
GENETIC MODIFICATION (GM) – CONSIDERATIONS FOR COUNCIL

1. Purpose of Report

This report provides information about GM research in New Zealand. It outlines the roles of government agencies and identifies monitoring opportunities for Wellington City Council.

2. Executive Summary

GM generally presents a low level risk to Wellington City Council.

GM is a technology for altering the genetic make-up of living organisms so they are able to make new substances or perform new or different functions. GM has been used in New Zealand for more than twenty years as a research tool, for medical purposes, and in food ingredients. It holds promise for managing diseases and pests, further contributing to New Zealand's knowledge economy.

GM technology as a research tool and its commercial use in therapeutic medicine is undisputed. However, the use of GM and the release of genetically modified organisms (GMOs) into the environment raise many scientific, social, cultural and ethical issues. New Zealand's evaluations of GMOs are based on the principle of case-by-case assessment through the Environmental Risk Management Authority (ERMA).

To date, there have been no conditional or full releases of genetically modified organisms in New Zealand. There are currently five fully contained field trials operating in New Zealand none of which are in the Wellington region.

The national approach to GM is to proceed cautiously. The GM rules are designed to support organic and conventional agriculture, while at the same time not closing the door to the contribution that GM may make to New Zealand.

3. Recommendations

It is recommended that the Committee:

1. *Receive the information.*
2. *Agree that Wellington City Council be placed on the Environmental Risk Management Authority notification list to actively monitor new organism applications. This will keep the Council informed and allow submissions to be made when appropriate.*
3. *Agree that officers will continue to engage with Mana Whenua over local genetic resources and the cultural knowledge linked to those resources.*

4. Background

GM, also referred to as Genetic Engineering 'GE', 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. GM is a kind of biotechnology that allows scientists to change genes in a 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 than would naturally occur. However, scientists have found that some genes have more than one function and not all of these functions may be known, or their interrelationships understood.

4.1 Gene technology in New Zealand

GM has been used in New Zealand for more than twenty years as a research tool, for medical purposes and in developing food ingredients.

As a research tool, scientists use GM in the laboratory and contained field tests to:

- understand how genes work
- improve characteristics of plants and animals used in agriculture
- seek treatments for diseases
- find new ways of controlling plant and animal pests.

Gene technology in New Zealand medicine includes the production of GM-produced drugs such as insulin and human growth hormone. A number of GM vaccines, such as that for hepatitis B, are also used in New Zealand.

To date, no fresh produce originating in New Zealand is genetically modified. However, research involving the genetic modification of vegetables, including onions that are herbicide resistant and potatoes that are disease resistant, is

being undertaken. Some processed foods may contain genetically modified ingredients such as soy or corn flour sourced from overseas. These ingredients must be assessed for safety by Food Standards Australia New Zealand before they can be used in New Zealand, and the final product must comply with New Zealand labelling laws.

4.2 Environmental aspects of GM

New Zealand's unique biodiversity is internationally important. High percentages of our indigenous species are found only in New Zealand – a result of isolated evolution and the diversity of New Zealand's land and seascapes. This country is also unusual among western nations in its reliance on the primary production sector for export income. Both the protection of rare species and the ongoing use of land for agriculture rely on healthy, well managed ecosystems.

Conservationists, environmentalists and scientists have all raised concerns about the possible impact of GMOs on global ecosystems. Further public debate is required at a national level as the development of molecular techniques enabling the change of the genetic makeup of species has moved ahead of ecological studies of the environmental impact of newly created GMOs.

Research into the ecological implications of releasing modified organisms into the environment is ongoing. The most frequently raised questions are:

- Can genes inserted into modified organisms spread to other organisms (horizontal gene transfer)?
- Can GMOs lead to the creation of new pests and diseases (super-weeds)?
- Because it can be done, should it be done?
- What will be the consequences across time? What options will be left for future generations?

New Zealand's native flora is generally only very distantly related to the crop plants currently targeted for modification, so the risk of gene flow from cropping to native plants is very low. A more pertinent debate may be the risk of gene flow from introduced domestic plants to introduced wild plants. The risk of gene transfer from cross-pollination is relatively low as both New Zealand and overseas studies show that cross-pollination falls off rapidly within a short distance of transgenic plants. However, the Royal Commission on Genetic Modification concluded that if New Zealand is to release GM plants into the environment, pollen drift should be investigated and appropriate distances established to separate GM and other crops.

As well as risks, there are potential environmental benefits from genetic research, including:

- improved pest control
- the extraction of heavy metals and toxic pollutants from contaminated soils by GM plants
- a reduction in contribution to climate change due to a reduction in methane emissions from sheep and cattle

- detecting unwanted exotic organisms such as didymo (*Didymosphenia geminata*) via genetic analysis.

GM may also assist with managing New Zealand's most menacing pest, the possum. To date, these animals have been controlled only by inefficient and labour intensive methods such as poisoning or trapping. Researchers are currently working on ways of making possums infertile by setting off an auto-immune reaction against their own productive organs. This technology may be a viable pest control alternative once it is established and there is no possibility of mutated infertility transfer to other mammals. Rendering the entire possum population infertile would save millions of dollars annually in pest control throughout the country.

4.3 GM in context

New Zealand has explored the scientific, commercial, social and ethical aspects of GM in some depth. In 2001, the Royal Commission on Genetic Modification concluded that the importance of GM technology as a research tool and its commercial use in therapeutic medicine were undisputed and, in their opinion, well-controlled. At the same time, the Commission recognised that the use of GMOs and their release into the environment raises many issues. New Zealand has resolved to proceed cautiously, making use of the opportunities that GM brings, whilst mitigating and managing the risks.

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 or be reproduced, whether or not it is a food or a medicine.

Before any new organism can be imported, developed, field tested or released into the environment, the applicant must get the approval of ERMA, an independent body that considers the potential risks and benefits of GM applications on a case-by-case basis. A full explanation of New Zealand's regulatory process for genetically modified organisms is attached as *Appendix 1*.

GM research has reached a point in New Zealand where increased field trials will be necessary. Gene technology has identified that a gene may act differently, depending on where it is spliced into its host's DNA. It is also clear that some genes have more than one function and not all of these functions may be known, or their interrelationships understood. As in conventional plant breeding, results of gene transfers are likely to be variable and will include some unwanted outcomes. The key lies in properly designed experiments. Laboratory tests may show how a GMO will behave but field trials are essential to study how the organism behaves in nature. Both approaches must be pursued before contemplating the release of GMOs.

To date, there have been no conditional or full releases of genetically modified organisms in New Zealand. There are currently five fully contained field trials, involving GM cows, onions and pine trees operating in New Zealand. None of these field trials is in the Wellington region. *Appendix 2* lists the locations of the contained field trials within New Zealand. However, it is likely that GM

research will reach a point in the future where an application is made for the conditional release of GMOs in New Zealand.

The issue of GM was not heavily represented within the public submissions to Wellington's draft Long Term Council Community Plan (LTCCP); a total of 12 submissions were received. The general sentiment of the submissions was that Council should adopt a cautious approach to GMO land use and manage local risks appropriately. Given that Wellington District is not an area of significant primary production, the risk level from within Wellington is relatively low. However, there is also a low risk of uncontrolled outbreaks of GMOs from future field trials or conditional releases of GMOs from other districts. It is appropriate then, that Wellington City Council seeks to actively monitor GM research applications through ERMA and identify potential cultural issues with Mana Whenua. In this way, future potential risks and opportunities will be recognised in good time to fully engage in ERMA's consultation processes.

4.4 Maori Concerns on GM

The Government established Toi te Taiao, the Bioethics Council, in December 2003. The 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 uses the results of that dialogue as a basis for its advice to Government. ERMA and Government departments may draw on the Council's advice in developing policies on biotechnology when making decisions.

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 Maori and their culture and traditions have with their lands, water, wahi tapu, flora and fauna and other taonga. This means that ERMA must assess the potential impact of the organism on plants and animals that are valued by iwi and hapu. The body providing advice on these matters is Nga Kaihautu Tikanga Taiao.

The basis for many of the Maori cultural objections varies among iwi, but most arise from concerns about breaches to whakapapa (genealogy), mauri (life forces), kaitiakitanga (guardianship) and rangatiratanga (sovereignty).

A primary concern for Maori relates to the misappropriation of indigenous knowledge and the use of their genetic resources by biotechnology companies. In 1991, Waitangi Tribunal claim 262 was lodged on indigenous flora and fauna. The claim argues that the Crown has failed to protect the rangatiratanga (sovereignty) of Maori over both their genetic resources and the cultural knowledge linked to those resources. The claim raises issues in respect of intellectual property rights that have not been addressed before. The hearing of evidence with respect to this claim will conclude in March 2007.

In addition to this general concern, many Maori have strong objections to gene technology because they see it as a breach of their spiritual belief systems and therefore as a moral and cultural offence. Maori have a sense of relatedness between themselves and nature which creates a feeling of

belonging to nature as integral to their identity, rather than being a separate element.

Wellington City Council officers have regular discussions with Mana Whenua and continue to utilise these opportunities to discuss issues as they are raised. In particular, officers are able to engage with Mana Whenua about genetic resources and cultural knowledge linked to those resources.

5. Discussion

GM is considered to be an efficient method of producing improved varieties of plants and animals that can be passed onto its offspring in ways not possible through traditional breeding. It holds promise for managing diseases and pests, and contributing to the knowledge economy; it may also enhance the international competitiveness of the primary industries so important to New Zealand's economic well-being.

However, the efficiency of GMOs in their ability to change and adapt to their environment is also a cause for caution. In considering a new organism for release, ERMA must decide whether or not the organism's ability to change and adapt 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.

It is clear that alongside the scientific issues, the cultural, political, and community aspect of GM must be considered. Of primary community concern is the potential future release, planned or otherwise, of genetically modified organisms into the environment.

5.1 Other Districts' responses to GM – managing the risks

The potential release of GMOs into the environment is a key issue for primary production districts. For example, submissions on GM were the highest for any single issue during consultation on the Whangarei District Council's (WDC) 2004 LTCCP. This has led to the WDC adopting the following stance towards GM in its LTCCP:

Council will adopt a precautionary approach to the management of biotechnology in general and to GMO land uses in particular. It will continue to investigate ways to maintain the district's environment free of GMOs until outstanding issues such as liability, economic costs and benefits, environmental risks and cultural effects are resolved.

Similarly, the Kaipara, Rodney, and Far North District Councils each received a large number of submissions requesting a precautionary approach to GM. This being the case, they decided to work collaboratively and commissioned a report investigating the risks and response options to the use of GMOs if such activities were to be carried out in their districts. The principal issues identified revolve around the question of who pays for financial losses or clean up costs should a GMO release result in adverse economic or environmental

effects. This issue of managing potential liability is also of importance to Wellington City Council.

5.2 Liability and Control

At present, under the HSNO Act, there is no liability on the party releasing GMOs to the environment for damage resulting from a release carried out in accordance with ERMA approval. Therefore, the costs of unforeseen adverse environmental effects will be borne by affected parties such as neighbouring farmers and tourist operators, and by local government. Yet local authorities have no authority over decisions to allow GMO uses in their districts or regions.

The absence of any 'veto' authority for local authorities with regard to ERMA new organism applications exemplifies the importance of ensuring that Council is aware of relevant research applications within the Wellington and neighbouring regions. To date, no applications for a conditional release of a GMO has been made within New Zealand. Whilst the timing of a possible GMO release is difficult to predict, it is highly likely that applications will arise in the future.

Given that Wellington is not a primary production area, local risks are most likely to result from the conditional release of GMOs in other districts. In considering a new organism for release, ERMA must first decide whether or not the organism would be likely to have a 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 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.

Wellington City Council has the opportunity to be notified by ERMA when any applications for new organisms are lodged within the Wellington Region or nationally. This will enable Council to consider any issues and make submissions. The ERMA consultation process is outlined in *Appendix 1*.

The types of issues that might feature in a Council submission include:

- field trial location
- field trial number and/or duration
- species within the field trial area requiring preservation
- cultural issues.

5.3 Opportunities and implications of GM

The Royal Commission of Genetic Modification refers to biotechnology as the 'new frontier' and sees the continuation of research critical to New Zealand's future. The importance of GM technology as a research tool and its commercial use in therapeutic medicine is recognised. However, the applications to farming and food production, and the release of genetically modified organisms into the environment, raise many issues. New Zealand has opted to proceed cautiously, making full use of the opportunities that GM

brings, but ensuring that it is not at the expense of the environment or existing agriculture, and does not cause unnecessary cultural offence.

While the environmental GMOs commercialised to date are generally directed at reducing harvest losses by combating pests and viruses, research into future plant varieties will considerably widen the scope for applications. This includes improved growth in plants and enhanced tolerance to environmental conditions. As the types of potential benefits available from these new GMOs are also generally available through alternative mechanisms, gains available from GM products need to be measured in terms of their net benefit over those alternative means.

Like all organisms new to New Zealand, GMOs have potential for positive or negative effects on the environment, the economy and our society. Each organism has unique characteristics, and the risks and benefits will depend on where and how each organism is used.

5.4 Risk control for Wellington City

Although genetically engineered medicines seem well accepted in New Zealand, the extension of the technique to farming and food production is the subject of ongoing public debate. Of particular importance is the possible future release of GMOs into the environment. The level of risk to Wellington City Council is generally considered to be low given that:

- Wellington is not a major primary production area and is geographically isolated from primary production regions
- ERMA strictly controls GM applications
- no controlled field trials are operation in the Wellington Region.

The risk of non-GMOs entering Wellington is arguably more of a risk to the region than that of GMOs. Non-GMOs arrive from various sources on a daily basis. It is the role of Biosecurity New Zealand to ensure the exclusion of these unwanted organisms and pests as well as the eradication or management of pests once they are here. The biosecurity system is highly dependent on the ability of scientific researchers to adapt and respond to constantly changing biosecurity risks, either by pathway, vector, pest or disease. In fact, GM research may be the key to the success of effective marine biosecurity. For example, genetic analysis can be used to rapidly identify unwanted marine organisms in ballast water and in environments that can not easily be searched.

The rapid pace of GM technology in New Zealand has necessitated an increase in the number of field trials. It is probable that at some point in the future an application may be made for one of those field trials to be in the Wellington region. The opportunity exists for Council and Mana Whenua to engage prior to such an application to discuss genetic resources and the cultural knowledge linked to those resources. By remaining aware of GM developments and a range of views, the Council will be able to fully consider issues and engage effectively in the ERMA submission process.

6. Conclusion

This report has described GM issues for consideration and identified how the Council can monitor risks and opportunities, and make submissions to ERMA on consideration of any proposal with regard to new organisms.

Report prepared by: *Genevieve Drake, Policy Advisor*

Supporting Information

1) Strategic Fit / Strategic Outcome

This report supports the Environmental outcome of making Wellington more actively engaged, more sustainable, healthier and more competitive. It supports the Economic outcome of making Wellington more entrepreneurial and innovative.

2) LTCCP/Annual Plan reference and long term financial impact

There are no funding implications.

3) Treaty of Waitangi implications

There are no Treaty of Waitangi implications.

4) Decision-making

The content encompassed within this report will not result in a significant decision.

5) Consultation

a) General consultation

Internal consultation has been undertaken in the preparation of this report.

b) Consultation with Maori

Consultation with our Mana Whenua partners has not been undertaken in the preparation of this report. The established communication protocols for the Council provide ongoing opportunity for Mana Whenua and the Council to engage as relevant issues arise.

6) Legal implications

Legal advice has not been received for this report.

7) Consistency with existing policy

The report is consistent with existing policy.

APPENDIX 1

GOVERNMENT REGULATIONS FOR GENETICALLY MODIFIED ORGANISMS

1. GM research approval

The Environmental Risk Management Authority (ERMA) regulates the introduction of any new Genetically Modified Organisms (GMOs), whether they are created for research or for commerce. ERMA operates under the Hazardous Substances and New Organisms Act 1996 (HSNO Act), which requires every project resulting in a genetically modified organism to go through a rigorous approval process.

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 committee within a research organisation) to assess the application. The Act requires that an approval for genetic modification can only be given if strict controls are in place to prevent the organism from escaping or causing harm to those who handle the organism. 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.

At times research needs to move outside the laboratory; for example to closely simulate release conditions. However, 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 a lab is proposed, reasons are required as to why laboratory or non-genetic modification methods are not applied.

2. Controls on field tests

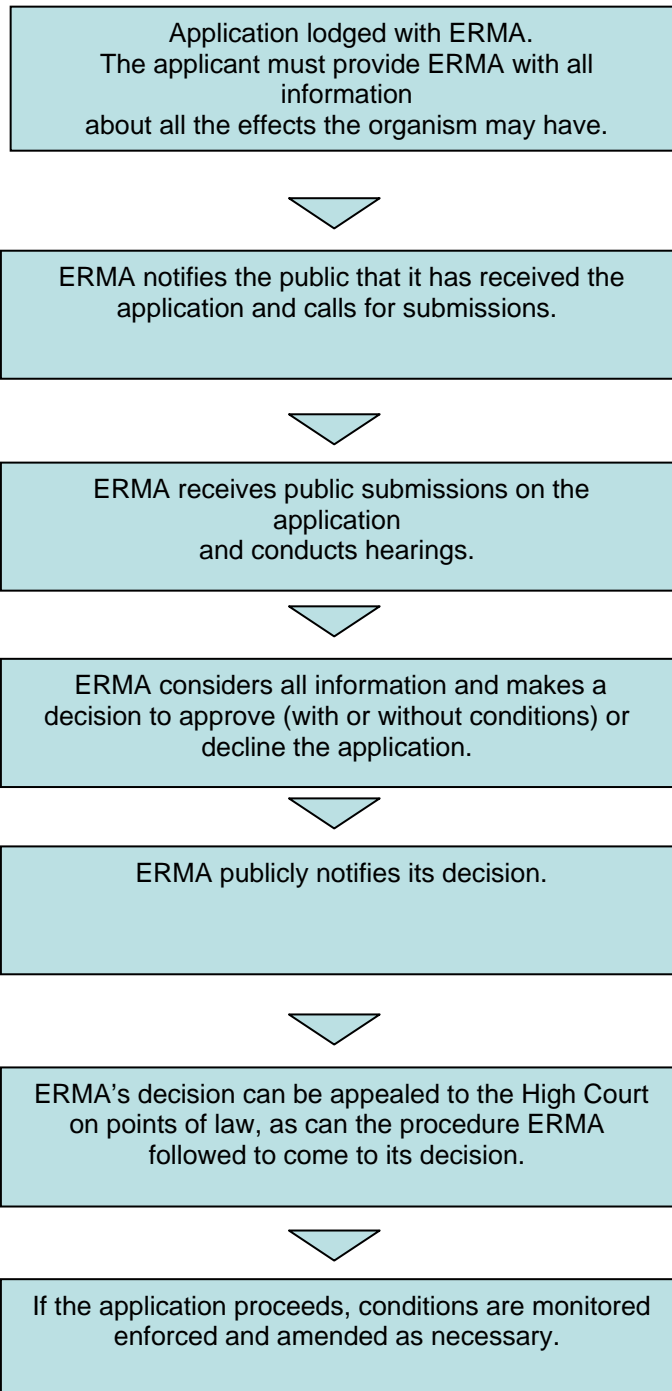
The HSNO Act requires strict conditions to be placed on field tests to reduce any potential risks. The genetically modified plants or animals are not allowed to escape or to be released outside of the trial area, access to the facility must be restricted and scientists must ensure that 'heritable material', such as seeds or cuttings from plants, does not escape from the field test site. All field tests must be inspected and monitored regularly to ensure requirements are met.

3. Conditional and full release

The HSNO Act 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 a 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.

4. The ERMA approval process

The following flow chart shows the rigorous process undertaken by ERMA as it considers applications regarding GMOs.



5. 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. MAF is the agency that enforces compliance with conditions laid down by ERMA.

6. Full release

Where ERMA decides 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.

7. Decisions on applications, and compliance monitoring

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. 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 (ANZFS), 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 Maori representative. IBSCs have delegated authority from ERMA and are regularly audited by ERMA for compliance with its rules.

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, including for checking that the unapproved release of new organisms does not occur.

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.

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

- it has complete information about the environmental, public health, economic and social impacts of the genetically modified organism; and
- release of the genetically modified organism meets strict environmental and public health standards set out in law; and
- the benefits of the application outweigh the risks.

APPENDIX 2

GENETICALLY MODIFIED ORGANISMS IN WELLINGTON

1. Genetically modified organisms in Wellington

GMOs are modified for various reasons including the expression of beneficial traits or to act as tools to study how specific genes, proteins or biological systems work. The GMOs in Wellington containment facilities include micro-organisms (such as non-pathogenic bacteria or yeast), mammalian and insect cell lines, and mice.

There is a number of registered containment facilities in the Wellington region in which GMOs are used or developed including:

- Victoria University of Wellington, School of Biological Sciences
- AgResearch Limited, Wallaceville
- Malaghan Institute of Medical Research
- Institute of Environmental Science and Research Limited
- Industrial Research Ltd. BioPharm
- National Institute of Water and Atmospheric Research
- Wakefield Hospital
- Aro Tec Diagnostics Limited.

All containment facilities are registered under the Biosecurity Act, 1993. These facilities operate under approved facility 'standards' which specify the structural and operating requirements for different types of containment facilities. All facilities undergo frequent audits by MAF quarantine officers to ensure that all ERMA controls and standards are met.

There are currently no GMO field trials in the Wellington region or in neighbouring districts. There are five fully contained field trials operating in New Zealand in the following areas;

- Rotorua – GM *Pinus radiata* – two trials
- Canterbury – GM onions
- Ruakura – GM cows
- Hamilton – GM cows