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appendix 1

Context and process

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2.1 Genetic modification legislation and regulation in New Zealand

Introduction

New Zealand has two key pieces of legislation that currently control genetic modification, genetically modified organisms and environmental protection from risks associated with genetically modified organisms. They are the Hazardous Substances and New Organisms (HSNO) Act 1996 and the Biosecurity Act 1993.

There are also other enactments and associated regulations that either deal with a specific aspect of genetically modified organisms or genetically modified products (such as the Medicines Act 1981 and the Food Act 1981) or potentially could be used or applied to genetically modified organisms and genetically modified products and their uses (such as conservation or environmental protection and management legislation, consumer and intellectual property laws).

Key legislation for genetic modification

Hazardous Substances and New Organisms Act

The purpose of the HSNO Act is "to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substances and new organisms". Genetically modified organisms come under the definition and regulation of new organisms by the Act.

It should be noted that the Act does not regulate or provide for any controls on genetically modified organisms once they have been approved for release into the environment. If genetically modified organisms are released (with or without approval), any restrictions on their movement or management would have to be under other legislation, such as the Biosecurity Act, the Conservation Act 1987 or the Health Act 1956.

The Environmental Risk Management Authority (ERMA) was established under the HSNO legislation. It is responsible for granting or withholding approval for:

- importing any genetically modified organisms into containment
- developing any genetically modified organism
- conducting contained field trials
- releasing any contained or imported genetically modified organism.

ERMA's responsibility is to prevent or manage any adverse effects of new organisms, including genetically modified organisms.

Its task intersects with several other agencies:

- **Ministry of Agriculture and Forestry** (MAF). ERMA and MAF have entered into a Memorandum of Understanding (MOU) and an operational agreement. The MOU deals with the interrelationships in:
  - administration of the new organisms provisions of the HSNO Act and the importation control provisions of the Biosecurity Act
  - administration of approvals under HSNO and the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 and the transitional provisions under these two Acts
  - coordination of policies in New Zealand and internationally.

  The MOU recognises the role of MAF in managing the border control and quarantine issues regarding new organisms, while ERMA exercises the clearance or approval process for any new organism identified to enter the country. The operational agreement relates to the responsibilities each organisation has for the containment of new organisms. MAF sets the import health standards for containment facilities and operators. ERMA must ensure that, where an approval is given to import any new organism into containment, the containment meets the controls and standards approved under the HSNO Act. The agreement provides that the HSNO containment requirements will be enforced by MAF inspectors acting under the Biosecurity Act.
- **Australia New Zealand Food Authority** (ANZFA). ERMA and ANZFA have an MOU under which they have agreed to notify and exchange

information about applications to develop or vary a standard allowing the sale of genetically modified foods or food ingredients in the case of ANZFA, and all applications for approval of genetically modified organisms (excluding development in containment) in the case of ERMA. They have also agreed, as far as is practicable, to coordinate approvals for the release of genetically modified organisms, genetically modified foods and ingredients derived from genetically modified organisms.

- Other government agencies also have obligations, and potentially powers of enforcement, under the HSNO Act, such as **Occupational Safety and Health Service**.
- Under section 97(g) of the HSNO Act, the chief executive of **Ministry of Health** has a specific duty and power to enforce the provisions of the Act to protect public health.
- **Department of Conservation** has a statutory role in advising on the impacts of new organisms that are being considered for introduction to New Zealand. Under section 53(4) of the Act, ERMA is required to notify the Department of Conservation of applications for approval of new organisms. Under section 58, the Authority is required to have particular regard to any submissions made by the Department of Conservation where any application is for approval to import, develop, field test or release a new organism.
- **Ministry for the Environment** (MfE) is responsible for administering HSNO and providing policy advice to Government. It also monitors ERMA's activities.

Biosecurity Act

This Act provides the mechanisms for the exclusion, eradication and management of pests and other unwanted organisms in New Zealand. New organisms, including genetically modified organisms, are treated as risk goods under the Biosecurity Act. New organisms that have containment approval from ERMA are "restricted organisms" under the Biosecurity Act and must be held in a containment facility approved under that Act.

Under section 101 of the Act, the Minister of Biosecurity formally recognises the Director-General of Health as having responsibilities for human health matters that could be adversely affected by certain organisms. The Ministry of Health uses powers under the Biosecurity Act to exclude, eradicate, and effectively manage pests and unwanted organisms of public health significance.

The Ministry is also able to use the powers under the Biosecurity Act to manage the exclusion, eradication or control of pests or organisms that pose a threat to

public health. This responsibility is carried out under a separate purchase agreement between the Minister of Biosecurity and Ministry of Health.

Legislation applicable to genetic modification

Resource Management Act

The Resource Management Act 1991 (RMA) provides the framework for management of use of the environment, including air, water, soil, biodiversity, the coastal environment, noise, subdivision and land use planning in general.

Ministry for the Environment is responsible for administering the RMA. The RMA operates through consent authorities (regional, district and city councils and, occasionally, the Ministers for the Environment or of Conservation), which grant permission by way of resource consents to use or develop a natural or physical resource and/or carry out an activity that affects the environment.

Granting of resource consents ensures that an activity can proceed provided any adverse effects on the environment are avoided, remedied or mitigated.

There are five types of resource consent under the RMA:

- land use consent
- subdivision consent
- water permit
- discharge permit
- coastal permit.

Part 3 of the RMA spells out the duties and restrictions under the Act. In most cases, the use of a resource is prohibited unless expressly allowed by a rule in a plan. The main exception is land use, which is permitted **unless** it contravenes a rule in a district plan. In this instance, a resource consent may be necessary for land use.

Under the RMA, district and regional plans must spell out when activities may require a resource consent and the type and category of consent that is necessary.

Applications of national significance

The Minister for the Environment has a power to "call in" a local proposal deemed to be of national significance. The decision then becomes the responsibility of the Minister for the Environment. The Minister decides whether a proposal is of national significance. Some of the criteria that can be considered are whether a

proposal:

- has aroused public concern or interest
- involves significant use of natural and physical resources or technology new to New Zealand which may affect the environment
- affects a nationally significant feature or area, or more than one region, or New Zealand's international obligations to the global environment
- is significant in terms of the principles of the Treaty of Waitangi.

Environment Act

The Environment Act 1986 established the Ministry for the Environment and the Office of the Parliamentary Commissioner for the Environment. The Commissioner is an officer of Parliament appointed for a five-year term to provide an independent check on the system of environmental management and the performance of public authorities on environmental matters.

The functions of the Ministry for the Environment, as set out in the Environment Act 1986, are:

- to advise the Minister on all aspects of environmental administration, including:
    - policies for influencing the management of natural and physical resources and ecosystems
    - significant environmental impacts of public or private sector proposals, particularly those that are not adequately covered by legislative or other environmental assessment requirements currently in force
    - ways of ensuring that effective provision is made for public participation in environmental planning and policy formulation processes in order to assist decision-making
- to obtain information, and to conduct and supervise research on environmental policies
- to provide Government, its agencies and other public authorities with advice on:
    - the application, operation, and effectiveness of the Acts specified in the Schedule to the Environment Act in relation to ensuring that, in the management of natural and physical resources, full and balanced account is taken of (i) the intrinsic values of ecosystems; (ii) all values which are placed by individuals and groups on the quality of the environment; (iii) the principles of the Treaty of Waitangi; (iv) the

sustainability of natural and physical resources; and (v) the needs of future generations
    - procedures for the assessment and monitoring of environmental impacts
    - pollution control and the coordination of the management of pollutants in the environment
    - the identification and likelihood of natural hazards and the reduction of the effects of natural hazards
    - the control of hazardous substances, including the management of the manufacture, storage, transport, and disposal of hazardous substances
- to facilitate and encourage the resolution of conflict in relation to policies and proposals which may affect the environment
- to provide and disseminate information and services to promote environmental policies, including environmental education and mechanisms for promoting effective public participation in environmental planning
- generally to provide advice on matters relating to the environment.

Agricultural Compounds and Veterinary Medicines Act

This legislation is not yet in force. It will replace the Stock Foods Act 1946, Animal Remedies Act 1967 and Fertilisers Acts 1960 and 1982.

The ACVM Act will regulate the agricultural compounds and veterinary medicines used in farming and the treatment of animals and plants, and is a companion measure to the HSNO Act. Together with the HSNO Act and the Pesticides Act 1979, it will regulate all substances applied to or used in association with animals and plants in New Zealand. The date of implementation of the ACVM Act and of the hazardous substances part of the HSNO Act has yet to be advised.

Under the new legislation, the Director-General of Agriculture and Forestry is responsible for administering the ACVM Act with the Animal Remedies and Pesticides Boards being dissolved at the completion of the transition process to the ACVM and HSNO Acts.

Medicines Act

The Medicines Act 1981 and the Medicines Regulations 1984 provide a framework for the approval of medical products. The Act and the regulations control the classification, standards, labelling and use of prescription or restricted medicines. (Dietary supplements are regulated under the Food Act 1981.)

Medicines are assessed for safety and efficacy by the Medicines Assessment Advisory Committee (MAAC) using international guidelines. Medsafe (a business unit of the Ministry of Health) supports MAAC. On MAAC's recommendation, the Minister of Health approves medical products for distribution. The Medicines Classification Committee classifies medicines according to categories such as 'prescription only' and 'restricted'.

Under the Medicines Act, clinical trials of new medicines cannot be undertaken before approval has been obtained from the Director-General of Health, who must seek the recommendation of the Health Research Council (HRC) about the proposed trial. When the trial involves gene therapy or xenotransplantation, the HRC refers the issue to its Genetic Technology Advisory Committee (GTAC), an expert technical committee which was established in 1995.

When the new medicine is a recombinant medicine or a genetically modified organism, the proposed trial would be referred to the HRC's Standing Committee on Therapeutic Trials (the SCOTT committee), as are all other trials of new medicines. If the new medicine is, or contains, a live genetically modified organism, the sponsor of the proposed trial would be advised to contact ERMA and seek the necessary approvals.

Australian and New Zealand Health Ministers are considering a single joint trans-Tasman agency to replace Medsafe in New Zealand and the Therapeutic Goods Administration (TGA) in Australia. The joint agency would be responsible for regulating therapeutic goods and healthcare products in Australia and New Zealand. Its broad range of functions would be substantially equivalent to the range of functions currently performed by the TGA and Medsafe, including:

- evaluation of medicines and medical devices
- standard setting
- compliance monitoring
- enforcement activities.

In the present system, approval of medical products in New Zealand involves a case-by-case consideration of the quality, safety and efficacy of a medical product. There is currently no requirement to label or distinguish recombinant medicines. Pharmaceutical companies follow a general practice of disclosing genetically modified components or technology. This is an entirely voluntary system of disclosure.

The Ministry of Health reports an increasing trend in the development of live genetically modified organism vaccines. Such medicines will need approval under the Medicines Act and the HSNO Act. (The application fee for Medsafe approval

is $15,300 and a mid-range fee for approval from ERMA for a genetically modified organism medicine is estimated at around $48,000.)

Except to the extent that it affects the quality, safety or efficacy of that product, the genetic modification status of a medicine is not used as a criterion for accepting or rejecting a product in New Zealand. Currently about 20–30 recombinant protein medical products have been approved for use in New Zealand and comparable countries.

Other agencies involved in the purchase and use of medicines include:

- Pharmac (Pharmaceutical Management Agency), which manages the Pharmaceutical Schedule of the Health Funding Authority, setting the purchase, pricing, subsidies and conditions of prescription of approximately 3000 prescription drugs and products, with the assistance of the following agencies
- Pharmacology and Therapeutics Advisory Committee
- National Advisory Committee on Health and Disability, which provides independent advice to the Minister of Health on health services and products, including the therapeutic uses of genetically modified products and therapies.

Food Act and regulation

Food is regulated under the Food Act 1981 and statutory regulations. Genetically modified food is regulated jointly by New Zealand and Australia. Currently, food regulation is in a transition period to this joint position.

The Agreement between the Government of New Zealand and the Government of Australia Establishing a System for the Development of Joint Food Standards ('the Joint Food Treaty'), signed in December 1995, came into force on 4 July 1996. The Treaty implements a single set of standards for the composition and labelling of food in both countries. These standards make up the Australia New Zealand Food Standards (the 'Joint Code'), which was approved and gazetted at the end of 2000. There is a transitional period of two years before the Joint Code becomes the sole food standard for New Zealand. During this time, food businesses may comply with either the New Zealand Food Regulations 1984, the Australian Food Standard Code (incorporated into New Zealand law under the New Zealand Food Standard 1996) or the Joint Code.

Standard A18: *Food Produced Using Gene Technology*, is incorporated into New Zealand law as a mandatory standard in the New Zealand Food Standard 1996, which must be complied with irrespective of the regime followed during the transitional period.

Genetically modified foods may not be sold unless specifically listed in A18. Such listing requires ANZFSC (the Australia New Zealand Food Standards Council) approval, on the advice of ANZFA (the Australia New Zealand Food Authority). Currently the following GM foods have been listed in the Standard:

- oil derived from glyphosate-tolerant canola line GT73
- food derived from glyphosate-tolerant corn line GA21
- food derived from insect-protected corn line MON 810
- oil and linters derived from glyphosate-tolerant cotton line 1445
- oil and linters derived from insect-protected cotton lines 531, 757 and 1076
- food derived from glyphosate-tolerant soybean line 40-3-2
- food derived from high oleic acid soybean lines G94-1, G94-19 and G168.

The approval process

ANZFA is responsible for developing food standards that ensure the safety of food. The Authority has adopted guidelines for the safety assessment of foods produced using gene technology. These guidelines are based on protocols and principles developed by the World Health Organization (WHO), Food and Agriculture Organization (FAO) and Codex Alimentarius Commission.

The safety assessments carried out by ANZFA are to determine that the food is as safe as its conventional counterpart. Using the guidelines and information supplied by the food biotechnology companies, food toxicologists, molecular geneticists, biologists and nutritionists assess the characteristics of the genetically modified commodities used in foods to determine if the foods have been changed in any way that would make them unsafe.

The ANZFA expert team examines individual applications, carries out a preliminary data assessment and then seeks public submissions. At this point, the application is rejected if it fails to meet these general requirements.

Subject to the response, a full safety assessment is conducted. The scientific team then assesses the characteristics of genetically modified commodity to determine if they have been changed in any unsafe way. A genetically modified food commodity is considered to be safe if all the characteristics (chemical, physical, nutritional and use) are the same as its conventional counterpart. A preliminary recommendation is made before a second round of public comment is sought. Finally, ANZFA makes a recommendation to Health Ministers, meeting as ANZFSC, for approval.

Australia New Zealand Food Authority Act (Commonwealth)

The Australia New Zealand Food Authority Act 1991 is a federal Australian statute which established the Australia New Zealand Food Standards Council and the

Australia New Zealand Food Authority. ANZFA is an independent, binational, statutory authority charged with developing and maintaining the laws and regulations pertaining to food in New Zealand and Australia as described above.

Animal Products Act

The Animal Products Act 1999 regulates the production and processing of animal material and products in New Zealand.

The Act's purpose is to protect human and animal health, and facilitate overseas market access. The Act defines a hazard as a biological, chemical or physical agent that is in (or has the potential to be in) animal material or product, or is (or has the potential to be) a condition of animal material or product, and leads (or could lead) to an adverse health effect on humans or animals.

The Act requires animal or animal product processing to be carried out under registered risk management programmes. Where it is inappropriate or impracticable to manage risks under these programmes, or special provision is required for the purposes of overseas market access requirements, MAF may impose regulated control schemes.

Health Act

The Health Act 1956 is the main legislation under which the Ministry of Health's principal role of improving, promoting and protecting public health (eg, notification of infectious diseases, quarantine) is established. The Act establishes public health officials, such as regional medical officers of health, who have wide and autonomous powers to act for public health.

The Act also regulates the collection, storage and uses of personal health information by health and disability service providers or funders (eg, health statistics and other related information).

The **New Zealand Public Health and Disability Act 2000** replaces the Health and Disability Services Act 1993. In general terms, the Act relates to, and reorganises, the public health and disability sector.

The Minister of Health's responsibilities under the Act include:

- determining health and disability strategies
- negotiating and entering into agreements under which the Crown provides money in return for the provision of health or disability support services
- establishing and appointing committees, including (among others) a national advisory committee on health and disability support services ethics.

District Health Boards (DHBs) are established, and take over functions of the former Hospital and Health Services (HHSs), which are dissolved.

Inquiry boards may be appointed by the Minister of Health to conduct an inquiry into, and report to the Minister on, matters such as the funding or provision of health services or disability support services, or the management of any publicly owned health and disability organisation.

The former Health Funding Authority (HFA) is dissolved, and its functions, transferred to the Crown, acting through the Ministry of Health. However, funding of the provision of health services or disability support services may be further devolved under the Act.

The **Health and Disability Commissioner Act 1994** establishes the independent statutory office of the Health and Disablity Commissioner for mediation and investigation of complaints against health and disability services providers. The Health and Disability Commissioner (Consumers Rights) Regulations are enacted pursuant under this Act.

Legislation and regulation potentially applicable to genetic modification

Animal Welfare Act

MAF has responsibility under the Animal Welfare Act 1999 for developing and promulgating standards of animal welfare; ensuring all complaints of cruelty are investigated; resolving objectively existing and potential animal welfare problems; identifying animal welfare research priorities; and liaising with New Zealand and international agencies involved in animal welfare policy formulation.

Two ministerial advisory committees play a key role in the development of animal welfare policy and standards, by way of a transparent and fully consultative process. These are the National Animal Welfare Advisory Committee (NAWAC) and the National Animal Ethics Advisory Committee (NAEAC).

Animals Protection (Codes of Ethical Conduct) Regulations

The Animals Protection (Codes of Ethical Conduct) Regulations 1987 relate to and provide for the observance of codes of ethical conduct relating to the welfare and humane treatment of live animals that are manipulated in any research, experimental, diagnostic, toxicity or potency testing work or are used in teaching involving the manipulation of live animals.

Conservation legislation

The Department of Conservation has responsibilities and powers under several Acts that provide for the management for conservation purposes of land and historic places and artifacts, native plants and animals, native and introduced species for recreational purposes, and the promotion of, and education about, conservation. These include:

- Conservation Act 1987
- Wildlife Act 1953
- Wild Animal Control Act 1977
- National Parks Act 1980
- Reserves Act 1977.

Intellectual property legislation

Legislation potentially applicable to genetic modification issues of intellectual property protection include:

- Patents Act 1953
- Plant Variety Rights Act 1987.

Consumer protection legislation

Two Acts relating to consumer protection have potential application to issues of genetic modification:

- Fair Trading Act 1986 involves consumer information and liability for false or misleading representations, together with products and services safety. The Minister for Consumer Affairs has power to impose regulations setting safety standards for products and services and labelling requirements for products.
- Consumer Guarantees Act 1993 covers statutory guarantees and consequent liability for goods and services as "fit for purpose".

Table 2.1 provides a schematic representation of the regulations, national and international agencies and agreements, and the relevant government organisations discussed above.

Research

There is no specific legislation or regulation that controls the research into genetic modification or biotechnology in general although, as noted, the HSNO Act controls the development and importation of genetically modified organisms.

Policy advice, which includes advice on priorities for science and technology research, comes from the Ministry of Research, Science and Technology. Currently there is no specific government policy on research into using genetic modification technologies.

Purchasers of research on behalf of Government include:

- The Health Research Council, set up under the Health Research Council Act 1990, funds research on health and medical projects. (See box "Health research projects".)

Health research projects

The following regulations, guidelines and papers have been adopted by the HRC as applicable to research projects it funds:

HRC Guidelines for Ethics Committee Accreditation, Health Research Council of New Zealand, 1996

Report and Guidelines on the Clinical and Research Use of Human Genes, Health Research Council of New Zealand, 1995

Guidelines for Institutional Animal Ethics Committees, National Animal Ethics Advisory Committee, Ministry of Agriculture, 1988

Revised New Zealand Guidelines for Genetic Manipulation Research, Advisory Committee on Novel Genetic Techniques, Ministry for Environment, 1982; and Amendment, 1988

National Standard for Ethics Committees, Ministry of Health/HRC, July 1996

Good Clinical Research Practice Guidelines, Ministry of Health, 1996

The Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996

International guidelines and regulations

Clinical Trials, Supplementary Note 3, NH&MRC Canberra Statement on Human Experimentation, 1988

Declaration of Helsinki, adopted by the 18th World Medical Association, Helsinki, Finland 1964, and revised in 1989 by the World Medical Association

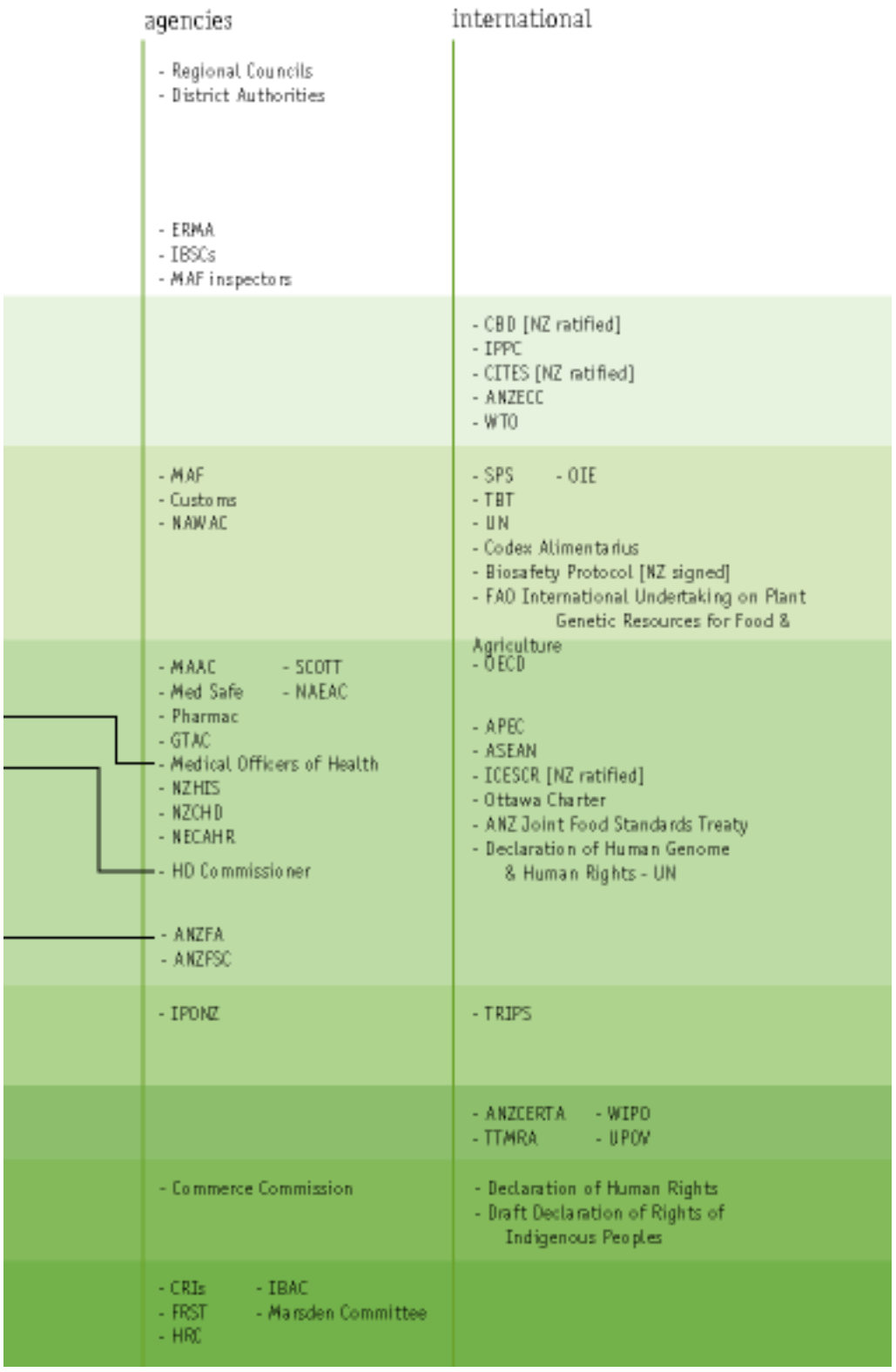
International Ethical Guidelines for Biomedical Research Involving Human Subjects, Council for International Organisations of Medical Sciences (CIOMS), 1993

Research Involving Patients, a report of the Royal College of Physicians, 1990

Table 2.1 Regulations, agencies and agreements relevant to New Zealand's

government	legislation	regulations
PCE	Environment Act 1986 Resource Management Act 1991	- National Environmental standards - National policy statements - Coastal policy statement - Regional policy statement - Regional Plans - District Plans
MFE	HSNO Act 1991	- applications - methodology - GMO def/exemption
DOC	Conservation Act 1987 Wildlife Act Wild Animals Control Act Reserves Act National Parks Act	- Pest control - Pest eradication - Native species protection
MAF	Biosecurity Act 1993 ACVM Act 1997 Animal Products Act 1999 Animal Welfare Act 1999	- Biosecurity regulations - Animal remedies regulations - Stock foods regulations - Animal Protection (codes of ethical conduct) - Animal Products regulations
MOH	Medicines Act 1981	- Medicines regulations - Consents for medicines/medical devices
	Health Act 1956	
	Health & Disability Commissioner Act Health & Disability Services Act 1993	- HDC (Consumer Rights)
	Food Act 1981 ANZFA Act 1991 (Aust.)	- Food - Food hygiene - Dietry supplements - Food standards [A18] - ANZ Joint Food Code [draft]
MED	Patents Act 1953 Plant Variety Rights Act 1987 Trade Marks Act	
MFAT		
MCA	Fair Trading Act 1986 Consumer Guarantees Act 1993	- Product Safety Standards - Consumer Information Standards
MORST	Crown Research Institutes Act Health Research Council Act FRST Act 1990	

inquiry into genetic modification.



- The Foundation for Research, Science and Technology (FRST), established and acting under the Foundation for Research, Science, and Technology Act 1990, funds social, economic and environmental research.
- The Marsden Fund is administered by the Marsden Fund Committee of the Royal Society of New Zealand. This fund is for "blue skies" research that contributes to the knowledge and skill base of research in New Zealand. There are no specific targets or priorities for this research fund.

Research providers include:

- nine Crown Research Institutes, established under the Crown Research Institutes Act 1992
- other public research institutes
- private research institutes.
- universities
- government departments and agencies
- private companies.

If research is into genetic modification or using genetic modification technology, it must comply with the HSNO Act and other regulatory controls, such as the Animal Welfare Act, Biosecurity Act and so on.

Proposed legislation that may affect genetic modification

Assisted Human Reproduction Bill

This Bill was introduced to Parliament on 19 February 1999. It is due to be reported back from Health Select Committee to the House on 21 June 2001. The Bill makes it an offence to clone humans, fuse animal and human gametes, implant animal or human embryos into the opposite species and use human cells to develop procedures or techniques to carry out any of these activities. The Bill also prohibits the sale of human gametes or embryos. It provides for the appointment and functions of the National Ethics Committee on Assisted Human Reproduction, which is responsible for developing guidelines and protocols in this area.

Human Assisted Reproductive Technology Bill

The purpose of the Bill is to formulate a legal framework for restrictions and controls on assisted reproductive technology, associated research and surrogacy and other practices, keeping such regulation in line with that of Australia, Canada and Britain, in particular.