chapter |

4.

Environmental and health issues

4. Environmental and health issues

1. This chapter discusses some of the issues of environmental and health safety that were raised in the evidence before us. The Commission responds to these issues in more detail in subsequent chapters of the Report.

2. Those who thought the ongoing development of genetic modification was of benefit to New Zealand largely based their arguments on the economic benefits or disadvantages inherent in a decision either to permit or limit the use of the technology. Issues of the safety of the technology could not be ignored, however, and many of the proponents of genetic modification sought to provide information that would allay public concerns about the risk of releasing genetic modification, genetically modified organisms and products from laboratory confinement.

Key questions:

- What are the scientific hazards of gene technology?
- What are the possible impacts on the environment and human health of uses outside laboratory containment?
- Can gene technology be managed safely?

Concern about the risks

3. During the course of our consultation, many concerns were expressed about the risks of gene technology. Some people were so opposed to the technology for cultural, ethical and spiritual reasons they did not wish it to be used in any circumstances. The main issue discussed, however, was whether genetic modification could be used safely in the wider environment or whether such use should be confined to the laboratory, either for research or for some

health purposes. Many people said the risks of genetic modification could be contained within the laboratory where, within reason, its safe use could be assured. But they submitted the technology was inherently unsafe outside the laboratory and there was an unacceptably high level of risk associated with its use, even under field trial conditions.

4. The belief that risks were unacceptably high reflected submitters' underlying concerns that negative impacts of uncontained genetic modification

L-Tryptophan[1]

L-Tryptophan is an amino acid, one of the building blocks of proteins. Tryptophan is important for brain function and is normally obtained from dietary protein. In the 1980s tryptophan became popular as a dietary supplement for such conditions as insomnia and depression. Tryptophan can be purified from plant and animal proteins, but is obtained more economically by vat fermentation. In this process, tryptophan-producing bacteria are fermented in tanks with sugars and a nitrogen source. When the tryptophan levels in the vat are high enough, the solution is purified by filtration. The bacteria used may be genetically modified. At the time, several companies, including Showa Denko KK, used vat fermenters and genetically modified bacteria to produce tryptophan.

Late in 1989, people consuming high doses of L-tryptophan began showing up with eosinophilia-myalgia syndrome (EMS), a new illness characterised by painful and swollen muscles, rashes, gastro-intestinal problems and large numbers of white blood cells in the body. In the United States 37 people died, 1500 were disabled and around 5000 were affected. These patients were all taking tryptophan from a single Showa Denko KK batch that used not only a new genetically modified organism producing a more concentrated product but also a different filtration system using less charcoal, which bypassed a membrane filtering step to purify the product.

The batch was found to contain 60 contaminants of which six were responsible for causing EMS. Three toxins (a dimer of tryptophan, along with two others) were identified by 1993, but it was not until 1999 that the remaining three toxins were identified accurately.

The United States courts decided that the manufacturing process rather than genetic modification was at fault. It is unclear whether the high concentration of tryptophan made by the genetically modified bacteria or the changes in the filtering system were responsible for the build up of contaminants. Attempts were made without success to reproduce possible faults in the filtration system. At the time, other tryptophan products made using genetically modified organisms were available on the market, but no problems were reported with them, suggesting that the use of genetically modified organisms alone was not to blame.

Although the first cases of EMS were not notified until late 1989, by early 1990 the Food and Drug Administration had recalled all dietary supplements containing manufactured L-tryptophan.

may be irreversible and rapidly get beyond control. These concerns are addressed throughout this Report: for example, discussion on the invasiveness of genetically modified organisms (paragraphs 51–57 of this chapter), xenotransplantation (paragraphs 61–72, chapter 9: Medicine), possum control (paragraphs 104–114, chapter 7: Crops and other field uses) and genetically modified forests (paragraphs 70–77, chapter 7).

5. For many who opposed the use of genetic modification outside the laboratory, especially in relation to food and food supplements, the events surrounding L-tryptophan (see page 43) illustrated the dangers of the technology.

6. The L-tryptophan disaster was used frequently by submitters to illustrate many of the aspects of genetic modification that caused public concern: the inherent unpredictability of gene technology; the potential for widespread and significant harm; the difficulty of implementing regulatory controls and standards; the lack of integrity by the companies that use gene technology; the need for dietary supplements to undergo the same vigorous testing as medicines; and problems associated with establishing liability for harm. Mere McGarvey (Tuhoe), speaking at the hui at Poho-o-Rawiri, Gisborne, said:

> We want to say that we do not oppose genetic modification in general, but wish to remind everyone here and the Royal Commission that technology out of control is potentially intolerable and dangerous and could lead to calamitous consequences.[2]

7. Since no direct link was established between using genetic modification in the production of the dietary supplement and eosinophilia-myalgia syndrome (EMS), the incident cannot be taken as clear evidence of the inherent risks of genetic modification or the need to prohibit the use of genetic modification outside laboratory containment. There are, however, some useful lessons. For example, the short time it took the United States authorities to withdraw the product in question illustrates the need for such authorities to maintain the ability to respond rapidly to indications of harmful effects. The length of time it took to identify accurately all the toxins responsible for the harm, however, highlights the need for ongoing research into the hazards of the technology.

Scientific risks

8. Many submitters spoke at length about their concerns regarding the risks of genetically modified organisms escaping into the environment. They were concerned that such escapes could lead to the production of new pests and pathogens, to "super weeds" or to disturbance of the natural ecology. The risk of escape, however, depends on factors such as the nature of the organism and its use.

For example, there are different risks associated with a weakened bacterial strain used within a containment laboratory, a caged transgenic mouse, a transgenic sheep or cow in a secure enclosure and a genetically modified crop capable of producing fertile genetically modified pollen and seeds.

9. Humans have traditionally developed crops and animals with improved or desired characteristics by methods of systematic selection and breeding which ensure that strains displaying the desired characteristics are retained. Those that do not are discarded. This deliberate engineering of crops and animals has been seen as benefiting human society and has therefore been accepted. Occasionally natural mutations of genes or chromosomes have occurred that have been deemed desirable and these too have been retained.

10. More recently, radiation mutagenesis has been used to create new plant varieties. Radiation mutagenesis causes chromosome breaks and rearrangements, or deletions. We were told by Dr Johannes Wirz, a senior scientist at the research institute at the Goetheanum in Dornach, Switzerland, and a witness for Bio Dynamic Farming and Gardening Association in New Zealand [IP61], that the dose of radiation given is usually enough to cause between one to three breaks per chromosome. Other evidence, however, suggested that the genome could be completely rearranged as a result of gamma irradiation.[3] Extensive outcrossing of variants created by this technology has occurred, but there was no evidence that concerns about radiation mutagenesis were equal to the level of concern over the use of genetic modification. The development of desired characteristics through the application of genetic technology was not, we were told, so readily acceptable because of the nature and extent of the risks associated with the technology.

11. If manipulation of genetic characteristics by traditional means has never been perceived by the public as having the same level of risk as genetic modification, and if there is not the same concern about radiation technology, the public perception of risk from transgenic crops and animals must arise from the nature of the artificial genetic changes.

Risks associated with the gene construct

12. Each genetically modified organism contains a "gene construct", which confers the required characteristic. A construct consists of some or all of the following DNA sequences, each of which may carry different risks:

- vector sequences (from viruses, bacteria or plasmids), to aid incorporation of the new genes into the organism's genome
- promoter sequences (such as the 35S promoter from cauliflower mosaic virus), to switch on the transgene in the genetically modified organism

- selection marker genes (such as antibiotic resistance genes), to enable the transgenic organisms to be identified
- the new gene that confers the desired characteristic to the genetically modified organism.

Vector sequences

13. The major perceived risk arising from the use of DNA from viruses or other microorganisms as transgenic vectors is the possibility of the generation of new diseases through recombination of the vector sequences with DNA from known pathogens. Dr Robert Anderson, a retired scientist with the Physicians and Scientists for Responsible Genetics New Zealand [IP107], wrote:

> Genes, like viruses, can infect the body, which should warn of the potential risks of transgenic organisms serving as a reservoir for new diseases and as a medium for the evolution of new pathogens because of their altered physiology and biochemistry.[4]

14. Dr Mae-wan Ho, Visiting Reader at the Open University in the United Kingdom, speaking by video link as a witness for GE Free New Zealand (RAGE) in Food and Environment [IP63], described the creation of a new mouse pox virus by Australian researchers who were trying to make a vaccine for fertility control. The issue was raised by other submitters as an example of the lack of safety of genetic modification.

> What they did was supply a gene from the protein interleukin 4 into the vaccine, and this succeeded. It was made from the relatively harmless mouse pox virus, which was used just as a vehicle to carry egg proteins into the mice. The hope was that the interleukin 4 would induce the immune system to make more antibodies against the mouse egg, thereby killing it. When the researchers injected the vaccine into the mice, however, all the mice died. In fact, this synthetic virus was so lethal that it also killed half of all the mice that had been vaccinated against mouse pox.[5]

15. It is clear that such experimental work requires rigorous containment and careful controls, but the Commission received no evidence suggesting that the new virus had escaped from containment or had infected any mice not involved in the experiment. Unexpected results such as these are a part of and, to some extent, the purpose of research.

Promoter sequences

16. Another perceived risk was the activation or suppression of other genes by strong promoters in the modified gene construct, especially when the construct was inserted randomly into the genome.

17. Some submitters had particular concerns about the use of the cauliflower mosaic virus promoter (CaMV 35S) to drive the expression of new genes in plants and animals because of the risk of activation of previously dormant genes. They

suggested that new diseases might arise, through gene activation or from the new transgenes with strong promoters jumping within the genome. Dr Mae-wan Ho said:

> CaMV is closely related to human hepatitis B virus, and less closely, to retroviruses such as the AIDS virus. Although the intact CaMV specifically infects plants of the cabbage family, its isolated 35S promoter is promiscuous across domains and kingdoms, and is active in all plants, algae, yeast, bacteria as well as animal and human systems. It can substitute in part or in whole for promoters of other viruses to give infectious viruses.
>
> It is known to have a 'recombination hotspot' where it is prone to break and join up with other genetic material, hence increasing the likelihood for horizontal gene transfer and recombination. It has the potential to reactivate dormant viruses, which have now been found in all genomes, plants and animals included, and to recombine with other viruses, dormant or otherwise, to create new viruses.
>
> In addition, the fact that it is active in animal and human cells means that, if transferred into their genomes, it may result in over-expression of certain genes that are associated with cancer.[6]

18. Dr E. Ann Clark, Associate Professor of Plant Agriculture at the University of Guelph in Canada, speaking as a witness for the Green Party of Aotearoa/New Zealand [IP83], said:

> In GM crops, genes coding for chitinase activity [are] stimulated to overproduce at very high levels (hyperexpress), typically using the CaMV S35 promoter. The result is the presence of [a] very high level of chitinase not normally seen in nature. What will happen to non-target fungi, including mycorrhizae, when residues of a GM crop designed to hyperexpress chitinase activity is soil-incorporated?[7]

19. Dr Robin Ord, genetics consultant and law student appearing for Pesticide Action Network New Zealand [IP87], saw a political aspect to the debate:

> As regards the much discussed cauliflower mosaic virus 35S (CaMV) promoter patented by Monsanto – I believe that the patent for the worldwide use of the enhancer gene that goes with it is or was owned (at least in part) by Lord Sainsbury, who also happens to be or have been the UK Minister of Science, and has sat on committees promoting GM foods … Lord Sainsbury has decided me against GM for the immediate future.[8]

20. Dr Daniel Cohen, a plant scientist in the Plant Health and Development group of HortResearch [IP5], also discussed the concerns about the CaMV 35S promoter in his witness brief:

> Most of the experimental data cited by Ho et al … is not disputed. It is well known that viral sequences recombine and on very rare occasions new strains of virus evolve. … Horizontal transfer is common among bacteria and transfer of viral and prokaryotic sequences has occurred during the evolution of plants and animals. What is disputed is

> the extrapolation of data from laboratory experiments under controlled, highly selective conditions to making claims that under field conditions major environmental and public health problems will occur.[9]

21. Dr Cohen told the Commission that CaMV was present in New Zealand brassicas and infection rates of up to 50% had been reported. He argued that the virus had clearly been part of the human diet in Europe, Asia and Australasia for a considerable period of time and that:

> … if … this virus has a tremendous power to recombine with other viruses and cause disease in other plants and animals, we might expect some evidence of remnants of the virus in other organisms. Extremely sensitive PCR tests have been developed to detect traces of the 35S in foods as evidence of GE ingredients. Such tests would be impossible if horizontal transfer had taken place.[10]

22. In this last sentence, we understand Dr Cohen to be saying that if the 35S promoter had jumped to other plants and organisms, the test for genetically modified ingredients would lack reliability. In a letter to the Commission, the Ministry of Health confirmed that, until recently, New Zealand relied on such tests for the 35S promoter and the nos terminator sequence to indicate the presence of genetically modified ingredients from 17 of the currently permitted genetically modified foods.

Selection marker sequences

23. We noted the concern from some submitters about the use of antibiotic resistance genes as markers for selection of transgenic organisms. It was suggested that the use of these markers might increase the spread of antibiotic and drug resistance genes, leading to new diseases. This fear was summarised on a workshop summary card from the Whangarei Public Meeting:

> The use of antibiotic marker genes (tool of GE) may prove to be dangerous – creating super bugs. GE food plants containing antibiotic resistant marker genes can transfer to bacteria in the gut making these resistant to that antibiotic.[11]

24. Te Runanga o Ngai Tahu [IP41] was also concerned about the use of these genes:

> Can antibiotic resistant genes integrate with the beneficial bacteria in the human digestive system and develop virile [strains] of harmful bacteria that are resistant to antibiotics? Who is liable if this happens and we are faced with serious infections that cannot be treated with traditional antibiotics? The relative speed with which genetically modified organisms are rushed into the environment without knowing possible future affects appears to be more "suck it and see" than scientific.[12]

25. The Environmental Risk Management Authority (ERMA) published a discussion paper in December 2000 entitled "The Use of Antibiotic Resistance

Marker Genes in Genetically Modified Organisms". The summary of this report suggests that the use of these marker genes has had little or no effect on the incidence of antibiotic resistance:

> The major source of the development and spread of antibiotic resistant microorganisms in humans is the human use (and often overuse) of antibiotics in both the community and hospitals. Within hospitals person-to-person transmission is aided if infection control practices are less than ideal.
>
> Some antibiotic resistant bacteria occur naturally in the environment but many are a result of contamination with human and animal excreta in sewage, slurry and manure. Antibiotic resistance is therefore also acquired through ingestion of resistant microorganisms from animals or soil contaminating food or water.[13]

26. Alternatives to antibiotic resistance genes are currently available and more are under development. The Advisory Committee on Releases to the Environment (ACRE) Best Practice Subgroup of the Department of Environment, Transport and the Regions in the United Kingdom said:

> Many selectable markers in common use encode resistance to antibiotics, although a number of alternative selection systems are available. Possible alternatives include reporter genes; genes that confer resistance to cytotoxic agents and genes that confer an ability to utilise compounds that are normally inaccessible.[14]

27. Furthermore, post-selection methods for excising the marker genes using site-specific recombination are being developed.[15]

Risks associated with the inserted gene

28. Genetic modification confers a desired trait on a plant or animal. Submitters who commented on risks associated with the inserted gene sequence were concerned with the eventual expression of that trait and the risks of the expressed gene on human health and the environment. Further discussion on this issue can be found in chapter 7 (Crops and other field uses) and chapter 9 (Medicine).

Horizontal gene transfer

29. Horizontal gene transfer is the transfer of genetic material from species to species, through the uptake of DNA and its incorporation into a new genome. Horizontal gene transfer appears to be common between microorganisms, such as bacteria and fungi. Professor Brian Goodwin, Professor of Biology at Schumacher College, Dartington, in the United Kingdom, and a witness for Sustainable Futures Trust [IP51], described the phenomenon in his witness statement:

> There is clear evidence that genes transferred to plants can transfer to soil bacteria and thence to other plants. This requires that there be DNA sequences in the construct that are

> homologous to those of bacteria. All constructs used in genetic engineering have such homologies … Therefore horizontal gene transfer can be expected to occur … It has been shown that such transfers occurred from transgenic sugar beet to soil bacteria, as monitored by the movement of an antibiotic marker gene from transgenic plant material to a strain of Acinetobacter.[16]

30. Professor Goodwin supplied the Commission with scientific references to show that there are many routes available for such transfer to occur:

> Plant material that remains in the field after harvesting can decompose and release DNA into the soil, where it can be stabilised by adsorption to polymers such as humic acid or soil particles and then be taken up by soil bacteria by transformation, or directly by the plants. Bacteria are capable of transferring genes to either closely or distantly related species, and transfers are known to occur from bacteria to yeast cells to plant cells and to mammalian cells. All species are therefore genetically linked via horizontal gene transfer.[17]

31. A number of submitters said, however, little is known about how common the movement of genetic material is between transgenic animals and other species or of the effects of horizontal gene transfer on soil ecology. Dr A. Neil Macgregor, a soil scientist from the Institute of Natural Resources, Massey University, a witness for Physicians and Scientists for Responsible Genetics, described this as an area of intense current research effort:

> Below ground, information about the effects of GE-plants and animals is growing but still rare and extremely fragmented. There is sufficient evidence to suggest that even in fragmentary form, that biological mechanisms in soil will likely play a crucial role in the overview [of] how GE and other production technologies should be developed, if at all.
>
> A living genetically modified plant exists in a tight ecological relationship with the soil microflora. Although the product of the modified gene (eg Bt) may be exudated from the live plant, little is known about actual DNA transfer from live plants.[18]

What happens to the DNA we eat?

32. The Commission heard many concerns that, through horizontal gene transfer, genes from ingested genetically modified organisms would be taken up by the body.[19] Nearly everything we eat contains DNA;[20] in fact, humans consume between 0.1 and 1.0 g of DNA per day.[21]

33. Most of the DNA we eat is broken down into fragments too small to be functional.[22] This occurs first by food preparation and cooking, and then by digestion through enzyme and microorganism action, which begins in the mouth, and continues through the gut.[23] A recent study using sensitive DNA detection techniques on farm animals fed Bt corn found no trace of Bt-corn genes, though fragments of natural chloroplast DNA were found in the blood

lymphocytes of cows and the muscle, liver, spleen and kidney of chickens.[24] Other similar studies have been unable to detect either transgenic or natural plant DNA in cow's milk.[25] Investigations into the effects of feeding high concentrations of DNA[26] to mice have, however, shown that some of this DNA survives digestion.[27] Though most was excreted,[28] some was transported into the white blood cells and into organs like the spleen, liver and kidney. When pregnant mice were fed DNA, fragments were found to transfer to foetuses through the placenta.[29]

34. These data do not, however, demonstrate that plant DNA can be transferred to, and stably maintained in, mammalian cells,[30] as there is no evidence to suggest that these fragments do anything except function as nutrients.[31]

35. Experiments have shown that injection of naked DNA into rabbits causes an immune system response or an allergic reaction.[32] This process is the body's natural defence against larger DNA fragments passing through the gut barrier, and is now being used to create vaccines.[33]

36. Because DNA is part of all plants and animals, it has always been a part of the human diet. The body, therefore, is designed to deal with it. Furthermore, many gut microorganisms are known to carry antibiotic resistance genes and no problem with transfer to gut epithelial cells has ever been reported.[34] Indeed, experiments in gene therapy have shown it to be very difficult to introduce genes into human cells.[35] Nevertheless, more investigation into the effects of substances entering the body is required, especially with respect to those people with known gut diseases.

Cross-pollination and outcrossing

37. The transfer of genetic material through cross-pollination or sexual reproduction within one species was sometimes referred to as vertical gene transfer. Professor Klaus Ammann, Director of the Botanical Garden, University of Bern, Switzerland, appearing for the New Zealand Life Sciences Network [IP24], told the Commission:

> The environmental risks of genetically engineered crops have been categorised as follows (Journal of Molecular Ecology, vol 3, 1994):
>
> 1. Invasiveness of the transgenic crop (in the agricultural system as a weed or in natural habitats)
> 2. Invasiveness of transgene itself (vertical gene flow through hybridisation with wild relatives)
> 3. Side effects of the transgenic products (for instance effects on non-target organisms).[36]

38. The risk of the escape of a transgene through vertical gene flow is different for plants and animals. Plants distribute their pollen and seeds using wind, insects

Kaatz's bees[37]

Various submitters described a case of apparent horizontal gene transfer of a herbicide resistance gene into the intestinal microflora of honeybees. The Pacific Institute of Resource Management [IP84] said:

> The German Television station ZDF reported on Sunday May 21, 2000 that a German researcher found a gene transfer from genetically engineered rapeseed to bacteria and fungi in the gut of honeybees. Professor Hans-Hinrich Kaatz from the Institut für Bienenkunde (Institute for Bee Research) at the University of Jena experimented during the last three years with honeybees on an experimental field with transgenic rapeseed in Saxony, Germany.
>
> The rapeseed was engineered to resist the herbicide glufosinate. Professor Kaatz built nets in the field with the transgenic rapeseed and let the bees fly freely within the net. At the beehives, he installed pollen traps in order to sample the pollen loads from the bees' hind legs as they entered the hive. This pollen was fed to young honeybees in the laboratory. Professor Kaatz then took the intestine out of the young bees and spread the contents on growth medium to grow the microorganisms. He probed the microorganisms for the pat-gene, the gene that confers resistance to glufosinate. In some bacteria and also in a yeast he found the pat-gene. This indicates that the gene from the genetically engineered rapeseed was transferred in the bee's gut to the microbes.[38]

Dr Beatrix Tappeser described this result as a "clear indication of horizontal transfer which has been, and is still, characterised as highly improbable". This case became a rallying point

and animals (birds eat the fruit, or seeds are picked up on wool or fur). Animals mate and therefore "contain" their eggs and sperm to a greater extent. Fish reproduction falls somewhere between these two examples. It would seem to be easier to contain the outcrossing of transgenic animals than transgenic fish or plants.

39. The Green Party was concerned about the escape of transgenic fish from commercial hatcheries. Their submission stated:

> One NZ example which has caused concern is the development in containment (until discontinued in February 2000) of transgenic salmon modified to express extra growth hormone and thus to grow much faster than natural salmon.
>
> The salmon were being raised in outdoor tanks, with water from a spring circulated through the tanks and then into the river. Until public concern led to a review of conditions by ERMA the screens designed to prevent the escape of eggs were not required to be regularly checked for holes and the mesh size was close to the lower range of egg size. There is still no way of knowing for sure whether any eggs escaped into the river and grew into adults.[40]

around which the discussions of horizontal gene transfer flowed. However Professor Klaus Ammann suggested that the results described were far from conclusive. Professor Ammann stated that he knew Professor Kaatz's work well and was "one of the committee members to revise his projects". He told the Commission that the research was a long way from being completed and had never been published in a scientific peer-reviewed journal, although Dr Tappeser stated, "Professor Kaatz had submitted his research to the science journal, *Nature*, but they had refused to accept it". Professor Ammann also considered that there was "no proof that this ... gene is not coming from normal sources". Under cross-examination from Greenpeace [IP82], Professor Ammann denied that horizontal gene transfer had ever been shown to be a significant risk:

> There have been at least 100 experiments conducted to prove that there is horizontal gene transfer from a higher organism like [a] flowering plant to bacteria, and it has not been proven. And, I must say I am appalled by Greenpeace Europe who, on the basis of two lines in an announcement of the German TV channel, just made a big story out of it. I think that's not the way we should proceed ... I can understand concerns, but I cannot understand blowing up a case which has not been scientifically proven. … I think everybody in this room should be concerned about horizontal gene transfer, but it just simply doesn't occur, you know. And, in many cases, where it would be really interesting to know it occurs, there have been done lots of experiments and nothing has been proven, nothing.[39]

The scientific world awaits the publication of the final results of Professor Kaatz's research with interest. Until then, this remains an unproven case of horizontal gene transfer between a plant and intestinal microorganisms.

40. The Green Party submission pointed to research using Japanese medaka carried out at Purdue University, Illinois. Computer modelling suggested modified fish might displace wild fish by out-competing them for food and by interbreeding with them. The Green Party said:

> Purdue University researchers found last year that a 0.1 percent intrusion of transgenic fish into a wild stock could bring that population to extinction within 40 generations where the gene reduces the offspring's ability to survive. They dubbed this theory the 'Trojan gene hypothesis' on the grounds that the gene gets into the population looking like something good but ends up destroying the population.[41]

41. However the public submission from New Zealand King Salmon said it was hard to predict the impact transgenic fish would make on ecological systems because testing the transgenics in the wild would require release. New Zealand King Salmon considered the impact of transgenic fish on the wild population would depend on the number of escaped salmon, their potential to reproduce and the potential of the transgene to confer advantage in the wild.

Randomness of gene placement and lack of gene stability

42. A further risk arises from the method of transgenesis used to create the genetically modified organism. Genetically modified organisms can be created by the random insertion of one or more copies of the gene construct into the DNA of the organism. Then some of the resulting genetically modified organisms may not be viable, if transgene insertion has disrupted essential genes. Even when the resulting genetically modified organisms are viable and stable over several life cycles, the transgene may later move within the genome, with unpredictable consequences. In her witness statement, Dr Mae-wan Ho said:

> GM constructs are also structurally unstable, and are frequently rearranged, deleted or repeated in part or in whole. The resultant GMOs, likewise are unstable and do not breed true, so significant genetic and epigenetic changes may occur in subsequent generations, multiplying the unpredictable risks to health and biodiversity. Current regulatory systems do not take this into account.[42]

43. We heard evidence from research scientists that new techniques are being developed to overcome risks associated with the gene construct and the method of transgenesis. Dr Phillip L'Huillier, a molecular biologist presenting for AgResearch [IP13], gave evidence that AgResearch's transgenic sheep and cows were created using a method called homologous recombination, which gives rise to a more specific gene insertion. This technique is similar to the methods used in animal cloning and results in the new gene being placed accurately within the genome, at a site normally occupied by a known, normal gene.

44. Similar techniques that can be used to integrate transgenes specifically into chloroplast DNA in plants are under development. The ACRE report stated:

> Transgenes can be integrated into chloroplast DNA by homologous recombination. In this way the precise location of the gene can be controlled. Because of the specificity of the integration event, fewer duplications or illegitimate insertions occur. [43]

45. This report also recommended that transgenic plants should be as similar as possible to their unmodified equivalents:

> There are a number of reasons to aim to produce transgenic plants with as little extraneous DNA as possible:
>
> - it facilitates analysis (characterisation, including sequencing) of the insertion site
> - it aids the monitoring of stability and inheritance of the transgene
> - it reduces the chances of pleiotropic effects
> - it simplifies the environmental risk assessment

- it removes one of the main criticisms of the technology regarding the propagation of plants containing antibiotic resistance genes and other marker traits, eg herbicide tolerance.[44]

46. The Commission is aware that the rapid pace of development of this technology will lead to improved techniques for the transgenesis of plants and animals over the next decade.

Environmental impacts

47. There were two main focuses for the anxiety about the use of genetic modification: the potential impact on human health, and the potential environmental impact. The level of concern about the latter was particularly high. The view expressed by one of the public submitters appeared to be shared by many:

> … humans are messing with something very unique and … doing so may cause irreversible harm to the ecosystem.[45]

48. Several of the organisations and individuals we heard were concerned that, if genetically modified organisms and products were released for use outside laboratory containment, the inherent instability of the technology and the high risk of human error meant it was likely modified organisms would escape from genetically modified crops and animals and contaminate unmodified plants, insects and animals in both the natural and the agricultural environments. Underlying the concerns about these adverse impacts was a widely held belief that the effects would be irreversible. Dr David Suzuki, a Canadian ecologist, wrote in his witness brief for the Sustainable Futures Trust:

> The difference with this technology is that once the genie is out of the bottle, it will be very difficult or impossible to stuff it back. If we stop using DDT and CFCs, nature may be able to undo most of the damage – even nuclear waste decays over time. But GM plants are living organisms. Once these new life forms have become established in our surroundings, they can replicate, change and spread, so there may be no turning back.[46]

49. The damage done by modified organisms, some submitters suggested, could be cumulative rather than acute. Dr Macgregor, for example, suggested that environmental harm could result from an accumulation of ecologically insignificant instances of horizontal gene transfers in the soil biosphere. He suggested there were largely unexplored areas of soil ecology for which testing procedures were not being developed.

50. The issue concerning submitters was not the speed with which such damage would be caused, but that it would be irreversible. The submission

received from the Green Party emphasised that harm caused to the ecology of the soil or through the food chain if New Zealand released genetically modified organisms into the environment would not be remediable. Some submitters, therefore, suggested no genetically modified organisms should be released from laboratory use until further research into potential risk pathways had been carried out. Other submitters clearly believed there should be a total ban or long-term moratorium on all uses of genetic modification in New Zealand.

Invasiveness of genetically modified organisms

Ecological impacts

51. Many submitters raised the possibility of invasive genes altering natural ecosystems as a result of the release of genetically modified organisms. A number of witnesses suggested that, because research sought to identify the linear effects of genetically modified organisms, insufficient attention was paid to the wider, ecological impacts of the hazards. Dr Peter Wills, a theoretical biologist and Associate Professor in Physics at the University of Auckland, who appeared for a number of New Zealand organisations,[47] referred to the need to look at and understand the "strange interconnectedness" of ecosystems. Dr Doreen Stabinsky, Science Adviser on the Genetic Engineering Campaign to Greenpeace US and Greenpeace International, told the Commission that studies done in the United States reviewing the results of field tests showed that ecological data had not been systematically collected. She suggested that, even if ecological data had been collected, there was a very limited base of knowledge about ecosystems and the interrelationships between organisms, and between organisms and their environment.

Weediness

52. Weediness is a characteristic of plants that allows them to be aggressively invasive, thereby upsetting natural ecological balances. Many submitters expressed concern that genetic modification of plants, particularly agricultural crops, would result in an increase in weediness.

53. Dr Stabinsky contended that the use of genetic modification to confer desirable traits on agricultural crops, such as insect or drought tolerance, could also confer characteristics on the recipient plant that made survival easier. A plant developing these characteristics had the potential to persist in the environment by withstanding either natural selection or conventional agricultural weed control methods, and thus increase in number. The development of weediness in plants, therefore, had implications for natural and agricultural ecosystems. It was suggested there was also potential for cross-pollination of future crops by the

genetically modified crops. However, recent data from a 10-year survey of genetically modified crops in the United Kingdom showed modified plants had no more tendency to weediness than their unmodified equivalents. These crops had all been modified for resistance to herbicides or insects. The study showed that all the genetically modified crops had a poor survival record in the field and were eventually replaced by wild counterparts.[48]

Outcrossing

54. The transfer of unexpected traits to living organisms could result from either sexual or non-sexual genetic transfers. The particular examples of outcrossing brought to the Commission's attention were from the accidental release of genetically modified salmon into the wild, and cross-pollination from genetically modified plants. Cross-fertilisation by genetically modified animals was not addressed, probably because the containment of such animals is easier and because, at present, modification of animals is not carried out extensively. Apart from welfare concerns, the issues relating to animals focused on the consumption by humans of products from genetically modified animals and the potential for horizontal gene transfer to organisms in the soil through animal excreta.

55. The hybridisation of unmodified plants by pollen from modified plants was of concern for a number of reasons. There was the potential for unmodified plants to develop unintended characteristics, such as weediness, that would have environmental effects. A number of submitters were concerned that foods manufactured from crops unintentionally cross-pollinated by modified crops would not be subject to the usual safety assessment processes. Accidental contamination by StarLink™ corn was cited as an example of this happening. Without assessment, it was feared, allergens and toxins resulting from genetic modification would not be detected.

56. Environmentalists and Maori expressed concern at the potential for indigenous plants to be cross-pollinated by exotic, genetically modified plants of the same genus. Maori were particularly concerned that plants that had traditionally provided food resources would be altered by cross-pollination, affecting their value as a resource and causing spiritual pollution.

57. Control of pollen flow was the focus of a number of submissions. Many submitters emphasised the difficulty of establishing satisfactory separation distances between modified crops and unmodified plants. Beekeepers highlighted the role that bees played in pollen transfer. The focus of their concern was primarily the commercial threat posed by the presence of genetically modified material in honey and other bee products.

Targeting the wrong species

58. A perception of modified genes and the modification process as inherently unstable and unpredictable caused many submitters to suggest that genetic modification would result in alteration to non-target species. Plants, animals and insects introduced into New Zealand in the past were used as illustrations of the devastation that unintended effects cause to non-target organisms. The Green Party, for example, said:

> … New Zealand's ecosystems have evolved in isolation from the rest of the world since the time when the Gondwanaland continent drifted apart. Our indigenous species tend to be very different from species in other countries. While New Zealand's ecosystems have been modified by introduced pests such as possums, deer, goats, gorse and others the lesson from these is that they have behaved differently from in their country of origin and their ecological impacts have been different.[49]

59. Many submitters isolated aspects of the research carried out on the effect of Bt-resistant corn on Monarch butterflies and cited these as examples of the potential for genetic modification to impact adversely on other species in the environment (see box opposite).

60. The Commission noted that a number of research projects being carried out in Crown Research Institutes included research into non-target effects. AgResearch advised research was currently being undertaken on the environmental impacts of new technologies, including the impacts of transgenic plants expressing insecticidal toxins. This involved quantification of the effects on the soil ecosystem, including soil foodweb composition, biomass and nutrient status. Research into pest control, especially the control of major environmental pests such as possums and stoats, we were told, included evaluating the effect of any proposed controls on non-target species. This work was being carried out by Landcare Research [IP12], which was involved in a range of projects aimed at the control and eradication of many introduced animal and plant species.

Reduction in biodiversity

61. People were particularly concerned that genetic modification would lead to a reduction of New Zealand's biodiversity. Submissions from environmental organisations, such as Greenpeace and the Royal Forest and Bird Protection Society of New Zealand [IP79], emphasised the depletion already caused by the introduction of exotic species and by cultivation, and the importance of protecting

Non-target species: Monarch butterflies and Bt corn[50]

Bacillus thuringiensis (Bt) is a soil bacterium that produces a protein with insecticidal qualities. Traditionally, a fermentation process has been used to produce an insecticide spray from these bacteria. In this form, the Bt toxin occurs as an inactive protoxin, which requires digestion by an insect to be effective.

Crop plants have now been engineered to contain and express the genes for Bt toxin, which they produce in its active form. Bt corn is used primarily to control corn borer (a lepidopteran insect), which is difficult to control by spraying. Bt-corn strains are therefore toxic to lepidoptera (moths and butterflies).

Monarch butterfly larvae feed exclusively on the leaves of milkweed plants, which are commonly found in and around cornfields in the United States. Pollen from nearby corn can become distributed on the leaves of these plants, and therefore be eaten by these larvae.

In 1999, two studies showed that Monarch butterfly larvae, and larvae from related species, had lower survival rates eating leaves dusted with Bt-corn pollen than after eating leaves dusted with non-Bt corn pollen. People used these studies to suggest that Bt corn was responsible for the recently observed decline in the Monarch butterfly population. However, the Environmental Protection Agency (EPA) noted that these preliminary controlled study data were not useful for risk assessment of widespread or recurring Bt-corn pollen effects on Monarch butterflies without additional field study information.

As a result the EPA issued a call-in of data on this topic. Shortly thereafter the data was presented to a scientific advisory panel for their recommendations. This resulted in a report evaluating many studies on the effects of Bt-corn pollen on Monarch larvae mortality.

Investigations have revealed that while a large percentage of Monarch butterfly larvae may feed on milkweed found in the corn belt region of the US, there is no overlap between breeding time and time of pollen shed through most of this region. Other studies have shown that corn pollen does not move far from the field, and that the quantity of pollen settling on an area decreases rapidly with distance. Together with toxicity studies showing low toxicity of many major Bt-corn strains, this implies that pollen densities that could represent significant exposure to feeding larvae are found only within five metres of cornfields, and then rarely. Even within corn fields pollen densities were usually found to be too low to cause mortality in Monarch larvae. Some preliminary investigations have suggested that Monarchs may avoid laying eggs on milkweeds surrounded by corn plants.

These findings indicate that, outside corn fields, Monarch larvae exposure to Bt-corn pollen is minimal, and that, within fields, Monarchs will have a low probability of encountering a toxic level of pollen.

The report also suggests that the elimination of pesticides through the use of Bt corn may be beneficial to Monarch butterfly populations, and concludes that there is not sufficient evidence to support the belief that there is significant risk to Monarch butterflies from Bt-corn use. The EPA is however continuing to monitor this situation.

New Zealand's unique flora and fauna from further threats. A member of the Royal Forest and Bird Protection Society, Nelson/Tasman Branch [IP43], Jocelyn Bieleski, said:

> Our natural ecosystems in New Zealand are unique, and their isolation, until recently, has made them vulnerable and valuable beyond measure. Indigenous forest – indigenous flora and fauna and fish belong here in their own right. … The forest is one of our living ecosystems which has successfully adapted and developed to a complex self-maintained diverse community, which has sustained its integrity over eons. Yes, there has been genetic change as adaption applies, but this has not been engineered by humans in haste. … Genetically modified organisms will threaten the indigenous biodiversity. With their release will also come changed soil composition, pollen production and insect mutation. Through mutations new bacteria and viruses are likely.[51]

62. The Commission, however, heard evidence of the potential for genetic modification to protect and preserve biodiversity. The Sustainable Futures Trust, for example, gave cautious recognition of the value of genetic modification for conservation purposes, but only where there can be an assurance of no adverse effects. Landcare Research described research currently under way into a possible genetically modified control for possums and for wasps, and the public submission from the Department of Conservation referred to its involvement in research involving conservation genetics where species are accurately mapped. It was clear from the Landcare Research submission that, while it sees genetically modified controls as being possibly the only method of dealing with this major environmental threat, it is adopting a cautious approach to the use of the technology. Other Crown Research Institutes indicated that genetic modification, rather than posing a threat to biodiversity, might provide the solutions to some of the hitherto more difficult problems associated with the management of natural resources and the environment.

Human health impacts

63. The Commission heard almost an equal amount of worry expressed about the dangers of genetic modification to human health as to the environment.

64. Some concerns were expressed about the use of the technology for medicines and therapeutics. Medicines, however, are subject to rigorous testing which minimises the potential for harm. In addition, submitters believed any adverse effects from using genetically modified pharmaceuticals and therapies would be limited to the individual. The use of the technology for personal health was, therefore, an issue of individual choice. As long as there was careful research into and limitations on any unethical uses of the technology, and as long as

pharmaceuticals and therapies were rigorously tested and clearly labelled, and patients advised of the genetic origin of any of the treatments they received, there appeared to be a greater acceptance of the use of genetic modification in these areas. However, because dietary supplements tend to fall between pharmaceuticals and food and may have less regulatory oversight than food, they were one use of genetic modification regarded as posing a special risk. Issues relating to the use of genetic modification for personal health are discussed in greater detail in chapter 9 (Medicine).

65. Submitters suggested that the development of characteristics such as herbicide resistance in genetically modified crops would lead to an increase in the use of more toxic herbicides. Particular mention was made of the link between glyphosate herbicides and non-Hodgkin's lymphoma in humans. The Commission's own research uncovered a considerable number of papers (one of which was presented by the Life Sciences Network during cross-examination of the Pacific Institute of Resource Management [IP84]) showing there was no significant risk of non-Hodgkin's lymphoma with glyphosate exposure and that Roundup was one of the least toxic herbicides currently available.

66. Submitters suggested the consumption of food either containing genetically modified ingredients or manufactured by a process using genetic modification would create serious risks of damage to human health. While there was some reference to possible carcinogenic effects of genetic modification[52] and to alterations to the nutritional value of modified foods,[53] the main worry was the creation of new allergens in foods that have not hitherto been considered allergenic, and new toxins in foods previously considered safe. Safe Food Campaign [IP86], for example, said:

> Part of our concerns centre around the "scientific risk-based approach" that ANZFA takes when testing GM foods. We do not believe that the allergenicity, toxicity and substantial equivalence tests are adequate to approve GM foods for consumption. Tests for allergenicity, like those for toxicity, are only for known allergens and toxins. As some GM foods include genes from organisms outside our diets, we believe that some GM foods may contain allergens and or toxins previously unknown to us and therefore outside those tested for.[54]

67. We noted, in particular, the expressions of anger that genetically modified food had entered the New Zealand market without any regulatory requirements other than those for conventional food. Permitting unassessed food to remain on the shelves, submitters suggested, exposed consumers to unacceptable risk.

68. Issues relating to genetically modified food are dealt with in greater detail in chapter 8 (Food).

Questioning the need

69. A number of submitters questioned whether there was a need for genetically modified products and technologies, particularly in agriculture. Submitters such as the Green Party suggested that genetic modification was seen as a "magic silver bullet" to solve problems without addressing the causes. Dr John Clearwater, an entomology consultant, in particular to the organic apple industry, and a witness called by Physicians and Scientists for Responsible Genetics, said:

> Many genetically engineered species are the product of the "magic bullet" concept that seeks a single, dramatically effective solution to a problem.[55]

70. The use of genetic modification, submitters suggested, was a "reductionist" approach to often complex problems that required a more holistic solution. In particular, there appeared to be little demand for a technology with so many risks. In its written submission, the Canterbury Commercial Organics Group [IP65] asked:

> Lack of clear need, adverse impacts on the organism "benefited" by the technology, lingering public health concerns, scientific uncertainty, and the need for clear labelling all lead to the questions: Why do we need these products? What consumers are clamouring for them?[56]

71. A number of submitters also considered that genetic modification tended to deflect attention from alternative solutions and technology, and to divert funding from the research and development of alternative health treatments and food sources which did not create the same degree of risk as genetic modification. The organics industry particularly felt it had not benefited from government research funding, and the Commission was pleased to note that additional funding was made available to this production sector during the period of our inquiry.

72. The Commission heard evidence that there might not always be a choice between genetically modified and unmodified solutions. For example, Dr Kenneth McNatty, a scientist with AgResearch, told us that, because animals are becoming increasingly resistant to conventional parasite control methods, research is under way into the development of genetically modified alternatives. Although some have suggested that treatments based on organic principles would provide more effective and safer control of animal and plant pests, there might be situations in which genetic modification would provide the best and possibly the only effective alternative to conventional methods. Landcare Research, for example, emphasised that using genetic modification in response to major environmental threats, such as from possums, that caused significant damage and did not respond to other

control methods, might be the only possible alternative:

> At present, pest problems in New Zealand, like possums and stoats, are being addressed by the best management strategies we have. The current way New Zealand is managing pests has substantial risks, particularly those from the use of poisons. GM offers more precise and better targeted ways of addressing these intractable pest problems, which could reduce or avoid the risks of current control methods, and reduce New Zealand's reliance on large scale use of broad-spectrum poisons.[57]

73. We also heard evidence from representatives of sufferers of rare diseases that genetic modification would provide the only viable option for treatment.

74. The Commission considers there may often be a need to find the most appropriate solution, in all the circumstances, regardless of whether it involves genetic modification or not. Short-term gains will always need to be balanced against long-term solutions in the decision-making process.

The corporate context

75. There was a significant level of doubt as to whether genetically modified products were anything more than a cynical manipulation of the consumer for corporate profit. Allan Fricker, speaking for the Sustainable Futures Trust, said:

> In the case of genetic modification in agriculture, and to a lesser extent in health, it is the commercial sector that is involved that carries those costs of development and production. And commerce cannot afford not to develop its products, not to apply and to sell its products. And so, in a sense, the commercial imperative gets in the way of the decisions that need to be made.[58]

76. Concerns about corporate involvement in the development of genetically modified products were raised particularly in relation to issues of liability for any harm caused by the technology and the creation of intellectual property. These are dealt with in later chapters. The Commission considers, however, that concern about corporate involvement in the development and promotion of genetic modification has had important implications for public perception of the safety of genetic modification. First, the relationship between commercial interests and science in the development of gene technology caused doubts about the integrity of science, of scientists and of the scientific process. Second, it was suggested that the commercial impetus behind genetically modified products, particularly food products, might influence and undermine the effectiveness of the regulatory agencies responsible for ensuring the safety of those products. In particular, we heard considerable criticism of the Australia New Zealand Food Authority (ANZFA) leading us to invite ANZFA to attend a special hearing to

respond. Issues relating to ANZFA and food safety are discussed in more detail in chapter 8 (Food).

Concern about scientists

77. A number of submitters raised the issue of public confidence in science and scientists. Some of the concern rested on doubts about whether scientific knowledge was sufficient to assess the risks of using genetic modification. Sometimes, however, the lack of trust of scientists in particular was explicitly linked to the relationship between commercial interests and the funding of science. For instance, Dr Morgan Williams, Parliamentary Commissioner for the Environment [IP70], while discussing the work commissioned on the control of possums and the possible use of genetic modification technology, told us:

> … what we've found, and it came out through this possum GE study, was that [the] New Zealand community's asking, how independent is our science voice today? Who actually owns that voice? … and there's a widespread perception that the soul of science is, or has been, bought, and … the objectivity, rightly or wrongly that was bestowed upon science in previous decades, is not seeking to be as strong as it was.[59]

78. Dr Roger Wilkinson, who appeared as a witness for Landcare Research, was responsible for the research into possum control carried out on behalf of the Parliamentary Commissioner. He said:

> People don't trust genetic engineering. … They also don't trust genetic engineers. Some groups described how scientists have let us down too many times … The Industry group observed the lack of trust in proponents. … Scientists were described in the Opponents group as arrogant. … Biotechnology companies were described as being interested only in profits: … Someone in the Provincial group even suspected a conspiracy. … Motives of scientists were regarded as important, along with the source of their research funds and who their employers were.[60]

79. Some submitters suggested that, because of commercial pressures, scientists and the corporate developers of genetically modified products might not carry out proper assessments of the risks of releasing genetically modified organisms. We heard this suggestion particularly in relation to the production of genetically modified food where the integrity of companies in providing research results was questioned. In New Zealand, scientists are guided by the code of ethics promulgated by the Royal Society of New Zealand. We were told by Emeritus Professor George Petersen, the immediate Past President of the Academy Council of the Royal Society of New Zealand [IP77], that:

> We have already collaborated with ERMA New Zealand in drawing up guidelines specifically for researchers in the field of genetic modification, as defined under the

> HSNO legislation, and this has been published which ERMA and distributed widely. ... I expect that we will incorporate these recommendations, and probably others, in our own general code of ethics that is due to be reviewed over the next few months.[61]

80. In response to questioning by the Commission about the integrity of scientists being compromised by the source of funding for their research, Dr Audrey Jarvis, appearing for the Interchurch Commission on Genetic Engineering [IP49], agreed that as long as scientists retained their integrity and independence, the source of funding was not an issue. She said:

> ... the integrity is terribly important. This has always been important for scientists. There will often be the odd scientist who does not have integrity. ... I guess any person [may] not have integrity. ... we're not saying that scientists don't have integrity. ... I've been to talks, been involved with scientists involved with ERMA, ... and they have concerns about the ethical issues ...[62]

Precautionary principle

81. Arguments for prohibiting the release of genetically modified organisms into the environment or for preventing the importation of genetically modified food often invoked the precautionary principle as the basis for this approach.

82. Since its introduction into environmental law in the 1970s the precautionary principle has been widely incorporated into a range of international laws, treaties, protocols and other instruments. Although it has become a principal tenet of international environmental law, it remains the focus of much debate, particularly in relation to biosafety and biotechnology. In addition, many differing definitions of the principle are found in different contexts.

83. Two formulations of the principle were held up by submitters as being applicable to the release of genetically modified organisms in New Zealand. In relation to possible environmental damage, Principle 15 of the 1992 United Nations Conference on Environment and Development (the Rio Declaration) was cited. This states:

> Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

84. Article 11.8 of the United Nations Cartagena Protocol on Biosafety (the Biosafety Protocol), agreed in Montreal in January 2000, is relevant to the release of genetically modified organisms for food or animal feed. It states:

> Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified

> organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimise such potential adverse effects.

85. Greenpeace New Zealand [IP82] called for the precautionary principle to be implemented in the Hazardous Substances and New Organisms Act 1996 (HSNO). The principle, Greenpeace suggested:

> … mandates action to prevent harm to the environment, without requiring full scientific certainty that the threat of serious or irreversible harm will be realised. Invoking the precautionary principle, Aotearoa/New Zealand will ban:
>
> - The deliberate release into the environment of genetically modified organisms in Aotearoa/New Zealand for the purposes of both field trials and commercial release.
> - The importation for food processing, human or animal consumption of living entities such as maize kernels, tomatoes or cereal grain that if released by accident or negligence could germinate and replicate in the environment. In the cases of seeded fruits and vegetables, these foods should be banned for import on the basis of the ability for the seed to retain their viability after passing through the human digestive system.[63]

86. The Green Party also invoked the Biosafety Protocol which, it said:

> … gives countries the power to protect their environment under international law. The agreement covers trade of genetically engineered organisms, including bulk commodities, seeds, animals and microorganisms. It is intended to protect countries from potential environmental impacts of importing genetically engineered organisms.[64]

87. In its submission, the Green Party made reference to the precautionary approach set out in section 7 of HSNO.

> All persons exercising functions, powers, and duties under this Act, … shall take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.

88. A number of the submitters suggested that a delay or ban on the release of genetic modification would accord with this approach.

89. Other submitters, while not specifically invoking any of the formal definitions of the principle, sought other ways of explaining their view of the approach that should be taken. Safe Food Campaign, for example, suggested:

> … [a] 'no regrets' approach would prove beneficial no matter what outcomes eventuate from genetic modification. If the best case scenario develops, with very few problems of minor consequence eventuating from genetically engineered foods, and only minor

> problems being experienced from the release of genetically modified organisms, New Zealand would still have benefited from the enhanced economic returns from the premiums gained from organic markets.[65]

90. Friends of the Earth (New Zealand) [IP78] considered the theme of its Interested Person submission was best summed up:

> … in the precautionary principle. It is our position that knowledge of the risks of genetic modification (GM) is at present extremely limited, uncertain and often based on assumptions that do not reflect the public interest.[66]

91. Submissions and witnesses on behalf of a number of the Crown Research Institutes pointed out that precaution is an element of scientific methodology, particularly of risk assessment. Dr Max Kennedy, from Industrial Research Limited, was a witness on behalf of the New Zealand Biotechnology Association (NZBA) [IP47]. To questions from Luke Anderson for GE Free New Zealand on the application of Cartagena Biosafety Protocol, he said:

> I think the concept which the Biosafety Protocol is putting forward, which is risk assessment and a detailed consideration of that on a logical basis, is something that the NZBA supports wholeheartedly. I think that the concept of doing anything without that risk assessment is really not something that is sustainable or supportable.[67]

92. Dr Kennedy went on to say that concern for protecting biodiversity or human health from risks posed by genetically engineered organisms was part of normal risk assessment methodology. The whole purpose of such methodology, he suggested:

> … is to consider the unknowns and to try to quantify those unknowns. So the fact that there is debate over it shouldn't be a surprise and it is not really something that risk assessment is unfamiliar with.[68]

93. The role of the precautionary principle in New Zealand law was considered at some length in the closing legal submission presented by the Life Sciences Network which pointed out that, although none of the international formulations of the principle were incorporated into New Zealand domestic law:

> … the concept of caution is incorporated into domestic legislation and policy by the promulgation of the Hazardous Substances and New Organisms Act 1996 ("HSNO" or "HSNO Act") itself. More particularly, that approach is overtly to be found in section 7 of HSNO requiring the adoption of a cautious or precautionary approach.[69]

94. Although we heard much discussion of the precautionary principle and the precautionary approach from those who opposed the release of genetically modified organisms into the environment, there was no consensus on the meaning of either term. The meaning of precaution often rests in the values held by the speaker.

95. The Commission considers there is more merit in hearing and responding to the message contained in the words than in seeking to define the meaning or determine how the principle should be applied. In any event, we were not convinced that a single principle could be applied across the board to the use of genetic modification in New Zealand. Decisions on the use of the technology must rest on a range of factors, including the risks and acceptability to the public of the proposed use. They are factors that should inform the process of managing genetic modification.

Risk analysis

96. It was clear to the Commission that a number of the people who spoke before us doubted genetic modification could be subjected to the usual methods of scientific risk analysis. In their view this was both because of the inherent instability of the process of genetic modification, and because there was, as yet, an inadequate body of knowledge on which to either base an assessment of the risks or establish risk management mechanisms.

97. Dr Mark Lonsdale, an ecologist with CSIRO in Australia, who appeared as a witness for the Parliamentary Commissioner for the Environment, spoke of the four pillars of risk analysis. He named these as being:

- Comparative risk analysis, which is how you compare one risk with another
- Risk assessment, which is how to decide what the risks are of a particular technology
- Risk management, which is how, having made a decision to proceed, you then manage the risks
- And then risk communication, which is how you talk to people about those risks and get people on side and keep them on side.[70]

98. Dr Lonsdale added monitoring as a fifth pillar:

> … to detect the impact of hazards at an early stage … or to provide data to refine future risk assessments.[71]

Risk assessment

99. Submissions from organisations involved in the research and development of genetically modified organisms emphasised the importance of research and the application of gene technologies being based on high-quality science and scientific knowledge. In its submission, the New Zealand Association of Scientists [IP92] said:

> Wherever possible, factual information and data should be used to address the risks and benefits of research, field trials and the release of GMOs and products. With research that

> involves risk, with field trials and with release, each situation should be considered on an individual, case-by-case basis.[72]

100. Dr Wills raised doubts whether it was possible to assess the risks of genetic modification accurately. He suggested that accepted methods of assessing risk were inappropriate for genetic modification because the risk factors associated with the technology could not be known or quantified in advance.

101. Other witnesses also suggested there was insufficient scientific knowledge of the behaviour of genetically modified organisms to allow for proper assessment of the risks. Professor Terje Traavik, a virologist from the Department of Medicine at the University of Tromsø, Norway, and a witness for Greenpeace, speaking in the context of horizontal gene transfer, said:

> There is already sufficient evidence on the unpredictability of genetic engineering techniques and the interaction of genetically engineered organisms with the environment to indicate that we do not understand enough about the short, medium or long-term consequences of their release. Horizontal gene transfer from GMOs is a real option. Such events may result in extensive and unpredictable health, environmental and socio-economic problems. Under some circumstances the consequences may be catastrophic. Our present level of knowledge about horizontal gene transfer is inadequate for reliable risk assessments. This applies to GMOs in general as well as to any particular GMO.[73]

102. However, Dr Cohen, a scientist in the HortResearch Plant Health and Development Group, said that scientific methods had been developed to evaluate and quantify the two components of risk assessment: assessment of the probability that something might occur and assessment of the consequences that might follow in the event of an occurrence.

103. In addition, the Association of Crown Research Institutes (ACRI) [IP22] and other organisations involved in researching genetic modification did not accept that gene technology was inherently unpredictable or that there was insufficient scientific knowledge to assess the risks adequately. In its submission, ACRI said:

> … that sufficient reliable research information exists, or is being rapidly developed, to allow society's decision-makers to have a workable understanding of the risks of the technology.[74]

104. The Commission also heard evidence that some of the anticipated risks of genetic modification were unlikely to arise, or would arise only in specific circumstances and were, therefore, capable of being managed.

Risk assessment models

105. Dr Lonsdale pointed out that risk assessment is "a very involved process". He suggested:

> We are early in the development of this science as it applies to GMOs. Even for small-scale releases, there is a feeling amongst proponents that they are being asked to address endless questions to no purpose, and a counter-view amongst regulators that they may be missing something. This is in part because of the newness of the technology, but there is also a need for systems thinking that will identify the range of risks that are pertinent to a particular GMO.[75]

106. The ACRE report explains the basic principles of best practice in the design of genetically modified plants and sets these within the context of risk assessment. Other agencies in New Zealand and elsewhere are revising existing assessment models to ensure that, based on current scientific knowledge, risk assessment methods identify the hazards and risks of the technology.

107. Public interest in risk assessment models is also high. The Commission had the benefit of a number of submissions from the public that addressed this issue. Wendy McGuinness provided a substantial public submission in which she addressed issues of decision-making in relation to the use of genetic modification. She said:

> My personal view is that the only way through this debate is the adoption and implementation of a rigorous decision-making methodology as to whether genetic modification should be adopted in terms of the scale, form and timing.[76]

108. The question of whether decisions on the use of genetic modification should rest on scientific principles of risk assessment, or should include wider issues was mentioned in some of the submissions we received. In its written submission, the New Zealand Arable-Food Industry Council [IP56] expressed its opinion that:

> … regulatory authorities give primary consideration to scientific assessment of risk in making GM decisions; the Council strongly opposes the possibility that political considerations become involved in GM risk assessment.[77]

109. Many of the groups asking for prohibition of the release of genetically modified organisms, however, were concerned that too much reliance was being placed on scientific risk analysis methods. Those people who opposed genetic modification on cultural and ethical grounds were particularly concerned that there appeared to be no mechanism for taking such considerations into account when making decisions on genetic modification.

110. Proponents of genetic modification, we noted, did not necessarily disagree with the view that factors other than scientific factors should influence decisions on genetic modification. The Life Sciences Network, while supporting the

effectiveness of scientific risk assessment, also suggested:

> At its most scientific, risk assessment and management is the process by which people, communities, organisations, countries make informed judgements about proposed activities and actions weighing relative risks and benefits. Having made the assessment it is then possible to ensure a positive balance of benefits over risks is maintained.
>
> However, the assessment of risk is only partially scientific and factual. Many risks are unable to be characterised in an objective sense and must be determined and weighed using subjective criteria.[78]

111. The New Zealand Dairy Board [IP67] also acknowledged the cultural, social, political and economic aspects of the risk management process. The Board, however, said this type of factor should not:

> … be allowed to impinge upon or distort the science. That should be as objective as it is possible to achieve. Other concerns should not be ignored, but they should be recognised and assessed for what they are, and not used as a basis for exaggerating, or minimising, the extent of the risk as assessed scientifically.[79]

Risk communication

112. As noted earlier, Dr Lonsdale discussed risk communication as one of the pillars of risk analysis. He pointed out that the costs of bad risk communication were high and that risk communication itself should be an area for research. He suggested that a model of communication "involving dialogue with regulators, stakeholders, and the public is likely to be more fruitful".[80]

113. A number of other submissions mentioned the need for more information about genetic modification to be made available. The Federation of Maori Authorities [IP69], for example, suggested:

> Transparency and easy flow of information will contribute significantly to educating the public in the issues we potentially face in having biotechnological research, development and practice undertaken in New Zealand.[81]

114. The New Zealand Association of Scientists supported the need for communication, saying:

> We think that communication is paramount. We believe that there has been too little communication. Science has worked in a world of its own and failed to recognise its wider social responsibilities and communication. We believe that this forum is part of the process of disseminating information, and we believe that the more widely these issues are discussed, at least the more knowledgeable and the more rational decisions will be made.[82]

115. The Royal Society of New Zealand [IP77b] in its submission discussed the public perceptions of genetic modification and pointed out that feelings of lack of

control contributed to a sense of the lack of safety of the technology. Rosemary Du Plessis, the Society's social science representative, said:

> There is public concern about GM research, and the effects of field trials, and the commercial release of GMOs. Improving mechanisms for public participation and decision-making about the use of GM technologies is one, not the only way, of improving people's sense of control over the risks that are involved in this field.[83]

116. Dr Lynn Frewer, a psychologist at the Institute of Food Research in Norwich, England, appeared as a witness for Crop and Food Research [IP4]. Dr Frewer's witness brief discussed public attitudes towards genetically modified food:

> Research has demonstrated that risk perception is "socially constructed" – that is, the way that people represent risks psychologically is a more important predictor of the way in which people will react to risks than probabilistic risk assessments used by technical risk experts to assess different hazards.[84]

117. Dr Frewer went on to say that risk perception research had demonstrated that risks that were perceived as involuntary and unnatural were viewed as more threatening than those over which people perceived they had a choice, even if the probability of occurrence of the involuntary risk was very low.

118. Some submissions suggested some of the concern about the safety of genetic modification might be dissipated if the public were more informed about genetic modification and its risks. In a background paper prepared for the Commission, Dr Michael Berridge wrote:

> Public perceptions about the risks and benefits of GM technologies are not always based on facts and are frequently dictated by uncertainty about the nature of gene manipulation, lack of knowledge about genes and natural genetic variation, and a lack of public trust in scientists and the scientific process … The main issue here is one of communication – the need to raise the level of public dialogue and to provide factual information and realistic evaluation of benefit and risk.[85]

119. The Commission agrees that the issue of communication is central to the future management of genetic modification in New Zealand. The level of concern about the potential risks to the environment and to human health is significant. While measures such as those discussed in later chapters of this report can and should be taken to manage the scientific and environmental risks of the technology, we consider careful thought should be given to the nature of the communication between scientists and others that should be an integral part of all management strategies. In his witness brief, Dr Cohen pointed out:

> There are two major components of in the analysis of risk. Firstly the probability that something might occur and secondly the consequences that might follow in the event of

> an occurrence. Scientific methods have been developed to evaluate and quantify both of these risk components. However, public perceptions of risk can arrive at completely different conclusions about both of these components.[86]

120. Dr Cohen made reference to the perception of risk sometimes being modified by an "outrage reaction" if a strongly held opinion is challenged. The Commission had the opportunity of viewing a video on general principles of risk communication by Dr Peter Sandman, a social scientist from the United States of America.[87] Dr Sandman also referred to the concept of "outrage". He suggested that the public viewed risk as being a combination of "hazard" and "outrage", where "hazard" was the actual risk and "outrage" the public's perception. Outrage, Dr Sandman suggested in his video, was as real, and therefore as measurable and manageable, as hazard. Since facts do not quench outrage, Dr Sandman's basic message was to emphasise the need for communication, transparency, consultation and acknowledgement of the areas of scientific doubt and public concern.

121 There is clearly a high level of concern about the environmental impacts of genetic modification, not just among the public but also among some members of the scientific community. Much of the evidence we heard about the risks of genetic modification, although properly drawing attention to possible hazards and risk pathways of genetic modification, is however the subject of ongoing debate, and we heard evidence from other witnesses, particularly scientific witnesses, that the risks of adverse impact could be assessed and managed. Some of the claims of possible environmental and health damage were exaggerated or based on inconclusive research data or on unproven hypotheses.

122. The Commission found it regrettable, for example, that the research into the health hazards of genetically modified potatoes carried out in the United Kingdom by Dr Pusztai had not been completed and therefore was not subjected to the normal scientific process of review. It must, therefore, be considered inconclusive. Dr Elaine Ingham, a witness for the Green Party, suggested research she had conducted showed that a bacterium designed to digest crop remnants to produce alcohol, *Klebsiella planticola*, could have had catastrophic consequences had it escaped into the ecosystem, but this evidence was discredited.

123. The Commission acknowledges that many of the scientists who appeared before us are committed to ensuring a cautious approach to the development of genetic modification because of concern about its potentially negative impacts. We are concerned that a significant degree of polarisation appears to have developed within the science community between those who promote the benefits and therefore the use of genetic modification and those who stress the

risks of this technology. The public would be better served by balanced, informed public debate about the issues raised by research and their implications for the use of the technology.

124. Most of the Interested Persons who appeared before the Commission urging caution suggested that the risks of gene technology were such that further research must be carried out and more scientific knowledge developed before the hazards and risks of genetic modification could be properly assessed. Some clearly thought that, because of the inherent uncertainties of the technology, it was unlikely there would ever be sufficient knowledge to provide an adequate assurance of safety. The point of tension between those who saw genetic modification as having the potential to provide benefits to the environment and those who saw it as having potentially catastrophic impacts lay, therefore, in the belief or otherwise that the risks of the technology could be subject to current scientific risk assessment processes and risk management techniques.

125. Issues relating to genetic modification do not give rise to easy debate. Nevertheless, we consider all the stakeholders in biotechnology should be prepared to continue the exchange of views and information that has been an important part of the Commission's process.