chapter |

6.

Research

6. Research

Key issues:

- The essential role of research in New Zealand's future
- Regulation of genetic modification research to ensure safety without stifling innovation
- Ethical and cultural issues in research
- Creating the right balance when allocating funding.

Introduction

1. Many submitters stressed the importance of research to New Zealand's future. Researchers and businesses were enthusiastic about the potential of future genetic research to bring benefits to health and the environment. Others, including many environmental groups, took a more cautious approach to the possibilities of the science. Submitters often distinguished between research in containment, and uncontained research and its impacts on the environment.

2. In this chapter we discuss the contribution of research to New Zealand's future, the current social and regulatory environment for research involving genetic modification, and changes that have been proposed to the current regulations. We also discuss the issue of research funding.

Asilomar to the present; the New Zealand context

3. The molecular structure of DNA was identified in 1953. In subsequent years understanding of the processes of DNA replication increased and by the early 1970s researchers had begun to understand how DNA could be cut and spliced between species. The consequent spliced DNA became known as recombinant DNA.

4. Some scientists raised concerns about the safety of these early experiments. In July 1974 the USA National Academy of Sciences called for a moratorium on

certain types of DNA experiments until the hazards had been evaluated. In 1975 scientists involved in gene research and experts in bacteria and viruses gathered at a conference at Asilomar in the United States. They evaluated the safety issues and established which strains of bacteria scientists should work with, recommending those that could not survive or reproduce outside the laboratory. They developed a set of guidelines for working with such bacteria. Thus the scientists took the physical risks seriously and voluntarily regulated their own activity.

5. The Environmental Risk Management Authority (ERMA) [IP76] described in its evidence the origin and development of controls on genetically modified organisms in New Zealand. In 1975 the Medical Research Council (MRC) requested the drafting of recommendations for recombinant DNA research, and directed that these be followed by all MRC-funded research. In 1977 there were requests for expanded guidelines. The then Department of Scientific Research (DSIR) laboratories, research associations, universities and the Ministries of Health, Forestry, and Agriculture and Fisheries were directed or requested to follow these. There was no private genetic research at that time.

6. The guidelines assessed experiments on a case-by-case basis. Research was to be done in specific containment facilities, and institutions appointed biological safety officers who ensured those containment requirements were fulfilled.

7. In July 1977 the Minister of Science and Technology set up a working party on novel genetic techniques to advise whether such work should be carried out in New Zealand, whether the interim guidelines were adequate, appropriate and effective, whether legislation was required and whether such legislation should cover the wider question of microbiological hazards in research. Their report was presented in April 1978.[1]

8. In July 1978 Cabinet appointed an Advisory Committee on Novel Genetic Techniques (ACNGT) to "adjudicate on all proposed experiments with respect to the capabilities and training of the scientists involved, the suitability of the laboratories in which the experiments would be carried out and the possible risks inherent in each experiment".[2] Enforcement of the recommendations of ACNGT rested with the controlling authority of the institution where the research took place. These research organisations also were required to appoint a biological safety officer (to provide supervision and advice on appropriate containment measures) and additionally an Institutional Biological Safety Committee (IBSC) (to approve research). Experiments were categorised on the basis of risk into four, later five, categories. From 1982 the IBSCs were delegated to approve lower risk experiments and were required to notify ACNGT. Other experiments were referred to ACNGT for approval.

9. Developments led to establishment of the Field Release Working Party, which recommended in 1987 that the Ministry for the Environment establish a committee to assess all proposals to field test or release genetically modified organisms. In 1988 the Minister for the Environment established the Interim Assessment Group (IAG). From this time all proposals for government-funded research outside contained laboratories, and the fermentation of genetically modified organisms in volumes greater than 10 litres, had to be submitted to the IAG. ACGNT continued to be responsible for contained experiments in glasshouses and laboratories. The private sector was also invited to apply for assessment by IAG[3] and did so voluntarily. The moratorium on field release, in place since 1978, was lifted at this point. Neither ACNGT nor the IAG had any legislative authority, and from 1988 the government began moving towards what was to become the Hazardous Substances and New Organisms Act 1996 (HSNO).

Technologies in use in New Zealand

10. We heard evidence of the wide range of genetic modification methods in use in research in New Zealand. Many submitters distinguished between the use of genetic technology to study the structure and function of genes in containment laboratories, and the development of a genetically modified organism for use, in or out of laboratory containment, as a crop or a product.

11. Much genetic research in New Zealand involves the use of genetic modification technology to isolate, identify and characterise genes from a wide range of species, including humans. Most of this research is carried out in containment and is low risk, because any modified organisms produced are of low virulence and are not able to reproduce outside the laboratory. New Zealand research using gene technology spans land-based production, human health applications, animal welfare and feed, environmental protection, and industrial applications. Some of the uses are described below.

12. The production of DNA libraries involves the isolation of DNA from a species. This DNA is cut into even-sized, smaller pieces and the pieces spliced into plasmids, viruses or artificial chromosomes from bacteria or yeast. These are then grown in bacteria or yeast to amplify the number of copies of each DNA fragment.[4] This form of cloning (the reproduction of organisms with the same genetic material) involves the creation of novel organisms containing DNA from at least two sources, and is therefore covered by the Commission's Warrant. The organisms used to amplify the number of plasmids or viruses are unable to survive outside the laboratory. They are weakened so that they can grow only in a special

medium containing the right nutrients, and therefore pose little or no risk outside the containment laboratory.

13. The use of cloning to identify and isolate genes, for example for sequencing or structural studies, is widespread in all university, medical and Crown Research Institute (CRI) laboratories studying gene structure and function in New Zealand. AgResearch [IP13] uses this technique to study the genes of cattle, sheep, plants, microorganisms, humans and mice. Dr Richard Newcombe, a plant molecular biologist with the HortResearch [IP5], stated:

> … HortResearch has created a variety of genetically modified organisms in containment including 1) bacteria that store our genes from plants in gene libraries, 2) bacteria and yeasts that express the protein products of genes to determine the protein's activity and 3) transgenic plants that disrupt or over-express genes to test their function in the plant.[5]

14. Dr Phil Cowan, leader of the research programme on possum control for Landcare Research [IP12], described the range of techniques used in this work:

> The current research programme uses genetic technologies for the cloning and sequencing of possum genes; the production of recombinant proteins for vaccination trials; the production of genetically modified bacteria expressing possum proteins ("bacterial ghosts"); and the production of transgenic plants expressing possum proteins. Most of the genetic modification is carried out by collaborators outside of New Zealand. The GM products from overseas are tested on possums in our contained facilities in New Zealand to evaluate their effect on possum infertility.[6]

15. Dr Dianne Gleeson, a population geneticist, also with Landcare Research, told us cloning techniques have helped to identify species of native fish to aid in conservation management. Dr Kenneth McNatty, a reproductive biologist with AgResearch, said that these techniques are used in research on the biology of fertility, whereas Dr Parry Guilford, a research scientist in the Cancer Genetics Laboratory at University of Otago [IP19], used similar methods to identify the gene causing familial stomach cancer in a New Zealand family. Further examples are given in Appendix 1 to this report.[7]

16. Other New Zealand research aims to understand how genes function in the whole animal. The importance of the use of transgenic mice was discussed by the New Zealand Transgenic Animal Users [IP45], which described how it can provide animal models for inherited or non-infectious disease, allowing the development of new treatments or cures. Dr Ingrid Winship, Associate Professor of Clinical Genetics at the University of Auckland, giving evidence for the Human Genetics Society of Australasia [IP59], said that:

> There are also many animals that have the same disorders as humans. So, hip dysplasia in certain dogs is analogous to hip dysplasia in humans. So, when we talk about animal

> models, they're not all artificially created. There are animal equivalents which manifest in the same way on the basis it is the same genetic disorder in animals.[8]

Professor Garth Cooper, Professor of Biochemistry and Clinical Biochemistry at the University of Auckland [IP16], explained the importance of animal models in the testing of genetically modified medicines:

> There is a system of clinical trials that has been developed over probably a couple of decades or more, I think in part in response to the thalidomide disaster that happened in the United States … [which] involves preclinical and then clinical trials. Preclinical trials are undertaken in animal models, and under normal circumstances there will be a requirement for trials of two species, of which one must be non-rodent.[9]

17. The development of the polymerase chain reaction (PCR) in the early 1990s made many of the cloning techniques used to amplify DNA concentrations obsolete. PCR has the advantage of avoiding the creation of new genetically modified organisms. Dr Graham Wallis, Senior Lecturer in genetics, University of Otago, described the use of PCR in ecological and conservation genetics research and said "We do not create any animal, plant or fungal genetically modified organisms."[10]

18. It was clear from the submissions received from Interested Persons that this technology is developing rapidly, and many new applications will emerge in the next few years. Associate Professor Michael Eccles, also a research scientist from the Cancer Genetics Laboratory at the University of Otago, appearing for the Transgenic Animal Users, discussed developments in the treatment of genetic diseases and of some forms of cancer using gene therapy. Professor Christine Morris, a researcher in cancer genetics at the Christchurch School of Medicine, speaking for Human Genetics Society, talked of the potential use of molecular diagnosis and treatment response monitoring for some types of cancer, enabling more targeted treatment. Crop and Food Research [IP4] described proposals for the modification of the biochemical pathways for carotenoids and flavonoids to improve nutritional quality and colour and to develop new colour combinations of ornamental flowers. The technology was also being used to develop potential pharmaceuticals and to introduce new pest and disease resistance characteristics in plants.

19. The Commission's survey of public opinion indicates that many New Zealanders know that genetic modification technology is used in research here. They are aware of its use in research using plants (79% of those surveyed), research using animals (67%) and medical research (72%). The numbers who approved of such research were greatest for medical research (65%) and research using plants (52%), with genetic modification research using animals approved by only 29%.[11]

20. It was difficult to assess to what extent public submitters were aware of the extent or use of genetic modification in research. In responding to the Warrant item on current uses and purposes of genetic modification in New Zealand, most limited their comments to genetically modified food. It is not clear if that was because they were primarily concerned with food, or because they chose not to comment on other areas despite being aware of them. Given the figures from the public survey, the first of these options seems more likely.

The contribution of research to New Zealand's future

21. Much evidence stressed the contribution of research to the future of New Zealand in terms of economic development, the education and knowledge sectors (also discussed in chapter 5: Economic and strategic issues), and the environment and health.

Economic benefits

22. A large number of Interested Persons argued that considerable benefits are expected to flow to New Zealand from genetic research. Many of these would be economic, building on and developing current primary industries. For instance, the New Zealand Dairy Board [IP67] argued that biotechnology will enable increased on-farm productivity benefits, for example through improved forage plants, and will enable diversification through production of new products, particularly those with functional foods, nutriceutical and pharmaceutical applications. Genesis Research and Development Corporation [IP11] stated that genetic research would also have important flow-on effects to other parts of the economy by employing a highly skilled workforce, attracting foreign investment and generating valuable intellectual property. Genesis Research and Development considered also that "success in health technology can be extended into New Zealand primary industries to add value to commodity industries and to benefit the environment".[12]

23. Woven through many submissions was an affirmation of New Zealand's international research competitiveness. First, New Zealand is at the forefront of genetic research with animals. For instance, Mark O'Grady, chief executive officer presenting evidence on behalf of the New Zealand Wool Board [IP30], told us that:

> New Zealand has a head start in the area of the ovine or sheep genome, and currently has many of the world's preeminent scientists in this field. However, other countries and other

> research institutes overseas are beginning to realise the opportunities that lie dormant in this area. And, if we're slow to respond we'll rapidly lose the competitive advantage and head start that New Zealand currently has in this area.[13]

24. In addition to expertise in sheep and cattle genomics, New Zealand has a healthy animal population, free of many of the diseases found elsewhere. This makes it an attractive venue for animal industries, such as those that produce pharmaceuticals in milk.

25. Secondly, New Zealand has a skilled workforce that is also competitive in terms of the costs of research. As Dr Arie Guersen of Genesis Research and Development said under cross-examination:

> We can do research … cheaper here in New Zealand than … in the US or in Europe, and that makes it attractive for [our overseas partners] to invest in a company [in] New Zealand.[14]

Salaries for scientists are lower than overseas, and there are savings from such costs as healthcare that would be required in the United States.

26. Thus, a strong case was made about New Zealand's comparative advantages in science and the value of research to the New Zealand economy.

Educational benefits

27. Genetic research generates direct benefits in the education and "knowledge" sectors. The Universities of Auckland, Otago and Canterbury [IP7] pointed out the importance of staff having access to new technologies for the creation of new knowledge from research into biological systems, the development of experimental therapies for human disease and the development of new biotechnologies. Such access is part of attracting and retaining high quality staff in an international market, and ensuring high quality scientific education for students. They argued that it is important to educate students in genetic technology not only to develop the research capacity of New Zealand, but also to ensure that we have the expertise to manage genetic technology in such areas as medicine and border control.

Environmental benefits

28. Dr Gleeson discussed the contribution of genetic research to understanding the diversity of indigenous populations and to consequent decisions about protection of habitats and biodiversity. Landcare Research also pointed out the contribution of genetic modification research to other aspects of conservation biology, to pest control and to bioremediation.

29. Dr Andrew Pearce, Chief Executive for Landcare Research, considered that research leading to a genetically modified possum control agent "offered opportunities to avoid or mitigate environmental, health and trade risks arising from New Zealand's use of more than 90% of the world's consumption of 1080 to kill environmental pests".[15]

30. Dr Stephen Goldson, AgResearch's Science Leader of the Biocontrol and Biosecurity Group, stated:

> The use of genetically modified organisms for studies in taxonomy, ecology and insect pathology is essential for advancement of fundamental knowledge in ecology and biology. Genetically marked microbes allow studies to be carried out to a level of detail that was not previously possible, with a consequent increase in knowledge of ecosystem function. There is little uncertainty about such an outcome and it is likely that appropriate use of molecular biology and marked organisms will become an increasingly common part of laboratory practice. Such work provides a pathway to understanding that would be impossible without using genomic techniques.[16]

31. Dr Goldson said that his research was also aimed at improving the understanding of potential environmental risks associated with genetically modified organisms, such as horizontal gene transfer. This work also served to develop new general insights into ecological systems and new pest management systems.

Health benefits

32. Virtually all current medical uses of genetic modification can be classified as research. In medicine, research is an on-going process that involves the monitoring of product safety. Commercialisation of products and processes occurs at the point of moving to wider community-based research, such as that involved in epidemiology, rather than at the end of laboratory-based research. Among other things, epidemiologists study the statistical relationships between any new treatment and the development of unwanted or unexpected effects. This enables targeted research to verify whether an association of factors has a causal relationship. However the ultimate standard in medical research is a "double-blind, prospective, crossover trial" and until enough such trials are completed, medical researchers and the medical profession take a conservative approach to new developments.[17]

33. Various patient groups argued for the importance of gene technology in understanding medical conditions, and improving both diagnosis and treatment options. We heard from Genesis Research and Development and Malaghan Institute of Medical Research [IP10] about their work to create vaccines for asthma, psoriasis, tuberculosis and some solid cancers. These issues are explored further in chapter 9 (Medicine).

Concerns about research

34. Some submitters were not supportive of research involving genetic modification. In many cases their arguments were to do with aspects other than immediate physical safety. For example, Nga Wahine Tiaki o te Ao [IP64] argued:

> It is within the main principles of mauri, mana and w'akapapa that Maori raise their absolute disagreement regarding genetic engineering and modification. If these principles are damaged or tampered with in any way, thus upsetting the holistic world balance, so too will be the mauri, mana and w'akapapa of Maori and following generations.[18]

35. Koanga Gardens Trust [IP72] questioned the paradigm or the assumptions behind the use of science and in particular of genetic modification, and is:

> opposed to any continuation of any "Genetic Engineering" until such time as we see in place a real desire by all parties involved to honestly address the "paradigm" within which it will operate.[19]

36. For some the risks of such research are such that it should never be done, or at least not at this stage. For instance, Nelson GE Free Awareness Group [IP100] called for "a complete ban on Genetic Engineering trials and crop releases and a fully legislated moratorium".[20] Physicians and Scientists for Responsible Genetics New Zealand [IP107] called for a moratorium on the release of any genetically modified organisms into the environment and the incorporation of genetically modified organisms, their parts, processes and products into the food chain.[21]

37. Others were prepared for research to continue in containment, but were more concerned about field tests (trials) or release into the environment. Their main concern was the safety of the environment. For instance, the Golden Bay Organic Employment and Education Trust [IP104] considered there is an unacceptable risk once research moves outside a strictly defined, monitored and enforced laboratory environment. The Northland Conservation Board [IP68] specified a ban on all field trials or releases of crops, and Friends of the Earth (New Zealand) [IP78] called for:

> an immediate halt to the further development of GM medicines without proper research and controls; and the strict legislative containment of any research involving genetic modification to the laboratory.[22]

38. Physicians and Scientists for Responsible Genetics raised concerns about the safety of research in containment in connection with the disposal of genetic material. It argued that we still have significant gaps in our knowledge of the genome, and do not know which recombination activities could take place in the environment, saying that "Effects on the microbial flora of the environment are not adequately minimised under current procedures".[23]

39. Dr Robin Ord, a genetics consultant and law student, appearing for the Pesticide Action Network New Zealand [IP87], raised concern about the lack of monitoring for the escape of genetic material from containment, in his cross-examination of the New Zealand Plant Protection Society [IP36]. The society responded, to its knowledge, no work was being done in this area and it would support such work being undertaken. In his witness brief, Dr Ord mentioned that "New Zealand does not have regulatory structures in place or testing facilities to monitor or manufacture in containment".[24] In particular he was concerned with the issue of "scaling up" in commercial situations, "where a mutation may be amplified through PCR" to a far greater proportion of the end product than would occur in nature.

40. Research that moves beyond strict laboratory containment raised concerns about the environmental impacts of research involving genetically modified organisms. As discussed in chapter 4 (Environmental and health issues), under horizontal gene transfer and other topics, we agreed that more research is needed into the enviornmental risks that genetically modified crops and non-food uses might pose for the ecosystems into which they could be released.

41. We note the concern of some submitters about the use of antibiotic resistance genes as markers for selection of transgenic organisms.[25] This is discussed in chapter 4, paragraphs 23–28.

The regulation of research in New Zealand

The current regulatory environment

42. Two key pieces of legislation control genetic modification, genetically modified organisms, and associated environmental protection risks: the Hazardous Substances and New Organisms Act 1996 (HSNO) and the Biosecurity Act 1993. The purpose of HSNO 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. HSNO does not regulate or provide controls for genetically modified organisms once they have been approved for release into the environment.

43. Under HSNO (Low-Risk Genetic Modification) Regulations 1998, low-risk genetic modification work is carried out under PC1 or PC2 conditions as defined by the Australia/New Zealand Standard 2243.3, "Safety in Laboratories, Part 3: Microbiology". PC1 conditions deal with situations where there is low individual and community risk, and where the microorganism is unlikely to cause human, plant or animal disease (Category A). PC2 deals with situations where there is a

moderate individual risk and a limited community risk, and the microorganism may cause human, animal or plant disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment (Category B).

44. Higher levels of containment are also specified in this standard, and would be considered as part of any approval of research on higher risk organisms. In New Zealand there are few laboratories offering higher levels of containment (PC3 and PC4); these are designed to deal with organisms, genetically modified or otherwise, that are of known risk to health or the environment.

45. While some research involving whole organisms is able to proceed in strict containment, this is more difficult for other work. For instance, large transgenic animals such as sheep or cows can be genetically modified to produce a specific protein in their milk. The size and nature of such ruminants means that it is better for their welfare to be grazed in secure paddocks. As the following HSNO definition shows, such an experiment is a field test:

> "Field test" means, in relation to an organism, the carrying on of trials on the effects of the organism under conditions similar to those of the environment into which the organism is likely to be released, but from which the organism, or any heritable material arising from it, could be retrieved or destroyed at the end of the trials; and includes large-scale fermentation of microorganisms.

46. Field testing, as well as laboratory research, are both classified by HSNO as contained research:

> "Containment" means restricting an organism or substance to a secure location or facility to prevent escape; and includes, in respect of genetically modified organisms, field testing and large scale fermentation.

47. It is important to note that when an organism is defined as contained ERMA can impose controls in the form of obligations or restrictions controlling adverse effects on people or the environment.

48. To develop a genetically modified crop, it may be necessary to extend the research beyond laboratory containment to understand the effects of the new organism on the environment. Field tests enable research on the effect of the transgenic organisms on soil ecology in a semi-contained situation. Some aspects of effects on insects, including bees, can also be investigated. However the effects of a new genetically modified crop on the wider ecosystem may have to be studied in a wider controlled release situation. New genetically modified medicines or vaccines developed in the laboratory, such as the asthma vaccine described by the Malaghan Institute, will require controlled release when they move into clinical trials.

49. The Biosecurity Act 1993 provides mechanisms for the exclusion, eradication and management of pests and other unwanted organisms in New Zealand. New organisms, including genetically modified organisms, are considered as risk goods under the Act. New organisms that have containment approval from ERMA are "restricted organisms" and must be held in an approved containment facility. Laboratories registered for research requiring high levels of containment are audited by the Ministry of Agriculture and Forestry (MAF) for compliance with the Act.

50. Dr Iain Lamont, a Senior Lecturer in Biochemistry at the University of Otago, stated each registered research facility is audited six-monthly both internally by the institution and externally by MAF to ensure it complies with the Standard relevant to that facility. The Standard covers areas such as physical containment, work practices, training of users, waste disposal, and maintenance of the Register of Organisms where all genetically modified organisms must be recorded. Similarly we heard from Dr John Fraser, Professor of Molecular Medicine at the University of Auckland, who said:

> … containment facilities are established to ensure good on-going management, documentation and auditing systems for laboratories handling genetically modified organisms … It is not uncommon for the University of Auckland Biological Safety Committee [the University's IBSC] to impose extra controls on applicants to further reduce the possibility of aerosol generation or to ensure the security of facilities. These controls are over and above the two standard sets of controls imposed by ERMA.[26]

Regulatory and ethics bodies

51. ERMA is established under HSNO and is responsible for granting or refusing approval for:

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

52. Some of ERMA's tasks are carried out in cooperation with other agencies. ERMA and MAF have an agreement that recognises the role of MAF to manage the border control and quarantine issues regarding new organisms, while ERMA exercises the clearance or approval process for any new organism to enter the country.

53. ERMA and the Australia New Zealand Food Authority (ANZFA) have an agreement under which they agree 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 ANZFA. 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.

54. Under HSNO, ERMA is required to notify the Department of Conservation of applications for approval of new organisms. ERMA is required to have particular regard for any submissions made by the Department where an application is for approval to import, develop, field test or release a new organism.

55. Under HSNO, ERMA can delegate the power to assess applications for some low-risk new organisms. Most delegations are to research institutions such as universities and CRIs. As mentioned above, a delegated institution must establish an IBSC to assess applications for low-risk genetic modifications. IBSCs assess applications against HSNO and Regulations, advise on containment and procedures for all genetic modification work, and ensure applications involving human genes and animals have appropriate ethical consideration and approvals. Applications to IBSCs that are not low risk must be withdrawn or referred to ERMA for consideration. ERMA visits institutions with delegated authority to review the decisions and processes of their IBSCs. If any delegated institution does not comply with the rules of its delegation ERMA may withdraw the delegation.[27] This has happened in the past. The costs involved in losing and regaining their delegation provide institutions with an incentive to comply.

56. The Genetic Technology Advisory Group (GTAC) was established in 1996 as a sub-committee of the Health Research Council's (HRC) ethics committee. It reviews proposals involving the introduction of nucleic acids, genetically manipulated microorganisms, viruses or cells into human subjects for purpose of gene therapy or gene marking, their use to stimulate an immune response against the person's own cells, or the use of genetically modified vaccines to treat cancer.

57. The HRC's Standing Committee on Therapeutic Trials (SCOTT) is responsible for the assessment of the scientific validity and safety of clinical trials in accordance with the Medicines Act 1981. In particular, SCOTT considers aspects of a proposed clinical trial such as whether there is a control group, how the trial compares new with existing treatments, whether investigators have the ability to conduct the trial, whether they have recruited sufficient subjects, and drug toxicity. The most common problems with clinical trials identified by SCOTT are definitions of endpoints, inadequate compliance, and incomplete trial design or protocol preparation. The majority of applications reviewed by SCOTT are for clinical trials sponsored by the pharmaceutical industry.

58. SCOTT will only approve clinical trials once they have been approved by the appropriate ethics committee. All medical trials, whether or not involving genetically modified organisms or their products, and whether in the private or public arena, must be approved by SCOTT at each phase of the trial, before proceeding to the next phase.

59. In phase 1 trials all research is laboratory based. If New Zealand does not participate in phase 1 trials, we might forfeit involvement in the multi-centre phase 3 trials. In phase 2 the new treatment is tested on small numbers of affected patients. In phase 3 many more patients and healthy volunteers are involved. Often large numbers of patients may be required to identify rare adverse reactions to the new treatment. For this reason collaboration is initiated with large international companies and the phase 3 trial is carried out in countries with large populations such as the United States. In phase 4 trials commercial availability of the treatment is concurrent with continued wider research over a longer time frame. This is a form of conditional release. In general New Zealand patients cannot access the new treatment until the trial moves to multi-centre trials in phase 3 or wider monitoring in phase 4, and they may go overseas to access drugs and treatments still in phase 2 trials.

60. The HRC is the major government-funded agency responsible for purchasing and coordinating health research and fostering the health research workforce in New Zealand.[28] The HRC Ethics Committee (HRCEC), a statutory committee, requires that ethics approval must be obtained from an accredited ethics committee before HRC funding for any research proposal may commence. HRCEC considers and makes recommendations to the HRC on ethical issues in relation to health research, especially those emerging through the development of new areas. Where funding applications involve issues of national importance or great complexity, HRCEC makes an independent ethical assessment. HRCEC may delegate authority to accredited regional or local institutional ethics committees to review research funding applications.

61. These committees, which are usually defined in terms of their relationship to animal research or human research involvement, are accredited by HRCEC. A number of accredited regional health ethics committees and some institutional ethics committees have been granted delegated authority to review applications for HRC.

62. The Animal Welfare Act 1999 provides the basis for review of animal ethics. HRCEC has delegated authority to institutional animal ethics committees under guidelines set by the National Animal Ethics Advisory Committee (NAEAC). These committees provide ethical review of all funding applications that involve

animals or animal tissues. Committee membership includes a veterinarian and members of the public.

63. In mid-2000 ERMA discovered 191 experiments involving genetic modification that had not been authorised under HSNO. An audit revealed that all non-compliant projects were being conducted safely in containment and that the situation had arisen largely through a lack of awareness of the requirements of the new regulations.

64. Dr Basil Walker, Chief Executive of ERMA, discussed this event during his presentation to the Commission:

> The regulatory agency, ERMA, moved promptly and strongly to deal with the situation, with full support from the science institutions I should add, and the rude shock administered has not resulted in a single known instance of non-compliance since.
>
> Moreover, the investigations at the time showed that there wasn't a single instance of deliberate non-application of containment standards, and certainly no evidence of any release or breach of containment.[29]

Although understandably this event caused a great deal of disquiet, the Commission is satisfied that ERMA handled the situation appropriately.

Anomalies in the regulatory system for contained research

65. The Commission heard considerable evidence about the practicalities of working with HSNO, and its implications for research in New Zealand.

66. There was widespread agreement that HSNO provided a good framework for the regulation of genetic modification research, and that there was a continuing need for a rigorous process of assessment and approval as carried out by ERMA. For instance, the New Zealand Biotechnology Association [IP47] recognised:

> … that [ERMA] is the appropriate regulatory body to manage GMO developments in New Zealand, and that ERMA must administer a regulatory framework that considers the safety of researchers, the general populace and the environment.[30]

67. The main focus of submissions about ERMA related to the practicalities of working with the current regulatory processes. Strong views were expressed about the high and, in the view of many submitters, unnecessary compliance costs related to approval processes, problems with definitions and coverage of HSNO. Emeritus Professor George Petersen, speaking as the immediate past President of the Academy Council and of the Royal Society of New Zealand [IP77a], stated:

> The Society supports retaining statutory regulation of GM as an essential part of maintaining public confidence in the use of this technology. However, there is strong dissatisfaction among experimental biological scientists with the wording of the HSNO

> legislation, and the consequent constraints it imposes on laboratory-based research in New Zealand. The regulations devised to try to get around the deficiencies of the Act are not in accord with international practice and have placed New Zealand scientists at a disadvantage relative to their overseas counterparts, while other deficiencies of the legislation which cannot be remedied by regulation (eg the rules governing the importation of low-risk GMOs into containment) threaten to undermine international research collaborations.[31]

68. The Commission is aware that, in the United Kingdom, Australia and the United States, developments of genetically modified organisms that clearly meet PC1 criteria are exempt from requiring approval for development. In New Zealand, development of these organisms requires an application to the IBSC for approval. Many professional and research organisations[32] suggested that all low-risk research conducted at PC1 level be exempt from approval by either ERMA or an IBSC. These organisations pointed out that the containment laboratory in which the research is carried out must be registered and all containment laboratories are audited by MAF. There were also submissions that research at PC2 level should continue to be approved by the local IBSC.[33] The Royal Society of New Zealand [IP77a] defined the problem created by the numbers of novel microorganisms that are developed daily in containment laboratories:

> Because of the way HSNO defines a 'new organism', a scientist carrying out standard recombination experiments will continually create 'new organisms', each of which legally requires a separate application.[34]

69. The Malaghan Institute said:

> Development of low risk organisms should be exempt from the regulations and for other research, the regulations should be altered so that the research project rather than the specific organism is approved.[35]

70. The University of Otago also submitted that "applications to develop genetically-modified organisms in containment … be assessed on a project rather than organism basis"[36] and ERMA called for a change to the definition of a new organism from "species" to "type".[37]

71. The Commission agreed that some changes are necessary. While it is important that IBSCs continue to have the opportunity to alert researchers to the cultural and ethical issues in their research, it is also appropriate to reduce and streamline the approval processes where levels of risk are low. The Commission recognises the current anomalies in the regulatory systems for contained research to PC2 level.

Recommendation 6.1

that applications to develop genetically modified organisms in PC1 and PC2 containment be assessed by the Institutional Biological Safety Committees on a project rather than organism basis.

72. Professor Alison Stewart, an expert on fungal biocontrol agents from the Fungal Molecular Biology Laboratory at Lincoln University [IP8], expressed confidence in her witness brief in the current regulations, but pointed out to the Commission some anomalies in the regulations for containment facilities. The containment regulation AS/NZS 2243.3 was written originally for microbiological laboratories:

> The current containment regulations do not differentiate between classes of organisms eg mammals, plants, viruses, bacteria and fungi. As the aforementioned organisms have diverse methods of reproduction and dispersal, specific protocols need to be made for these in PC2 regulations. Small changes are therefore required, specifically where it relates to containment of different types of organisms.

73. Professor Stewart provided a specific example of this problem, citing an excerpt from AS/NZS 2243.3 Section 3.5.2 (g) which states "where the laboratory is provided with opening windows, flyscreens shall be fitted". She added that:

> Whilst the flyscreens will prevent insects accessing the laboratory it will not prevent the escape of fungal spores which are designed to be wind dispersed.[38]

74. The submission from Physicians and Scientists for Responsible Genetics supported Professor Stewart's claim that these regulations need to be reviewed in the light of the rapid development of this technology. Irrespective of amendments to HSNO arising from our recommendations, the Commission considers it is time to review these regulations.

Recommendation 6.2

that all approval forms, standards and regulations relating to the development of genetically modified organisms in containment be reviewed and updated.

75. In particular, there is currently a single application form (Form 3) for approval to develop in containment any genetically modified organism, which covers all research from PC1 to field test.

Recommendation 6.3

that a separate, simplified form be developed for low-risk (Categories A and B) applications to Institutional Biological Safety Committees.

76. It may be possible in the light of future guidelines developed by the Toi te Taiao : the Bioethics Council (we propose the establishment of this Council in chapter 14) for low-risk research in containment involving flora and fauna larger than microorganisms for approval by IBSCs to be in the form of retrospective audit of whether guidelines are being followed.

Importation versus development of genetically modified organisms in containment

77. The Malaghan Institute pointed out that currently there is no provision for a delegated authority (IBSC) to consider an application to import a transgenic mouse or a genetically modified microorganism into containment. However the IBSC may approve the development of the same organism in containment in New Zealand. The time and cost of applying to ERMA to gain approval for the importation of previously characterised genetically modified organisms may be greater than that of developing a similar organism here. Submitters argued that low-risk genetically modified organisms should be treated in the same way whether they are imported or developed. ERMA also considered that the delegations to IBSCs could be extended to cover importation of low-risk genetically modified organisms.

78. The University of Otago submission was concerned by the illogical nature of the current situation:

> At present, importation of organisms into containment must be approved by ERMA whereas development of the same organisms in containment in New Zealand can be delegated to IBSCs. This is clearly illogical as the level of risk associated with a genetically-modified organism must be the same wherever it is developed. Delegating to IBSCs the power to approve importation of low-risk genetically-modified organisms into containment, and exempting demonstrably low-risk organisms from requiring prior approval, would result in significant cost-savings both in terms of dollars (as there would be no ERMA processing fee) and time. Importation would still require a MAF importation permit and associated quarantine measures and, as part of this, the importing laboratory must be part of a registered containment facility.[39]

79. The New Zealand Association of Scientists [IP92] suggested "that both importation of GM organisms into physical containment and development of these organisms be handled by a single delegated authority".[40] Transgenic Animal Users strongly urged the Commission to recommend the relaxation of

the regulations for importation of transgenic animals, and their development in containment.

80. The Commission agrees that change is required.

Recommendation 6.4

that the Hazardous Substances and New Organisms Act 1996 be amended to allow for the efficient importation of low-risk genetically modified organisms, through delegation of the approval process to the Institutional Biological Safety Committees.

81. ERMA also pointed out that the "HSNO Act does not at present deal specifically with the holding or breeding of a genetically modified organism, once developed or imported".[41] They suggest that approvals to develop and import organisms should also cover holding and breeding. We agree.

Recommendation 6.5

that approvals to develop or import genetically modified organisms be deemed to cover their holding and breeding.

HSNO coverage of cell cultures

82. ERMA pointed out the difficulty with genetic modification of human cell cultures:

> It is unclear in HSNO whether genetic modification of human cells and related tissues is covered by the Act or not. It is evident that genetic modification of humans [and of human organs] is excluded, but the boundary of what should be covered is not clear. This can lead to situations where experiments involving, for example, monkey cells would be covered by HSNO, but the same experiments involving the equivalent human cells would not, yet these human cell experiments would not be covered by the Genetic Technology Advisory Committee or the HRC Ethics Committee either.[42]

83. We agree that research using human cell lines should not avoid oversight.

Recommendation 6.6

that the Hazardous Substances and New Organisms Act 1996 be amended to clarify that research involving genetic modification of human cell lines or tissue cultures is covered by the Act.

84. Another issue raised was the current approval processes for research involving genetically modified animal cell cultures or cell lines. The Biotechnology Association requested that, along with work requiring PC1

containment, work using animal cell culture lines be exempt from approval unless they harbour agents of sufficient toxicity to put laboratory workers at risk. It pointed out that:

> Animal cell culture lines do not survive outside of laboratories and do not regenerate to whole organisms ... Current good laboratory practice is such that all cell lines, whether genetically modified or not, should be handled in PC2 containment hoods to protect from the possibility of adventitious agents in the cultures. This handling procedure ensures that animal cell cultures are already contained.[43]

85. We agree that research with genetically modified animal cell cultures will normally be in category A regarding risk, while recognising that, because of the requirements for survival of the cell cultures, the work will often take place in PC2 facilities.

Recommendation 6.7

that approval for development of genetically modified animal cell lines be delegated to the Institutional Biological Safety Committees.

High-risk contained research and field tests

86. The Australia/New Zealand Standard 2243.3, "Safety in Laboratories, Part 3: Microbiology" defines the conditions required for working with hazardous organisms in PC3 and PC4 containment laboratories. These research facilities are audited by MAF, and genetic modification of high-risk organisms requires a full application to ERMA. The Commission did not hear of any problems associated with research involving genetic modification in PC3 and PC4 laboratories.

87. Many witnesses, although accepting the need for a rigorous regulatory process, argued that it is often appropriate and necessary to continue with research outside strict laboratory containment. Some research, such as that with large mammals, is logistically difficult in strict containment, and knowledge of environmental impacts can sometimes only be gained through field trials.

88. Field trials are an essential part of risk/benefit analysis prior to any release into the wider environment. Without field trials it is not possible to assess safety. ERMA has approved a number of field trials, including research with genetically modified sheep, cows, tamarillos, brassicas and pine trees. For further detail see chapter 7 (Crops and other field uses). As noted previously, this is still "containment" under the HSNO definitions. Trials have specified containment conditions. For instance, the animals are contained with double fencing or electric fencing and there are provisions for the avoidance of pollen release by removal of

reproductive structures from the pine trees. In addition, it is possible to tag the animals electronically to monitor their whereabouts.

89. Such work, it was argued, can be carried out safely, based on previous research and forms of biological containment. The safety of field trials and the adequacy of methods to contain risk, can be adequately assessed and dealt with through risk management programmes by ERMA. As noted in paragraph 45, any heritable material involved in a field test must be removable.

90. We heard from Dr Daniel Cohen of HortResearch that he was carrying out a field trial of transgenic tamarillos at HortResearch's Northland Research Station. We heard considerable public doubt about the adequacy of the containment of this trial.[44] The Commission considers that this public concern was justified.

91. In light of concerns that have arisen this year in connection with horizontal gene transfer (HGT) we consider that rigorous monitoring of field trials is essential and that all material associated with the trial must be removable from the site.

92. ERMA argued that:

> ... it would be helpful if HSNO permitted it to require, particularly for field trials, that the research be extended to encompass matters which might show the degree or type of risk which would have to be considered if there were a subsequent application to release the organism concerned; or which might identify risks and hazards that might eventuate in different field trials. The more knowledge available to the Authority and to applicants, the more likely are they to be able to eliminate uncertainties.[45]

93. In other words, ERMA recognised that field trials provide an opportunity for other work that will be required in future applications.

94. It is important to note that no one argued for completely unregulated research. Even the most enthusiastic supporters of genetic modification were clear that it was vital that research was conducted within a context of a robust regulatory framework, and that risks should be carefully managed.

95. There is additional discussion in chapters 7 and 9 of aspects of research beyond containment and the issues as they apply to release of genetically modified organisms and the use of genetic modification in health, including some aspects of research and innovative clinical practice, such as gene therapy.

Conditional release

96. ERMA and other submitters[46] asked that HSNO be amended to provide for a further class of approval between development and import of genetically

modified organisms in containment, and release. Under the current provisions of the Act, release is defined as full release with no restrictions or controls other than those provided for under the Biosecurity and Conservation Acts.

97. The submission from New Zealand Vegetable and Potato Growers' Federation/New Zealand Fruitgrowers' Federation/New Zealand Berryfruit Growers' Federation [IP75] stated:

> We believe the current regulatory processes of ERMA need to be extended to include provision for post approval monitoring and control of GM Organisms to be implemented and enforced. Whether post release monitoring or control is required at all and the degree of post release monitoring and control should be decided as part of the ERMA case-by-case consideration of applications for trial and release.[47]

98. Dr Lin Roberts, an ecologist, director of Business and Environment Consultants and former manager at the Ministry for the Environment [IP101], said under cross-examination:

> What I … think … we were missing at that time [the stage of first applications to ERMA], was other types of controls. And, I think, in the context of hindsight, the ability to have monitoring and research controls, … that allowed us to gain knowledge from the releases that were made, and also things like risk to other farmers in terms of spread of GM pollen, for instance, being a problem for those who wanted to keep their crops GM-free.[48]

99. ERMA identified this as a weakness in the Act, since applications may only be approved or declined and ERMA has no ability to set controls or conditions on releases. Some examples ERMA provided of situations where such an ability might be used were:

- to enable the progress of the release to be monitored, which may include the spread of the organism, the incidence of adverse effects and the effectiveness of any "controls" set in place
- in the case of animals released for farming, the separation of these animals to prevent interbreeding
- in the case of crops, limitations on the location and extent of plantings.

100. The Commission supports the addition of a class of approval for release with conditions or controls, after a contained field test. This would allow ERMA to impose conditions on the release, which might include the number of organisms released, the location and extent of the release and the auditing of environmental or health impacts. Conditional release would be analogous to the clinical trials that have been part of medical research for decades.

Recommendation 6.8

that the Hazardous Substances and New Organisms Act 1996 be amended to provide for a further level of approval called conditional release.

The rapidly evolving research environment

101. ERMA pointed out that the Act is currently structured in a very prescriptive manner, which has not always anticipated technological developments:

> The boundaries are being perpetually pushed. As one result of this ERMA New Zealand is compelled to invest considerable time and effort in the interpretation of the Act, in order to accommodate technological change within a framework which did not contemplate such changes.[49]

102. Techniques used in mammalian cloning such as nuclear transfer and cell fusion are examples where new technologies have had rapid uptake. ERMA also said that while "the potential risks from such techniques are similar to risks from modifications that are covered by the Act",[50] currently this work falls outside the legislation. However, these techniques could provide a means by which new organisms could be created. In our view, this is clearly an area which should be covered by ERMA, and we recommend that the Act be amended to achieve this.

Recommendation 6.9

that the Hazardous Substances and New Organisms Act 1996 be amended to cover procedures used in mammalian cloning, such as nuclear transfer or cell fusion.

103. The New Zealand National Commission for UNESCO [IP90] pointed out it was important for any future legislation dealing with the genetic modification of humans or the use of human embryonic cells (for example, the Human Assisted Reproductive Technology Bill and the Assisted Human Reproduction Bill both currently before the House) to be consistent with HSNO and any existing ethical and safety requirements for genetic research.

104. It is likely that as research further expands our knowledge, additional areas not clearly covered by HSNO will emerge. It is also possible developments will emerge falling outside any of the current regulatory structures.

105. Thus, structures and procedures should be put in place anticipating some of those changes, identifying gaps, and responding appropriately to developments. In chapter 14 (The biotechnology century), we propose the appointment of a Parliamentary Commissioner on Biotechnology, one of whose functions will be to monitor developments in biotechnology and provide recommendations.

Ethical and cultural issues

106. A number of researchers discussed the ethical review of research, and the Health Research Council [IP27] provided evidence of the requirements for review of research involving human participants and the use of their tissue.

107. We heard nothing that made us question the adequacy of the current ethics committee structures for the work that they do. Indeed, we heard evidence that there is an insistence for rigorous ethical review and appropriate consultation. For instance, Dr Garth Cooper, Professor of Biochemistry and Clinical Biochemistry at the University of Auckland, who also identified himself as a member of Te ORA (the Maori doctors' organisation), said:

> My experience in this area has to do with the cloning and sequencing of the genes from Maori themselves. And, in that area there are regulations … that govern ethical research within the country. And so, for example, one has to get permission from the RHA Ethics Committees, again through the standard procedures, and then in addition to that the Ethics Committee has an expectation that you will undertake and have evidence of having undertaken appropriate consultation with the iwi groups on whom … that type of work is to be performed.[51]

108. However, there are two areas of concern additional to the work of ethics committees requiring more attention: consideration of cultural issues that fall outside their domain, and provision for generic policy decisions.

109. Some Maori cultural issues are not considered by ethics committees, including those arising in areas of research such as transgenics and the use of indigenous flora and fauna.

110. We were made aware that some research had proceeded without appropriate consultation with local iwi. For instance, Bevan Tipene Matua (Ngai Tahu, Kahungunu) told us at the Christchurch hui that the delegation of approval of low-risk genetic modification research to IBSCs:

> … resulted in the last two years in GM work on the kokako, the saddle back, the tuatara, pipi, kuku, tio, toheroa, a native gecko, tuere, tuangi and others. Those are the ones we know about … only two of those we knew about before they even went through. We found out … about six months after they were approved. [52]

111. In his judgment in the *Bleakley* case[53] (discussed in chapter 11: Te Tiriti o Waitangi), Justice McGechan noted that the application to the IBSC for (delegated) approval of the initial creation and storage of the genetically modified embryos did not require public notification. The Judge described this as "a quirk of the legislation".

112. It would be superfluous and add unnecessary expense and delay to require every low-risk application to be publicly notified. However, IBSCs should be alert to applications having the potential to cause concern or offence on cultural or ethical grounds, which will require appropriate consultation notwithstanding the absence of significant physical risk.

113. Dr Mere Roberts, Associate Dean (Maori), Faculty of Science, University of Auckland, appearing for Nga Kaihautu Tikanga Taiao, the Maori advisory committee of ERMA, discussed these difficulties, emphasising the need to develop consultation mechanisms. She suggested:

> … that all research institutions should be encouraged to set up a consultative committee to develop long-term relationships with Maori and to engage in constructive dialogue on research issues of concern to Maori. I believe this is an area much broader than that of solely genetic engineering. There is not enough consultation between scientists and the Maori community, and I don't believe our institutions do enough to deal with that.[54]

114. She acknowledged the need to develop models that address those situations where national consultation is required, and where different iwi may expect to be included in consultation.

115. The timing of that consultation is also important. Often low-risk research is lodged under the rapid assessment procedure, and the researcher may leave consultation until after the application has been lodged, when insufficient time is available. Dr Roberts stated:

> I think the emphasis I want to make here, is that scientists must be encouraged to engage in this dialogue before they lodge the application, and if it takes them two years to walk up and down the country and talk to every hapu, so be it.[55]

116. We agree it is important that scientists engage in this dialogue before they lodge an application. But we also think it is in everyone's interest to find more effective ways to carry out the consultation. If the costs, in time and money, of consultation are too high, scientists will move the focus of their research away from areas, such as conservation genetics, that are of interest to Maori and the wider community. Indeed, scientists may leave the country for less restrictive work conditions. If for Maori the difficulties of consultation are too great, they will be unable to respond quickly or authoritatively.

117. Work in this area has begun. In addition to the initiatives of Nga Kaihautu Tikanga Taiao, some research institutions have taken steps to create better relationships with Maori communities and to develop appropriate mechanisms for consultation. These steps can both resource Maori for the demands of c onsultation with researchers, and better manage the workload of researchers developing the

research. For instance, Dr Ian Smith, Deputy Vice-Chancellor, presenting evidence for the University of Otago, told us:

> … the way that the University is doing this to facilitate the consultation is … to pay to Ngai Tahu enough money for them to devote a full half time position from a person to work with the senior members of the iwi who have to be consulted to make the decision. And I think that that work load is one of the major issues, and I think that often the consultation work load, or the scientists feel that it's a lot of work for them, I think they sometimes need to remember that there might be 70 applications, and so the people sitting on the other side of the table have at times as much work to do in the consultation. So, we made the decision to allocate some money from our research budget towards this process in the hope of building a long-term relationship with the two-way understanding, which will make it more efficient.[56]

This relationship seems to work, as we heard from tangata whenua and the Maori representative at the Dunedin regional hui held at Otakou kaik.

118. The resource issue was also recognised by Dr Andrew Pratt, the Chair of the University of Canterbury's IBSC, who told us when speaking as a witness for the University:

> … Maori are not resourced to deal with these issues, they don't have financial support to deal with their responsibilities of – under consultation, they're working out of good faith, … We believe that the resource issue has not been properly addressed … there's an ad hoc development of policy which in several years time will evolve in a reasonable policy …[57]

119. The resourcing of Maori to be able to contribute this expertise to the approval process extends beyond the immediate costs. We also became aware of the need to resource the training of more Maori so that they will have not only cultural but also scientific expertise to contribute to the process.

120. We note that the authority delegated by ERMA to IBSCs requires that they carry out ERMA's responsibilities to consult with Maori with manawhenua. It is important that IBSCs understand the nature and extent of the consultation required, and indeed ERMA should not delegate to IBSCs unless it is satisfied that the IBSC has the capacity to consult appropriately.

121. Dr Oliver Sutherland, Deputy Chair of ERMA, told the Commission as a witness for ERMA that "in the middle of last year we required any IBSC that was dealing with native species, transgenic work with native species, to include a Maori member from the local iwi on that IBSC". The Commission is aware that not all IBSCs currently have Maori membership. This may raise questions about how they consult Maori over applications. A further issue is that of ensuring consultation is carried out with Maori who have manawhenua for an area, and have the mandate

to speak on behalf of the relevant Maori community. We refered to these matters in more detail in chapter 3 (Cultural, ethical and spiritual issues).

122. We are of the view that local IBSCs, with their delegated authority from ERMA, are responsible for advising researchers when consultation is required. In addition, it is important that research institutions both understand the resource requirements on local communities with whom they consult, and take responsibility to develop the relationships between the research institution and those communities. We discuss an appropriate model of consultation in chapter 11 (Te Tiriti o Waitangi).

Recommendation 6.10

that Institutional Biological Safety Committees include at least one Maori member, appointed on the nomination of the hapu or iwi with manawhenua in the locality affected by an application.

123. During our deliberations it became clear that some cultural and ethical decisions needed to be addressed at a generic level, rather than on the case-by-case approach currently taken by ethics committees. Examples are germ line gene therapy, and the use of human genes in animals.

124. To this end, as mentioned earlier, we are proposing the establishment of Toi te Taiao : the Bioethics Council to which issues can be referred by ethics committees, ERMA or Government. We discuss this further in chapter 14 (The biotechnology century: three major proposals).

Research funding

125. In New Zealand research funding is a combination of public funding and private investment. In the 2000/2001 Budget, Government allocated $474 million to research. The principal distributors were:

- $383 million: Foundation for Research, Science and Technology (FRST) [IP21]
- $26 million: Marsden Fund, Royal Society of New Zealand
- $40 million: Health Research Council.

126. In its submission, FRST estimated that of the $383 million it allocates, $130–135 million (approximately 35%) is invested in research directly involving genetic modification technology. HRC estimated that $16 million (40%) of its allocation was assigned to research involving the use of genetic technologies.

127. Of the $383 million allocated by FRST, key areas of expenditure relevant to the work of the Commission identified were:

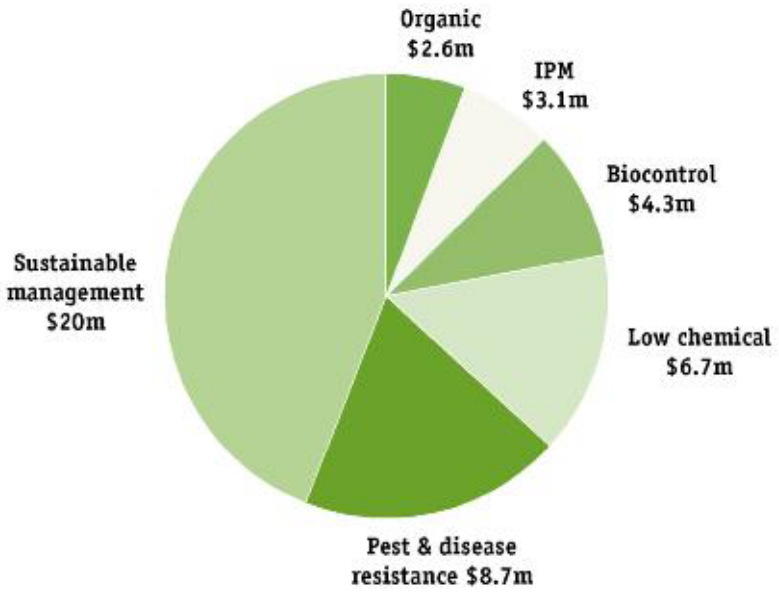
- $171 million: research for industry to improve competitiveness
- $51 million: New Economy Research Fund for leading-edge research capability to underpin new and emerging industries and enterprises
- $84 million: environmental research.

128. The Commission received no evidence about the amount of private research investment involving genetic modification.

129. When asked to compare their research funding allocation to genetic modification as compared with the organic industry, FRST estimated that its expenditure of $214 million on biologically related funding was assigned as follows:

- $35 million for research where genetic modification is a key technique
- $95 million may use gene technology tools
- $45 million for organic industry outcomes.

130. The $45 million is described in the following chart based on information supplied by FRST.



131. FRST made the point that clear differentiations are not possible because much research underpins more than one production system. Research in sustainable management, for example, benefits conventional as well as organic farmers. Pest control is likewise of benefit to all production systems. The point was also made that differentials in the dollar amounts allocated do not necessarily mean one industry is valued more than another. Industries vary according to size, and research in some areas carries greater costs than in others.

132. Some submitters expressed the view that there is a need for greater investment in research in New Zealand, and/or a redistribution of the funds available to provide greater emphasis and support to some areas of research. In addition to the need for research to support societal needs for knowledge, greater investment in research and a stable regulatory environment are necessary to attract and retain high quality staff.

Compliance costs

133. There was a strong view among researchers and companies that the current ERMA processes result in unnecessary and burdensome compliance costs for low risk areas of research, and that the approval process ought to differentiate between low-risk and high-risk genetic research.

134. For instance, the Biotechnology Association said:

> The process required regarding the release of GM organisms or products is appropriate, but for routine containment the science involved does not warrant the justifications required. … The present cost structure for university laboratories is not sustainable. In some instances research projects have been changed because the compliance cost to ERMA is more than the grant received from the government to do the work.[58]

135. Dr Pratt described the current situation as unworkable:

> It is inordinately difficult to do some of this work here because of the nature of the regulations. In fact, it's easier to go overseas and perform the research overseas and return to New Zealand and pay all the attendant costs, than to go through the regulatory compliance. Because even for experiments that overseas would require no formal risk assessment, it's cheaper to go to America where the regulations accept that the proposed experiments are of negligible risk. To do the experiments in America and then return here – and in fact that type of activity is already ongoing – it's a huge disincentive and we would contend it's a misuse of resources.[59]

136. Genesis Research and Development submitted:

> … that the regulations for control of every experimental GMO made in … a containment facility be amended to decrease the bureaucratic load on scientists and that the oversight of laboratories as containment facilities be rigorously monitored.[60]

137. The University of Canterbury was of the view that HSNO had led to an overly regulated environment for low-risk work, which established serious disincentives to biological research without improving safety. The New Zealand Forest Research Institute [IP2] agreed with this view and in addition thought that the cost of compliance with HSNO needed to be budgeted into the funding portfolios related to FRST-funded projects.

138. Federated Farmers of New Zealand [IP34] expressed the view that the high costs of the ERMA process could provide perverse incentives for people to import organisms illegally. They cited the recent New Zealand experience of biosecurity breach by illegal importation of the rabbit calicivirus.

139. MAF agreed the cost of compliance had been a key driver in recent reviews of regulatory regimes they administered. MAF submitted that:

> New Zealand's isolation and border control activities ensure one of the world's highest levels of biosecurity protection, but the border is not impenetrable. While it is illegal to import unapproved GM organisms into the country, border control alone could not prevent accidental or deliberate introductions of GM organisms. MAF could take actions under the Biosecurity Act to manage any GM organisms that were declared to be 'unwanted organisms'. [61]

Recommendation 6.11

that the funders of research portfolios be resourced to include the costs of compliance with the Hazardous Substances and New Organisms Act 1996.

140. Together with recommendations earlier in this chapter, this should have the effect of reducing compliance costs for contained research.

Priorities for funding

141. The Commission identified particular areas of research as in need of greater research investment. These were the environmental impacts of genetically modified plants (including the nature and extent of horizontal gene transfer), organic and integrated pest management methods of sustainable agriculture, and the social, cultural and ethical aspects of genetic modification.

Environmental effects

142. Little is yet known about the environmental impacts of genetically modified organisms, and in particular in New Zealand "on the potential adverse effects, or risks of such effects, on the indigenous biota".[62] Landcare Research reported on two small studies it has underway, and AgResearch has established a Public Good

Science Fund programme entitled Environmental Impacts of New Technologies. While FRST had called for tenders for work in this area, Landcare Research:

> … believe that this level of funding [for environmental impact research] is inadequate for researching such risks. It is far below the levels of funding invested in other risks to indigenous biota such as vertebrate pests ($6.8 million), invasive weeds ($2.7 million), or invasive invertebrates and microbes ($2.6 million). Landcare Research believes that a significantly greater investment is required in research to assess the risks of adverse effects on indigenous biota from GM crops and other GM products released into the environment.[63]

143. Others affirmed the importance of funding such research. For instance, Dr Stephen Goldson, for AgResearch, argued that such research would benefit the public through increased understanding of the activity of genetically modified organisms. Referring to such research taking place in the laboratory, he suggested:

> such work would alert the public and commercial companies to any potentially damaging impacts of GMOs before expensive development costs are incurred and field releases take place. Only opportunists seeking rapid returns from untested technologies would be disadvantaged.[64]

144. There is a particular and specific need for further research to be carried out on horizontal gene transfer. While it is established that pathways exist for gene transfer between species, it is not known under what conditions gene flow occurs and with what possible impacts. We heard evidence of some research in this area, but there are some significant gaps in knowledge on which to base risk assessments for field trials or release of genetically modified organisms. As Dr Jack Heinemann, an expert in horizontal gene transfer from the University of Canterbury, said under cross-examination:

> … the current state of events or affairs with horizontal gene transfer is that it's a very interesting natural phenomenon we have to follow. We're informed by doing this kind of work, but gene transfer itself is not risk. It's a natural process. What we have to understand is whether or not there will be a risk from a recombinant event.[65]

145. While international research will increase our knowledge in this area, there is also a need for research specific to the New Zealand environment.

Recommendation 6.12

that the Environmental Risk Management Authority require research on environmental impacts on soil and ecosystems before release of genetically modified crops is approved.

Organics and sustainable agriculture

146. Several submitters called for more funding for research into organics and sustainable agriculture. For example, the Green Party of Aotearoa/New Zealand [IP83] in its written submission said:

> New Zealand should increase science funding and capacity building in areas of research that will support organic production, sustainable land management and fundamental understanding of ecosystems, both natural and farmed.[66]

147. We also heard concern about the distribution of public research funding across different areas of work, and that research involving genetic modification may be getting an inappropriately high level of support, to the detriment of other important areas which are also of economic and environmental importance.

148. For instance, Seager Mason, the Chief Organic Certification Inspector for BIO-GRO New Zealand [IP58], said:

> We would dearly love some percentage, 50% even would be lovely, for organic research … [of] research monies that are being put into genetic engineering.[67]

149. New Zealand Worm Federation [IP94] asked that "the New Zealand government spend as much money on organic agricultural research as that on agricultural genetic modification research".[68]

Recommendation 6.13

that public research funding be allocated to ensure organic and other sustainable agricultural systems are adequately supported.

Social science and research

150. There was a call for further economic research. As the Organic Product Exporters Group [IP53] wrote:

> There has been only a modest amount of research investigating potential negative economic impacts on other sectors like organics, Integrated Pest Management (IPM) systems (like KiwiGreen which reject the use of GM technologies), conventional producers not using GMOs, or other sectors like tourism. The negative impacts that might be felt by other industries need to be matched against the potential economic gains from GMOs.[69]

151. The New Zealand Catholic Bishops' Conference [IP38] linked the need for economic research with any balancing of individual rights and the common good:

> The extent of individual rights in relation to the common good cannot be determined without sound and neutral research to resolve competing claims about the effects on the New Zealand economy of allowing or not allowing the use of GM.[70]

152. There was also a call for more research into the social effect and acceptability of genetically modified organisms, and the ethical, moral and spiritual issues that arise at the interface between science and society. There were two aspects to this. For instance, SAFE (Save Animals From Exploitation) [IP85] maintained that:

> There is a widening gap between society's technological gains and the gains of ethical science (understanding/practical wisdom). This is related to the fact that 'hard sciences' like biotechnology are significantly funded by commercial interests and government research funding, whereas social sciences are not.[71]

153. Landcare Research, which is mainly publicly funded, added:

> Social research is invaluable in defining some of the uncertainties about the likely use of particular GM products, and hence the specifications that a GM product will need to meet. We strongly believe that ongoing research on attitudes, social learning and public acceptance will be essential.[72]

154. ERMA pointed out that:

> … if the question of the "acceptability" of genetic modification is considered to be important, it is essential that more is known about how our society forms those types of judgementsand how acceptability can be measured. That requires properly designed and targeted research.[73]

155. While FRST has had one tender for work in this area, AgResearch submitted that more funding is required for work that "is clearly in the public interest and in the interest of industry supply chains delivering products to consumers".[74]

156. We also heard calls for research on the bioethics of genetic modification. For instance, the Catholic Bishops' Conference wrote:

> Sufficient resources need to be provided for research and teaching in bioethics and similar disciplines, to allow them to contribute more fully to the debate about new biotechnology.[75]

157. Research involving genetic modification is one area that requires support, but it is not the only one, and funding decisions need to address the total social and economic context.

Recommendation 6.14

that public research funding portfolios be resourced to include research on the socio-economic and ethical impacts of the release of genetically modified organisms.