Submission to the Royal Commission on Genetic Modification

Ministry of Agriculture and Forestry
November 2000

1. Executive Summary

MAF's regulatory roles

1. The Ministry of Agriculture and Forestry (MAF) was created in 1998 by merging the Ministry of Agriculture with the Ministry of Forestry. MAF exists to create opportunity for, and manage risk to, New Zealand and the food, fibre, forestry and associated industries. This encompasses economic, social and environmental goals. For example, MAF aims to improve the profitability of land-based industries, maintain vibrant rural communities, and protect New Zealand from unwanted pests. MAF's key roles are:
   - to provide policy advice on the trading environment, sustainable resources use and the regulation of product safety, biosecurity and related matters;
   - to administer the regulation of product safety, biosecurity and related matters; and
   - to provide services where government needs to be the provider.
2. MAF has statutory responsibilities for:
   - preventing unauthorised organisms (including GM organisms) from entering the country, whether they are being imported or they are associated with other imported goods;
   - preventing non-living material that could pose a risk to animals or plants in New Zealand (e.g. stockfeeds) from entering the country (if there is a human health concern then the New Zealand Customs Service stops the product at the border and waits for advice on further action from the Ministry of Health);
   - enforcing any controls set for the importation, development or field-testing of organisms (including GM organisms) in containment, and standards for containment facilities;
   - certifying that agriculture and forestry exports have met certain standards;
   - ensuring domestic food safety for animal products and dairy;
   - regulating agricultural chemicals and stockfeeds; and
   - overseeing animal welfare including codes of ethical conduct for research involving animals.

   MAF is the New Zealand contact point for the Codex Alimentarius Commission, which sets international food standards to protect consumer health and ensure fair trade practices, and the World Trade Organisation's Committee on Sanitary and Phytosanitary Measures.
3. It is critical for primary producers that consumers have confidence in the safety of their products. Confidence in the integrity and reputation of New Zealand's regulatory processes underpin our access to many overseas markets. It is also important to protect health and safety for the living and working environments of people in those sectors.
4. It is impossible to have a perfect understanding of every situation and the amount of variation that exists. Like all other technologies, it is almost certain that genetic modification will have unforeseeable social, environmental or economic impacts. Current regulatory systems provide mechanisms for weighing up the risks and benefits of new technologies. In its regulatory activities, MAF uses risk management within limits set by the government, rather than attempting to eliminate all risks. MAF is careful to recommend actions that are known to deal with expected variations and confidently reduce risks to at least the levels desired.

5. This submission distinguishes between genetically modified (GM) organisms and genetically modified (GM) products because they are treated differently by legislation.
   - GM organisms are organisms produced by genetic modification, e.g. GM soybeans.
   - GM products include every medicinal, commercial, chemical, and food product that (while not itself capable of replicating genetic material) is derived from, or is likely to be derived from, genetic modification. Both flour and oil from GM soybeans are GM products, but the oil usually contains no modified DNA or novel proteins because they are removed during processing.

Context

6. Agriculture, horticulture and forestry are vitally important to New Zealand's economy, society and environment. They account for about 15 percent of New Zealand's gross domestic product, employ roughly 13 percent of the total labour force, and make up around 63 percent of the value of all merchandise exports. Assets in these industries represent the second-largest group of Maori-owned assets, and they make a large contribution to the economic, social and cultural welfare of Maori. The competitiveness of our land-based industries affects the whole economy, and since almost 60 percent of New Zealand's land area is occupied by farm land or plantation forest, they also have an important impact on the environment.
7. Gene technology is being rapidly developed and implemented in agriculture, horticulture and forestry around the world. There are large quantities of commercial GM crops grown in the USA, Argentina and Canada, with smaller quantities grown in several other countries. Development of second and third generation GM crops, offering benefits to consumers or new traits not seen before in primary production, has already begun.
8. Currently, all commercial agriculture, horticulture and forestry in New Zealand is non-GM but genetic modification is an important research tool for understanding how plants, trees and animals grow. Since 1988 there have been over 50 approvals for field trials of GM organisms including GM crops, trees and animals. There have been no applications or approvals to release any GM organisms into the environment in New Zealand.

Issues

9. There are some **issues and gaps in the existing regulatory system**, including:
   - the legislation covering new organisms does not recognise the capacity for post-release controls under legislation administered by MAF;
   - ethical approvals are not required for research on animal foetuses less than halfway through term; and
   - stockfeeds that are GM products may not require safety assessments because there is no risk factor specific to genetic modification that would trigger the requirements.
10. New Zealand enjoys one of the **highest levels of biosecurity protection** available anywhere in the world, but it is not perfect. Some factors will be beyond New Zealand's control. 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. The experience with rabbit calicivirus highlighted the difficulty of preventing a deliberate introduction of an organism.
11. Genetic modification, like other breeding processes, **may have environmental risks and benefits** and many of the concerns raised about GM plants also apply to other technologies. For example, herbicide resistant crops have been produced using conventional breeding. These risks and benefits are considered when assessing whether or not to release GM organisms into

New Zealand. Since 1992, MAF has been involved in research into biological control of possums that includes the possibility of using genetic modification.

12. The decision-making processes for genetic modification in New Zealand will have to **balance conflicting ethical views and perceptions of risk**. In the absence of a clear consensus for these issues, it will be difficult to know how to balance them against scientific evidence while at the same time maintaining consistency.

13. New Zealand's primary industries rely on access to overseas markets. Access depends on **operating within the trading framework** provided by multilateral and bilateral commitments of New Zealand and its trading partners. New Zealand gains significant benefits from these trade commitments, particularly those that require risk assessments to be scientific and barriers to be the least trade restrictive possible. New Zealand's regulatory processes are highly regarded and play an important role in our trading relationships. New Zealand's regulatory regime for genetic modification may have implications for our trading relationships.

14. Around 90 percent of New Zealand's agricultural produce and 70 percent of forestry production is exported so external consumer demands and regulatory requirements will play a major role in the profitability of these sectors. **There are likely to be opportunities in both GM and non-GM markets**. New Zealand could be seriously disadvantaged if its producers were locked out of a technology (GM or non-GM) that provided significant opportunities in the future.

15. **It will be critical to examine the extent to which GM and non-GM production can coexist in New Zealand.** This will depend, to a large extent, on consumer confidence in the integrity of non-GM supplies and the separation of products. Pollination of non-GM crops by GM crops would not be an issue for crops of different species (e.g. GM corn and non-GM apples). For crops of the same species, different production and processing systems already coexist in New Zealand, particularly for market access to countries with different requirements. Buffer zones or separation could minimise cross-pollination, and a number of emerging technologies could potentially help to biologically isolate particular crops. A zero tolerance for unavoidable mixing would make it very difficult for both systems to coexist.

Conclusion

16. MAF believes that it is important that the agriculture, horticulture and forestry sectors have access to the latest technology in order to remain internationally competitive. Gene technology is being rapidly developed and implemented around the world, and presents opportunities and risks that will need to be evaluated on a case-by-case basis. Those who could benefit from its application should have the choice to use it where it does not adversely affect others.

17. 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'.

2. Context

Agriculture, horticulture and forestry make a significant contribution to New Zealand's economy, environment and society, including to Maori development

(relevant to issue k of the Warrant)

18. New Zealand's gross domestic product for the year ended March 2000 was estimated to be $104 billion. Of this, the land-based sectors together with first-stage processing contributed 15 percent. This compares with a 14 percent contribution from finance, insurance, business services and real estate, and a 13 percent contribution from wholesale and retail trade. In the medium term, MAF expects that the proportion of the land-based sectors' contribution to GDP will rise through improved productivity and competitiveness.

19. Almost 60 percent of New Zealand's total land area is occupied by farm land or plantation forest. Therefore it is essential to consider the role of agriculture and forestry in any issue that affects New Zealand's physical environment.

20. An estimated 115,000 people are employed on farms, with another 100,000 people directly employed in servicing agriculture, either at the input stage or in processing agricultural products. An estimated 9000 people are directly employed in forestry and logging. The processing of forestry products through sawmills, panel products plants, and pulp and paper manufacture employs another 16,000 people. Overall, the agriculture and forestry sectors together with first-stage processing employ about 240,000 persons or 13 percent of the estimated total labour force. Given the nature of these industries, those employed have a wide range of skill levels, and many of them work and live outside the main urban areas.

21. Maori-owned agriculture, horticulture and forestry assets are estimated to be the second-largest group of Maori-owned assets[1]. These land-based assets make a large contribution to Maori economic, social and cultural welfare. The 1996 census showed that 12,798 Maori were employed in agriculture, horticulture and services to agriculture, making up 9.4 percent of the workforce in this sector. A further 7,545 Maori were employed in forestry and related industries, comprising 22.6 percent of the forestry sector workforce[2].

22. Agriculture and forestry generate more export receipts than any other sector of the economy – $15.6 billion or 63 percent of New Zealand's total merchandise exports in the year to June 2000. Pastoral-based exports made up $10.4 billion (42 percent). Meat, wool and meat by-products were valued at $4.34 billion with dairy products (excluding casein) worth $3.97 billion. Forestry products were valued at $3.11 billion or 13 percent of total exports for the year to June 2000.

23. Currently, all of New Zealand's agricultural, horticultural and forestry output is non-GM. Certified organic exports earned more than $60 million in 1999-2000 (roughly 0.5 percent of agriculture-based export revenue). This value is expected to rise in the immediate future[3].

24. New Zealand has a history of outstanding scientific research that has underpinned our success in agriculture, horticulture and forestry. Innovation is essential for maintaining our competitive advantage in these industries. New Zealand's scientists and research institutes have an excellent international reputation, backed up by an impressive record in developing new products and bringing them to the market.

---

[1] Rose et al., *The nature and extent of the Maori economic base*, Business and Economic Research Ltd, 1997
[2] Te Puni Kokiri, *Maori in the New Zealand Economy*, 1999
[3] Organic Products Exporters Group, *OPEG member survey 1999-2000*, August 2000

25. Consumer acceptance of new food technologies can be slow and take decades. The pasteurisation of milk was strongly opposed when introduced but is now recognised as an important safety measure in many countries. Margarine is an example of a novel food that took many years to be widely accepted by consumers in the US.

Genetically modified crops have been rapidly adopted by farmers in some overseas countries but genetic modification is mainly used as a research tool in New Zealand

International developments in commercial releases of GM organisms

(relevant to issues h, k, l of the Warrant)

26. China was the first country to commercially grow GM crops in the early 1990s and GM foods have been available to consumers in the USA since 1994. However, widespread commercial plantings of GM soybean and corn commodity crops first occurred in the USA in 1996. In 1999, close to 40 million hectares (an area approximately 1.5 times the size of New Zealand) of GM crops were grown in 12 countries. Most of this area was in the USA (72 percent), Argentina (17 percent) and Canada (10 percent), with minor plantings (<0.1 million ha) in China, Australia, South Africa, Mexico, Spain, France, Portugal, Romania and the Ukraine[4]. The crops planted include soybean, corn, cotton, canola, potato, squash and papaya that have mostly been genetically modified for herbicide tolerance or insect resistance. These modifications aim to reduce production costs for farmers and provide alternative production methods that may have less adverse effects on the environment.

27. GM crops have been adopted by US farmers at very high rates, claimed by some to be the highest rate for any new technology adopted by agricultural industry standards[5]. US farmers are this year expected to plant 54 percent of soybeans, 25 percent of corn, and 61 percent of cotton with GM varieties[6]. Only the acreage for corn is estimated to be less than in 1999 (down 12 percent) with increases expected for soybeans (up 7 percent) and cotton (up 13 percent).

28. MAF is not aware of any commercial releases of GM animals or commercial plantings of GM trees in overseas countries. However, the World Wide Fund for Nature has reported more than 100 field trials of GM trees involving 24 species in 17 countries[7]. There is ongoing research using animals that have been genetically modified to alter their growth characteristics or produce novel products (e.g. pharmaceuticals in their milk).

29. While the first generation of GM crops has been largely targeted at altering agricultural production, the second generation of GM crops nearing commercialisation overseas comprise crops offering benefits to consumers (e.g. high stearate soybean oil). Further away from commercialisation, but already under research and development, is a third generation of crops containing traits not seen before in primary production. For instance the production of chemical reagents and plastics in plants to replace less sustainable systems.

Genetic modification research in New Zealand's primary industries

(relevant to issue a of the Warrant)

30. The most significant use of genetic modification in New Zealand's agriculture, horticulture and forestry industries is as a research tool for understanding how plants, trees and animals grow. It is now a routine part of many biological research programmes. Genetic modification is also being used to breed new varieties of plants and animals to alter the production or quality of food, crops and fibre, and to develop new products such as animal vaccines.

[4] James C, *Preview: Global review of commercialised transgenic crops: 1999*, ISAAA Brief No. 12, 1999
[5] James C, *Preview: Global review of commercialised transgenic crops: 1999*, ISAAA Brief No. 12, 1999
[6] US Department of Agriculture, June 2000
[7] Oswusu R A, *GM technology in the forest sector: A scoping study for WWF*, 1999

31. New Zealand has invested heavily in GM research since the 1980s. Part of this funding (MAF estimates it to be more than $100 million) has come from government, initially through MAF and the Department of Scientific and Industrial Research, and subsequently through the Public Good Science Fund since 1992.

32. Contained field trials of GM organisms began in New Zealand in 1988 with plantings of asparagus and potato plants modified with marker genes. Since then there have been more than 50 approvals for contained field trials of GM organisms. The organisms have included pasture plants (clover), fruit (apple, kiwifruit and tamarillo), vegetables (asparagus, broccoli, potato), field and grain crops (barley, canola, forage brassica, maize, peas, sugar beet), ornamental crops (*Lisianthus*, *Petunia*), animals (goats, sheep, cattle), trees (*Pinus radiata*) and microorganisms (bacteria). The traits added to crop plants include virus resistance, insect resistance, herbicide tolerance, altered post-harvest quality, flavour enhancement and altered flower colour. Animals (e.g. sheep) have been modified to alter growth characteristics and to produce pharmaceuticals in milk, bacteria have been modified to develop new vaccines (e.g. for hydatids), and forest trees (*Pinus radiata)* have been modified with marker genes. Applications for field trials are publicly notified.

33. There have been no applications or approvals to release any GM organisms into the environment in New Zealand.

3. Existing Regulation – MAF's Regulatory Roles

MAF uses a risk management approach to regulation

34. The government uses a 'managed risk' approach in many areas of activity, which means using the most cost-effective ways of reducing risks rather than trying to eliminate all risks. The Biosecurity Act prescribes this approach for biosecurity risks from imported goods that might damage New Zealand's fauna or flora.

35. Biosecurity agencies (MAF, the Ministries of Health and Fisheries, and the Department of Conservation) as well as other relevant agencies (the Ministries of Economic Development, Foreign Affairs and Trade, and Research, Science and Technology, and Te Puni Kokiri) are working through the Biosecurity Technical Forum to develop an interdepartmental statement on the application of precaution in managing biosecurity risks under the Biosecurity Act. This work is still in progress.

36. Legislation administered by MAF has the facility for post-release controls and conditions for agricultural material and products, including GM products.

MAF's risk management approach to biosecurity

37. New Zealand's isolation gives it a high level of natural biosecurity protection. Together with active border control, this gives New Zealand one of the highest levels of biosecurity protection available anywhere in the world. But it is impossible for any country to completely insulate itself against biosecurity risks. Even if New Zealand prevented all imports, zero risk could not be assured. For instance, organisms could be brought in illegally or by natural movements such as migratory birds or windblown insects. Each country must decide on factors that will contribute to an appropriate level of protection from risks to biosecurity. MAF Biosecurity adopts a level of precaution when deciding if the available scientific evidence for a risk analysis is sufficient to recommend action.

38. Consistency in risk management is required to provide natural justice. It is also important in an international context for demonstrating that trade restrictions are not arbitrary. MAF aims for consistency in biosecurity risk management through the consistency of its processes, which has these elements:
    - using a systematic risk analysis process;
    - applying biosecurity measures that are firmly based on the supporting risk analysis;
    - comparing proposed risk management decisions with those taken previously for similar risks or similar products; and
    - having this whole process well-documented and transparent.

39. MAF is working to enhance consistency in biosecurity by:
    - Working with the New Zealand Customs Service to improve risk management decision-making at the border. This joint project is the result of a recommendation arising from a recent review of New Zealand's border activities.
    - Finalising a biosecurity policy statement on conducting and applying import risk analyses, which has been subject to extensive public consultation. This policy statement will apply to all biosecurity groups within MAF, and will be proposed as the basis for a Biosecurity Council policy statement on risk analysis (to apply to all biosecurity departments).
    - Developing, in conjunction with other biosecurity departments, a policy statement on the use of 'precaution' in managing biosecurity risks.

- Leading an interdepartmental team on further developing a statement on New Zealand's overall appropriate levels of protection against biosecurity risks.
- Preparing a handbook on animal biosecurity risk analyses that will be completed shortly. It will greatly help to achieve consistency and rigour in animal health risk analyses, and will be considered for application to plant health and forest health risk analyses.

MAF's risk management approach to food

40. Food safety risk management involves evaluating the likely impact of different risk management options on reducing the risks to human health. In most cases, it will also consider other factors that are legitimately part of the decision-making process such as technological feasibility and economic concerns.

41. In June 2000, the MAF Food Assurance Authority and the Ministry of Health jointly adopted this generic approach to food safety and published *Food Administration in New Zealand: a risk management approach for food safety.* This framework comprises four steps:
    - risk evaluation – identification of a food safety problem, a need to develop a food safety standard, development of food safety policy that achieves broad food safety goals, and the development of sanitary measures that are necessary to achieve specified food safety goals;
    - risk management option assessment – identifies available risk management options in light of qualitative and quantitative information on risks;
    - implementation of the risk management decision – possibly involving the setting of regulatory standards, establishment of performance and/or process parameters, and verification of the system; and
    - monitoring and review – gathering and analysing data from appropriate points so as to service ongoing risk assessment and risk management activities.

42. This framework specifically acknowledges developments outside New Zealand, particularly policy and scientific decisions made under the World Trade Organisation Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and Australia New Zealand Food Authority (ANZFA) decisions on food labelling and composition. A domestic risk management framework that reflects internationally agreed principles and practices ensures that our obligations under multilateral and bilateral agreements are, and are seen to be, transparent and consistent. This facilitates the equivalence of sanitary measures for food in our international trade.

Managing food safety

43. MAF is responsible for food safety in the animal products and dairy sectors. Food processors that are licensed or registered under legislation administered by MAF are exempt from the hygiene requirements under the Food Act. To facilitate exports, MAF sometimes provides official assurances to foreign governments verifying that certain requirements or standards have been met.

44. MAF is the New Zealand contact point for the Committee on Sanitary and Phytosanitary Measures and the Codex Alimentarius Commission, which sets international food standards recognised by the World Trade Organisation. There are more details about Codex in the background paper on international aspects[8]. MAF leads the New Zealand delegation on the Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology, which is mainly concerned with risk assessment, safety issues, and testing methodologies. MAF and Ministry of

[8] Ministry of Foreign Affairs and Trade, *International Aspects of Genetic Modification – background paper for the Royal Commission on Genetic Modification*, August 2000. Available at www.gmcommission.govt.nz.

Health jointly represent New Zealand on the Codex Committee on Food Labelling, which is considering labelling of GM foods.

MAF interface with other food regulatory regimes

45. MAF is closely involved in food safety and labelling issues that affect the agriculture and horticulture industries, although statutory responsibility mainly rests with the Ministry of Health through the Food Act. For details relating to GM foods, see the Ministry of Health submission. MAF played a significant role in developing the labelling regime for GM foods, mainly from a scientific perspective.

46. Cost of compliance considerations has been a key driver in recent reviews of regulatory regimes administered by MAF. To this end, it has been important to remove duplication across regimes and improve the interface where necessary.

47. For example, to date there has been no requirement to apply the generic risk management approach to GM foods in primary processing. This is because primary processing almost always involves live genetic material and to date no live GM organisms have been approved by the Environmental Risk Management Authority (ERMA).

48. In relation to secondary processing, MAF supports the Ministry of Health view that, once a GM food has passed safety assessments by competent authorities such as ANZFA, it is as safe as its conventional counterparts. Therefore, as a compositional attribute of processed foods, MAF considers that ANZFA's pre-market assessments of GM foods satisfy the food safety risk assessment of secondary processing.

49. This primary/secondary food processing interface is also reflected in the regulatory regimes for food administered by MAF. The most recent risk-based food legislative regime implemented by MAF is the Animal Products Act 1999. It provides a mechanism for secondary processors to switch between risk-based management systems under the Food Act and the Animal Products Act. It also provides for setting standards for genetically modified animal material or products or ingredients or additives (section 44(2)(e)) should it be necessary to complement ANZFA provisions or requirements of other New Zealand regulatory regimes in the future.

Managing risks from pests, unwanted organisms and new organisms

50. The Biosecurity Act 1993 is the principal statute for the exclusion, eradication and effective management of pests and unwanted organisms. It is the legislative basis for the biosecurity activities of MAF, Department of Conservation, Ministry of Fisheries and Ministry of Health. The act prescribes a risk management approach, rather than assuming that risks can be eliminated entirely. MAF is responsible for enforcing the Biosecurity Act at New Zealand's borders, ie for preventing unauthorised organisms and goods that may pose a biosecurity risk from entering the country.

51. There is a close relationship between the Biosecurity Act and the Hazardous Substances and New Organisms (HSNO) Act 1996 for managing the risks associated with new organisms. Under the HSNO Act, new organisms cannot enter New Zealand unless they are approved by ERMA. 'New organisms' means organisms of a type not already at large in New Zealand and also includes GM organisms, whether they are imported into New Zealand or developed here. MAF enforces the controls set by ERMA for importation, development, or field-testing in containment. A memorandum of understanding between ERMA and MAF Biosecurity Authority clarifies their respective roles and responsibilities.

52. When a new organism is detected in New Zealand, the government decides whether to attempt eradication based on the technical feasibility and an analysis of the costs and benefits.

Government priorities for the long-term control of established organisms are also guided by cost-benefit analysis.

Managing biosecurity risks at the border

53. All goods that could be harmful or that could harbour harmful organisms, including imported GM organisms, are biosecurity 'risk goods' and must meet the conditions set out in import health standards. MAF inspects the goods and/or any accompanying documents when they arrive. Commercial consignments must generally have documents certifying that specified conditions have been met. This may include freedom from specific pests and diseases in the exporting country, or that certain treatments have been carried out, or that other biosecurity measures have been applied.

54. Passengers bringing in potentially harmful goods do not usually carry such certification. MAF inspects goods that are declared or detected on arrival, to ensure they meet the entry requirements. In some cases treatments may be required, in other situations the goods would be confiscated and destroyed or returned to their country of origin (at the importer's expense). Similar options also apply to commercial consignments.

55. X-ray machines are installed at Auckland, Wellington, Christchurch and Hamilton international airports and the International Mail Centre in Auckland to improve MAF's ability to detect potentially harmful goods. Detection rates vary depending on the type of goods. For example, since X-ray machines were installed MAF estimates that between 85 percent to 95 percent of material that can harbour fruit flies is detected, depending on the product type. Before the X-ray machines were installed, the detection rate of agricultural risk goods was approximately 55 percent. Even with X-ray machines, some risk goods are difficult to detect. For example, seeds are often brought in with passengers or sent through the mail, but are not easy to detect because of their size and composition.

56. These examples show the difficulty in locating agricultural risk goods, let alone any goods that are also GM. An inspector cannot tell by sight that particular goods either contain GM material or are non-GM. Testing is expensive and time consuming and only possible where a test has been developed. Currently there are tests that can identify specific genetic modifications or categories of modifications that use common techniques (e.g. the same marker genes). There is no generic test for genetic modification. Currently, MAF relies on importers obtaining the appropriate approvals from ERMA before importing GM organisms. Border control is likely to continue to rely on documentation to determine the GM status of incoming goods.

Managing GM organisms in New Zealand

57. No GM organisms have been approved for release in New Zealand. So far, the only approvals for GM organisms under the HSNO Act have been for containment, according to controls set by ERMA.

58. The containment controls are based primarily on standards approved by ERMA in accordance with the HSNO Act. MAF and ERMA have developed a range of standards for different classes of organisms based on the Australia/New Zealand Standard, Safety in Laboratories, Part 3 Microbiology (AS/NZS 2243.3:1995). Containment facilities are approved under the Biosecurity Act according to these standards. The operators are also approved under the Act.

59. Inspectors appointed by MAF under the Biosecurity Act ensure that the controls set by ERMA are being met. Facilities are inspected according to the requirements of the MAF standard and any additional controls required by ERMA. The frequency of inspection is specified in the standard or by ERMA if they require a different frequency.

60. Inspectors assess a number of factors, including the following as appropriate:

    - that the identity of the organisms held in the facility correlates with the species specified on the permit to import, the export certification is in order and any post-arrival requirements of the import health standard have been, or are being complied with;
    - that the procedures as required in the containment manual are practised (including procedures for meeting the containment controls);
    - that the structural requirements as set out in this Standard are being maintained; and
    - that the organisms in containment correlate with the register.

61. As well as meeting an import health standard, imported GM organisms cannot obtain a biosecurity clearance or proceed beyond border controls without some type of approval under the HSNO Act. In most instances, they will have ERMA approval for importation into containment and are directed to a containment facility on arrival. Depending on the health status of the exporting country, they will sometimes be held in containment in a transitional facility (e.g. a quarantine facility) to ensure they are not carrying pests and diseases.

62. GM organisms undergoing field tests must also be contained. Field test sites are places where organisms are held under conditions similar to those into which the organisms are likely to be released. The area in which the field tests are conducted is approved as a containment facility under the Biosecurity Act and must meet the standard for that type of facility.

63. GM organisms that have been approved for containment are considered to be 'restricted organisms' under the Biosecurity Act. If any such organisms escaped from a containment facility, they would become 'unauthorised goods' and 'unwanted organisms' as defined in the Act, enabling MAF to take certain actions. The Act provides for surveillance activities, including obtaining information about unwanted organisms. The Act also allows inspectors to seize and dispose of unauthorised goods and to carry out such acts that they consider necessary or expedient for eradicating or managing unwanted organisms.

Managing agricultural and veterinary products

64. MAF has a role in approving agricultural and veterinary products through the Pesticides Act 1979, Animal Remedies Act 1967, Fertilisers Act 1960 and Stock Foods Act 1946. These acts will be replaced by the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997, which will commence at the same time as the hazardous substance sections of the HSNO Act (expected early 2001). Any agricultural compound or stockfeed that contains a new organism (such as a GM organism) would have to be approved through the HSNO Act process.

65. Regulations under the ACVM legislation would not be triggered by the fact that a product is GM, but by the product's characteristics and how it is used. Whether or not they are GM, almost all veterinary medicines undergo a safety assessment while most stockfeeds do not pose any inherent risk to trigger a safety assessment or registration. Regulations will impose an obligation on manufacturers and suppliers to ensure their products are safe to use.

Managing animal welfare

66. Under the Animal Welfare Act 1999, research, testing or teaching must not be carried out on a live animal unless the person or organisation involved has a code of ethical conduct. These codes are approved by the Director-General of MAF after consulting the National Animal Ethics Advisory Committee. Every project must be approved and monitored by an Animal Ethics Committee. Regulations specify that records must be kept and returns filed annually on the number of animals used in research.

4. Gaps and Issues

There are some gaps in the existing regulatory system

(relevant to issues 2, n of the Warrant)

67. The HSNO Act does not recognise any pre-release assessments or post-release controls provided by other legislation. An amendment to the HSNO Act to recognise these provisions during ERMA's assessment could avoid duplication and provide reassurance about post-release control.

68. Although MAF enforces the controls set by ERMA for the containment of GM organisms, MAF's responsibilities only start after the ERMA approval is given. The Ministry for the Environment is considering an amendment to the HSNO Act to list MAF as an enforcement agency for all activities dealing with new organisms. However, this may not extend to ensuring that researchers have ERMA approvals before genetic modifications occur.

69. In a recent decision to approve an application to field test GM sheep, ERMA concluded there was a jurisdictional gap in the Animal Welfare Act in relation to foetuses that are less than halfway through their term. The Animal Welfare Act specifies that ethics approvals are only required for foetuses more than halfway through their term. The legal argument was raised that the potential for suffering and deformity would have been created at the time the embryos were modified by knocking out a particular gene (myostatin), which preceded the point at which ethical approval was required.

70. Stockfeeds that are not GM organisms but are GM products may not require an assessment and registration under the ACVM Act. This is because they may not trigger any safety or risk thresholds. For consistency with food regulation, it could be argued that GM stockfeeds should undergo a mandatory safety assessment. While it is possible to require a safety assessment of GM stockfeeds, it could then be argued on technical grounds that there is equal or greater uncertainty about the safety of conventional products for which safety assessments are not mandatory. This may cause problems with consistency and transparency under the regulations unless the safety assessment was specifically provided for in legislation, such as in ANZFA Standard A18.

Border control alone could not guarantee that New Zealand could remain non-GM

(relevant to issues 1, i, k, m of the Warrant)

71. 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.

72. Should New Zealand decide to commit to non-GM primary production, there would need to be agreement about what is meant by 'non-GM'. Definitions range from exercising 'due diligence' to avoid GM inputs and mixing, to an absolute GM-free requirement proved by audit trails and/or testing for modified genetic material. Some degree of GM mixing from other countries may be beyond New Zealand's ability to control but may be identified in testing, so a practical definition of non-GM may have to reflect what standards are realistically attainable and enforceable.

Genetic modification, like other breeding processes, may have environmental risks and benefits

(relevant to issues c, j, k, m of the Warrant)

73. An OECD report[9] relating to the environmental risks from GM crops states that:

> *It is recognised that the safety of an organism is independent of the process of genetic modification per se…it is the characteristics of the organism, including new traits (however introduced), the environment and the application that determine the (likelihood of) risk of the introduction.*

74. The issue of cross-pollination between sexually compatible plant relatives is not new. Only with genetic modification is it possible to track the spread of specific genes, and to accurately control the transfer of genes when breeding.

75. Genes could be transferred to related plants via pollen in suitable circumstances. The types of genes most likely to be transferred to other plants in the short-term are those conferring herbicide tolerance and pest resistance. For example, glyphosate-tolerance genes in GM canola could be transferred to other species of *Brassica*. However, this could also occur with genes conferring tolerance to the herbicide triazine, which have been selected with traditional breeding processes. Such transferred genes could confer some selective advantages on those plants exposed to the specific herbicide, but without selective pressures they tend to be lost from the plant population. The consequences of such gene transfers would be considered under ERMA's risk assessment processes for approving any GM organisms.

76. There is potential for genetic modification to provide cost-effective environmental benefits. One example that MAF is involved in concerns the biocontrol of possums.

Biological Control of Possums

Successive governments have identified possum control as one of the highest priorities for pest management in New Zealand and MAF supports research into the biological control of possums. The research follows two main directions: finding ways of disrupting possum-specific physiological pathways, and finding ways of delivering a control agent.

Most of the physiological research focuses on the reproductive system. At this stage much of it is fundamental research that involves studies on gametes, fertilization, embryonic development and endocrine control of reproduction.

Delivery systems could possibly be genetically modified to enable disruptive genes that interfere with health or reproduction to spread among the possum population. For example, a number of potential viruses have been identified, including a possum-specific adeno virus, although it has not yet been grown in the laboratory. The possibility of using a horizontally transmissible virus to immunise a population has been proven in a number of situations[10].

The research programme has received $2 million a year since July 1993 through Vote: Agriculture. There is now complementary funding through the Public Good Science Fund so MAF's contributions currently account for only 37 percent of annual investment in possum biocontrol research.

MAF recognises that any new biocontrol technology needs public acceptance before it can be introduced. This may be difficult to achieve for agents that can be transmitted without human involvement, but it appears to depend on how it is delivered. For example, a possum-specific nematode carrying a sterilising agent appears to be more acceptable than a GM virus carrying a gene that expresses the same agent. If such an agent was effective when eaten there would be other possibilities such as using GM carrots to express it or using a GM plant virus that caused infected plants to produce the agent.

However, possum control in the foreseeable future will depend on a number of technologies used in an integrated manner, with 1080 as the cornerstone.

[9] OECD, *Safety Considerations for Biotechnology: Scale-up of Crop Plants*, 1993.
[10] Torres et al, *Vaccine* 19 (2001), 174 – 182

Maori views

(relevant to issues c, j, k of the Warrant)

77. MAF understands that genetic modification has raised issues of significant cultural concern for some Maori, e.g. whakapapa and tapu. On the other hand, MAF is aware that Maori stakeholders in agriculture and forestry consider that the potential economic benefits from genetic modification should not be overlooked.

78. MAF does not seek to pre-empt the role of the Federation of Maori Authorities and other Maori representative organisations in conveying Maori views. However, based on our contact with Maori in agriculture and forestry, the ministry considers that Maori, like other New Zealanders, are still weighing up the various implications of genetic modification.

Perceptions of risk and ethical concerns

(relevant to issues 1, j, k, m of the Warrant)

79. MAF understands that perceptions of risks can be very different from actual risks. Public perceptions about risks from genetic modification depend on how the technology is being used. For instance, there appears to be a greater acceptance of genetic modification in medicine than in food. This may be because there is a defined benefit to the users of genetic modification in medicine that outweighs any risk, whereas there is less obvious personal benefit to the consumers of food modified to alter agricultural production.

80. Ethics are considered in MAF's regulatory activities, primarily in approving codes of ethical conduct for research involving animals, on the basis of recommendations from the National Animal Ethics Advisory Committee. However, animal welfare generally reflects the community's ethical position on harm to animals.

81. Regulatory systems based on perceptions of risk or ethical considerations could have unintended consequences unless there were a clear societal consensus and decisions were made having regard to all known consequences. It would not be possible to use scientific assessments of risk or economic assessments of costs and benefits. Also, since perceptions vary among people and change over time, it could create uncertainty for industry and consumers and discourage investment. Finally, other countries could regard it as an arbitrary trade barrier.

International trade agreements benefit New Zealand

(relevant to issues h, I of the Warrant)

82. Access to overseas markets is critical for the prosperity of New Zealand's primary industries. New Zealand gains access by operating within the trading framework provided by bilateral and multilateral agreements applying to New Zealand and its trading partners. These are outlined in the background paper[11] and the Ministry of Foreign Affairs and Trade submission.

83. The integrity and reputation of New Zealand's regulatory processes are central to gaining market access through these agreements. These processes are highly regarded internationally and many countries see them as examples of best practice. As a result, New Zealand exports of animal and plant products have earned a level of safety recognition from foreign regulators that has been often denied to our competitors. For example, our bilateral veterinary agreement with the EU accords 'equivalence' to New Zealand's regulatory system. New Zealand's regulatory regime for genetic modification may have implications for our trading relationships.

[11] Ministry of Foreign Affairs and Trade, *International Aspects of Genetic Modification – background paper for the Royal Commission on Genetic Modification*, August 2000. Available at www.gmcommission.govt.nz.

There are likely to be economic opportunities for both GM and non-GM primary production

(relevant to issues 1, c, h, i, j, k, m of the Warrant)

84. Around 90 percent of New Zealand's agricultural produce and 70 percent of forestry production is exported so external consumer demands and regulatory requirements will play a significant role in the profitability of these sectors.

85. Over the last 20 years, agricultural reform both in New Zealand and around the world has attempted to remove distortions to market signals. In New Zealand, this has been achieved by progressively removing government intervention and regulation. If New Zealand were to make a national commitment to support certain forms of production over others, it would reduce the ability of producers to react to changes in consumer attitudes, market prices, or failure of particular technologies.

86. There can also be hidden costs from regulatory barriers that are set too high. Such barriers would make border control more expensive than it needs to be and take up regulatory resources that could be better spent controlling other risks. They can also encourage illegal activities. Finally, they can discourage investment in research, stifle innovation, and result in skilled people leaving the country.

87. MAF believes there are likely to be opportunities for New Zealand in both non-GM (including organic) and GM agriculture. There may be economic benefits from a national commitment to non-GM production in terms of product promotion in some international markets. However, there may be economic benefits in using GM technologies to maintain our competitive advantage and to supply emerging high value markets for GM products. Opportunities would be lost if products are unable to be sold in the markets for which they were intended (e.g. if they were accidentally mixed). The future value of these opportunities will depend on consumer demands and cannot be predicted with any degree of certainty. This is precisely the situation in which markets work best to allocate resources.

88. Some people believe that New Zealand's image as a 'clean and green' source of safe, high quality products may be undermined if GM technologies are permitted in primary production. On the other hand, using biotechnology to reduce the reliance on pesticides and fertilisers or to reduce the environmental impacts from pollution and pests could enhance this reputation.

Can GM production and non-GM production coexist?

89. Given that there are likely to be opportunities for both non-GM and GM products, and that the value of these opportunities is difficult to predict, the issue becomes whether a choice of one precludes the other, ie whether both forms of production can coexist. A 'mixed strategy'[12] that includes product labelling would allow producers and consumers to choose between non-GM and GM products, as they currently do between organic and other non-organic products. Producers could earn returns from either method and there may be no economic grounds to support or restrict one or the other.

90. The key to coexistence is keeping GM and non-GM products separated. Different production and processing systems already coexist in New Zealand, particularly for market access where countries may have different requirements, but GM crops have the added complexity of pollen movement.

91. Pollen movement would not be an issue for different species of crops, e.g. GM corn and non-GM apples. For producers of non-GM crops for which a sexually compatible GM counterpart was being grown, or for honey producers who wished to avoid GM pollen, there would have to

[12] Wright J C, *The economics of genetic modification* Background for the Royal Commission on Genetic Modification, August 2000. Available at www.gmcommission.govt.nz.

be mechanisms to minimise cross-pollination and mixing. Buffer zones and separation distances have been used to ensure purity in seed production[13], and could possibly be used for GM and non-GM crops[14]. A number of technologies are emerging that could help to biologically isolate particular crops, for example by controlling flowering or fertility[15]. During harvest, processing or distribution there would need to be either segregated supply chains or cleaning of shared equipment at potential mixing points.

92. The costs and feasibility of segregation depends on the level of guarantees demanded or tolerances allowed. In some cases it may be impossible to prevent accidental mixing so a zero tolerance for GM material could make coexistence unfeasible. Even where segregation is both technically feasible and financially viable, consumers must have confidence in the integrity of supply chains. Establishing a credible labelling or certification system is one way to facilitate consumer choice. New Zealand and Australia have jointly developed an approach to labelling GM foods that delivers such a system. It is based on the presence of novel DNA and/or protein and is underpinned by documentation or testing where feasible.

93. Second and third generation GM plant products will require different production and marketing strategies than first generation products. They will need to be segregated and identified from production through to sale in order to capture the value added by the genetic modification.

94. In several countries (Argentina, Australia, Canada, USA), organic production coexists with GM crops, although organic producers question whether this is realistic or sustainable. The International Federation of Organic Agricultural Movements is currently debating whether organic standards should allow for the accidental presence of any GM products.

95. If it were not possible to segregate non-GM supply chains from GM production and its effects, then it may be necessary to decide whether to remain non-GM or to permit GM technologies. This decision would not necessarily have to be at the national level but could be at a regional level based on what is required to ensure separation to the satisfaction of consumers. For example, some regions of New Zealand are declared to be free from certain diseases for export purposes.

5. Conclusion

(relevant to issues 1, h, i, j, k, m of the Warrant)

96. MAF believes that it is important that the agriculture, horticulture and forestry sectors have access to the latest technology in order to remain internationally competitive. Gene technology is being rapidly developed and implemented around the world, and presents opportunities and risks that will need to be evaluated on a case-by-case basis. Those who could benefit from its application should have the choice to use it where it does not adversely affect others.

97. 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'.

[13] Ministry of Agriculture and Forestry, *Seed Certificaiton 2000-2001 Field and Laboratory Standards*, Wellington 2000.
[14] Moyes C & Dale P, *Organic farming and gene transfer from genetically modified crops*, John Innes Centre, May 1999.
[15] Department of the Environment, Transport and the Regions (UK), *Guidance on best practice in the design of genetically modified crops*, October 2000. Available at www.environment.detr.gov.uk/acre/bestprac/consult/guidance/bp/index.htm.