



ERMA NEW ZEALAND

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Genetic Modification: an overview

Introduction

Genetic modification may eventually affect all of us in some way, so it is important that this new technology is discussed and understood widely. This information sheet provides a brief introduction to genetic modification for anyone approaching the topic for the first time. We hope it will assist informed debate in the community.

What is a gene?

A gene is a unit of hereditary material that, by itself or with other genes, determines a characteristic of an organism. For example, a gene or combination of genes may determine flower colour or height in plants, or litter size or milk production in animals. Genes may also determine less visible characteristics such as pesticide resistance in insects or toxicity in plants. Associated with genes are related genetic regulatory elements such as promoters which control when and how much the gene expresses its function and terminators, which tell when the gene stops functioning. These are also pieces of nucleic acid incorporated into the organism's genome (the sum of all the organism's genes and associated nucleic acid elements).

An organism's genes, working together, determine how it will develop – whether it becomes a broad bean or a baboon. In fact, many genes are similar across species, as they control processes vital to the survival of any cell. The difference between a guinea pig and a gorilla is controlled by only a small proportion of their genes.

Genes are found in almost every cell of every plant, animal or micro-organism. Most are in the cell nucleus, on long narrow structures called chromosomes. Chromosomes are made of a chemical called deoxyribose nucleic acid or DNA. In sexually reproducing organisms each body cell has two sets of genes, one inherited from each parent of the organism.

What is genetic modification?

Scientists have learnt how to locate individual genes and to transfer them to different cells – and these cells can be in a different individual, or a different species. This science is called molecular biology, genetic engineering, or genetic modification. The organisms produced are called genetically modified organisms (GMOs).

Transferring a gene also transfers the inheritable trait that the gene codes for. Genes can be transferred to other organisms of the same species (intra-specific transfer), or they can be transferred between species (inter-specific transfer). Organisms containing genes from two or more species are called transgenic organisms.

When genetic constructs are developed, scientists usually select not only the gene they want but also the genetic regulatory elements that will control how well and where in the host organism the gene is expressed. Two terms often used are phenotype, the physical trait (such as flower colour), that results from expression of the specific genotype, the genetic material.

What are the differences between genetic engineering and conventional breeding?

When plants or animals are crossed in conventional breeding, the offspring receives half its genetic material from each parent. But there is no way of controlling which genes are transferred. Many unwanted traits are inherited along with the desired ones. To produce a plant or animal with the best characteristics of both parents, breeders must carry out large numbers of crosses, and then select the best of the progeny over many generations.

Intra-specific gene transfer, on the other hand, can insert a single desired gene into an organism while retaining the genes already present.

Conventional breeding can cross only plants or animals of the same species, or closely related species. Genetic engineering can transfer genes between different species. For example, novel colours can be produced in carnations by inserting genes from petunias. Genes can even be transferred between animals and plants. Strawberry plants have been made frost resistant by introducing a gene that produces an “anti-freeze” chemical. That gene came from an arctic flounder.

What is the legal definition of a genetically modified organism?

The Hazardous Substances and New Organisms Act (1996) (HSNO) states that:

“Genetically modified organism” means . . . any organism in which any of the genes or other genetic material –

- (a) have been modified by *in vitro* techniques; or
- (b) are inherited, or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by *in vitro* techniques.

This definition includes organisms produced by either intra- or inter-specific gene transfer, and all offspring of these for an unlimited number of generations.

Regulations made under the Act narrow the definition by listing types of organism that are not considered to be genetically modified. Plants regenerated naturally from organs such as tubers and bulbs, or propagated vegetatively from cuttings or grafts, or organisms grown without modification through tissue culture techniques are not genetically modified organisms. These techniques aim to produce clones which are genetically identical to the original organism.

Animals produced solely from artificial insemination, superovulation, embryo transfer or embryo splitting are not genetically modified organisms. These techniques are based on normal sexual reproduction.

Other organisms considered not to be genetically modified are those resulting from random changes in genes (mutations) or random re-arrangement of the genetic material. This applies even when the cells are irradiated or treated in other ways known to promote these genetic changes. Similarly, organisms produced by protoplast fusion, where the contents of the cells of two different organisms are physically mixed, are not

considered to be genetically modified organisms. [For more details, see then Hazardous Substances and New Organisms (Organisms not Genetically Modified) Regulations 1998.]

The HSNO Act and GMOs

All genetically modified organisms are classed as “new organisms” under the HSNO Act unless they have been approved for uncontrolled release. Consequently, they are controlled by ERMA New Zealand. The Authority’s approval must be sought for the importation, development, field testing, conditional release or release of any genetically modified organism. If approval is given for development in containment, or for importation into containment, further approval must be given before the organism can be field tested, conditionally released or fully released. Approval is only given if, in the opinion of ERMA New Zealand, the benefits of the GMO outweighs the risks or adverse effects of the GMO. There are different decision criteria for low-risk GMOs that are developed in laboratories or are qualifying medicines or veterinary medicines.

Decisions on the development of low-risk GMOs, and their importation into secure containment can be made through a rapid assessment process. Power to make these decisions may be delegated by the ERMA New Zealand to Institutional Biosafety Committees (IBSCs) established by research organisations. The committees must keep detailed records, and report their actions to ERMA New Zealand. Decisions on low-risk qualifying medicines and veterinary medicines may be delegated to the Chief Executives of ERMA New Zealand, MAF and Ministry of health. Applications for these low-risk operations are not publicly notified.

Applications for the importation or development in containment of GMOs that are considered to pose greater risks, or for any field testing, conditional release or full release of GMOs, must be publicly notified. After notification, anyone may make a submission. ERMA New Zealand may call for further information if it believes this is needed. A hearing will be held if the applicant or any of the submitters request one, or if the Authority thinks one is necessary. After the hearing, ERMA New Zealand will decide on the application and publicly notify its decision.

If an application is made for an approval that will have significant effects or consequences, the Minister for the Environment may “call in” the application for decision. In these cases the Minister may appoint additional members to the Authority if additional expertise is needed. ERMA New Zealand will deal with the application in the same way as other notified applications but, instead of deciding on the application, will prepare a report to the Minister who will make the final decision and notify it publicly.

How does the HSNO Act compare with the previous system?

Before the New Organisms provisions of the HSNO Act came into effect on 29 July 1998, many genetic engineering experiments were overseen by the Advisory Committee on Novel Genetic Techniques. Field testing of GMOs was “controlled” by the Interim Assessment Group for the Field Testing or Release of Genetically Modified Organisms. These bodies reported to the Minister for the Environment, and were supported administratively by the Ministry for the Environment.

Seeking approval from these bodies was, however, voluntary, and they had no legal power to prevent experimentation or release by groups that chose to by-pass them. However once the HSNO Act came into force, anyone wanting to develop, import, field test, or release a genetically modified organism, was required to have the prior approval of ERMA New Zealand. The Act stipulates severe penalties for breaches of the law. These penalties can be imposed on both the person who directly carries out the illegal action, and on his or her employers.

ERMA New Zealand's approach

When considering an application to import, develop, field test, or release a genetically modified organism, ERMA New Zealand's first obligation is to fulfil the purpose of the HSNO Act – to protect the environment and the health and safety of people and communities. The Authority must take into account:

- the sustainability of all native and valued introduced flora and fauna
- the intrinsic value of ecosystems
- public health
- the relationship of Maori culture and traditions with their ancestral land, water, sites, waahi tapu, valued flora and fauna and other taonga
- the economic and related benefits and costs to be derived from the organism
- New Zealand's international obligations.

The HSNO Act requires that anyone making decisions under the Act takes into account the need for caution if there is scientific or technical uncertainty about the adverse effects of the organism. Particular caution is needed when deciding on the release of a new organism into the environment. Once released, the organism may be difficult or impossible to retrieve.

When, however, an application is made to import into, or develop or field test an organism in containment, the issues to be decided are likely to be defining containment conditions to prevent the organism escaping, as well as effectively managing the risks of the organism. For field tests, besides the applicant having to show that there are not more adverse effects from the use of the GMO than other means of achieving the research objectives, once the test has been completed all heritable material must be removed or destroyed from the site. ERMA New Zealand is required to ensure controls are placed on any field test approval to achieve this.

For more information on ERMA New Zealand's approach, read the *Annotated Methodology for the consideration of applications for hazardous substances and new organisms under the HSNO Act 1996*, available from ERMA New Zealand.

ERMA New Zealand and Genetically modified food

Genetically modified food is food which contains ingredients derived from genetically modified micro-organisms, plants or animals. The regulation of genetically modified food in New Zealand, and ERMA New Zealand's role in that, is outlined in another Information Sheet *Genetically Modified Food and the HSNO Act*.

ERMA New Zealand Information Sheets

ERMA New Zealand publishes information sheets on a range of topics to provide background information on current issue or proposals being dealt with by the Authority.

All publications may be viewed and downloaded from our website at www.ermanz.govt.nz or may be requested by contacting ERMA New Zealand, P O Box 131, Wellington. Ph +64 4 916 2426 Fax +64 4 914 0433 Email info@ermanz.govt.nz