genes into selected cells in the body to treat diseases caused by an absence of an important gene, such as in cystic fibrosis. In these cases the genetic changes are not passed down to future generations. Research is under way to investigate the potential to modify the DNA in sperm, eggs or embryos to eliminate serious inherited diseases such as Huntington's disease. This area of research is highly controversial because of the safety and ethical issues involved.

Genes work by coding instructions for making proteins and proteins are the chemicals that have a strong influence on biological functions.



GENETIC MODIFICATION IN NEW ZEALAND

The Hazardous Substances and New Organisms Act 1996 (HSNO Act) regulates research into and release of all living things that do not already exist in New Zealand, including those that are genetically modified. The HSNO Act applies to anything that can potentially grow, reproduce and be reproduced, whether or not it is also a food or a medicine.



Before any new organism (including a genetically modified organism) can be imported, developed, field tested or released into the environment, the applicant must get the approval of the Environmental Risk Management Authority (ERMA). ERMA is an independent, quasi-judicial body set up specifically for this purpose, and it considers each application on a case-by-case basis, reflecting the fact that each organism is different and will therefore pose different potential risks and/or benefits (see page 17).

What is genetic modification used for in New Zealand?

Genetic modification has been used in New Zealand and overseas since the 1970s.

Research. New Zealand scientists use genetic modification in the laboratory and in contained field tests to try to understand how genes work, to improve traits of plants and animals used in agriculture, to seek treatments for diseases, and to find new ways of controlling pests. Since 30 October 2003 applications can be made to conditionally release genetically modified organisms to study the effects on the New Zealand environment.

Medicine. Some medicines used in New Zealand are produced from organisms genetically modified for that purpose. Genetic modification may also be used as a diagnostic tool in a laboratory. Some genetic modification research is being carried out to help us understand and treat human diseases and medical conditions such as cystic fibrosis, multiple sclerosis and cancers (see page 11).

Education. Laboratory techniques and the potential uses of genetic modification are taught as part of science-based courses at universities and other educational institutions.

Food. Some work is going on at the development stage involving the genetic modification of vegetables (eg, onions that are herbicide resistant and potatoes that are resistant to disease). To date, no fresh produce (fruit, vegetables, meat or milk) originating in New Zealand is genetically modified. Some processed foods may, however, contain genetically modified ingredients sourced from overseas (eg, soy or cornflour). These ingredients must be assessed for safety by Food Standards Australia New Zealand (FSANZ) before they can be used in New Zealand, and the final food product must comply with the labelling laws (see page 12).

How is genetic modification controlled?

"Genetic modification means that for the first time humans can make living things to our own design, without relying on nature. The implications are vast. Although any new technology may have its risks, this one has special features. They need to be addressed with wisdom and discernment."

Royal Commission on Genetic Modification, July 2001

The Government established the Royal Commission on Genetic Modification in May 2000 to examine issues surrounding genetic modification, hear people's views and advise on the way forward. The Royal Commission reported its findings in July 2001. Its main conclusion was that New Zealand should keep its options open. "It would be unwise", the Commission commented, "to turn our back on the potential advantages on offer, but we should proceed carefully, minimising and managing risks".

That approach was adopted by the Government and provided the basis for many of the decisions they made, including legislative changes. These decisions included:

- amending New Zealand's already rigorous laws covering genetic modification to strengthen the way they operate in managing the potential risks posed by the technology
- establishing or strengthening research programmes investigating the potential social, economic, ethical, environmental and agricultural impacts of genetic modification

- exploring ways to ensure that genetic modification and other forms of agriculture can coexist, including through the introduction of a new category of release called 'conditional release'
- ensuring the Treaty of Waitangi relationship is appropriately provided for under the Hazardous Substances and New Organisms (HSNO) Act 1996
- setting up Toi te Taiao: The Bioethics Council to advise, guide and promote dialogue on the cultural, ethical and spiritual issues associated with biotechnology
- developing a Biotechnology Strategy to ensure New Zealand keeps abreast of developments in biotechnology, including maintaining a balance between benefits and risks.

All of these changes have been completed.

A two-year restricted period (or moratorium) preventing applications for the release of genetically modified organisms was put in place in 2001 to allow time for this work to be completed. It also allowed time for research into the potential benefits of genetic modification for New Zealand and ways of more effectively managing any potential risks. The restricted period expired in October 2003.

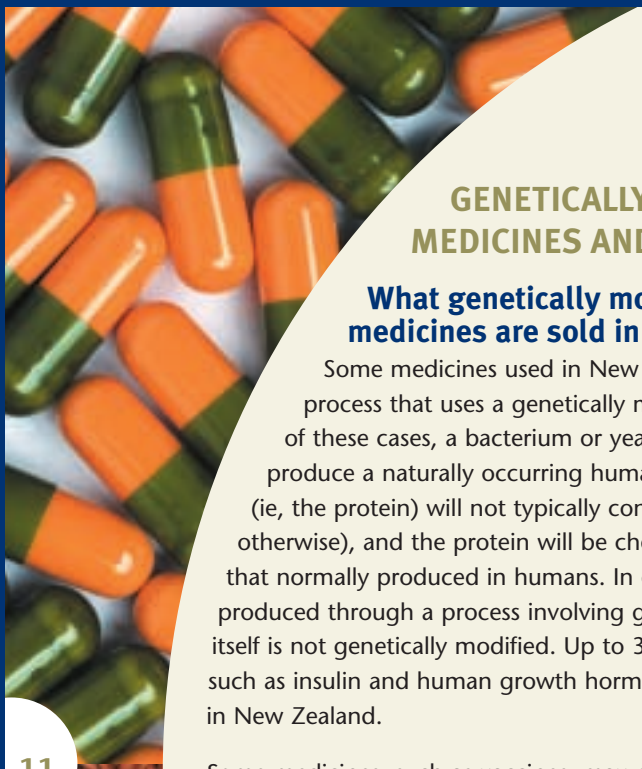
New Zealand's laws and regulations governing genetic modification are among the most rigorous in the world, and strike a balance between protecting our health and environment and preserving opportunities for all types of production – genetically modified and non-genetically modified. Our laws regulate the importation and use of genetic modification technology and the genetic modification of plants, animals and other living things, as well as food and medicines containing genetically modified ingredients.

Did you know?

Releasing a genetically modified organism in New Zealand without approval is illegal.

Public input is an important part of this process. All applications to release a genetically modified organism or field test a genetically modified organism in containment must be publicly notified and go through a public consultation process. For more information on how to make a submission on an application, contact ERMA (see 'Where can I find out more?' page 25).

In New Zealand you cannot import, develop, field test or release a genetically modified organism without approval from the Environmental Risk Management Authority.



GENETICALLY MODIFIED MEDICINES AND FOOD

What genetically modified medicines are sold in New Zealand

Some medicines used in New Zealand are manufactured by a process that uses a genetically modified organism. In the majority of these cases, a bacterium or yeast will be modified to enable it to produce a naturally occurring human protein. The resulting medicine (ie, the protein) will not typically contain any DNA (modified or otherwise), and the protein will be chemically very similar or identical to that normally produced in humans. In other words, while the protein is produced through a process involving genetic modification, the protein itself is not genetically modified. Up to 30 of these types of medicines, such as insulin and human growth hormones, have been approved for use in New Zealand.

Some medicines, such as vaccines, may contain live genetically modified organisms but none have yet been approved by the Environmental Risk Management Authority (ERMA) for use in New Zealand.

What controls are there on medicines?

Medicines must be approved by the Minister of Health under the Medicines Act 1981. Only then can they be distributed or sold as medicines.

Medsafe is part of the Ministry of Health and is responsible for assessing the quality and safety of all medicines before they can be used in New Zealand. This is done according to internationally agreed guidelines and standards.

If a medicine contains a live organism that has been genetically modified, both the Minister of Health and ERMA (under the HSNO Act) must approve its use.

This means that if someone wants to introduce a medicine that contains a live genetically modified organism – such as certain vaccines – they must apply to both ERMA and Medsafe

to have the medicine assessed. ERMA would assess the environmental risks and Medsafe would examine its effectiveness and safety for people. If the medicine meets the criteria for 'low risk' (that is, it will not cause serious harm to humans or the environment), ERMA has the ability to delegate the decision making to Medsafe.

What genetically modified foods are sold in New Zealand?

No genetically modified crops are grown commercially in New Zealand. No fresh fruit, vegetables or meat sold in New Zealand is genetically modified. However, some processed foods may contain approved genetically modified ingredients that have been imported. For example, many soy-based products are derived from genetically modified soya beans.

Processed food

The main genetically modified crops grown overseas are soybeans, canola, corn and cotton. Some of the food ingredients that could be produced from these crops are soybean paste, canola oil and cottonseed oil. Foods derived from these genetically modified crops can be sold here only if they have been assessed for safety by Food Standards Australia New Zealand (FSANZ) and approved by the Australia New Zealand Foods Standards Council (ANZFSC), a council of Australian and New Zealand Health Ministers. You can check the label for genetically modified ingredients in canned, packaged or processed foods.

What is labelled?

There are labelling standards for genetically modified food in New Zealand. Genetically modified food must be labelled so consumers can choose whether or not to buy it.

Any food, food ingredient, food additive, food-processing aid or flavouring that contains genetically modified DNA or protein must have this fact noted on the label. If a food or ingredient has altered characteristics, this must also be on the label. For example, if an oil was made from a plant that had been genetically modified so that its oil boils at a higher temperature, the oil would have to be labelled, even though no genetically modified material would be present. A genetically modified ingredient does not have to be listed on the label when:

- it is a flavouring in the food and makes up less than 0.1 percent of that food
- an ingredient unintentionally contains genetically modified material at levels of less than 1 percent of that ingredient.

Food ingredients can be processed to remove all DNA or protein, including those that have been changed by genetic modification. An example is canola oil from a genetically modified canola plant. The oil from this genetically modified canola plant can be the same as oil that comes from a canola plant that has not been modified. When food has been processed to remove all genetically modified DNA or protein, and does not have altered characteristics, the food does not need to be labelled as GM. Meat and other products from animals that have been fed GM food are not labelled as genetically modified.

Did you know?

These labelling rules apply only to foods and ingredients approved for food use in New Zealand. Genetically modified material not approved for food use is not allowed at any level in food.

None of the fresh meat, fruit and vegetables currently sold in New Zealand have been genetically modified. Food Standards Australia New Zealand (FSANZ) would have to assess any such foods for safety before they could be available for consumption here. They would also have to be labelled as being genetically modified.

Safety assessment

No genetically modified food or food ingredient will be allowed on to the New Zealand market unless it has gone through the FSANZ safety assessment process. Information about this process can be found on FSANZ's website (see page 25).

If a genetically modified food is considered safe, FSANZ advises the Australia New Zealand Foods Standards Council which must give formal approval before it can be sold or used as a food. Our Minister of Health is on the Australia New Zealand Foods Standards Council. If a food that is also a living organism (eg, a genetically modified tomato) were ever released in New Zealand, it would need approval from ERMA as well.

Food in restaurants and takeaways

As with all food items, there are no labelling requirements for foods prepared in restaurants, as takeaways or at supermarkets. If you want to know whether foods sold in these places contain genetically modified ingredients you can ask.

Foods containing genetically modified DNA or protein, or that have altered characteristics, must be labelled 'genetically modified'.

SPIRITUAL, CULTURAL AND ETHICAL ISSUES IN GENETIC MODIFICATION

The science of genetic modification has opened up new knowledge about medicine, environmental management and food production. However, this is a controversial area of science. Some people argue that it would be unethical not to use the tools genetic science has provided us, but to others this ability to move genes around is unnatural.

The Royal Commission on Genetic Modification recognised the significance of the cultural, ethical and spiritual aspects of biotechnology in general. It suggested that Toi te Taiao: The Bioethics Council be established to provide advice and promote ongoing dialogue among New Zealanders on the issues. The Government agreed with this approach and the Council was established in December 2003.

The Bioethics Council's role is to promote public dialogue on issues in current and future biotechnology research and development that have significant cultural, ethical and spiritual dimensions. It is to use the results of that dialogue as a basis for its advice to Government. Government departments may draw on the Bioethics Council's advice in developing policies on biotechnology. The Environmental Risk Management Authority (ERMA) can take the findings of the Bioethics Council into account when making its decisions (see p17).

The Royal Commissioners also recommended that the Hazardous Substances and New Organisms (HSNO) Act 1996 be amended to give effect to the principles of the Treaty of Waitangi. As a result, the legislation has been amended to give greater recognition to the knowledge and experience of Māori values by those involved in the decision making process on new organisms, including genetically modified organisms. It does this by adding knowledge of the Treaty of Waitangi and tikanga Māori to the range of expertise and experience the Minister considers when appointing members to the Authority.

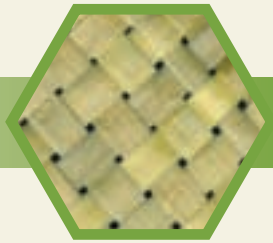
As well, Ngā Kaihautū Tikanga Taiao (the body that advises ERMA on Māori issues) is given a statutory basis within the Act. Previously there was no requirement in law for the Authority to have a Māori advisory committee. Now this has been changed to make it mandatory.

The Government is also encouraging a series of initiatives aimed at establishing better lines of communication between Māori and potential applicants for new organisms research. These include initiatives to improve the engagement of Māori early on in the development of research programmes that may lead to an application to ERMA, and extending work already underway on developing a network of Māori representatives on the Institutional Biological Safety Committees.

Protection of taonga

When applications for the release of genetically modified organisms in New Zealand are considered by ERMA, the HSNO Act requires the Authority to take into account the relationship Māori and their culture and traditions have with their ancestral lands, water, sites, wāhi tapu, flora and fauna and other taonga. This means that ERMA must assess the potential impact of the organism on indigenous plants and animals — as well as introduced ones — that are valued by iwi and hapu. In doing so, it draws on the expertise of Ngā Kaihautū Tikanga Taiao. Māori members of Institutional Biological Safety Committees have a similar role in decision making on applications that meet the low-risk criteria of the Act.

The HSNO Act also requires that ERMA consider the principles of the Treaty of Waitangi when making decisions on applications.



WHAT APPLICATIONS CAN BE MADE TO ERMA?

Laboratory research and contained field tests

Research is the main use of genetic modification in New Zealand. Scientists are trying to:

- understand how genes work
- develop resistance to diseases and pests in plants and animals
- improve plant and animal breeding techniques
- modify plants and animals to produce medical products
- identify genetic variation in endangered and other native species.

Some research is focused on finding ways to better control pests such as possums, to protect native animals and plants and control bovine tuberculosis. Other New Zealand research is aimed at improving crops (eg, to modify pine trees to produce more wood and less pollen, or to produce potatoes that are disease resistant). There is also research into the genetic modification of crops that are neither food nor medicines, such as changing flower colour in ornamental flowers.

Getting approval to use genetically modified organisms in research

The Hazardous Substances and New Organisms Act 1996 (HSNO Act) requires that anyone who wants to conduct research involving genetic modification must obtain approval. Approval is also required for the release of any living organisms that do not already exist in New Zealand, including any genetically modified organisms.

Research using genetically modified organisms must have approval from Environmental Risk Management Authority (ERMA). In certain cases where approval is sought for an application that meets 'low risk' criteria, ERMA may delegate authority to an Institutional Biological Safety Committee (a special committee within a research organisation) to assess the application. This may include research that

involves experiments with certain types of organism such as microbes that do not cause disease. The laboratory research is subject to strict controls. The Act requires that an approval for genetic modification can only be given if strict controls are in place to prevent the organism escaping or causing harm to those who handle the organism. Laboratories must meet a certain level of containment before they can undertake certain types of research. The Ministry of Agriculture and Forestry (MAF) inspects research facilities to make sure the organisms are properly contained and the controls are being followed. An Animal Ethics Committee must also approve any research involving animals under the Animal Welfare Act.

Sometimes, research needs to move outside the laboratory; for example, to see how the organism would behave in conditions similar to those in which it might eventually be released. However, these field tests are not always intended to lead to general release or commercial use — a field test can be the end point of an experiment. When genetic research outside the lab is proposed, reasons need to be given why laboratory or non-genetic modification methods cannot be used.

What are the controls on field tests?

Field testing does not mean that a genetically modified organism is simply let out into the nearest paddock. The HSNO Act requires strict conditions to be placed on the field test to reduce any potential risks to humans, our environment, plants or animals. The genetically modified plants or animals are not allowed to escape or to be released outside of the trial area, access to the facility must be restricted and scientists must ensure that 'heritable material' (eg, seeds or cuttings) from plants does not escape from the field test site. All field tests must be inspected and monitored on a regular basis to make sure these requirements are being met.

Here is an example of the requirements for a contained field test of genetically modified pine trees.

- Trees taken from the secured laboratory for the field test are counted before and after planting in a securely enclosed field.
- Limits are placed on the numbers of trees planted in the test.
- Plants are carried from the secured laboratory to the contained field test site in closed, crush-proof packaging.
- Trees are destroyed at a maximum age of six years or sooner if they start producing pine cones.

- A few trees are allowed to grow beyond this age – in which case all their male cones are removed before they shed pollen. Up to 10 female cones per tree are allowed to remain, until they reach a certain maturity stage.
- All reproductive structures (cones) removed from the tree are transported back to the secure laboratory in a secure container and destroyed when no longer required.
- Trees no longer needed for the research are destroyed.
- The site has a security fence, and a record is kept of all people with access to the site.

Conditional and full release

The HSNO Act also provides for the release of new organisms, including genetically modified organisms, into the wider environment. In considering a new organism for release, ERMA must first decide whether or not the organism would be likely to have any significant effect on the environment or human health and safety, taking into account any conditions that could be placed on the release. ERMA must decline an application if it fails to meet these minimum requirements. ERMA then looks at any potential economic and other benefits and weighs these up against the risks. This cost/benefit analysis provides a basis for the final decision on whether or not an organism should be released.

There are two types of release approvals under the HSNO Act:

- conditional release
- full release.

Conditional release

After carrying out their assessment, ERMA can approve an organism for release subject to certain conditions. In the case of crops, these conditions might include restrictions on where the genetically modified crop can be grown, compulsory buffer zones between the modified crop and conventional crops, regulations on the planting (and therefore flowering) time, or controls on how the crop is harvested and processed.

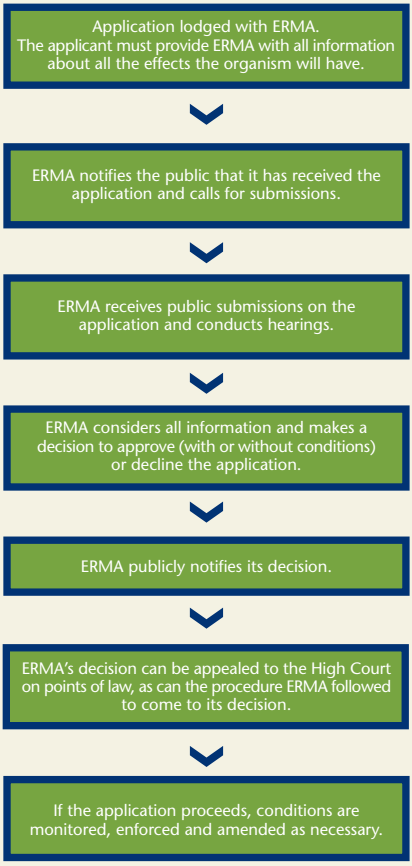
In the case of genetically modified animals, conditions could include a limit on the number of released organisms, high-security fencing and requirements for disposing of wastes.

Conditional release may be for commercial purposes, but may also be part of the development of a genetically modified organism. For example, scientists may need to know how a modified organism behaves and performs in the wider environment and in a variety of situations — something that is not always possible in a more confined field test setting.

The Ministry of Agriculture and Forestry is the agency that will enforce compliance with conditions laid down by ERMA.

Full release

Where ERMA sees that a new organism has no potential risks that need to be managed by the imposition of conditions, it may grant a full release. At that stage, the organism is no longer considered new to New Zealand and is no longer subject to the Hazardous Substances and New Organisms Act, which means it can be grown, used or held anywhere in New Zealand.



In summary, ERMA can only approve an application for conditional or full release when:

(a) It has complete information about the environmental, public health, economic and social impacts of the genetically modified organism; **and**

(b) release of the genetically modified organism meets strict environmental and public health standards set out in law; **and**

(c) the benefits of the application outweigh the risks.

ERMA's decision to approve or decline an application can be appealed to the High Court. If the application goes ahead, conditions are monitored, enforced and amended as necessary by the Ministry of Agriculture and Forestry and ERMA.

WHO MAKES THE DECISION ABOUT APPLICATIONS?

The Environmental Risk Management Authority (ERMA) is responsible for regulating all research, importation, development, field testing and release of genetically modified organisms. Its assessment process is public, and public hearings must be held on any applications to field test or release a genetically modified organism, except for some low-risk medicines and veterinary medicines. ERMA is an independent Crown agency established under the HSNO Act.

Food Standards Australia New Zealand (FSANZ) is the agency that develops food standards for both Australia and New Zealand, emphasising the protection of public health and safety. The final approving body for standards developed by FSANZ is the Australia New Zealand Food Standards Council (ANZFSC), which is made up of the New Zealand Minister of Health and the Australian Commonwealth, state and territory Ministers of Health.

The New Zealand Food Safety Authority (NZFSA) protects and promotes public health and safety and facilitates access to markets for New Zealand food and food-related products. It administers the Food Act 1981, and in that role oversees standards for the safety, labelling and composition of food sold in New Zealand, including imported food and food ingredients produced using genetic modification.

Medsafe is the unit of the New Zealand Ministry of Health which approves medical products for distribution and regulates products used for therapeutic purposes. It both approves products before they are put on the market in this country and monitors their safety afterwards.

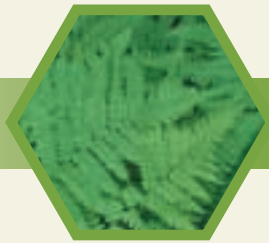
Decisions on low-risk genetic research are made by the Institutional Biological Safety Committees (IBSCs) in the university or research centre concerned. IBSCs usually consist of members of the institution where the research would be undertaken and

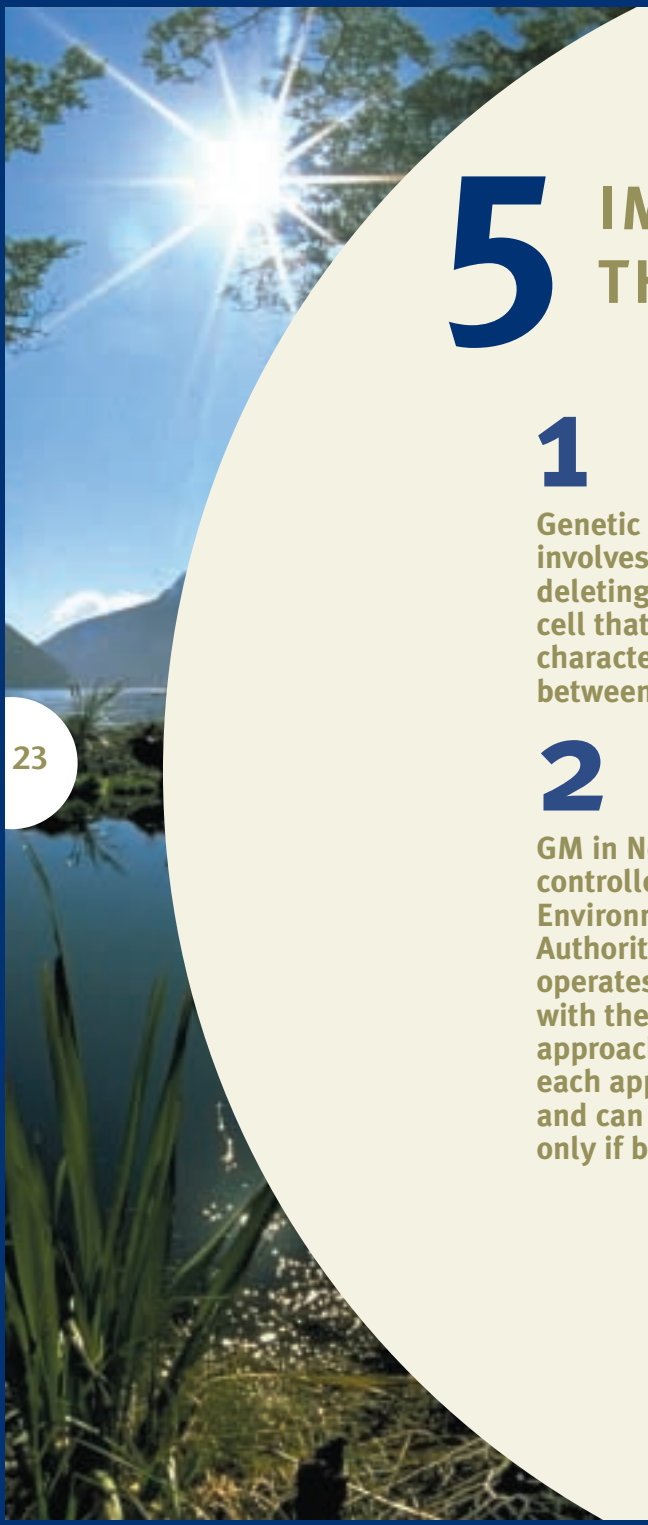
members of the community in which the institution is situated, including a Māori representative. IBSCs have delegated authority from ERMA and must follow ERMA's rules. IBSCs are regularly audited by ERMA to check that they are following the correct procedures.

The Ministry of Agriculture and Forestry (MAF) enforces compliance with the conditions for genetically modified organisms imposed by ERMA on approved field tests and conditional release applications. It also inspects laboratories doing GM work to make sure they are secure and have the proper approvals. MAF is responsible for ensuring importers comply with both the HSNO and the Biosecurity Acts. MAF also has other responsibilities under the Biosecurity Act and for checking that the unapproved release of new organisms does not take place.

The Ministry for the Environment advises the Government on environmental laws and policies, including managing the risks of introducing new organisms. It is responsible for the management and maintenance of the Hazardous Substances and New Organisms Act 1996.

MAF also has other responsibilities under the Biosecurity Act and for checking that the unapproved release of new organisms does not take place.





5 IMPORTANT THINGS ABOUT

1

Genetic modification (GM) involves moving, inserting or deleting genes (the part of the cell that determines individual characteristics) within or between species.

2

GM in New Zealand is strictly controlled through the Environmental Risk Management Authority (ERMA). ERMA operates under strict laws, in line with the Government's cautious approach to GM. It considers each application on its merits and can approve an application only if benefits outweigh risks.

GENETIC MODIFICATION

3

The GM rules are designed to allow New Zealanders to enjoy the opportunities of organic and conventional agriculture, while at the same time not closing the door to the contribution that GM may make to our way of life (especially medicinal and therapeutic).

4

GM is used in New Zealand for research and education, with much of the research being medical (eg, investigating treatments for multiple sclerosis or cystic fibrosis).

5

Any food that is genetically modified or contains genetically modified material must be approved as safe by Foods Standards Australia New Zealand and must be clearly labelled.

GLOSSARY

Biotechnology
Any technological application that uses biological systems, living organisms or derivatives of these (whether genetically modified or not) to make or modify products or processes for general use.

Chromosome
Strands of DNA that contain genetic information. Each chromosome contains numerous genes.

Clone
A genetically identical copy. The term may be applied to a fragment of DNA, a plasmid (see next page) that contains a single fragment of DNA, or a bacterium that contains such a plasmid. It may also apply to larger organisms, such as a plant propagated from a cutting or a pair of identical twins created naturally from a single fertilised egg. Many aphids are (unfertilised) clones of their mother. Clones may also be created artificially by transferring the nucleus of a cell from an animal into a recipient egg.

Conditional release
A class of approval for release of new organisms (including genetically modified organisms), where the release is subject to strict conditions or controls.

Containment
An approval category where a new organism or hazardous substance is restricted to a secure location or facility to prevent escape. This includes, in respect of genetically modified organisms, field testing and large-scale fermentation.

DNA
Deoxyribonucleic acid, the chemical that encodes an organism's genetic information and is responsible for the inheritance of traits from one generation to the next. Genes are made up of DNA.

Field test
A contained trial that monitors the behaviour of the organism, under conditions similar to those of the environment into which the organism is likely to be released.

Gene

A sequence of DNA on a chromosome that contains an instruction leading to specific inherited characteristics.

Genetic engineering (GE)

Another term for genetic modification.

Genetic modification (GM)

The use of modern laboratory techniques to alter the genetic material of cells or organisms to make them capable of producing new substances or performing new functions. Also referred to as genetic engineering or genetic manipulation.

Genetically modified organism (GMO)

A plant, animal or micro-organism whose genes have been altered using genetic modification. The foreign material may contain sequences derived from the same or a different species, or it may be synthetic.

Plasmid

A small, usually circular piece of DNA found in bacteria but separate from the bacterial chromosome. Plasmids are important tools in genetic research and are often used to create, and sometimes insert, the genetic modifications.

Release

Under New Zealand law, 'release' of a new organism (including a genetically modified organism) means use in the wider environment, for which permission must be obtained. Release of new organisms in New Zealand may be approved without the requirement of any conditions or controls, or it may be approved with conditions (see 'Conditional release' on the previous page). Overseas, 'release' is taken to mean a commercial application for a genetically modified organism or release onto the market and it may have voluntary or mandatory controls on it.

WHERE CAN I FIND OUT MORE?

The websites listed below give information on genetic modification. Some of the organisations below also have publications they will send on request.

A government website that contains information about genetic modification:
www.gm.govt.nz

Ministry for the Environment:
www.mfe.govt.nz

ERMA New Zealand:
www.ermanz.govt.nz

Ministry of Research, Science and Technology:
www.morst.govt.nz (for general information on biotechnology, including the Biotechnology Strategy)

Ministry of Agriculture and Forestry:
www.maf.govt.nz

Food Standards Australia New Zealand:
www.foodstandards.govt.nz

New Zealand Food Safety Authority:
www.nzfsa.govt.nz

Medsafe:
www.medsafe.govt.nz

The Report of the Royal Commission on Genetic Modification, 2001, four volumes, and the Government's response:
www.gmcommission.govt.nz (or ask at any bookshop specialising in government publications)

Toi te Taiao: the Bioethics Council
www.bioethics.govt.nz

Acknowledgements

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Disclaimer

While we have tried to ensure that the information provided is accurate, the nature of this booklet requires that the information be simple and general. Information on the regulatory environment and uses of genetic modification in New Zealand is current as of May 2004 but may be subject to change in future. This booklet is intended as an informational guide only and should not be relied upon as a legal resource. For more precise and detailed information you should consult the HSNO Act and regulations, ERMA New Zealand, FSANZ and NZFSA.

You can find more about
genetic modification in New Zealand
from the website

www.gm.govt.nz