

chapter |

# 8



Food

# 8.

## Food

### Key issues:

- Is genetically modified food safe to eat?
- Are the current food safety standards satisfactory?
- Can people choose whether or not to eat genetically modified food?

1. From the submissions received and the statements made at the public hearings it was clear genetically modified food was one of the issues that dominated the discussion. This was no surprise. Food is a matter of personal importance to individual New Zealanders. As food production for domestic consumption and for export contributes significantly to the economy, it is also of national importance.

2. Some submissions questioned the need for genetically modified food. To some people, the genetic modification of food and food crops is part of globalisation and the free trade agenda, another avenue for multinational corporations to exploit developing economies. To others, developments in food, such as Golden Rice, have the potential to provide part of the solution to third-world hunger and poverty.

### Golden rice<sup>1</sup>

Rice is the staple food for two billion people. It is usually milled to remove the outer seed layers to prevent their high oil content causing spoilage. The remaining grain is low in  $\beta$ -carotene (Vitamin A). Some 400 million people worldwide suffer from vitamin A deficiency and over 3.7 billion people are iron deficient. These deficiencies lead to poor development and increased susceptibility to disease. Vitamin A deficiency causes five million deaths annually, and blindness in a further 500,000 people, while iron deficiency causes anaemia and birth defects.

Golden Rice is a transgenic crop created by Dr Ingo Potrykus and his colleagues to improve the nutritional quality of rice, by increasing the quantities of  $\beta$ -carotene, the precursor to vitamin A and improving its iron content. Several genes have been inserted into the rice

genome, including a daffodil gene, allowing the endosperm (the part that remains after milling and polishing) to produce  $\beta$ -carotene. Additionally a phytase gene (which produces an enzyme to release chemically bound iron), a gene to increase organic iron and a gene to aid iron absorption in the digestive tract have been added. The presence of  $\beta$ -carotene in the endosperm of the transgenic rice gives it a golden colour. The Golden Rice project is trying to achieve the strategy of the FAO and WHO to “ensure that sustainable food-based strategies are given first priority particularly for populations deficient in vitamin A and iron, favouring locally available foods and taking into account local food habits”. The research was funded by the Rockefeller Foundation, the Swiss government and the EU.

The Golden Rice project hopes to provide a cheap form of vitamin supplementation to help prevent these deficiencies. It is not the product of profit-seeking companies. When viable, the rice was to be freely distributed with no patents blocking access to it. Dr Potrykus stated that he was somewhat surprised when it was found that in the creation of his Golden Rice there were 70 intellectual property rights belonging to 32 different companies and universities for which he needed free licences to be able to establish a “freedom to operate” situation. Currently, intellectual property issues are being resolved.

Some believe that Golden Rice is being over-hyped, because it allays public fears about genetic modification, and that it is not the best solution to the nutritional problems in developing countries. They point out that, despite all the time and money spent on Golden Rice, it is not yet available to those it was designed to help, and in fact is several years away from commercial production. They have also pointed out new agreements with AstraZeneca and Greenovation mean that, though the companies will donate seeds to developing countries, only farmers earning less than \$10,000 annually from the sale of the rice will be exempt from paying royalties.

It is also argued that problems with malnutrition have little to do with the nutritional value of the food consumed. Rather the problems are:

1. *Food distribution.* Malnourished people often come from countries with food surpluses. Golden Rice is a high yield crop and may be grown for export rather than for local supply. If this happens, people who are too poor to buy food will not be aided by Golden Rice.
2. *Food preferences.* Because of cultural preferences people may choose not to eat Golden Rice, despite its nutritional benefits.
3. *Food variety.* Vitamin A deficiency rarely occurs in isolation, but rather with other vitamin and mineral deficiencies. Since many species of plant contain  $\beta$ -carotene, it would be better to diversify crops and encourage people to eat a wider range of foods rather than rely on Golden Rice as a single major source of the vitamin.
4. *Effects on agriculture.* There are fears about the possible associated effects of the technology itself on human health and on farming practices in developing countries.

3. The Commission's Warrant, however, confines our considerations to issues relating to genetically modified food in New Zealand. Although diverging views about the value of genetic modification to developing and developed countries are important in the overall debate about the use of the technology, issues such as Golden Rice are not material to our inquiry. We have included an information panel about it only because the subject was mentioned so often.

4. The need for genetically modified food was also questioned on the grounds that New Zealand is self-sufficient in food.<sup>2</sup> The importance of imported food to the New Zealand population, however, was identified in the submission from the New Zealand Grocery Marketers Association [IP54]. The submission pointed out that New Zealand now has a higher proportion of imported processed food than any other country in the western world.

5. The Association suggested that there were two reasons for this high rate of importation. First, the New Zealand climate limited the foods that could be grown here and, second:

... a very high dependence on pre-processed food imports is associated with that of economies of scale. With a domestic population of 3.8 million people New Zealand cannot sustain high volume sophisticated (manufacturing) plants just to supply the domestic base.<sup>3</sup>

6. The submission also referred to the importance of international companies in the food production sector in New Zealand. As the Commission listened to submissions from organisations such as the New Zealand Dairy Board [IP67], we could not but become aware of the importance of international trade to the New Zealand companies, growers and food producers who are involved in the export market. Again, the Grocery Marketers Association explained:

New Zealand's economy is dependent on the food industry. It contributes 42% of the country's export earnings (the exports for the year ended June 2000 were \$24.746 billion of which food contributed \$10.336 billion). In addition the processed food industry contributes \$11 billion to the domestic economy.<sup>4</sup>

7. For reasons we will set out, the Commission does not accept that it is a viable option to ban the production, importation or sale of genetically modified food in New Zealand. It considers, however, to ensure the health and safety of the public, the food industry must be subject to rigorous standards enforced and monitored by competent and careful regulatory bodies.

## The current status of genetic modification in food and food processing in New Zealand

8. Genetically modified food may have been on the New Zealand market for as long as a decade. The Grocery Marketers Association stated that the first food products modified by gene technology were a yeast used in baking, which was approved for use in the United Kingdom in 1990, and chymosin, the enzyme used in cheese making, which was approved for use in the United States, also in 1990. The Flavr-Savr tomato, which was the first whole food produced using gene technology, received approval in the United States in 1994. Transgenic soybeans, corn, cotton and potato, from which many ingredients are now derived, were approved overseas during the 1990s.<sup>5</sup> These foods could have come into New Zealand as ingredients in imported food.

9. It was difficult to establish the nature and range of the genetically modified food available on the New Zealand market. The Australia New Zealand Food Authority (ANZFA) is required to conduct a scientific assessment process prior to genetically modified foods being released. At the time the Commission's inquiry began, there were a number of genetically modified foods on the New Zealand market that had not completed this process. This was because, during the time that Standard A18: *Food Produced Using Gene Technology*, which regulates the sale of genetically modified food, was being developed in 1996 and 1997, a number of genetically modified foods entered the Australian and New Zealand markets legally without being assessed by ANZFA. These were largely components of imported processed foods. Subject to certain conditions, these foods were allowed to remain on the market while they went through the ANZFA system for assessing compliance with Standard A18. At the hearing before the Commission, ANZFA was questioned further on this matter. (See paragraphs 129 to 202.)

### Processed food

10. The submission from the Grocery Marketers Association stated there are “no whole genetically modified foods on the market” in New Zealand. At the time of the Commission's hearings, therefore, all genetically modified foods were used as ingredients in imported foods. The Association provided a list, reproduced overleaf, of examples of the products that might be present in foods currently available in New Zealand. The Association pointed out, however, that it is not possible to state the extent to which the products listed are used in New Zealand.<sup>6</sup>

### Ingredients derived from genetically modified crops

Genetically modified organisms	Ingredient, additives and processing aids	Used in following foods
Soybean	soybean flour	soy drinks, soy sauce, tofu
	soybean protein	processed meats/sausages/salamis
	hydrolysed vegetable protein	bread
	textured vegetable protein	dairy – drinks, yoghurts, desserts, ice cream
	soybean oil	baked goods – cakes, pies, pastries, biscuits
	lecithin	soups and sauces
	additive and flavour carriers/diluents	cooking oils, salad dressings
	tocopherols – vitamin E	margarines and spreads, peanut butter confectionery, savoury snacks, infant food
Corn/Maize	flour	bread
	corn starch	dairy products – drinks, yoghurts, desserts
	corn oil	baked goods – cakes, pies, pastries, biscuits
	corn protein and isolates	soft drinks and cordials
	corn syrups	soups
	modified starches	sauces, pickles and chutneys
	dextroses	cooking oils, salad dressings
	maltodextrins	margarines and spreads
	glucose syrups	confectionery, fruit flavoured spreads
	humectants, food acids	savoury snacks
	additive and flavour carriers/diluents	herb and spices (through carriers and diluents)

**Ingredients derived from genetically modified crops** *continued*

<b>Genetically modified organisms</b>	<b>Ingredient, additives and processing aids</b>	<b>Used in following foods</b>
Canola	canola oil lecithin	baked goods – cakes, pies, pastries salad dressings cooking oils margarines and spreads confectionery
Cotton	cotton seed oil	baked goods cooking oils salad dressings margarines
Sugar beet	sucrose  mono sodium glutamate (MSG)	dairy products – drinks, yoghurts, desserts  bread baked goods – cakes, pies, pastries, biscuits soups sauces fruit drinks, soft drinks and cordials jams and preserves confectionery savoury snacks
Potato	potato potato starch modified starch	soups sauces, pickles and chutneys confectionery savoury snacks

## Microorganisms

11. The Grocery Marketers Association told the Commission that, in addition to the genetic modification of whole plant foods, microorganisms could be designed to improve the efficiency of fermentation and other primarily enzymatic processes, and be used in the production of ingredients. The Association listed these uses as being:

- microbes to produce amino acids for the synthesis of aspartame
- plant cells grown in fermenters to produce flavours such as vanilla
- chymosin, a replacement for calf rennet, overseas supplies of which are inadequate to meet needs
- alpha-amylase, which is used in the production of high fructose corn syrups
- lactase, which is added to milk to reduce the lactose content for persons with lactose intolerance
- bakers' yeast modified to provide faster carbon dioxide production, which improves dough characteristics
- brewers' yeast with an ability to degrade starch and for use in making reduced calorie beer.

## Grains and cereals

12. The first generation of genetically modified crops were the important grain and cereal crops, tomatoes and some niche products, such as papaya. Traditionally, most of New Zealand's supplies of these products have been imported and no genetically modified crops have yet been approved for commercial cultivation in New Zealand.

## Fresh produce

13. The submission from the New Zealand Vegetable and Potato Growers' Federation/New Zealand Fruitgrowers' Federation/New Zealand Berryfruit Growers' Federation (Vegfed, Fruitgrowers, Berryfed) [IP75] pointed out that very few genetically modified fruit cultivars or species are being traded on world markets, possibly because the development of genetically modified fruit has been of lower priority than mainstream agronomic crops. No genetically modified fresh fruit or vegetables are currently imported into New Zealand. Any fresh produce would require ANZFA approval before it was released on to the New Zealand market, and any produce that contained viable seed or provided propagation material would also require approval from the Environmental Risk Management Authority (ERMA).

## Meat

14. We heard no evidence of products from genetically modified animals, either raised in New Zealand or imported, being available on the New Zealand market. Both would require ANZFA approval. Dr Phil L’Huillier, a scientist with AgResearch [IP13] at Ruakura, informed us of research currently underway into myostatin knockout sheep to increase musculature and, as a result, to improve meat quality. The submissions from both Meat New Zealand [IP31] and the New Zealand Game Industry Board [IP33], however, confirmed that neither organisation would sanction the entry of transgenic products into the food chain without strong public support. The same view was expressed by a number of primary industry sector representatives.

## Dairy products

15. We understood from the evidence that, at present, there is only limited use of genetic modification in the New Zealand dairy industry. The New Zealand Dairy Board said that, as a result of public attitudes towards the use of gene technology, policy decisions had been taken in at least two instances not to make use of the available technology. It confirmed that the industry does not take milk from cows that have been treated with injections of bovine somatotropin (bST), and does not use genetically modified bacterial cultures in cheese making. The Dairy Board’s submission also confirmed that no pasture plants or dairy cattle used in the production of milk were genetically modified. It said that “apart from some well-known and approved additives and processing aids” no foods derived from genetically modified organisms are used in any of the range of food products manufactured from milk.<sup>7</sup> There was limited use of the enzyme chymosin, produced by genetic modification, in cheese for overseas markets.

## Animal feed

16. At the hearing before us, the New Zealand Feed Manufacturers Association/ Poultry Industry Association of New Zealand/Egg Producers Federation of New Zealand [IP35] confirmed that poultry in New Zealand was fed a combination of modified and unmodified soy meal.<sup>8</sup> Meat New Zealand advised that, while genetically modified soy products are being used in animal feeds, they do not appear to be being used in the red meat industry in New Zealand. We discuss the safety of genetically modified stock feed in paragraphs 121 to 126.

## Future developments

17. We heard evidence that, while the first wave of genetically modified food was seen as having benefit primarily to commercial interests, the second wave would have clear consumer benefits in addition to those for food growers and manufacturers.

18. Many of the references to the future developments of genetically modified food were general in nature. There were claims that the use of gene technology in relation to food will have the following benefits for the food industry:

- improved productivity with increased efficiency, sustainability and cost-effectiveness
- improvements to food safety; for example, use of the technology to detect food-borne pathogens, toxins and chemical contaminants
- improvements to storage properties, such as by extending the shelf-life of foods
- the use of gene technology for checking alterations in product quality and checking for temperature abuse.

19. Benefits for the consumer are expected to be:

- products with improved tastes, textures and keeping qualities
- foods that are less allergenic and contain lower levels of toxins
- new foods with elevated levels of nutrients and bioactive agents
- reduced chemical use during the growing process, with a consequent minimisation of chemical residue
- reduction in pathogens causing harm to human health.

We heard a number of claims that gene technology will result in the development of foods with properties that will have a range of direct benefits for human health. This area of ‘functional’ or ‘nutraceutical’ foods is considered in more detail in chapter 9 (Medicine).

20. The New Zealand Grocery Marketers Association provided a list, as shown opposite, of genetically modified foods currently being developed.<sup>9</sup>

## Public perceptions

21. Throughout the Commission’s processes, many people expressed concerns about the safety of consuming genetically modified food. Over 68% of the written submissions we received from the public expressed the view that the use of genetic modification in food production was unacceptable. Many of the Interested Persons who appeared before us at the formal hearings referred to the widely held

## Genetically modified foods under development

Genetically modified food	Modification	Potential benefit
Potatoes	Increased levels and better distribution of starch levels	More effective processing, less absorption of fat when frying potatoes
Potatoes	Developed to contain a high volume of proteins	Lower fat absorption. Improved texture. Replacement for non-animal proteins and synthetic protein derivatives
Rice	Enhanced with $\beta$ -carotene, a precursor for Vitamin A. Improved nutrition	A cure for blindness in third world countries. Improved nutritional value
Corn and soy	Lower levels of saturated fats. Fats higher in oleic acid	Improved nutritional values. Enhanced use
Rice	[Reduce allergenic proteins]	Of advantage to people with rice allergies
Tomatoes	Higher lycopene levels	An antioxidant
Garlic cloves	Higher allicin levels	Cholesterol lowering agent
Strawberries	Higher ellagic acid content	Health benefits
Vegetables, fruits, and seafood	Enhanced flavonoids, carotenoids and omega fatty acids	Improved nutrition and enhanced health benefits. WHO has reported that more than 30% of non-communicable diseases can be prevented by diet. The evidence of the health benefits of flavonoids, carotenoids and omega-3 fatty acids are increasing
Cereal grains	Changes to the structure of the grain	Improves the digestibility of cereal and bakery products with improved control of glycaemia
Milk	Enhanced casein and calcium content	Improved nutritional and health benefits

public uncertainty about the consumption of genetically modified food. Some of the Interested Persons and many of the people who spoke at the public meetings urged caution, largely because of concerns about safety. Some of the Interested Persons, such as GE Free New Zealand (RAGE) in Food and Environment [IP63] and Nga Wahine Tiaki o te Ao [IP64], strongly opposed genetically modified food and sought a total ban on allowing genetically modified food to be either sold or grown in New Zealand. The Safe Food Campaign [IP86] recommended that a “no regrets” approach should be adopted and suggested that:

... in order to prevent harm from occurring rather than manage the risks once harm has occurred, New Zealand should not utilise GM as a strategic option. As an alternative strategic option the Safe Food Campaign supports New Zealand becoming a GM-free zone and an organic nation.<sup>10</sup>

22. The Commission’s own survey, conducted by BRC Marketing and Social Research, confirmed that the wider New Zealand public were aware of the use of genetic modification in relation to food and many also had concerns about the technology.

23. Almost all the people who responded to the survey were aware that genetic modification was being used in processed food. Significantly, well over half of the respondents thought that genetic modification was already being used, to a greater or lesser extent, in commercial crops in New Zealand.<sup>11</sup> Although there was no direct questioning on the subject, it is possible that some of those people believed that genetically modified food crops were already being grown for sale, rather than just as small research plots within some degree of containment.

24. A significant number of people questioned (69%) saw genetically modified processed food as having more disadvantages than advantages. We were interested to note that over half the respondents who saw genetic modification as being important to New Zealand’s future also thought that genetically modified processed food had more disadvantages than advantages.<sup>12</sup> Clearly, even some of those who were generally positive about the use of the technology had reservations about its use in relation to food. It was not surprising, therefore, that processed food was the area of genetic modification with the highest disapproval rating both by those who saw genetic modification as being important to New Zealand’s future and those who saw it as being unimportant.<sup>13</sup> Clearly genetically modified food is a source of concern, at times great anxiety, for a significant proportion of the New Zealand population.

25. Submissions received from both the public and the Interested Persons focused mainly on the safety of genetically modified food and on the possible adverse impacts from consumption. In particular, we heard concerns about the

development of allergens and toxic substances in foodstuffs that had hitherto been considered safe to consume, about increasing antibiotic resistance among humans and animals as a result of the use of antibiotic marker genes, and about possible changes to the nutritional and other properties of modified food.

26. People were concerned about not only their personal health but also the possible impact of genetically modified food on their family's health and that of future generations. One public submission we received said:

I wish to claim under the Human Rights Act the right to protect the future gene pool and health of our food and children by banning genetically modified foods from growth or food production in New Zealand. I will be horrendously angry with any government that

## Bovine spongiform encephalopathy (BSE)<sup>14</sup>

Bovine spongiform encephalopathy (BSE), widely known as “mad cow disease,” is a chronic, degenerative disease affecting the central nervous system of cattle. Worldwide there have been more than 178,000 cases since the disease was first diagnosed in Great Britain in 1986. Although the disease has also been confirmed in native-born cattle in other parts of Europe, over 95% of all BSE cases occurred in the United Kingdom. Epidemiologic data suggested that BSE in Great Britain is a common-source epidemic involving animal feed containing contaminated meat and bone meal as a protein source.

In 1988, the UK Government introduced legislation that required all cattle suspected of suffering from BSE to be destroyed and sent for diagnosis. In 1989 controls were imposed that banned from the human food chain tissues of cattle, sheep and goats known to, or that might potentially, harbour detectable BSE infectivity.

In 1996, BSE was linked with a new variant form of Creutzfeldt-Jakob Disease (CJD).

Classical CJD, which was first diagnosed in the 1920s, is a slow degenerative human disease of the central nervous system which occurs sporadically worldwide, including in Australia and New Zealand, at a rate of one case per one million people per year. On 20 March 1996, the UK's Spongiform Encephalopathy Advisory Committee (SEAC) announced the identification of 10 cases of a new variant form of CJD (vCJD). All the patients developed onset of illness in 1994 or 1995 and the features of CJD in these 10 cases differed from the sporadic form of CJD.

The SEAC concluded that, although there was no direct scientific evidence of a link between BSE and vCJD, based on current data and in the absence of any credible alternative, the most likely explanation at that time was that the cases were linked to exposure to BSE before the introduction of control measures, in particular the specified bovine offal ban that had been imposed in 1989. Research reported later in 1996 and in 1997 found further evidence to support a causal association between vCJD and BSE.

The official report into BSE strongly criticised government ministers and officials for consistently playing down the risk to humans and for failing to coordinate properly a government response.

has neither the foresight or the courage to stand up to the pressure of multinational conglomerates in this matter.<sup>15</sup>

27. The submission from the social scientist members of the Royal Society of New Zealand [IP77b] cited evidence to show that international consumer reaction to genetically modified foods is becoming increasingly negative. Dr Hugh Campbell, giving evidence in support of Organic Products Exporters Group [IP53], suggested that, in New Zealand, the public's concern about genetically modified food was a "food scare".<sup>16</sup> Certainly, a number of the people who made submissions to us drew parallels between genetically modified food and BSE in order to illustrate both the hidden dangers of food and an apparent lack of scientific or regulatory rigour. A major outbreak of foot-and-mouth disease in Britain and Europe at the time of the Commission's inquiry served to heighten public awareness of the potential for rapid spread of disease among animals.

28. Although some people clearly have a high level of anxiety about genetically modified food, the Commission is not persuaded that the general level of concern in New Zealand can be described as a "food scare". We agree, however, that there is widespread public unease about the use of genetic modification in relation to food, which should be taken into account by central government and the relevant regulatory agencies when making any decisions relating to genetically modified food in New Zealand.

29. Dr Lynn Frewer presented useful evidence on public attitudes to genetic modification. Dr Frewer, who was called as a witness by Crop and Food Research [IP4], is a psychologist and Head of the Consumer Science Section in the UK Institute for Food Research. In her discussion of international consumer attitudes towards genetically modified food, Dr Frewer suggested that:

... consumer negativity towards genetically modified foods appears to have arisen because of the order of entry of products into the market place. The public perceived that the first genetically modified foods available were of benefit to industry rather than the consumer, which led to increased rejection of products. Research has shown that novel foods with direct and tangible consumer benefits are more acceptable than those from which only industry will benefit or profit. Perceptions of need and advantage (particularly associated with human health, environmental advantages, or animal welfare) will offset perceptions of risk, but only if the claims made about these benefits are realistic.<sup>17</sup>

30. The Commission was told that some producers and sellers of foods overseas were responding to consumer preferences by declining to use or sell genetically modified products. Primary sector industries in New Zealand involved in food production indicated they would be cautious of using genetically modified products because of negative public perceptions.

31. In her written brief and at the hearing before us, Dr Frewer commented on the complexity of the causes for public concern and the variability of consumer attitudes towards genetically modified food. Dr Campbell's comments on Dr Frewer's evidence and his own views on consumer attitudes were noted by the Commission. There were significant areas of agreement in their evidence, particularly with regard to the complex causes and variability of public attitudes, and the potential difficulty of changing established attitudes. We agree there is a need for the public's concerns to be taken into account in all discussions about the use of the technology, particularly in relation to food, with which, as Dr Campbell pointed out, humans have an "ongoing ambiguous and paradoxical relationship".<sup>18</sup>

32. The Grocery Marketers Association suggested that, while consumers perceive the genetically modified foods and food ingredients currently on the market as having benefit only to corporate and agricultural interests:

In the future, genetically modified foods will have many direct benefits for the consumer. For example, the ability to produce foods with higher nutrient and health qualities such as lower saturated fats, higher vitamin levels and higher antioxidant levels, will have enormous benefit for consumers, particularly as the link between diet and health is becoming increasingly evident.<sup>19</sup>

33. Dr Frewer, however, suggested that, while this second wave of genetically modified foods might be more acceptable, attitudes were unlikely to be changed easily where consumers had already formed strong opinions against genetic modification. She said:

Recent information campaigns in Europe, which have emphasised the positive and beneficial aspects of genetic modification, have not convinced consumers that genetic modification of foods is desirable, or even acceptable in principle. Other information provided by pressure groups which oppose the technology, appears to have been more influential.<sup>20</sup>

34. On the evidence, there is currently a high level of mistrust of genetically modified food. Among some people, possibly the group Dr Frewer described as "being very vocal in providing input into the public debate",<sup>21</sup> mistrust may amount to acute anxiety about the safety of genetically modified food, while for others there may be simply a level of uncertainty based on a variety of reasons. The Commission's survey, and other surveys of public opinion, suggest that, even though there may be some personal benefit to consumers from the second wave of genetically modified food, there is no certainty it will be acceptable to a significant proportion of the population in the near future.

35. We noted, however, Dr Frewer's opinion that consumer unease about genetically modified food may relate to the lack of public inclusion in the debate

on genetic modification, rather than, or as well as, a lack of confidence in food testing measures.<sup>22</sup> We concur in her view that there is a need for communication about genetic modification to take into account public concerns about the use of the technology, and for the public to be included in the ongoing debate about genetic modification, particularly given the increasing use of genetic modification in relation to food crops and products overseas. We consider the debate should extend beyond discussion of the risks and should encompass a broad range of issues relevant to the use of gene technology in relation to food and human health. We suggest that the agencies responsible for regulating the sale of genetically modified food in New Zealand have an important role in this debate. We would encourage regulatory agencies such as ANZFA, the proposed New Zealand Food Administration Authority and the Ministry of Health to take every opportunity for communicating with and for listening to the public. In particular, we commend the establishment of interactive websites that provide accurate, current information on issues relating to the genetic modification of food and food products, and that allow for the public to express their views.

## Current New Zealand regulatory responsibilities for food

36. Submissions from ANZFA, and the Ministries of Health, Agriculture and Forestry, Consumer Affairs and Foreign Affairs and Trade provided information on the regulatory framework and international obligations relevant to genetically modified food.

### Food standards

37. Food standards, which regulate the quality and composition of the food available on the market, are designed primarily to protect public health and safety. In December 1995, the New Zealand Government entered into the Food Standards Treaty, formally known as the *Agreement between the Government of New Zealand and the Government of Australia Establishing a System for the Development of a Joint Food Standards*. The Food Standards Treaty encompasses primarily food composition and labelling requirements. It does not cover the setting of maximum residue limits, food hygiene (including food safety plans) and export requirements relating to third-country trade. The Food Standards Treaty, together with the Trans-Tasman Mutual Recognition Arrangement (TTMRA), which came into effect in 1998, are part of the economic agreements and arrangements between Australia and New Zealand as a result of the Australia New Zealand Closer Economic Relations Trade Agreement, known as CER,

signed in 1983. TTMRA gives effect to mutual recognition principles relating to the sale of goods and the registration of occupations.

38. The practical implications of TTMRA are that food that can lawfully be sold in New Zealand may also be lawfully sold in Australia and vice versa. In New Zealand, these rights are subject to the Fair Trading Act 1986.

39. One of the key outcomes of the Food Standards Treaty was the implementation of a single set of standards for the composition and labelling of food that applies in both New Zealand and Australia. These standards comprise the Australia New Zealand Food Standards Code (“the joint Food Code”) gazetted in New Zealand on 20 December 2000. This will become the sole food code for both countries in December 2001. Although during the transitional period, New Zealand food businesses have the option of complying with one of the current New Zealand Food Regulations, the Australian Food Standards Code, or the joint Food Code, all food businesses must comply with any “mandatory standards” in the New Zealand Food Standard 1996. Standard A18, which regulates the sale of genetically modified food in New Zealand, is a mandatory standard.

#### **Australia New Zealand Food Authority: structure and role**

40. The Australia New Zealand Food Authority (ANZFA), which develops food standards for inclusion in the joint Food Code, is a body set up under Australian law by the Australia New Zealand Food Authority Act 1991. Following the signing of the Food Standards Treaty in 1995, the existing ANZFA Board was expanded to include New Zealand representation. New Zealand has two members and a further representative was appointed as a special member for a limited term at the request of the New Zealand Minister of Health, specifically to assist in the process of transition to the new joint Australia New Zealand Food Standards Code.

41. In response to criticism of the nature of the Board membership, its expertise and understanding of community issues expressed during the course of the formal hearings, Ian Lindenmayer, Managing Director of ANZFA, provided further details. He said:

Six of the ten members are themselves scientists. Two of them have high-level medical qualifications. In fact, both of those two also have a distinguished record in relation to human nutrition and its medical implications. Two others, one from New Zealand and one from Australia, [are] distinguished in the areas of nutrition and dietetics, and two others, again one from New Zealand and one from Australia, have expertise in the areas of food, science and technology.<sup>23</sup>

42. The remaining members, he said, were he and three others, including a New Zealand representative, with experience at senior level in government. At the hearing, Mr Lindenmayer advised that the most recent appointment to the Board was:

... herself a Maori and who has worked very closely with that community over more than 25 years. ...<sup>24</sup>

43. Later, at the Gisborne hui, we heard from the appointee, Hiki Pihema (Ngati Porou), who is the nutritionist at Cook Hospital, about her hope of facilitating communication between ANZFA and the Maori community.

44. The Australian State and Territory governments, the Commonwealth government and the New Zealand government fund ANZFA. Through the Minister of Health, New Zealand enters into an annual Partnership Agreement with the Chairperson of ANZFA. Under these arrangements, New Zealand makes financial contributions to ANZFA's work in developing food standards for both countries, but not to ANZFA functions that lie outside the Treaty. The financial contribution is based on population share.

45. ANZFA conducts risk assessments, initiates and coordinates expert panels and reference groups and undertakes consultation to develop recommended food standards. In reviewing food standards and developing its recommendations, ANZFA seeks advice from the broad community (including industry, consumers and others) and government agencies from both countries. It also receives advice from government agencies in Australia and New Zealand through the Australia New Zealand Food Authority Advisory Committee (ANZFAAC) and a working group of Senior Food Officers. Currently, nominees of the Ministry of Health and the Ministry of Agriculture and Forestry represent New Zealand on both these committees.

46. ANZFA does not have authority to make final decisions to adopt new food standards. These are made through consensus or a majority vote of the Australia New Zealand Food Standards Council (ANZFSC). The council comprises ten Ministers of Health; the New Zealand Minister of Health, the Federal Minister of Health and the Ministers in the eight Australian States and Territories.

### **Proposed changes to the process for establishing food standards**

47. ANZFA's written submission advised that the Authority will be replaced by a new organisation, Food Standards Australia New Zealand (FSANZ). This alteration will require amendments to the Australia New Zealand Food Authority Act and, as a consequence, to the Food Standards Treaty. At the time of writing

this Report, the amendment had been considered by the Australian Senate but had not completed its legislative passage.

48. The proposed changes will affect the membership and function of the new Authority's governing body and the role and responsibilities of the Ministerial Council. It is also possible that the powers of the Australian Federal government in relation to food standards may be increased.

49. Some Interested Persons had reservations about these proposed changes. In particular, there were concerns that New Zealand representation on the governing Board may be proportionately less than it currently enjoys, and that any additional power given to the Federal government would be to the detriment of New Zealand's sovereignty. The proposal that Ministers from portfolios other than Health should sit on the Ministerial Council also gave rise to concern.

50. During the hearing attended by representatives of ANZFA, Sue Kedgley MP, representing the Green Party of Aotearoa/New Zealand [IP83] and the Safe Food Campaign, sought confirmation that changes to ANZFA and the composition of the ANZFSO were being considered under Australian legislation and without any discussion in the New Zealand Parliament. Mr Lindenmayer responded:

The legislation which is currently before the Parliament in Australia is legislation which is intended to give effect to changes which have been developed by a committee, not including my organisation, but a committee representing all ten of the jurisdictions.

Secondly, the advice of that committee has gone to government level, to ministerial level, and I understand there have been discussions encompassing Ministers of New Zealand and Ministers from the Australian side as well.

An intergovernmental agreement was signed in Australia between the Commonwealth Prime Minister and the Premiers and Chief Ministers of the States and Territories, indicating agreement to proceed with the sorts of changes to which you are referring.

My understanding is that, prior to that occurring, there were discussions also with the Government of New Zealand, and there was acceptance that a move – that such a move would be acceptable.

... It was certainly envisaged that the next stages would be a combination of the development and passage of legislation through the Commonwealth Parliament, and discussions between Australian and New Zealand Governments to modify the existing Treaty, and that there would be some Parliamentary process, and I'm not sure of the detail, on the New Zealand side too – as part of that latter process.<sup>25</sup>

51. Ms Kedgley then pointed out that treaties are not discussed in the New Zealand Parliament. Discussion of proposed treaties by Parliament as a whole is a constitutional issue outside the scope of our Warrant. Negotiations between the

New Zealand and Australian Governments over the proposed legislative changes, and the consequential changes to the Food Standards Treaty, are ongoing. We anticipate, therefore, that there will be debate within New Zealand about the issues raised by the proposed amendments.

52. Until the amending legislation has passed through the Australian legislative process, and the negotiations between the two Governments in relation to the Food Standards Treaty have been finalised, the full impact of the changes cannot be known. The Commission makes recommendations relevant to this matter later in this chapter.

### **Standard A18 Food Produced Using Gene Technology**

53. ANZFA Standard A18: *Food Produced Using Gene Technology*, Division 1, is the standard that regulates genetically modified foods. Standard A18 is incorporated into New Zealand law as a mandatory standard in the New Zealand Food Standard 1996. Standard A18 regulates the sale and labelling of genetically modified foods. The text of the Standard is available on the ANZFA website at [www.anzfa.govt.nz](http://www.anzfa.govt.nz).

54. In standard A18, a food produced using gene technology is defined as “a food which has been derived or developed from an organism which has been modified by gene technology”. A food derived from an animal or other organism that has been fed food produced using gene technology is specifically excluded from the definition.

55. Clause 2 of Division 1 of the Standard is a general prohibition on the sale of genetically modified food. Foods that are exempt from the prohibition are listed in the table under clause 2, together with any special conditions the Authority has imposed on them. To be included in the table, a food must have been assessed as being safe for human consumption in accordance with the Authority’s approved safety assessment criteria. Having satisfied the assessment, the food requires the consent of ANZFSC before it is listed in the table.

56. Clause 2A in the Standard is a transitional exemption to the general prohibition on sale. It allows certain genetically modified foods to remain on the market pending ANZFA assessment. This exemption addresses the fact that genetically modified foods were imported into New Zealand and Australia before the Standard came into force in May 1999. Clause 2A(2) permits genetically modified foods to stay on the market where:

- an application was made to ANZFA before 30 April 1999 for the food to be permitted under Standard A18

- there is evidence that the food is lawfully permitted for sale in one or more countries other than New Zealand and Australia, by a national food regulatory agency
- ANZFSO has not become aware of evidence that the food poses a significant risk to public health and safety.

### **ANZFA process**

57. In its written submission, ANZFA stated that, in developing food regulatory measures such as food standards, its objectives (in order of priority) are:

- protecting public health and safety
- providing adequate information relating to food to enable consumers to make informed choices
- preventing misleading or deceptive conduct.

58. In making recommendations on food standards, ANZFA must also give regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence
- the promotion of consistency between domestic and international food standards
- the desirability of an efficient and internationally competitive food industry
- the promotion of fair trading in food.

59. ANZFA outlined the process for developing new food standards or varying existing standards, initiated either on receipt of an application from an external body or through ANZFA's own preparation of a proposal. If, after it has made a preliminary assessment, ANZFA decides to accept an application, submissions are invited from the public. A full assessment report is made, based on a scientific risk assessment, taking account of all evidence received in submissions from interested parties and the public. At the hearing before the Commission, ANZFA representatives provided further details on the scientific risk assessment that is carried out as part of the full assessment, and tabled the extensive documentation related to one such assessment.<sup>26</sup>

60. On the basis of this full assessment, ANZFA would either reject the application or prepare a draft new standard or a variation to an existing standard. The draft new or varied standard and the full assessment report are circulated to all individuals and groups that made submissions on the matter, and public advertisements seek commentary on the appropriateness of the drafting. Finally, ANZFA makes a recommendation to the ANZFSO based on its consideration of information and comment received in the third stage.

61. Before an ANZFSO decision is incorporated into New Zealand law, the New Zealand Minister of Health must issue an amendment to the New Zealand Food Standard 1996 that recognises the variation to the Australian Food Standards Code. The Minister’s amendment is then gazetted, and the standard becomes law in New Zealand after 28 days.

62. Under the Treaty, New Zealand may opt out of a food standard if it considers the standard to be inappropriate on the grounds of “exceptional health, safety, third-country trade, environmental or cultural factors”. Susie Lees, cross-examining on behalf of the Environment and Conservation Organisations of New Zealand (ECO) [IP102] and Nelson GE Free Awareness Group [IP100] at the special hearing attended by ANZFA, questioned whether, in reality, New Zealand could choose to opt out of Standard A18.<sup>27</sup> In a letter responding to questions posed at the hearing, ANZFA confirmed New Zealand could opt out of Standard A18, even after it had been adopted, by initiating a process leading to a decision by the ANZFSO that the standard should not apply in New Zealand.<sup>28</sup> However, because of TTMRA, unless exceptional health, safety and environmental concerns exist, a New Zealand variation will not prevent Australian food permitted to be sold under Standard A18 being sold on the New Zealand market. Many submitters considered ANZFA to be predominantly Australian, and saw the determination of food standards by this organisation as an abrogation of New Zealand’s sovereign right to determine its own affairs for the benefit of its citizens.

63. Dr Peter Wills, a witness for Physicians and Scientists for Responsible Genetics [IP107], Greenpeace New Zealand [IP82], Green Party, Friends of the Earth (New Zealand) [IP78], Sustainable Futures Trust [IP51] and Pacific Institute of Resource Management [IP84], expressed the mistrust shared by a number of submitters when he wrote:

Successive New Zealand governments have become parties to a number of agreements affecting citizens who have had no say in the matter. In respect of the safety of our food supply, we are now subject to decisions that are made by an international body (ANZFA) which is dominated by industrial interests. All considerations in relation to these international obligations are dominated by scientific and technical matters and the unique cultural and ethical perspective of New Zealanders is given absolutely no weight.<sup>29</sup>

64. Understandably, others may share the concern that Australian commercial interests may dominate ANZFA and undermine the Authority’s ability to carry out its functions. The Commission considers, however, that Australia and New Zealand have the same desire to achieve high standards of food safety and we see no likelihood that joint activity in this area will be detrimental to New Zealand’s interests. Moreover, collaboration between the two countries allows New Zealand

to share the cost of a better resourced and equipped safety assessment process than might be possible if a parallel agency were established and funded internally.

### **Public consultation**

65. A number of submissions raised doubts about the nature and extent of public involvement in the development of food standards. In its written submission, ANZFA said that calling for public submissions on food standards applications is a requirement under the Australia New Zealand Food Authority Act 1991. It stated:

Community participation in the development of effective food standards enables:

- the tendering of relevant data not already available to ANZFA
- the views of the community to be presented and understood
- sound decision making following review of all available information
- a form of peer review for scientific and technical matters
- increased accountability and transparency in decision making
- smooth implementation following decision making.<sup>30</sup>

66. ANZFA's submission advised that it has developed a Community Involvement Strategy "which will provide a framework for improved consultation with the broad range of interested community participants". A consultation strategy for Maori, including the formation of a Maori Reference Group in July 2000, is intended to facilitate greater participation of Maori in the food standard setting process.

67. ANZFA stated that the role of the Maori Reference Group is to provide advice on Maori culture and community processes. The Reference Group will assist in identifying:

- food standards issues of significance to Maori
- strategies for effective communication with Maori
- strategies to involve Maori in food standards issues
- projects and research relating to food standards.

68. We understood from Mr Lindenmayer that the Maori Reference Group, in its meetings to date, has emphasised the significant spiritual role that food plays within Maori communities and the importance of developing effective and meaningful relationships and dialogue on issues.<sup>31</sup> The Commission considers it essential that Maori are closely involved with the development of food standards because of its fundamental importance to their physical and spiritual well-being. During the course of our inquiries, we heard much said about the loss of traditional Maori food. Cheryl Smith (Ngati Apa, Te Aitanga a Hauiti), in the course of the presentation by Nga Wahine Tiaki o te Ao, emphasised that there is

an active and ongoing dialogue among Maori about changes to food, including changes through genetic modification. She pointed out that:

The issues of kai, for example, and the safety of our kai, and the loss of our kai or of our traditional kai, has been a point of discussion among us from the time colonisation began. Genetic modification, of course, is yet another issue. What's happened is that we're finding more and more a need to protect ourselves in regard to growing our own kai and ensuring the safety of what we actually feed our own children. One of the key motivations for our people to return to growing their own kai at the moment is the issue of genetic modification.<sup>32</sup>

### Labelling requirements

69. Standard A18 Division 2 regulates the labelling of genetically modified food. ANZFA's written submission said that, under Standard A18 as it stood at the time of the Commission's inquiry, genetically modified foods must be labelled regarding the origin and nature of the characteristic or property modified, where:

- the modification results in one or more significant compositional or nutritional parameters having values outside of the normal range of values for the existing equivalent conventional food or food ingredient
- the level of anti-nutritional factors or natural toxicants are considered to be significantly different in comparison to the existing equivalent conventional food or food ingredient
- the food contains a new factor known to cause an allergenic response in particular sections of the population
- the intended use of the food or food ingredient is different to the existing equivalent conventional food or food ingredient.

70. Following the recommendations of an ad hoc inter-governmental task force, which included New Zealand representatives, the ANZFSC decided to extend the labelling requirements of genetically modified food. From 7 December 2001, food will be required to be labelled as being genetically modified where:

- novel DNA and/or protein is present in the final food; and
- the food has altered characteristics when compared with its conventional counterparts.

71. There will be exemptions in relation to:

- highly refined food where the effect of the refining process is to remove novel DNA and/or protein
- processing aids and food additives, except those where novel DNA and/or protein is present in the final food

- flavours that are present in a concentration less than or equal to 0.1% in the final food
  - food prepared at the point of sale.
72. The amended Standard will allow an ingredient to contain up to 1% of unintended presence of a genetically modified product without requiring labelling. In its written submission, ANZFA stated that this provision is not to be interpreted as a “general threshold”.
73. The New Zealand Ministry of Health, in its written submission, said that this amendment was determined following public consultation in New Zealand and in Australia in which consumers expressed a desire for comprehensive labelling. The Ministry said that, in making a decision about the labelling of genetically modified food, four criteria were used to assess options: meaningful information, cost of compliance, international trade implications and enforceability.<sup>33</sup>
74. The labelling requirements will be reviewed three years after they are implemented, in December 2004.
75. Public concerns about the adequacy of the new labelling requirements are discussed later in this chapter.

## Regulatory responsibilities in New Zealand

### **Genetically modified food**

76. At the time of submissions to the Commission, two New Zealand Ministries had responsibility for matters relating to food. The Ministry of Health had primary responsibility for managing the relationship with ANZFA, including contributing to, reviewing and commenting on standards developed by the Authority and coordinating responses by New Zealand government agencies on matters related to food standards. The Ministry of Agriculture and Forestry (MAF) reviewed and commented on ANZFA standards affecting primary produce.
77. Both the Ministry of Health and MAF had roles in international forums, with MAF coordinating New Zealand’s input into Codex Alimentarius decisions. MAF also had responsibility for policy advice on primary production and agricultural trade issues and the Ministry of Health provided policy advice on public health issues.
78. The Ministry of Health was responsible for coordinating the enforcement of food standards in New Zealand. Complaints regarding actual breaches of food standards are investigated by designated officers in public health units of hospitals and health services around New Zealand. The Ministry of Health also has responsibility for monitoring public health and responding to and identifying

the causes of outbreaks of ill effects, such as those that occurred as a result of the L-tryptophan incident in the United States of America.

79. Animal feed is regulated under the Animal Compounds and Veterinary Medicines Act 1997. Regulations under that Act come into force in July 2001. Genetically modified animals, if used in the production of food, will be regulated under the Animal Products Act 1999, which had not come into force at the time of the Commission's hearings. The written submission from the Ministry of Agriculture and Forestry stated that the legislative regime under this Act provides a mechanism for secondary processors to switch between risk-based management systems under the Food Act 1981 and the Animal Products Act 1999. It also provides for setting standards for genetically modified animal material or products or ingredients or additives.<sup>34</sup>

80. In chapter 7 (Crops and other field uses) we considered the use of animals as bioreactors for the production of biopharmaceuticals. In that chapter we recommended that, to avoid such animals entering the food chain, it is preferable that only non-food animals used should be used as bioreactors. Meat from any genetically modified animal, regardless of the purpose for which it has been modified, will require approval by ERMA and ANZFA and will have to satisfy the labelling requirements before it is allowed to enter the food chain.

### **Food Administration Authority**

81. Since the Commission has completed its public inquiry, the Government has announced the formation of a separate food safety agency, under the umbrella of the Ministry of Agriculture and Forestry. Although no details of the new agency have been released to date, we understand it will assume many of the responsibilities for food previously undertaken by the Ministries of Health and Agriculture and Forestry, although epidemiology and other public health issues will remain with the Ministry of Health.

82. The Commission considers that the creation of a separate agency is appropriate. We agree with the frustration expressed by the Grocery Manufacturers Association which said:

Food safety administration and monitoring and enforcement activities of food are undertaken by a myriad of agencies in New Zealand including the Ministry of Health, Ministry of Agriculture and Forestry and local authorities. This has long been of considerable concern to all sectors of the food industry for the following reasons:

- the lack of resources in some situations to carry out the necessary tasks
- inconsistent rulings and interpretations that result from having a multiplicity of agencies involved
- companies can be subject to many audits.<sup>35</sup>

83. There are a number of responsibilities related to the management and oversight of genetically modified foods in New Zealand that the Commission would want to see the new agency undertake. These responsibilities are identified during the course of this chapter and summarised in paragraphs 208 to 213.

## International obligations

84. The written submission from the Ministry of Foreign Affairs and Trade provided information on New Zealand's international obligations. The Ministry suggested that participation in the international community was important "for a small nation like New Zealand, which has limited ability when acting alone to influence other governments to its advantage".<sup>36</sup> New Zealand is a party to a number of international treaties and agreements.

### World Trade Organization

85. The Ministry's submission included reference to the World Trade Organization (WTO) and focused on two WTO agreements relevant to genetic modification, the Agreement on Technical Barriers to Trade (TBT) and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS). The submission pointed out that the TBT Agreement, which embodies the principle that products from one country should be subject to the same rules as like products imported from another country, or produced domestically, applies to technical regulations, including mandatory labelling requirements. The Ministry commented that the principles under the Agreement were important considerations in the development of the Standard A18 labelling provisions. The SPS Agreement, which allows for a country to impose standards in respect of plant and animal pests and diseases that are necessary to protect a country's biosecurity (including food safety), also embodies the principle of non-discrimination between countries.

### Codex Alimentarius

86. The Codex Alimentarius Commission (Codex) is the United Nation's joint Food and Agriculture Organization/World Health Organization body responsible for setting food standards. The main purpose of Codex is to protect the health of consumers and to ensure fair practices in food trade. It also promotes coordination of food standards work undertaken by governmental and non-governmental organisations. New Zealand was a founding member of Codex, which now consists of 165 member countries. The submission from the Ministry of Foreign Affairs and Trade advised that Codex comprises a number of committees that consider a range of matters related to standard setting.

Committees with activities on their work programmes that relate to food derived from biotechnology include:

- the Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology
- the Codex Committee on Food Labelling (CCFL)
- the Codex Committee on Methods of Analysis and Sampling (CCMAS)
- the Codex Committee on General Principles (CCGP).

87. In 1978, the New Zealand government directed that, where practical, New Zealand should adopt Codex food standards.

88. Both ANZFA and the Ministry of Health provided information on matters currently being considered by Codex. The Codex process for finalisation of the international documents and standards relating to the safety of foods derived from biotechnology is required to be completed by 2004 and a determination of labelling standards for genetically modified foods may also take as long to be completed. The ANZFA submission appended two draft documents currently being developed by the Codex Taskforce on Foods Derived from Biotechnology, both of which relate to assessing the safety of genetically modified food. The joint submission from Vegfed, Fruitgrowers, Berryfed cited with approval the draft *Guideline for the Conduct of Safety Assessment of Foods Derived from Modified Plants*.

### **OECD Task Force**

89. In its written submission, ANZFA said that it participates in the OECD Task Force for the Safety of Novel Foods and Feeds. The Task Force builds on the work done by the OECD in the 1990s to develop scientific principles for the safety assessment of products of modern biotechnology.

### **Inclusion in the global community**

90. Inclusion in the international community is one of our common values and New Zealand's international obligations are important to the country's economic well-being. Participation in international forums both allows New Zealand to contribute to the debate about genetically modified food and also keeps current the knowledge and understanding of officials charged with protecting the safety of the general public.

91. The Ministry of Agriculture and Forestry and the Ministry of Health held a joint public consultation meeting on 12 February 2001 at Wellington, and invited written submissions from interested parties on the work of the Codex taskforce. Public involvement of this nature in the debate about genetically modified food should be encouraged to ensure that the views of the community are incorporated into New Zealand's responses to the deliberations of international forums.

92. The Commission is aware of the concern among some of the public that membership of international bodies such as the WTO may impinge on New Zealand's ability to exercise self-determination. During the course of cross-examination, the Dairy Board<sup>37</sup> spoke of the value of the World Trade Organization and the Board's written submission said:

As a small nation, with little economic and political power, New Zealand is highly dependent upon the international community of nations respecting the framework of legally enforceable rules created by the WTO. Any actions which undermine respect for that system have negative implications for New Zealand.<sup>38</sup>

93. Greenpeace discussed New Zealand's international obligations and made reference to decisions of the Appellate Body of the World Trade Organization in respect of a number of appeals against restrictions imposed on trade in food. WTO has been instrumental in providing environmental protections and, only recently, New Zealand took advantage of the WTO dispute resolution process to protect important agricultural exports to the United States. We consider that such cases illustrate the value of membership of the international body, even where this may involve relinquishing some degree of national autonomy.

94. Membership of the international community requires reciprocity. Exports, for example, are protected against discriminatory trade practices imposed by other nations by the provisions of the TBT and SPS Agreements. In return, New Zealand must not implement statutory requirements that may be discriminatory against countries from whom we import. The international trading community is very watchful in ensuring this does not happen. The Ministry of Foreign Affairs and Trade, for example, pointed out that New Zealand and Australia, along with the European Union, had been among the first countries to develop comprehensive labelling for genetically modified foods. Approaches to labelling differed among countries, with some countries preferring to avoid mandatory labelling. Assurances had already been sought that the labelling requirement under Standard A18 were consistent with provisions of the TBT Agreement.

## Significant issues

### Is genetically modified food safe?

95. Many of the Interested Person groups prominent in the campaign against genetically modified food, and many of the people who spoke at the public meetings and workshops, expressed concerns about the risks associated with the consumption of genetically modified food. A number of scientists from New Zealand and overseas gave evidence that the insertion of genetic material into an organism would create unexpected effects that, in food, could have adverse effects

on human health. For example, in her witness brief for the Safe Food Campaign, Ms Kedgley identified most of the concerns shared by submitters when she said:

Scientists warn that food with altered genes could introduce a range of unanticipated health risks to consumers, including increased levels of naturally occurring toxicants, the appearance of new, not previously identified, undetectable toxicants, reduced levels of nutrients, the presence of new allergens, the creation of antibiotic resistance, immuno-suppression and the potential nutritional degradation of foods.<sup>39</sup>

96. In addition, some submissions also expressed a belief that horizontal gene transfer could transfer recombinant DNA from a modified organism to an unmodified organism, including a mammal. GE Free New Zealand said:

There is also serious concern about the dangers of using genetically engineered viruses as delivery vehicles (vectors) in the generation of transgenic plants and animals. This could destabilise the genome and lead to horizontal gene transfer to other species, including mammals. This risk is known because recent research suggests that disabled viral material used in recombinant DNA techniques can recombine with other viral material in plants or in the human or animal gut to produce new active forms of viral material.<sup>40</sup>

97. Scientific witnesses, such as Dr Beatrix Tappeser, a molecular biologist with the Institute for Applied Ecology at Freiburg and a witness for the Pacific Institute of Resource Management, and Dr Mae-wan Ho, a witness for GE Free New Zealand, as well as members of the Physicians and Scientists for Responsible Genetics, provided evidence about the risks of genetically modified food, including the possibility of horizontal gene transfer to humans through the consumption of genetically modified food. Together with many other submitters, these witnesses stated that, because of lack of experience with modified foods, the risks could neither be known nor predicted. They called for foods to be subject to tests similar to those undertaken in relation to pharmaceuticals and suggested that, until genetically modified food could be shown to pose no risk to human health, all modified foods currently offered for sale should be removed from sale. The view was expressed that, in the absence of adequate testing, humans were being used as “guinea pigs”.

98. One of the more publicised and controversial research projects was that carried out by Dr Arpad Pusztai and Dr Stanley Ewen into the toxic effect of inserting lectin genes into potatoes. Witnesses such as Professor John Mattick of the University of Queensland, a witness for Auckland UniServices [IP23], maintained the study was flawed. Dr Pusztai and Dr Ewen appeared before the Commission as witnesses for Friends of the Earth, and the Commission had the opportunity to ask questions about their research.

## Pusztai's Potatoes – the controversy<sup>41</sup>

Dr Arpad Pusztai, a senior scientist at the Rowett Institute, Aberdeen, Scotland, came to international attention when he announced to the media that eating genetically modified potatoes depressed rat immune systems and caused changes in their intestinal tract.

Dr Pusztai and his colleague, Dr Stanley Ewen, tested the dietary effects of potatoes genetically modified to contain and express a gene for snowdrop lectin, called *Galanthus nivalis* agglutinin (GNA). Lectin was introduced to potatoes as an insecticidal protein, but is also an antimetabolite, ie it slows down cell growth.

Dr Pusztai and co-workers compared rats fed genetically modified potatoes with those eating non-modified potatoes, with and without added GNA. The genetically modified potatoes appeared to cause changes in the rats' immune response and the structure of the intestinal lining. They asserted that this outcome was the result of the way the lectin gene had inserted into the potato genome, rather than the expression of lectin by the potatoes.

While the experimental design appears to be correct for this type of feeding study, there were difficulties with the use of a raw potato diet. Rats do not like to eat raw potato, and a standard 110-day trial had to be abandoned after 67 days, because the rats were starving. Starvation affects gut histology, and the lining of the gut of control rats eating unmodified potatoes was shown to be abnormal. This led to confusion regarding the significance of Dr Ewen's histological results, particularly to the reported 'over growth' of gut epithelial cells of rats eating genetically modified potato. The presence of other potato toxins could also have had a confounding effect on cells in the intestine, especially since the potato lines were not substantially equivalent:

*"... we couldn't come to any other conclusion but this, that the GNA gene insertion into our potatoes induced changes in the levels of all these things ... So we had to say at the end, the GNA GM potato lines were, therefore, not substantially equivalent to the appropriate parent tubers. And I can take it further, that the two lines of genetically modified potatoes were not substantially equivalent to each other".<sup>42</sup>*

It is also noteworthy that evidence used by Dr Pusztai to indicate that the rats had depressed immune systems was not the result of standard immune response tests.

Within the scientific community there is general agreement that the results of Dr Pusztai's experiment are inconclusive insofar as there were flaws in the process, and the project was incomplete. Extensive testing carried out by Chinese researchers, similar to that described by Drs Pusztai and Ewen, has not replicated their results.

99. The Commission, having heard evidence directly from Dr Pusztai and his colleagues, is also of the view that the results are inconclusive. It was unfortunate that the process of peer review was pre-empted by premature media release, thus preventing further scientific assessment.

100. Although evidence was presented about the risks of genetically modified food, we also heard that risks have been overestimated. Many witnesses pointed out that, although genetically modified food had been available internationally for over a decade, there was no evidence it had caused harm. The Grocery Marketers Association considered that:

If very little was known about genetically modified foods, even a suspicion of harmful effects might deter their being marketed. But a considerable amount is known, which has allowed regulatory agencies around the world, such as the OECD, the WHO, FDA, to state that genetically modified foods are as safe as conventional foods.<sup>43</sup>

101. Dr Brian Jordan, Director of the Nutrition and Health Institute of Food, Nutrition & Human Health at Massey University, a witness for the New Zealand Arable-Food Industry Council [IP56], said:

Of particular concern to the public is the ability of this new technology to supply consistently safe food. This concern has been addressed many times recently by a number of world organisations, such as the OECD, FAO and Codex Alimentarius. The overall conclusion is that there are no credible reports of adverse health effects from consuming GM foods. For instance, the OECD conference held in Edinburgh in March 2000 on “the scientific and health aspects of genetically modified foods” concluded that GM food was not a health risk.<sup>44</sup>

102. HortResearch [IP5] also suggested that there were no risks associated with the genetically modified foods available in New Zealand. Its written submission said:

While everyone should have the choice as to what they eat, there are no known health risks associated with eating GM-sourced foods available in New Zealand under current legislation. ... Most people take a far greater risk every day in eating food potentially containing pathogens like Salmonella or Campylobacter. The apparent high level of public concern about the safety of GM foods is based more on a range of other concerns (such as moral and ethical issues) rather than on the technical risks to food safety.<sup>45</sup>

103. Many of the submissions were concerned about the relationship between antibiotic resistance marker genes and increased human resistance to antibiotics. As discussed in chapter 4 (Environmental and health issues) and chapter 6 (Research), the Commission considers increased antibiotic resistance has resulted from a combination of factors, including the overuse of antibiotics in medicine, other than the use of antibiotic marker genes. However, given the increasing frequency of antibiotic resistance, we would encourage the use of alternative strategies to antibiotic resistance marker genes in the development of transgenic organisms.

104. The Commission was told that food retailers overseas are responding to consumer concerns by refusing to sell produce such as meat, poultry, milk and eggs coming from animals or birds fed on genetically modified feed, and by using positive labelling mechanisms such as “organic” or “GE Free”.

105. None of the organisations involved in the research and development of food crops or in food production and distribution, however, suggested that the safety of genetically modified food should be assumed. They supported ANZFA’s view that, in the absence of a history of safe use:

... a cautious approach is applied to these foods that involves scientific risk assessment prior to their being permitted for sale in the food supply.<sup>46</sup>

106. The Commission considers this to be the appropriate approach to follow. Witnesses said that there may be risks associated with the application of gene technology to food. While we accept that, to date, there has been no evidence of unsafe foods entering the New Zealand market, we are conscious that there is always a possibility of adverse effects from unsafe food. We are aware of the serious concerns about the long-term effects of food on human health raised by the incidence of BSE. At the same time, we are in agreement with the statement made by the New Zealand National Commission for UNESCO [IP90] that:

... if genetic engineering can lead to increased productivity of crops, growth rates and usable plant product; quality of crops including nutritional quality and storage properties, adaptation of plants to specific environmental conditions, a broadening of plant tolerance to environmental stress; increase in disease and pest resistance and less need for the use of agrochemicals; production of substances in food crops of importance to human health and the utilisation of hitherto unused species for human consumption, then these benefits for humanity cannot be foregone.<sup>47</sup>

107. Many witnesses said that the “second wave” of genetically modified foods will have greater direct benefits for consumers. We do not, therefore, consider it would be in the best interests of New Zealand to ban genetically modified food. We do, however, consider that consumers should be protected by rigorous scientific assessment processes and by proactive and effective post-market monitoring systems, and should also be able to exercise their own choice as to whether or not they consume genetically modified food.

108. Organisations such as the Safe Food Campaign suggested that a prohibition on genetically modified food and a thrust to make New Zealand “an organic nation” would lead to increased consumption of organic food with a commensurate improvement in public health.<sup>48</sup> We have seen no evidence to support this assertion. We acknowledge the importance to people of being free to choose food produced through a process they consider to be safe. Based on the

evidence we heard, we see no reason to assume that the continued presence of genetically modified foods assessed to be safe by the appropriate regulatory body will prevent individuals being able to exercise their choice to eat organic food. Steps should be taken, however, to avoid the contamination of organic food crops growing in New Zealand and this is discussed in chapter 7.

### **Unapproved genetically modified food**

109. Several submissions expressed concern that ANZFA had permitted genetically modified food to remain on sale in New Zealand pending the completion of safety assessments. Sue Kedgley, on behalf of the Green Party and the Safe Food Campaign, cross-examined Mr Lindenmayer on the ANZFA decision not to require these foods to be withdrawn. She questioned whether, in the absence of a safety assessment, ANZFA was meeting the obligation under the New Zealand Food Act 1981 that “food in New Zealand must be safe and must not contain anything harmful to health”.<sup>49</sup>

110. In its original written submission, ANZFA advised it was considering 18 applications for approval for the release of genetically modified foods, covering soybeans, corn, canola, potato, sugar beet and cotton, all but one relating to the introduction of genetic traits designed to improve production characteristics, such as a crop’s insect resistance or tolerance to herbicides. The other application related to changes in the oleic acid content of a soybean. The written submission advised that, on 28 July 2000, ANZFSC approved two genetically modified foods: glyphosate-tolerant soybeans (Roundup Ready soybeans) and oil and linters derived from insect-protected cotton lines 531, 757 and 1076 (Ingard cotton). Ten safety assessments had been completed and sent for final approval to the Council. Assessments for the remaining six “were at an advanced stage” and would soon be released for public consultation.<sup>50</sup>

111. At the time of the written submission, therefore, only two genetically modified foods had been approved under Standard A18, although a number were in the process of being approved. Later, at the hearing before us, Mr Lindenmayer was asked about the foods that might still be on the market awaiting assessment. He said:

My expectation is that 18 of them would be on the market – market still, of which, I think it is seven, have already been approved and are therefore under the ongoing regulatory arrangements. Another group have now gone through the ANZFA Board processes and recommendations are with – or are about to be with the Ministerial Council. And, I think safety assessments have been completed for all but two, and those two are two in respect of which we have been requiring further information from the applicant companies in order to allow us to complete our safety assessment.<sup>51</sup>

112. Because most of the foods approved by ANZFA are used as ingredients, a list of foods that have been approved does not give a clear picture of the foods on the supermarket shelves that could be classified as genetically modified. Few if any of these foods were required to be labelled in accordance with the provisions of Standard A18, which is currently being extended. Many submitters, however, suggested to us that the labelling required under the amended Standard A18 will still not provide the level of information about the use of genetic modification in food they think is necessary. We consider this issue later in this chapter.

### **Compliance with Standard A18**

113. Submissions raised two situations in which genetically modified foods that had previously been approved under Standard A18 could cease to comply with the standard: accidental unnotified changes to gene constructs, and contamination by unapproved genetically modified products and changes.

### **Changes to construction of approved food**

114. Ms Lees, cross-examining for ECO and Nelson GE Free Awareness Group, raised with ANZFA the issue of unnotified changes. She questioned whether the Authority regularly tested for changes in gene constructs and suggested that, had there been an unexpected change in the gene construct, it might not have been possible for the applicant to notify ANZFA of this change. She asked whether, in such a situation, ANZFA could assure the safety of that food.<sup>52</sup>

115. Mr Lindenmayer pointed out that it was ANZFA's responsibility to establish food standards and to amend the Food Standards Code to indicate approval for foods. Once approval had been given, responsibility for monitoring and enforcing standards in New Zealand rested with the Ministry of Health.

### **Accidental contamination of approved food**

116. The StarLink™ incident (see overleaf) was frequently mentioned as an example of how the safety of genetically modified foods could be compromised. Many submitters seemed to see the events as an illustration of the overall lack of safety of genetically modified food.

117. The Commission does not consider that cases of the accidental contamination of human food by unauthorised genetically modified material cast doubt on the safety of all genetically modified food. They do, however, raise issues about the need for vigilance on the part of regulatory agencies. Many submitters discussed the possibility of foods available in New Zealand being accidentally contaminated and were concerned that a complaint would be needed to trigger action from the responsible regulatory agency.

## StarLink™ Corn<sup>53</sup>

In 1998, and subsequently in 1999 and 2000, the US Environmental Protection Agency approved for use as animal feed a corn modified by insertion of the Cry9C gene from Bt encoding for an insecticidal crystal protein endotoxin. The corn was marketed as StarLink™. Because of concern that the protein Cry9C could be allergenic, the Agency could not find that there was a reasonable certainty of no harm to humans. The corn was not, therefore, approved for use as human food.

In September 2000, a coalition of environmental and food safety groups announced that Cry9C DNA fragments had been found in a popular brand of taco shells sold in the United States. In addition, the Cry9C protein was discovered in some non-StarLink™ seed corn. As a result, there was a voluntary recall of corn-derived food products in the United States by manufacturing companies, some of who took steps, such as mandatory testing requirements, to ensure no further contamination.

Late in 2000, a further review of the potential allergenicity of Cry9C, and of mechanisms for assessing suspected allergenic reactions to StarLink™ corn concluded that the Cry9C protein had a medium likelihood of proving to be a potential allergen and that seven out of 34 reactions to a meal containing corn products were probably allergic. A definitive conclusion would have required further studies.

The presence of Cry9C protein in seed corn was thought to be a result of physical contamination, although cross-pollination from StarLink™ corn could not be ruled out as the source.

The StarLink incident illustrates a number of issues relating to genetic modification of food and crops:

- The difficulties of restricting a genetically modified food for use for animals or industrial purposes when there are almost indistinguishable unmodified counterparts available for human consumption.
- The difficulty of preventing accidental contamination of human foods by imposing segregation requirements on modified food crops.
- The difficulty of ensuring adherence to separation requirements to prevent cross-pollination of genetically modified and unmodified crop species, and the failure of the companies promoting genetically modified crops to require or ensure proper growing practices.
- The need for appropriate labelling, and for post-market monitoring to identify allergic reactions rapidly and accurately.
- The externalisation to producers and to consumers of costs created by growing genetically modified crops.

118. In New Zealand, enforcement of food standards was, at the time of writing this Report, the responsibility of the Ministry of Health. It is a function that, we assume, will be moved to the proposed Food Administration Authority. Given the level of public concern about the safety of genetically modified food for human consumption, it is important that the Food Administration Authority, when

established and, until then the Ministry of Health, are proactive in enforcing food standards and in providing the public with assurance that the safety of genetically modified food is closely monitored. We are concerned that this appears not to have been done in the past nor was the capability there to do so.

119. The Ministry of Health advised that genetically modified food is not routinely tested to ensure compliance with Standard A18. Once the amended mandatory labelling regime comes into force, the Ministry intends to investigate substantiated complaints of breach of the Standard, as well as undertaking a project to look at compliance with the labelling requirements.<sup>54</sup>

120. It is not sufficient for the Ministry to rely on complaints before initiating an investigation. Testing for the presence of unauthorised genetically modified material in foods is an issue of food safety, not of regulatory compliance. The Commission notes that the Ministry has contracted the Institute of Environmental Science and Research to establish and maintain analytical capability to test genetically modified food. We expect that such tests will be carried out routinely as part of the Total Diet Survey, which already tests for pesticide residues and heavy metals in food.<sup>55</sup>

### **The safety of genetically modified stock feed**

121. The Green Party expressed concern about the possible risks to animal welfare and human health from the use of genetically modified animal feed. It suggested that any products incorporated into animal feed should be required to undergo well-controlled feeding studies in the target animal comparing the new plant variety with the conventional plant.

122. The Feed Manufacturers Association, Poultry Industry Association and Egg Producers Federation were questioned at the hearing on the use of genetically modified soy and corn meal fed to chickens in New Zealand. In response to questions from Tom Bennion on behalf of the Green Party and GE Free New Zealand, John Foulds, speaking on behalf of the Associations, said that he did not know if any assessment or testing was carried out prior to the meal being used in New Zealand. In response to questions on the steps taken to source unmodified feed, the Associations' representatives stated that they experienced difficulty sourcing feed that could be guaranteed to be free from genetic modification because overseas suppliers were unable to give such a guarantee. The Associations also said that, if they were able to source such feed, it would be more expensive.

123. ANZFA acknowledged that concerns were raised from time to time about the human health consequences of the feeding of genetically modified feed to animals. It cited information from the Federation of Animal Science Societies (FASS), an association of three prominent American animal agriculture societies

(the American Dairy Science Association, the American Society of Animal Science and the Poultry Science Association), indicating that no DNA and/or protein could be detected in products such as meat muscle, whole milk, poultry and eggs from animals or birds fed a variety of genetically modified commodities.<sup>56</sup> In a report prepared recently for the Ministry of Health, Institute of Environmental Science and Research reproduced a review by Dr Marjorie Faust at the Department of Animal Science, Iowa State University, of studies designed to detect any unintended effects in livestock fed genetically modified crops. Dr Faust's review stated that conclusions from the more than 40 animal feeding studies that had been completed or were currently in process had been consistent in finding no detrimental effects in livestock fed genetically modified crops.<sup>57</sup>

124. ANZFA submitted that possible consequences to human health should be assessed on a case-by-case basis, taking into account any potential hazards identified combined with a consideration of the animal feeding practices used for the particular feed in question. The submission suggested that, if any hazards were identified during an assessment of genetically modified animal feed, consideration should be given to the potential human exposure to that hazard through the use of the feed. Genetically modified stock feed will have to meet the regulatory standards that come into force on 2 July 2001. These standards require the importer of stock feed to satisfy the Ministry that the product is safe and fit for stock feeding purposes. The submission from MAF, however, advised that stock feeds that are not genetically modified organisms but are the products of genetic modification may not require an assessment and registration under the Animal Compounds and Veterinary Medicines Act 1997 (ACVM) if they do not trigger any safety or risk thresholds.

125. The Commission noted the call for separate testing of animal feed. With regard to human health, although we heard evidence of potential risk pathways, particularly through horizontal gene transfer, no evidence was presented of actual harm to human health. We do not, therefore, consider a mandatory safety assessment on stock feed should be imposed unless there is evidence of either novel DNA or other potentially harmful novel material being found in the products of animals and birds fed genetically modified stock feed.

### **Recommendation 8.1**

**that the Food Administration Authority monitor research studies on stock feed and act on any that indicate a need for stock feed to be assessed in relation to human health.**

126. Products from animals or birds fed on genetically modified pasture or stock feed do not require assessment under Division 1 of Standard A18 because they are not considered to be genetically modified, nor will they require labelling under the labelling provisions to be implemented later this year. It is important that consumers are able to choose to avoid consuming the products of animals and birds fed on genetically modified feed. Where a claim that animals and birds have not been fed genetically modified food can be sustained, labelling that identifies the product as being free of genetic modification will be appropriate. We discuss genetic modification-free labelling later in this chapter. Without such a label, consumers must assume that a genetically modified food may have been used.

### Are the current food safety standards satisfactory?

127. Those people who worried about the safety of genetically modified food were also doubtful about the ability of regulatory agencies to identify and manage the associated risks. Nelson GE Free Awareness Group referred to the anxiety of environmentalists and said:

Many are extremely concerned over the lack of adequate testing carried out by the regulatory agencies and multinationals and the rapid introduction of foods from this technology reaching the supermarket. The public wish to preserve their health and understand that their consumption of safe, nutritional food is the best way to ensure continued health.<sup>58</sup>

128. Joanna Gamble referred to the importance of consumer confidence in regulatory agencies in the background paper provided for the Commission on public perceptions of genetic modification. She pointed out that a 1998 study conducted with focus groups by HortResearch revealed that, because consumers were reliant on particular organisations (ANZFA, governmental) to provide them with information on the use of genetic modification, a high degree of trust in those entities was required for the information to be accepted.<sup>59</sup>

129. As the regulatory body most closely identified with responsibility for ensuring the safety of genetically modified food, ANZFA attracted considerable criticism from those submitters who were concerned about the safety of the technology. During the public hearings, and in written submissions, the Commission heard serious allegations about the inadequacy of ANZFA's processes and standards. The Authority was, therefore, invited to appear before the Commission and respond to criticisms. The hearing was open to the public so that not only the Commission but also Interested Persons were able to question the ANZFA representatives. In inviting ANZFA to appear, the Commission

particularly drew their attention to the strong criticism expressed by the National Nutritional Foods Association of New Zealand (NNFA) [IP106]. The submission from the NNFA, and the witness brief from its Executive Director, Ron Law, referred to events relating to royal jelly (a bee product) and said:

The Australia New Zealand Food Authority is an Australian government agency given legal authority to set food standards. ANZFA assures the public that it has vigorously determined the safety of GE product approved to date. The NNFA will provide prima facie evidence that ANZFA has a track record of using false, falsified and even fabricated data to establish food standards.<sup>60</sup>

130. Mr Law also raised issues about the credibility of the Therapeutic Goods Administration (TGA), the Australian equivalent of Medsafe, which is discussed in the following chapter on Medicine. Mr Law said:

Based on the NNFA's experience with the regulatory process, New Zealanders can have zero confidence in ANZFA, TGA or the Ministry of Health regulating GE products in an objective, transparent and equitable manner that is commensurate with good regulatory practice.<sup>61</sup>

131. The Commission was able to form its own opinion of ANZFA based on what it heard during the course of the hearing. As will emerge in the conclusions later in this chapter, the Commission does not share Mr Law's views.

132. The doubts we heard expressed about the quality of the safety standards applied to genetically modified food tended to focus on the following issues:

- lack of independent testing of genetically modified foods by ANZFA
- reliability of the scientific data on which safety assessments are based
- reliance on Food and Drug Administration (FDA) approval
- testing standards applied to determine the safety of genetically modified food
- application of a “substantial equivalence” test to determine whether or not a modified food was safe
- adequacy of scientific knowledge of the effects of genetically modifying food.

### **Lack of independent testing of genetically modified food**

133. Concern about the lack of independent testing arose primarily from doubts about the integrity of applicant companies and the reliability of any information they would supply. For example, GE Free New Zealand said:

ANZFA regulations do not contain provisions for independent testing of the safety of novel foods. ANZFA relies on the assessments and submissions provided by the

manufacturers and regulators in the country of origin of the novel foods. This process is open to abuse. It is a highly risky method of assessing safety as the manufacturers have commercial reasons for hurrying their products to market and may cut corners with safety testing and assessment.<sup>62</sup>

134. ANZFA confirmed that it does not carry out any scientific testing of its own but, in the absence of internationally agreed guidelines, followed an assessment process based on recommendations from internationally recognised organisations such as the OECD.<sup>63</sup>

135. During the hearing, Mr Lindenmayer pointed out that the cost of testing at product level would be “vast”. Moreover, he questioned whether independent testing would add anything significant to the assessment process. Any testing that would be carried out would be more limited and would:

... raise the question of what more should be tested for than what is already tested for by the applicant organisation in gathering the data for the data packs.<sup>64</sup>

### **Reliability of the scientific data provided by applicants**

136. There was also concern that ANZFA based its assessment on scientific data put forward by applicant companies involved in developing and promoting genetically modified food. It was suggested that the data was not reliable because it had not been peer reviewed or published, nor was it tested by ANZFA. Dr Judy Carman, an epidemiologist and immediate past-president of the South Australian Branch of the Public Health Association of Australia, who appeared as a witness for Pesticide Action Network New Zealand [IP87], said:

one of the concerns of course is that the information that comes to ANZFA now only comes from the applicant company; there are no independent safety assessments done that ANZFA can collect that they can look at. This is a worry because clearly the company is going to benefit financially from the food if it is assessed as being safe, yet ANZFA appear to be accepting their safety evidence without discount, and in the complete absence of produced independent assessments.<sup>65</sup>

137. ANZFA staff provided considerable detail about the scientific data and information used by the Authority in the course of its scientific assessment. Dr Marion Healy, ANZFA Chief Scientist, discussed the scientific information used in carrying out assessments. She stressed that the information requirements ANZFA set out in publicly available guideline documents are indicative only and that ANZFA reserves the right to require additional information if necessary. Dr Paul Brent, ANZFA’s Manager (Biotechnology) advised that:

... of the 18-odd assessments done so far, there wouldn’t be one where we haven’t gone back on many occasions to the applicant and challenged them to clarify bits and pieces of applications, particularly the molecular characterisation.<sup>66</sup>

138. Dr Healy commented that the quality of the data presented with an application was a critical part of the evaluation process. She said that, when assessing the quality, ANZFA took into consideration matters such as:

- the relevance of the data to the hazard, the food and the consumption of the food
- the appropriateness of the methodology: is it up-to-date? has it been validated?
- the adequacy of the study design, including the length and sufficiency of the testing, whether or not there is a dose response curve
- the appropriateness of any relevant statistical analysis
- the reproducibility of the data
- the totality and the weight of the evidence.<sup>67</sup>

139. Dr Healy emphasised that totality and weight were key factors in assessing the safety of a food, rather than individual studies alone. She told the Commission that, in situations where there is scientific uncertainty, a number of additional steps are built into ANZFA's risk and safety assessment process, such as:

- determining whether a pre-market product-by-product assessment should be carried out or whether general permissions should be given
- determining whether case-by-case assessments or generic assessments should be carried out
- the scope and relevance of the data, including issues relating to the veracity of the data, its sources, its production
- the relevance of the data to the target population
- modelling the exposure scenarios.

140. Dr Healy stated that the higher the level of uncertainty, the more conservative would be ANZFA's approach to modelling the exposure scenarios. She also commented that, in determining any appropriate risk management strategies, ANZFA would also be more conservative according to the level of uncertainty in the information.<sup>68</sup>

141. Dr Brent provided further information about the data on which ANZFA based its recommendations. He advised that, as part of the application, the Authority received the raw data from every experiment conducted by the applicant, which, he suggested, allowed for a more rigorous analysis than could be done on the summary data submitted in support of publication of a scientific journal article. Dr Brent also emphasised the quality expected, saying:

... for the data to be accepted as reliable, relevant studies must be conducted using internationally accepted protocols for research, such as good laboratory practice, and they are usually independently audited.<sup>69</sup>

142. Dr Brent advised that data was required on:

- how the food was developed, including the molecular biological data which characterises the genetic change:
  - data on the donor, the host, the method of transformation
  - the full sequence of the gene construct and the vectors
  - regulatory elements, construct maps, number of insertion sites
  - information on the stable inheritance over generations
- data on the composition of the novel food compared to the non-modified counterpart foods:
  - nutritional information
  - potential for toxicity and allergenicity.

143. Following the hearing, Commission members had the opportunity to read documentation presented in support of an application for approval of Roundup Ready Soybeans.<sup>70</sup> From our reading of these 15 substantial volumes, and also documentation relating to other genetically modified food applications, we conclude that ANZFA required comprehensive studies, including raw data, and did not rely on the conclusions reached by the applicant company’s own employees or contractors. We consider that the ANZFA staff is well qualified to analyse the data and to assess the safety of genetically modified food based on current scientific knowledge.

### **Provision of false information**

144. At the hearing, the Commission raised with ANZFA staff the possibility of false information being supplied by applicant companies. The Commission asked whether the Authority could be certain that false test results had not been given, and also queried whether there was a risk that the applicant might suppress unfavourable test data.<sup>71</sup>

145. Dr Healy replied it was not hard for an experienced scientist, knowledgeable in the relevant discipline, to identify a “disjunction” between the data presented and what the body of scientific literature says should occur. In response to the second question, Dr Brent agreed that suppression of unfavourable test results by a company would be difficult to detect. Mr Lindenmayer pointed out that not only were regulatory bodies, such as ANZFA and ERMA, developing systems for exchanging information but also it was likely that such behaviour would become public. He reminded the Commission that companies wished to protect their reputations.

### **Reliance on FDA approval**

146. A number of submitters were particularly concerned that ANZFA had approved the entry of genetically modified food to the New Zealand and

Australian markets on the basis of prior approval by the United States Food and Drug Administration (FDA). ECO said:

ANZFA needs to investigate more fully the actual testing that has been done on the foods approved. They should not rely on FDA testing, as the FDA has been shown to ignore its own scientists' advice and a "revolving door" between industry employees and the FDA has been documented. This calls into question the impartiality of the FDA's decisions. When ANZFA's decisions are contrary to the New Zealand public's wishes, then New Zealand should be free to make independent decisions based on public preferences.<sup>72</sup>

147. Steven Druker, a witness for the Nelson GE Free Awareness Group, gave further details of the doubts about the FDA. Mr Druker, an American public interest attorney, who was representing nine scientists in a lawsuit against the FDA, related a number of concerns about genetically modified food, and also questioned the soundness of FDA policy, which he described as "irresponsible and immoral".<sup>73</sup>

148. At the hearing before the Commission, the Authority was questioned on two occasions about its reliance on FDA approvals during the course of safety assessments. Questions from GE Free New Zealand specifically addressed this issue:

MR COLLINS QC: In undertaking the assessment, to what extent was there reliance on FDA prior approvals?

DR BRENT: There was no reliance on the approvals. They don't do a pre-market safety assess, so we've never used any evidence from the FDA as part of our approvals.

MR COLLINS QC: Yet there are many many foods that were introduced into New Zealand and Australia which were approved because they were authorised by FDA?

DR BRENT: No, that's not correct. I think you will find in the interim arrangements we use the words "regulatory authorities".

MR COLLINS QC: Yes.

DR BRENT: And that would include the UK, the EEU, Japan and Canada.

MR COLLINS QC: Not the FDA?

DR BRENT: The FDA has never been in a position – or we have never used the FDA as a standpoint to base our safety assessments. They don't do one.

MR COLLINS QC: So you are able to categorically assure the Commission that there has been no reliance placed on "FDA approval", if I can use that word in quotation marks, in giving approval to a food introduced into New Zealand or Australia as part of that interim regime?

DR BRENT: Not for a GM food, no.<sup>74</sup>

149. Later in the hearing, after a brief discussion on whether the FDA had a voluntary or mandatory notification process, the Commission asked for confirmation of the relationship between FDA and ANZFA approval:

CHAIR: So, whether it was at the voluntary stage or at the more recent mandatory stage, the fact that something has been submitted to the FDA, plays no part in ANZFA's decision-making?

DR HEALY: That's right. Obviously we monitor what's going on at regulatory agencies as well as the scientific literature around the world and we're well aware of the types of products that are being discussed with the FDA, as we are with a number of other regulatory agency. But, the decision, or the kind of discussions that the FDA are having, do not directly at all impact on the sort of decision-making that we at ANZFA have. If they alerted us to a particular problem then obviously we would take cognisance of that information as with any piece of information that we derive from anywhere; regulatory scientist, wherever, to make us look a bit more closely at what the issue was.<sup>75</sup>

150. The Authority went on to state that the fact that a food had been on the market in a country other than New Zealand for a significant period without adverse effects would be one of the factors taken into account in the decision-making process.

151. The Commission was satisfied that reliance on FDA approval does not, on its own, play a role in either the scientific assessment process or the overall process for making decisions on applications under Standard A18.

### **Standard of ANZFA safety assessments**

152. Many of the submissions we received questioned whether ANZFA's safety assessment process was adequate to provide an assurance of the safety of approved genetically modified food. In its written submission, GE Free New Zealand said:

The Environmental Risk Management Authority (ERMA) and the Australia New Zealand Food Authority (ANZFA) are operating case-by-case assessments of biotechnology food products whereby most gene-altered foods are passed as safe with minimal testing and sold to the unsuspecting public without health warnings to identify these novel food risks. The safety assessment procedures involve no long-term health testing of novel foods. Therefore the ERMA and ANZFA regulatory framework is prima facie inadequate to protect consumers from health hazards.<sup>76</sup>

153. Moreover, Dr Carman in her evidence suggested that ANZFA has:

... as a philosophy the idea with genetically engineered foods that they are safe until they are proven to be unsafe.<sup>77</sup>

154. During the course of the hearing, Dr Healy and Dr Brent described in some detail the process ANZFA followed in carrying out safety assessments. Dr Healy described the risk assessment, safety assessment framework within which

decisions on the safety of novel foods are made and the policy considerations relating to decision-making in respect of those foods. She told the Commission that a safety assessment is viewed as a modified form of hazard identification and is a comparative approach, aiming to identify new or altered hazards relative to the comparator and to identify changes relevant to human health in relation to key nutrients. She mentioned that assessments of genetically modified foods also took into account the potential dietary exposure of the foods.<sup>78</sup>

155. In discussing the safety assessment process, ANZFA staff stressed the qualifications and scientific experience of its own staff. There were five staff on the scientific side, in addition to the Chief Scientist. ANZFA also confirmed that it used external scientists for specific assessments. A list of names was included in the additional information the Authority provided in response to criticisms made of it during the course of our inquiries.<sup>79</sup>

156. We were also advised that, before any recommendation is forwarded to the Ministerial Council (ANZFSC) for approval, there is opportunity for comment, including comment on the science, from a range of people with knowledge of food safety issues. These included internal and external peer reviewers, the senior health officials of all the jurisdictions covered by the ANZFA process, and Health Ministers on the Council.

157. Dr Carman stressed the importance of public health expertise in the safety assessment process<sup>80</sup> and during the course of cross-examination Ms Kedgley questioned the public health expertise of ANZFA staff. Dr Healy responded that, in addition to the staff with molecular genetic qualifications, ANZFA staff had a range of qualifications, including qualifications in nutrition and public health. Mr Lindenmayer confirmed that there were a number of external sources of public health expertise available to the Authority.

158. In response to a question from the Commission, Dr Healy discussed what might constitute scientifically reasonable grounds for withholding approval for a genetically modified food. She identified allergenicity as being a particular ground for withholding approval, as well as evidence of abnormal toxins. She also mentioned that a deliberate nutritional modification might create issues about any consequent alteration to the impact of particular nutrients in the nutrient profile in the context of diet, and confirmed that the Authority would have particular concern about the potential for the production of a protein of unknown function or unknown impact.

### **Use of “substantial equivalence” as a test for safety**

159. Several of the Interested Persons expressed concerns about the use of substantial equivalence as a test for the safety of genetically modified food. The

Safe Food Campaign, for example, said it believed that:

... substantial equivalence testing jeopardises consumer safety by allowing the quick introduction of GM foods into the human diet without adequate testing. We believe that ANZFA should not be approving these recently and relatively developed untested products to be consumed. The lack of safety testing and the labelling of GM foods we believe does not address the risks surrounding GM foods, and does not adequately protect consumers, or provide them with adequate opportunity to avoid GM foods.<sup>81</sup>

160. As well as listening to ANZFA's comments on this issue, the Commission considered the views expressed by the Expert Panel of the Royal Society of Canada.<sup>82</sup> We noted also the discussion of approaches to the nutritional and food safety evaluation of genetically modified foods contained in the report of the meeting of a joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology held towards the middle of 2000.<sup>83</sup>

161. The report from the Royal Society of Canada explored the uses of "substantial equivalence" within the Canadian regulatory environment. It cited the original OECD formulation of the concept as saying: "If a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety."<sup>84</sup> The Canadian Royal Society pointed out that this could be interpreted in two ways. It suggested that one interpretation was:

... to say that the new food is "substantially equivalent" is to say that "on its face" it is equivalent (ie it looks like a duck and it quacks like a duck, therefore we assume that it must be a duck – or at least we will treat it as a duck). Because "on its face" the new food appears equivalent, there is no need to subject it to a full risk assessment to confirm our assumption.<sup>85</sup>

162. Under this interpretation, the Expert Panel suggested, the concept of "substantial equivalence" functions as a decision procedure for facilitating the passage of new products, both genetically modified and unmodified, through the regulatory process.

163. The second interpretation the report identified was to treat the concept as a standard of safety. In this interpretation, "substantial equivalence" functions as a scientific finding or conclusion justifying an assumption of safety:

This interpretation requires a scientific finding that the new food does not differ from its existing counterpart in any way other than the presence of the single new gene and its phenotypic change. In every other way, phenotypically and in terms of its impacts on health and the environment, it will have been demonstrated to be identical to the existing food.<sup>86</sup>

164. The Royal Society of Canada concluded that, in practice, regulatory agencies, in Canada at least, relied on “substantial equivalence” as a decision threshold. The report recommended that approvals for new transgenic organisms should be based on “rigorous scientific assessment of their potential for causing harm to the environment or to human health”.<sup>87</sup>

165. The report of the joint FAO/WHO Expert Consultation also discussed substantial equivalence and pointed out that:

The application of the concept is not a safety assessment in itself; it does not characterise the hazard, rather it is used to structure the safety assessment of a genetically modified food relative to its conventional counterpart.<sup>88</sup>

166. The report then went on to outline the comparative approach that should be taken to identify any intended and unintended differences between the modified food and its closest traditional counterpart. These differences, the report said, then become the focus for the safety assessment.

167. During the formal hearing process, we heard a number of Interested Persons active in the campaign against genetically modified food state that ANZFA used substantial equivalence as a test to determine the need for further assessment. In the light of the views expressed in the reports from the Royal Society of Canada and the FAO/WHO, the Commission was particularly interested to hear and evaluate the information provided by ANZFA on its application of the concept of “substantial equivalence”. We noted the statement, contained in the written response to criticisms made of ANZFA during the course of the Commission’s inquiries, that:

... they [the Canadian Royal Society] endorse substantial equivalence when it is used in the way that ANZFA uses it, ie when it is used as a starting point for comparison with existing food as suggested by the FAO Expert Consultations.<sup>89</sup>

168. Bearing in mind the findings of the Canadian Royal Society on the application of substantial equivalence by regulatory agencies, the Commission was keen to hear ANZFA’s explanation of the role the concept played in its assessment process. We therefore noted carefully the description of the assessment process given by ANZFA staff during the hearing and their responses to questions in cross-examination.

169. Dr Healy sought to clarify how ANZFA has been using the concept of substantial equivalence. She referred to “the comparative approach” and said:

We do use the approach of comparing food produced using gene technology with conventionally produced food ... it’s well accepted in the community that the conventional food supply has a history of safe use and, if you like, there’s a community standard that we can use as a basis.

In undertaking this comparative approach we're looking for similarities and differences in key constituents between the two foods. The aim of this comparison is to identify the similarities and particularly the differences. And particularly to see whether, in these differences, there may be new or altered hazards that we need to give some consideration to.<sup>90</sup>

170. Mr Law, questioning on behalf of the NNFA, said he presumed that the purpose of a safety assessment of a food produced using gene technology was to confirm substantial equivalence. In response, Dr Healy disagreed with the presumption. She explained that the question of the safety of the food and to confirm it as a food with all the benefits and risks normally associated with food were two separate questions. She said:

... substantial equivalence is a tool to guide decision-making to look for potential new – to look for differences that may – and those differences may be hazardous. You would then go on to analyse whether any of those differences do in fact have an adverse health impact. They may or may not. They may or may not even be biologically meaningful.<sup>91</sup>

171. Having listened to ANZFA's description of its assessment process, its discussion of how the Authority uses substantial equivalence in that process and, in particular, having regard to the extensive documentation, consisting of 15 thick files of information, relating to the assessment of food derived from Roundup Ready soybeans (Application A338), we concluded that the concept of substantial equivalence is not used by ANZFA as a decision threshold to determine whether or not a safety assessment of the genetically modified food should be conducted. We accept that the concept is part of a process of comparative analysis that is a springboard for consideration of a range of matters relevant to establishing the safety or otherwise of the food. We are confident that ANZFA does not assume that, just because it looks like a duck and quacks like a duck, it is a duck.

### **Adequacy of scientific understanding of the effects of genetically modifying food**

172. Issues raised in a number of submissions included the relative newness of genetically modified food, the absence of a history of consumption and the perceptions that the current body of scientific knowledge is not sufficiently developed. GE Free New Zealand, for example, questioned whether there was sufficient knowledge to assess the potential risks of genetically modified food, saying:

GE Free New Zealand believes that this indefinite and immediate ban on all genetically engineered food, crops and animals in our food and environment is necessary because we dispute that there will ever be sufficient long term and independent scientific research which will guarantee the safety of genetically engineered food, crops and animals. This is

due to the lack of scientific knowledge about the complexities of DNA and the technology itself, and because it is difficult to conduct research into possible risks of this technology, when the risks themselves are unknown.<sup>92</sup>

173. Many people expressed particular concern that genetically modified foods were not subject to the same rigorous testing as pharmaceuticals, including long-term testing and human clinical trials. Some submissions suggested that, in the absence of safe testing procedures, a history of safe use or an assurance of no risk, the only safe course was to prohibit genetically modified food.

174. Dr Brent addressed the adequacy of toxicity tests at the hearing before the Commission. He described the approach taken by ANZFA as “holistic” in requiring a comprehensive data set on the molecular characterisation, as well as compositional and nutritional data and data on the toxicity and allergenicity:

We argue that where these demonstrate no significant concerns in comparison to conventional breeding techniques, then the potential for long-term effects is considered no different to that for conventionally produced foods.<sup>93</sup>

175. He went on to explain the difficulties of applying testing methods used for drugs, chemicals and food additives to the testing of whole foods. He also explained the role of acute studies, required for the newly expressed proteins in genetically modified food, and suggested that the purpose of such studies had been misconstrued.

176. In response to a suggestion from Ms Lees that there was a need for more research before the potential risks of novel organisms could be known, Dr Healy said there was an implicit, but incorrect, assumption that the only information about new genetically modified crops could come from the crops themselves. She pointed out that there had been a long history of research into some of the products of the different genes under discussion, adding:

... there is a lot of research about many of the genes and their gene product and their safety. What is different is their method of delivery and that’s where the intensive analysis needs to take place.<sup>94</sup>

177. It was clear from ANZFA’s presentation that the Authority did not rely solely on the knowledge and experience of its internal staff. The Authority mentioned on several occasions its use of external experts. Dr Healy said:

Quite early on we decided that, given the newness of us all learning how to do these safety assessments, that it would be highly beneficial to have the input of a number of external people. So, we approached a number of people who were experts in the field in, kind of in a range of slightly different areas so we could get some coverage. And, we have used that group, but from time to time we have supplemented it when we have felt that we needed some additional expertise as we’ve gone along.<sup>95</sup>

178. Referring to the Royal Society of Canada report, the Commission asked whether ANZFA saw the need for more research into the methodology used to test food. Dr Healy said that ANZFA had recently revised its guidelines, but saw no alternative ways of testing. She did, however, suggest that there might be need for long-term testing and post-market surveillance in response to community concerns. There would also be a need to alter the Authority's assessment processes in response to changes in technology and information.

### Commission's conclusions on the ANZFA process

179. We heard no evidence to suggest that the standards applied by ANZFA were below internationally recognised best practice. Based on the evidence presented to us, the Commission is confident that the Authority's assessment is independent and that by international standards its methodology is sound. Having heard and had an opportunity to question the senior staff at the hearing, we are confident that the Authority carries out its functions appropriately and with due regard to international developments in a rapidly changing area. We were impressed with the conscientious approach that the senior ANZFA staff took to the discharge of their duties.

180. The Commission was also reassured that ANZFA carries out its functions with an appropriate degree of independence not only from political influence but also from the influence of commercial interests. Given the extent of the public mistrust of commercial influence, we believe that a degree of distance from industry is important in maintaining the credibility of the Authority.

181. We understand the concerns that genetically modified foods were allowed to remain on the market pending assessment and approval by the Authority and we suggest that this decision might have served to undermine public confidence in the Authority. Nevertheless, we consider this was a practical transitional response in a situation where withdrawal of the foods may have been difficult and costly to enforce, and might have been in breach of international obligations.

182. It is not correct that, in allowing these foods to remain, ANZFA relied solely on approvals from external agencies. We are pleased, however, that the majority of these foods have now been assessed. We suggest that the results of these tests should be clearly communicated to the general public.

183. The Commission noted that ANZFA is required by statute to consult with the public, and that it carries out this requirement as widely as possible. The development and maintenance of public confidence in the regulator requires, however, not only consultation as directed but also a commitment to transparency of process and clear and appropriate communication of the principles and

outcomes of those processes. Questioning, particularly by other professionals, is important to ensuring maintenance of the highest possible standards.

184. The Commission would encourage ANZFA to make every effort to establish appropriate communication channels with the public. Effective communication will ensure that the public understands the role the Authority plays in setting food standards, is aware of the results of individual assessments, particularly for genetically modified foods, and is able to contribute to the development of standards as is appropriate. The recent appointment of Hiki Pihema to the ANZFA Board shows that steps have already been taken to improve the communication between the Authority and the Maori community. We hope that this is the beginning of better communication between ANZFA and not only Maori but also other groups within the wider community.

185. The Commission is aware of the concerns about the amendments to Australian legislation that will establish Food Standards Australia and New Zealand and effect other changes to the current regulatory system. Some aspects of the proposed changes are the subject of discussion at government level, and we do not, therefore, consider it appropriate to comment on these matters. We see no reason to believe, however, that the standard of the safety assessment currently undertaken by ANZFA will be diminished as a result of the changes.

## Labelling

186. The labelling of genetically modified food was one of the key issues raised at many of the forums we attended. Those submitters whose first preference was for all genetically modified food to be removed from the market also addressed the issue of labelling as an alternative in the event this did not happen. Companies such as Monsanto New Zealand [IP6], and umbrella organisations such as the Grocery Marketers Association also supported labelling. Views diverged, however, over the nature and extent of the labelling that should be required. The Dairy Board, for example, suggested that mandatory labelling systems did not necessarily meet consumer needs and were difficult and costly to implement. The Board indicated its preference was for a voluntary labelling system such as that adopted in Canada and the United States.

187. Labelling of genetically modified food was promoted or supported for a number of reasons. The NNFA, for example, said that its members:

... strongly believe that consumers should be able to make informed choices about what they eat. Many consumers choose not to eat GE foods and have a fundamental right to know whether food or food ingredients are derived from GE product.<sup>96</sup>

188. Submitters as diverse as the Ministry of Consumer Affairs and Monsanto supported this view of the consumer’s right to informed choice.

189. We heard that the right of choice could arise out of concerns for the safety of genetically modified food, or because consumption of modified food would be offensive for cultural or spiritual reasons. The New Zealand Jewish Community [IP80] explained in detail the Jewish dietary laws and the importance of informed choice to observance of those laws and we are aware it might be unacceptable to members of other religious groups to consume genetically modified food. We are also aware that there are people who would find it unethical to consume food that has been modified through technology, particularly when modification has involved the use of human genes.

190. Many Maori voices called for the labelling of genetically modified food. The Green Party explained the Maori view of the relationship between the natural world and the human world, and the importance of labelling to ensure Maori are able to exercise rangatiratanga and choose to consume foods “which have not been genetically interfered with”.

191. Dr Carman spoke of the importance of labelling to facilitate monitoring and response to illness or disease resulting from genetically modified food. Several organisations raised this as a reason for labelling, pointing out that, without labelling, genetically modified foods could not be identified and could not, therefore, be associated with any adverse effects.

## Proposed labelling regime

192. We heard a number of complaints that, because of the exemptions within the amended Standard A18, the labelling regime to be implemented late in 2001 will not meet consumer needs. The Safe Food Campaign thought:

GM food labelling being introduced by ANZFA will not be adequate to inform consumers, consumers will not have perfect product knowledge and everyone will not have the ability to choose not to consume GM products.<sup>97</sup>

193. There was particular concern about the exemption from labelling allowing 1.0% of unintended and unknown presence of genetically modified matter and one part per thousand of genetically modified colouring. Those who believed that genetically modified food was not safe emphasised that any presence of genetic modification posed a risk to human health. Similarly, submitters suggested that highly refined foods also had the potential for harm, even where novel DNA or protein had been removed, because they were derived from a process of genetic modification.

194. Submitters also questioned the exemption allowed to processing aids and to food additives that did not result in novel DNA and/or protein in the final food. Several, such as Dr Michael Antoniou from Guy's Hospital in London, a witness for the Green Party, pointed out that L-tryptophan would not have triggered labelling under the proposed regime. Dr Antoniou said:

... current New Zealand labelling laws for GM foods should be extended to include genetically modified organism-derived foods, which contain little or no GM protein or DNA. This will assist in the tracing of any future problems that may arise from these products. It is important in this context to bear in mind that the deaths and sickness resulting from Eosinophilia Myalgia Syndrome that has been linked to the consumption of tryptophan derived from GM bacteria, was not only free of protein and DNA, but contaminated by a toxin present at less than 0.1 percent of the final marketed product.<sup>8</sup>

195. In general, the submitters who had concerns about the consumption of food that had any association with genetic modification, even in the production process, emphasised the need for comprehensive labelling. Without such labelling, they said, consumers could not avoid the potentially harmful effects of genetic modification. Dr Joan Mattingly-Cameron, a witness for Pacific Institute of Resource Management, argued it was possible to analyse and detect amounts of DNA in food less than the ANZFA exemption threshold. The Commission considers that, while it may be possible to detect much lower concentrations, the accuracy and reliability of the tests breaks down at very low levels.

196. Dr Geoffrey Annison, Scientific and Technical Director of the Australia Food and Grocery Council, and Michael Rosser a former Director-General of Health in New South Wales and a Director of KPMG Consulting, were witnesses for the New Zealand Grocery Marketers Association. They gave evidence of the difficulties associated with establishing a labelling system that provides meaningful information to the consumer. Dr Annison told us that, during the consultation that preceded the amendment to Standard A18, the Australian Food and Grocery Council had argued for the exclusions contained in the amended Standard because trace-back and audit for refined foods and additives without modified DNA or protein and for processing aids would be difficult and costly. Mr Rosser provided information about the number of ingredients that comprise many manufactured food items, each of which would require tracing, auditing and labelling. He said that a typical processed food could have between five and 15 ingredients, each of which might have their own ingredient streams requiring what Mr Rosser called “due diligence certification” to establish their status. The evidence illustrated the cost and complexity of providing sufficient information to ensure that the presence and level of genetically modified material was

accurately identified. Without the necessary assurances provided by the “due diligence certification”, it was pointed out, any claim that a food contained no genetically modified material was likely to be inaccurate and misleading. The ANZFA thresholds were designed to permit minor accidental contamination but, ANZFA pointed out, were designed to allow for unintended contamination only, and were not a minimum threshold.

197. The Commission does not consider that a wholly voluntary system, as advocated by the Dairy Marketing Board, would provide adequate protection of public health and safety. We therefore support the mandatory labelling system provided under the amended Standard A18 Division 2. We understand that some people are concerned that food not requiring labelling under the new regime may still contain genetically modified material or will have been manufactured through a genetically modified process. From the evidence we heard, however, we accept there are issues of cost, traceability and testing difficulties that mitigate against the imposition of a mandatory labelling requirement covering not only the product but also the manufacturing process.

### **Point of sale**

198. Submitters were also concerned that food prepared at point of sale was exempt from labelling. At the ANZFA hearing, counsel for GE Free New Zealand stated that consumers would not be able to make an informed choice when purchasing food prepared at the point of sale. Mr Lindenmayer responded:

Consumers will have the prerogative of seeking that information from the restaurateur or staff in the restaurant. There will be an obligation on the supplier of the food to the food service outlet to provide the information and an obligation on, as I said, the restaurateur or the staff, to relay that if requested.<sup>99</sup>

199. In response to questions from the Commission, Mr Lindenmayer provided more information about the effect of the United Kingdom requirements for point of sale labels. He said:

... I have found it of some interest that, when I have been in the UK and visited restaurants and other commercial providers of ready to eat foods, I was not able to find on any menu any information in relation to GM, the presence of GM materials. I understand there is an alternative obligation upon the food service sector to make – to place a notice in outlets inviting customers to ask for that information from staff of restaurants. In no case did I find such a notice. I inquired of staff about that information and was told that no-one ever asks for it, and I have also been informed by enforcement authorities that there is little interest in seeking that information.<sup>100</sup>

200. The draft Compliance Guide to Standard A18, being developed by ANZFA at the time of our inquiries, states that consumers can request information on the genetic modification status of food prepared for immediate consumption, such as restaurant and take-away food. In New Zealand, the prohibitions against misleading or deceptive conduct in the Fair Trading Act 1986 ensure that, when requested, these businesses must provide accurate information about the status of the food they provide.

### **Vigilance needed**

201. We understand the public health concerns underlying many of the calls for comprehensive labelling of products that use genetically modified ingredients, or are manufactured in processes that involve genetic modification, or are prepared at the point of sale. There are fears that unanticipated toxins or allergens in genetically modified food not requiring labelling will have adverse health effects.

202. We have confidence in the ANZFA safety assessment process. We consider it unlikely that foods that have satisfied the food standard will have harmful effects. It is important, therefore, that the New Zealand regulatory agency responsible for ensuring food safety, either the Ministry of Health or the new Food Administration Authority, is vigilant in ensuring no unauthorised or unsafe genetically modified foods enter the food chain.

### **Labelling food that is free of genetic modification**

203. Many of the people the Commission heard wished to avoid consuming not only genetically modified food but also food produced by a genetically modified manufacturing process. We consider that a standard label should be used, on a voluntary basis, to indicate that a food contains no genetically modified material and has not been manufactured in a genetically modified production process. Such a label would allow those who choose to avoid genetically modified food to do so.

204. We contemplate that the genetic modification-free label will be simple and easily recognised, a symbol similar to the Heart Foundation “Pick The Tick” logo. The Commission suggests a working party of consumer and industry representatives, together with officials from relevant Ministries is convened to develop the symbol that will indicate a product is 100% free of genetic modification. The working party should also consider the standards and accreditation requirements for products wishing to use the symbol, and possibly develop a strategy for promoting its use.

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### **Recommendation 8.2**

**that Government facilitate the development of a voluntary label indicating a food has not been genetically modified, contains no genetically modified ingredients and has not been manufactured using a process involving genetic modification.**

### **Consumer information**

205. The level of public concern about the safety of genetically modified food, and the comments made by submitters on the lack of information, shows there is a need for accurate, independent information about gene technology, and about the foods produced using the technology. Information should also be readily available to consumers about labelling standards and about the consumer's right to ask about the status of food sold in restaurants and takeaways.

206. Responsibility for providing consumer information about genetically modified foods and Standard A18 should rest with the Food Administration Authority. Identifying the appropriate information to be disseminated may be a subject addressed by the working party discussed above.

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### **Recommendation 8.3**

**that, as a matter of priority, the Food Administration Authority disseminate information on the labelling regime for genetically modified foods and consumer rights in relation to foods made available for consumption at restaurants and take-away bars.**

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### **Recommendation 8.4**

**that the Food Administration Authority produce and distribute consumer information on the use of gene technology in the production of food.**

### **Enforcement of labelling provision**

207. The labelling requirements under Standard A18 will be enforced under the Fair Trading Act, administered by the Ministry of Consumer Affairs, an operating division of the Ministry of Economic Development. The Ministry also has the responsibility of ensuring that consumers obtain accurate information on products. The Commission considers that the high level of public interest in genetically modified food will ensure that any possible breaches of the fair trading provisions will be brought to the attention of the Ministry and the

Commerce Commission. Breaches relating to genetically modified food should be placed high on the Commission's list of priorities for prosecution.

## Recommended roles and responsibilities for the Food Administration Authority

208. The Commission welcomes the establishment of the new Food Administration Authority. We consider that amalgamation of regulatory responsibility for food and food safety into one agency will ensure a coordinated approach to matters relating to food safety.

209. In relation to genetically modified food, we would envisage that the Authority assumes the following responsibilities:

- enforcement of food standards
- monitoring health effects of genetically modified food
- management of ANZFA/FSANZ relationship
- public information.

### Enforcement of food standards

210. The Food Administration Authority should be responsible for:

- monitoring and enforcing food standards set by ANZFA, including testing for and recalling any product intended for human consumption where there is evidence of possible failure to comply with Standard A18
- managing rapid response food recalls where either there has been accidental contamination of food by unapproved genetically modified substances, or an unapproved genetically modified food has been released into the food chain
- random testing to ensure compliance with standards
- testing regularly for unauthorised genetically modified substances as part of the Total Diet Survey
- prosecuting all significant breaches of food standards relating to genetically modified food.

### Monitoring health effects of genetically modified food

211. The Authority should be responsible for developing and implementing public health surveillance systems to monitor unexpected allergic reactions. The Commission noted ANZFA's information on the feasibility study being carried out by the United Kingdom food safety agency.

## Management of ANZFA/FSANZ relationship

212. The Authority should be resourced adequately to manage the relationship with ANZFA/FSANZ in a manner that ensures that New Zealand's views are heard in decisions regarding genetically modified food.

## Public information

213. The Authority should be responsible for:

- providing and promoting accurate, independent information to the public about genetically modified food
- ensuring that the public is informed of the Authority's activities
- receiving information from the public on public concerns about genetically modified food. The Commission commends the public consultations already arranged by the Ministries of Agriculture and Forestry and Health in relation to Codex.