CHAPTER 2

BACKGROUND ON GENE TECHNOLOGY

Introduction

2.1 The focus of the Committee's inquiry was to examine the proposed regulatory system for genetically modified organisms (GMOs) as set out in the Gene Technology Bill 2000. Understanding what is involved in gene technology is important when considering the consequences of the products of this technology, and the adequacy of the regulatory arrangements that have been formulated to ensure the protection of the community and our environment.

2.2 This chapter aims to provide sufficient information for people to understand gene technology, without purporting to provide a detailed scientific explanation of the concepts and processes associated with gene technology. The chapter also highlights some of the concerns raised in evidence about the way the Bill defines genetically modified organisms, and the risks and benefits associated with gene technology.

What is gene technology?

2.3 The principle of altering various organisms is not new–for centuries, a range of techniques have been used to alter the properties of plants and animals through selective breeding or plant grafting. Today, gene technology has greatly increased the number of plant and animal traits that can be manipulated and, significantly, transferred across the species barrier.

2.4 Gene technology, sometimes also referred to as biotechnology[1], has been used to describe techniques involving the genetic modification of organisms. Gene technology refers to 'the transfer of DNA between living cells to produce a certain outcome'.[2] Gene technology has also been described as the field of research that uses 'gene transfer techniques to produce recombinant proteins and genetically modified organisms'.

2.5 The Gene Technology Bill 2000 defines gene technology as 'any technique for the modification of genes or other genetic material'. The Bill defines a genetically modified organism (GMO) as:

---

1 Note: some people consider gene technology to be a form of biotechnology, with biotechnology to refer to techniques including cross-breeding, as well as those usually associated with modern gene technology, such as recombinant DNA. See for example, Submission No.8 (Serve-Ag Pty Ltd) which states: 'Biotechnology includes harnessing the natural biological processes of microbes, plant and animal cells for the benefit of humans. GM is a branch of biotechnology.'

2 See Therapeutic Goods Administration, *Genes, genetics and transgenics*, p.2 [website: http://www.health.gov.au/tga/gene/genetech/genetics.htm].

- an organism (any biological entity that is viable, capable of reproduction or capable of transferring genetic material) that has been modified by gene technology; or
- an organism that has inherited particular traits from an organism (the initial organism), being traits that occurred in the initial organism because of gene technology; or
- anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms.

2.6 The use of the term GMO to describe a genetically modified organism is often used interchangeably with the expression GEO or genetically 'engineered' organism, although some may claim that genetically modified is not an adequate description where recombinant DNA techniques have been used. Organisms that have been genetically manipulated have also been described as having been 'genetically improved (GI)'. This report uses the term GMO to refer to organisms that have undergone genetic modification, except where the report has quoted directly from evidence or submissions which use an alternative expression.

2.7 The term transgenic is often broadly used to mean genetically modified. A more generally recognised understanding of the term is that a transgenic organism is one in which genes have been incorporated from a source other than its parents, ie there is a transfer of genetic material from one species to another.[3]

2.8 Apart from viruses, all living things are made up of cells or small structures bound by a membrane and filled with a solution of interacting chemicals.[4] Biological instructions are necessary for an organism to reproduce itself and to produce the substances–proteins–required for it to function. These instructions are encoded in a substance called deoxyribonucleic acid[5], or DNA for short.

2.9 DNA is a complex chemical molecule called a polymer ('having many parts') a beaded string-like chemical structure that is made up of many smaller chemical units. These smaller parts are called nucleotides and are themselves comprised of three elements: a sugar, a phosphate group and a ring structure of nitrogen and carbon, called a base. There are four bases called adenine (A), guanine (G), thymine (T) and cytosine (C). A DNA molecule comprises two strands of a number of nucleotides joined together. The two strands are wrapped around each other to form a double helix. The sugar and phosphate parts form the backbone of the DNA molecule, with the bases facing inwards like the rungs of a ladder (see below). The chemical

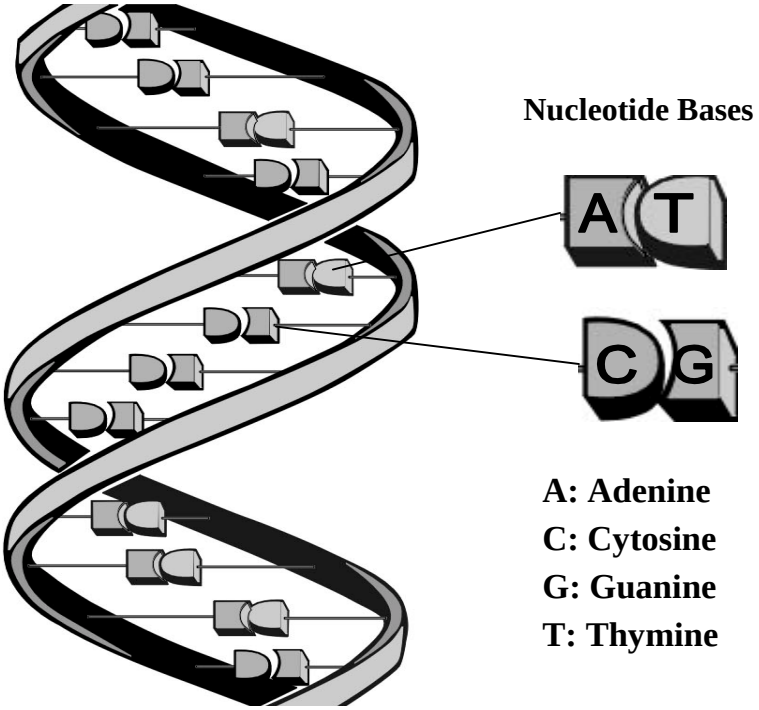
3 *Genes, genetics and transgenics*, p.5.

4 Viruses are comprised of a 'nucleic acid genome surrounded in a protein coat'. Viruses are parasites which use the host (infected) cell's replication apparatus and ability to synthesize protein. Bacteria can also be infected by specific viruses called bacteriophages.

5 The term 'deoxyribonucleic acid' describes certain characteristics of the molecule.

characteristics of the bases are such that the adenine binds to thymine and cytosine binds to guanine across the ladder.

Figure 1: Diagram showing double helix structure of a DNA molecule



2.10 The pairing of bases, known as complementary base pairing, is an important feature of the double helix because it means that if you know the order of bases on one strand, you can determine the order on the other—something that is crucial to ensuring that the integrity of genetic information is retained during the replication of DNA during cell division and during the production of proteins. This raises concerns with the Committee in terms of the addition of new genetic material during the genetic modification process.

Genes and gene expression

2.11 A gene is a discrete segment of DNA that provides the information necessary for synthesising a particular protein at the right time and place, enabling an organism to function. The genetic information is determined by the sequence of bases in the DNA.

2.12 An important component of a gene is a sequence of DNA that occurs at the beginning of a gene, called the promoter. The gene promoter determines whether the gene will be expressed in a particular cell.

Gene expression

2.13 Gene expression is the process by which the biological information contained in genes is made available to cells. During gene expression, one of the DNA strands is

used as a template to produce another molecule, RNA, or ribonucleic acid. This step is known as transcription. During a second step known as translation, the RNA directs the synthesis of proteins in accordance with the sequence of bases making up the strand of RNA. The RNA contains sequence codes for 20 amino acids, which are the building blocks of proteins.

Recombination

2.14 Recombination is the process whereby new combinations of genetic material are formed by the techniques of genetic engineering. There are three main applications of recombination used in genetic engineering or modification:

- the production of biologically useful proteins to be used in the treatment of human medical conditions and in industrial processes;
- the modification of plants, primarily to provide resistance to herbicides and insects attacks and resistance to infection by viruses; and
- the modification of animals to introduce new traits.

2.15 The use of recombinant DNA techniques allows variants of naturally occurring proteins to be produced.[6]

Selectable markers

2.16 In order to verify that a chosen gene has been incorporated into the DNA of the organism to be modified, selectable marker genes are also often attached to the gene. These are predominantly antibiotic resistance gene markers, but herbicide-resistance genes also may be used as markers. The theory behind the use of these markers is that, in the case of the antibiotic resistance markers, the gene confers resistance to a specific antibiotic. If the organism into which the chosen gene has been inserted is cultured in a medium containing that antibiotic, the organism will survive if it has incorporated the new DNA which includes the gene for antibiotic resistance. If

---

6 Generally a small piece of circular DNA called a plasmid, found in bacteria, is used to introduce the desired gene into the host cell, usually the bacterium *E. coli*. Certain properties of the plasmid enable numerous copies of the desired gene to be copied and subsequently isolated for further analysis. Many plasmids contain antibiotic resistance genes which make it possible to identify those plasmids that have taken up the desired gene (see section on selectable markers). Plasmids are also used to direct the expression of desired proteins in *E.coli*, used to produce most of the recombinant proteins.

Viruses that infect insects, called baculoviruses, have also been used as vectors to introduce the desired gene into the insect host cell. This technique is used to produce the hormone erythropoietin and the anti-virus agent β interferon.

Some recombinant proteins used for the treatment of human diseases must be expressed in mammalian cells. Specific DNA sequences, derived from bacteria, are manipulated and propogated in bacteria before being transferred to an animal cell for protein expression. Human recombinant drugs produced with this technique include growth hormone, blood clotting protein and erythropoeitin. Some recombinant proteins used for the treatment of human diseases must be expressed in mammalian cells. Specific DNA sequences, derived from bacteria, are manipulated and propogated in bacteria before being transferred to an animal cell for protein expression. Human recombinant drugs produced with this technique include growth hormone, blood clotting protein and erythropoeitin. (*Instant Notes in Genetics*, pp.325-330).

the organism did not integrate the new DNA into its own genome, it would not survive in the medium.

Plants

2.17 Cross breeding and grafting have been used for centuries to produce hybrid plants by selectively crossing plants with desired traits. Genetic engineering can now provide a direct method for incorporating new traits into a plant.

2.18 One of the features of plants that make them particularly suitable for genetic modification is that a whole plant may be grown from a single genetically engineered cell. Two techniques are used to transfer genes into plants. The first involves inserting a gene from bacteria into a plant and the second, known as biolistics, is a procedure whereby gold or tungsten balls are coated with DNA and fired into the plant cell from a special gun. The DNA is released from the ball and integrates into the plant DNA.

2.19 Goals of genetic modification in plants include:

- herbicide tolerance;
- resistance to the attack of insects;
- resistance to infection from viruses;
- increased yield in food crops;
- drought resistance; and
- the ability to tolerate harsh environmental conditions, for example, salinity.

2.20 To make a plant herbicide tolerant, a bacterial form of an enzyme unaffected by a particular type of herbicide, for example, gylphosate, is transferred into the plant. Two approaches have been used to give plants insecticidal qualities. The first involves transferring a gene from a bacteria that produces protein which is toxic to some insects. The second technique genetically engineers the expression of a protein to interfere with the insect's ability to digest plant tissue. Providing resistance to viruses has been achieved by introducing a gene which encodes for a viral coat protein.

2.21 In addition to these qualities, plants have also been engineered to delay ripening of fruits to increase shelf life, alter colours in flowers, and improve the nutritional quality of crops.

Animals

2.22 While artificial selection, or selective breeding, of animals has been used to produce domestic animals with desirable traits such as increased milk yield, some desired traits cannot be introduced without affecting existing ones. Transgenic animals can be produced by the transfer of genes encoding the desired traits.

2.23 There are three techniques for producing transgenic animals, all of which involve the genetic modification of a fertilized egg sometimes called an early stage

embryo. The modified embryos are then transplanted into a host animal's uterus. The first method involves the use of a particular type of virus, called a retrovirus, which is used to infect embryo cells. Microinjection is another method which involves injecting DNA directly into the nucleus of the egg cell. Another method is through the use of cells that are taken from the early stage of an embryo. These so-called embryonic stem cells may be genetically modified before being reimplanted in the animal.

2.24 Animals may be used in GMO research, for example, the production of so-called 'knockout mice', that is, mice which have been engineered to remove a gene to provide information on the function of that gene. Another application is to use transgenic animals to simulate human diseases which are the result of defective genes and to test new drugs for their treatment, for example, in the case of arthritis and Alzheimer's disease. Finally, transgenic sheep and goats may be used to secret recombinant human proteins in milk, including blood clotting factors and plasma proteins.[7]

2.25 As well as the addition of genes, genetic modification may involve the cancelling or augmenting of an existing gene. Genes may also be activated artificially, for example by spraying a crop with a specific chemical.[8]

2.26 Evidence presented to the Committee raised a number of issues associated with gene technology and how it should be regulated. While proponents of gene technology have claimed potential benefits, opponents have also highlighted potential risks and the need to ensure that adequate safeguards are in place to manage or eliminate these risks.[9] These competing views are discussed below, with references to other chapters where the regulatory implications of these concerns are discussed.

Benefits associated with gene technology

2.27 Proponents of gene technology cite its potential benefits for agriculture, the environment and human health.

Agriculture

2.28 The Interim Office of the Gene Technology Regulator (IOGTR) argued that gene technology promises to be more precise, produce results more quickly and cost effectively, and introduce traits not possible through conventional techniques.

2.29 In relation to crop improvement, one of the major benefits was seen to be the speed with which desired traits may be inserted into the crop. AWB Ltd stated:

---

7 *Instant Notes in Genetics*, pp.325-330.

8 Dr Rod Panter, *Biotechnology in Australia*, Parliamentary Library, Current Issues Brief 16, 1998-99, p.4.

9 Websites that include arguments for and against gene technology include: http://genetech.csiro.au/debate1.htm; http://www.afaa.com.au/paper_01.asp; http://203.89.217.15/pages/fact_sheets/fs10_public_consultation.htm

> …the process of wheat breeding has basically been going on ever since wheat was introduced into Australia to develop certain quality characteristics such as larger grains, better yielding grains in terms of flour extraction rates, better frost tolerance, rust resistance and these sorts of things. That breeding process has been continual. The time taken to do that through traditional plant breeding methods is quite significant–eight to 10 years…What gene technology will be doing will be taking those desirous genes from some of those lines which are showing, for instance, rust resistance and putting those genes into another type of wheat which shows a good quality flour product, for instance, so that it has got both good quality flour and rust resistance, which will be a much quicker process in terms of breeding than the traditional approach of growing each of those plants out and selecting on a year-to-year basis.[10]

2.30 Dr T J Higgins from CSIRO cited an example of conventional breeding attempts to introduce rust resistance from rye into wheat. While rust resistance was conferred on the plant offspring, other undesirable genes were also transferred which led to the production of sticky dough. Proponents of gene technology claim that gene technology is more efficient than conventional techniques because only the desired gene is transferred.[11]

2.31 While there may be risks associated with transferring undesirable traits through conventional breeding, a major concern about gene technology is not with the crossing of two of the same plant species, but the transfer of genes from one species, for example a fish, into another species such as a tomato, or a bacterium into a plant. This ability to 'cross the species boundary' through genetic engineering introduces an additional uncertainty and potential for serious harm. The ability of the Gene Technology Bill to manage the risks posed by gene technology and ensure that people and the environment are protected are discussed in Chapters 3 and 4 of this report.

2.32 The National Farmers' Federation (NFF) identified a number of production benefits from crops derived from gene technology including:

- varieties with increased resistance to pests and diseases which lead to benefits including reduced pesticide and herbicide use, reduced input costs and reduced adverse environmental impacts from chemical use;
- new varieties which make better use of soil nutrients, leading to reduced fertiliser use;
- reduced labour costs and energy costs;
- improved yields, quality and produce that is better adapted to requirements of the food industry and consumers;

---

10 *Committee Hansard*, 24.08.00, pp.285-6 (AWB Ltd).

11 *Committee Hansard*, 14.08.00, p.3 (Dr T J Higgins).

- quicker adaptation of crops to environmental and climatic factors, such as reduced water use, salt resistance and drought tolerance;
- crops which incorporate the nitrogen fixing ability of lucerne, peas and soya into other crops, assisting improvement of soil nutrition and enhancing productivity; and
- accelerated breeding of plants with improved characteristics leading to productivity gains, such as faster growing trees for wood production and higher quality grains.[12]

2.33 Herbicide-resistance in crops is a major objective of plant gene technology for reasons including:

- increased production efficiency;
- new options for weed management, such as allowing flexible timing of herbicide application; and
- decrease in overall herbicide use, leading to increased use of more environmentally friendly herbicides, for example glyphosphate.[13]

2.34 The NFF also referred to potential benefits for consumers, including:

- fruit and vegetables that keep fresh for longer, reducing spoilage of food in transport and storage;
- foods which contain healthy fats and oils and cooking oils with lower saturated fat content;
- increased nutritive value such as higher expression of vitamins;
- soybeans with a higher expression of anti-cancer proteins naturally found in soybeans;
- elimination of allergy-causing substances; and
- food products which carry with them medicinal properties.[14]

Environmental

2.35 The IOGTR outlined potential benefits to the environment, including reducing the use of conventional chemicals and pesticides. This would lead to more specific targeting of pests and weeds, and reduce ground water contamination. Polluted or salt-affected land could be reclaimed by the production of genetically modified salt-tolerant crops, while higher agricultural productivity would reduce the need for land

12 Submission No.88, Attachment, p.3 (National Farmers' Federation).

13 Huppatz, JL and Fitzgerald, PA. 'Gene technology is a new form of biotechnology with much greater potential applications', *MJA*, 2000, 172: 170-173.

14 Submission No.88, Attachment, p.3 (National Farmers' Federation).

clearing. Other potential benefits of gene technology are the cost-effective production of biodegradable plastics and biodiesel, as well as the use of GMOs for bio-remediation, for example, using micro-organisms to decompose toxic substances and clean-up industrial sites or environmental accidents.

Health and medical

2.36 As described earlier in the chapter, gene technology also has been used in the areas of public health and medical applications. A number of products are already being used in Australia, including enzymes, hormones, blood coagulation factors, a Hepatitis B vaccine, and a treatment for flu symptoms. IOGTR claimed that the advantages of these products are improved efficacy, greater availability, cheaper production, reduced allergenicity, and reduced risks of transmission of infectious agents.

2.37 Living GMOs have yet to be introduced for therapeutic use in humans, however, it is claimed that they have the potential to provide vaccines for cholera, malaria and HIV, and treatment for cancer and diabetes.[15]

Risks associated with gene technology

2.38 While many potential benefits of gene technology have been identified, evidence presented to the Committee also highlighted a range of potential risks associated with genetically modified organisms.

2.39 The IOGTR and others identified risks arising from modern genetic manipulation techniques, especially transferring genes from one species into a different species, including:

- introduction of unidentified allergens into GM food;
- contamination of traditional or organic crops by neighbouring GM crops;
- the inability to eliminate a GMO once it is released and found to have an adverse impact, as observed by the Organic Federation of Australia (OFA):

  > Unlike chemicals in agriculture which are recallable and have a half life and then eventually cease to be biologically active, GEO's are live replicating organisms that once released, are likely to be [un]controllable;[16]

- increased environmental damage due to increased use of chemicals;
- increased environmental competitiveness of GMOs creating weeds, in the case of plants, or pests in the case of animals;

15 Biotechnology Australia, *Background Information: Biotechnology in Medicine*, June 2000.

16 Submission No.54, p.3 (Organic Federation of Australia Inc).

- insect-resistant crops adversely affecting non-target insects, exemplified by study of the impact of transgenic cotton on the Monarch butterfly;[17] and
- the transfer of genes for herbicide tolerance from GM crops to related species resulting in herbicide-resistant weeds.[18]

2.40 In relation to the latter point, Mr Scott Kinnear from the OFA advised:

> …in Canada…farmers have found cross-pollination, three canola crops resistant to three types of chemicals…It will lead to increased use of that herbicide, and it has to lead to increased use of that herbicide.[19]

2.41 Opponents have argued that while the products of gene technology, such as herbicide resistant crops, long shelf life melons and delayed ripening tomatoes, are likely to bring some benefits to consumers, these products have been mainly developed to meet the needs of those in the food supply system, growers, transporters, wholesalers and retailers.

2.42 Notably, the crops that have been subject to genetic engineering are those that are economically important in the industrialised not the developing nations, for example maize, oilseed rape (canola), sugarbeet, tomato and potato. Nevertheless some research and trials have been conducted on wheat, rice, and cassava, an important food source in African and South American countries.[20] Additionally, the main applications of genetic modification are producing herbicide and pesticide resistant plants, with much of the benefit going to the producers rather than consumers.

2.43 In referring to claims about the potential environmental benefits of GM plants, Mr Phelps of the ACF GeneEthics Network, stated:

> There are none with the existing crop on offer. Of all the releases to date, 70 per cent have been for herbicide tolerance by companies which also sell the chemicals. They are selling farmer seed chemical packages, which intensify the destruction being done to our environment. Our land and water are making us so unsustainable that we are likely to have to be net importers of food and fibre before long rather than exporters.[21]

2.44 The transfer of herbicide-resistant genes from transgenic to wild or weedy relatives does occur through cross pollination. The solution could require farmers to

---

17 See also *Committee Hansard*, 24.08.00, p.265 (National Genetic Awareness Alliance) who advised that 'there is evidence that GM crops with BT toxins–that is, *Bacillus thuringiensis*–kill beneficial insects such as bees and lacewings.'

18 Submission No.77, p.17 (IOGTR).

19 *Committee Hansard*, 23.08.00, p.155 (OFA).

20 Ruibal-Mendieta, NL and Lints, FA (1998). 'Novel and transgenic food crops: overview of scientific versus public perception', *Transgenic Research*, 1998, 7: 379-386.

21 *Committee Hansard*, 24.08.00, p.331 (ACF GeneEthics Network).

resort to alternative, environmentally less friendly herbicides, and this would reduce the attractiveness of growing the transgenic varieties. It has been argued that 'controlled experiments cannot predict whether unexpected consequences will occur'.[22]

2.45 The role of viruses in genetic modification, was also raised in evidence to the Committee. Dr Dalling, from the companies Florigene and Nugrain, indicated that viral 'switches' are used in the genetic modification of carnations to produce violet varieties. He stated:

> The genes came from a range of other flowers in the first place–petunia or pansy. Pansy was an important source of intense blue. There are genes in there though that, from memory, have come from a construct or a part of a gene from a virus. You might have picked up the term '35S', which is a well-known regulator of gene expression. To get genes to work you have to have a switch. One of the more ubiquitous switches that is used commercially is 35S. It was isolated from a virus back in the early 1980s. It has been the basis of a very large number of constructs that have been used, not just by our company, but by other companies around the world with currently released corn, soybean, cotton, canola.[23]

2.46 However, virologist, Professor Adrian Gibbs, expressed concern at the lack of research currently being conducted into the consequences of using viruses for genetic modification purposes. He cited two cases which he considered may cause serious problems:

> I put down two examples to mention to the committee: one is the development of viruses for controlling mice by CSIRO division of wildlife research; and another is putting virus genes into potatoes to try to control infection by other viruses. Both of those technologies could result in major problems and, as far as I know, there is no scientific work being done at present on the safety to the environment of either of those developments. So I am worried about the lack of research.[24]

Food

2.47 While there is greater community acceptance of the use of gene technology in pharmaceuticals and medicine, public concern related to GMOs in food remains high and increasing. This has been expressed in calls for a ban or moratorium on all general releases of GM crops and for clearer labelling of food products containing GMOs or GM products.

2.48 The risks to human health of greatest concern are:

---

22 Rubial-Mendieta & Lints (1998).

23 *Committee Hansard*, 24.08.00, p.337 (Florigene Ltd).

24 *Committee Hansard*, 25.08.00, p.429 (Professor A Gibbs).

- transfer of allergens to new food products; and
- the possibility of delayed effects similar to CJD.

Antibiotic resistance markers

2.49 The use of antibiotic resistance markers in gene technology are controversial because of public fears about the resistance trait transferring to bacteria in human and animal stomachs. While studies have indicated that antibiotic resistance genes in crops or crop products will have a negligible impact on food safety, there is still a concern that the use of antibiotic resistance as a selectable marker will 'compromise the therapeutic use of antibiotics in humans and animals'. Studies on the effect on food safety have shown, however, that 'such transfer occurs, if at all, at extremely low frequency'.[25]

2.50 Despite the conclusion of a 1996 report to the Nordic Council responsible for directing food policy issues in five nordic countries, that 'the overall risk is effectively zero, and that the therapeutic use of antibiotics in humans or animals will not be affected by commercialisation of transgenic crops containing antibiotic-resistance selectable marker genes', the London Royal Society in 1998 recommended that antibiotic resistance markers should no longer be used in GM food crops.[26]

2.51 In evidence to the Committee, Dr Tribe of the Australian Biotechnology Association, was critical of what he considered to be an 'overstated' problem of antibiotic resistance markers.[27]

2.52 One of the reasons advanced for using antibiotic resistance selectable markers is because of the inefficiency of the techniques used to transfer DNA into host organisms, and the need to be able to identify whether the target gene has actually been inserted into the host cell. These markers can now be 'zipped out' leaving only the desired gene in place.[28]

2.53 The Committee considers that the potential risks associated with the transfer of antibiotic resistance genes to other bacteria is another reason for ensuring extreme caution in the regulation of GMOs, and this is discussed in detail in Chapter 4.

Allergens

2.54 The possibility that an allergy-causing protein may inadvertently be transferred during the genetic modification of a food product was raised in evidence to

---

25 Huppatz and Fitzgerald (2000).

26 Huppatz and Fitzgerald (2000).

27 *Committee Hansard*, 24.08.00, p.242 (Dr Tribe). Dr Tribe referred to ANZFA's Occasional Paper Series– No. 1: *GM Foods and the Consumer–ANZFA's Safety Assessment Process for Genetically Modified Foods*, June 2000 which, he argued, presents 'a much more reasoned and understandable description of the antibiotic resistance issue' [see ANZFA website: http://www.anzfa.gov.au/].

28 *Committee Hansard*, 25.08.00, p.419 (CSIRO).

the Committee.[29] The dangers to human life that this could pose led to the question of whether GM foods should be tested to the same degree as medications. Dr Dalling from Florigene Ltd, responded:

> In principle I do not oppose it so long as all food is subject to the same testing. At the moment anything that has the word 'GM' in front of it is subject to the most unbelievable scrutiny. Long ago the concept of substantial equivalence was well and truly established. I understand that people are debating it now. A huge amount of evidence has been gathered to support the idea, but it is an evolving process. More and more evidence may well be demanded and gathered, presumably, so long as there is no discrimination as to what the products are.[30]

2.55 Mr Buz Green of Serve-Ag, supported the stringent testing of GMOs where there is a possibility of the transfer of allergens.[31] Mr Gary Burgess representing the South Australian Farmers Federation, considered that issues of allergenicity in GM products should be part of the risk assessment process.[32]

2.56 The Committee acknowledges that there are concerns about the reliance on current scientific understanding to identify risks, particularly given past experience when it was discovered that scientific 'fact' turned out to be incorrect.

2.57 The case of the transfer of an allergen from the Brazil nut into the soybean is a major concern. The case involved the transfer of a protein gene from the Brazil nut into the soya bean to improve the quality of soya bean protein. After testing, it was discovered that the gene caused allergic reactions in humans.[33] While the Committee notes that in this case, the problem was identified before it had been commercially released, the Committee considers that this is a serious risk and that risk assessment processes must be rigorous enough to pick similar instances up early. Risk assessment processes under the Gene Technology Bill are discussed in Chapter 4 of this report.

Food labelling

2.58 One of the areas that is considered to be important in allowing consumers to make informed choices about genetically modified food is the issue of food labelling. While a meeting of New Zealand and Australian State and Territory Health Ministers in Wellington in July this year discussed labelling of genetically modified foods,

29 See for example *Committee Hansard*, 23.08.00, p.152, 157 (OFA).

30 *Committee Hansard*, 24.08.00, p.355 (Florigene Ltd).

31 *Committee Hansard*, 23.08.00, p.194 (Serve-Ag).

32 *Committee Hansard*, 22.08.00, pp.57-8 (SA Farmers Federation).

33 *Committee Hansard*, 14.08.00, pp.8-9 (Dr T J Higgins).

different views were expressed in evidence to the Committee about the extent of labelling required.[34]

2.59 The issue of food labelling is not covered by the Gene Technology Bill, however, the Committee notes the important consumer links between GM foods and labelling. One area of concern relates to the issue of substantial equivalence with respect to GM food products, and how it effects how these products may be labelled.

Substantial equivalence

2.60 Huppatz and Fitzgerald explain the concept of substantial equivalence in foods as follows:

> Substantial equivalence is established if food products are essentially the same in composition, nutritive value, functional characteristics and organoleptic properties (taste, smell, mouthfeel).[35]

2.61 If a genetically modified crop is determined to be substantially equivalent to a conventionally grown crop, 'the focus of testing becomes the introduced genes and their specific products', however, if the GM crop is not judged to be substantially equivalent, then the crop must be 'assessed for food safety on a case-by-case basis'. Thus, for example, rice with enhanced vitamin A would be considered as a 'new food'.[36]

2.62 Dr Annison of the Australian Food and Grocery Council (AFGC), explained how the concept of 'substantial equivalence' was applied in food testing:

> It essentially says that, if we accept one product as being safe, the most rational way of approaching assessing a second product it is to look for differences from one to another. The principle of substantial equivalence looks at the chemical composition and nutritive value and looks specifically for levels of toxins and allergens. It compares one with another and determines whether they are essentially the same. That seems to me to be a very practical way to go…If there are different materials in foods, we also consider the chances of their being bio-active in any way. We know that in some foods it will be classified as substantially equivalent. There would be DNA in there from the genetic modification. But there is no evidence whatsoever that DNA itself, either from a genetic modification or just as we eat it, is biologically active. In fact, we know it is not biologically active. We eat DNA all the time, and we so know it is not biologically active. If there were an expression production from that DNA present in any great quantity, it would be picked up by the substantially equivalent definition

34 See for example, *Committee Hansard*, 22.08.00, pp.109-110 (Ms E Attwood); *Committee Hansard*, 23.08.00, p.192 (Serve-Ag).

35 Huppatz and Fitzgerald (2000).

36 Huppatz and Fitzgerald (2000).

> anyway. That, on top of the tests that are done by the companies who are developing these products, I believe provides a very sound framework.[37]

2.63 A genetically modified product that is deemed 'substantially equivalent' to its non-genetically modified counterpart will not be labelled as a GMO.

2.64 In response to questions about whether the products of cattle fed with GM crops should be considered GM, Mr Downer of the AFGC replied 'I would class them as GM free'. The AFGC added that:

> …it depends on exactly what you are feeding them, but if you are feeding them a substantially equivalent GM crop–for example, if you are feeding them Roundup ready soya beans as supposed to conventional soya beans, because they are substantially equivalent; the differences between the soya beans are virtually non-existent–there will be no differences in the animals feeding on those crops. By definition, that is what 'substantially equivalent' means—there will be no difference. So when you come to analyse the meat, you will not be able to tell whether the meat came from an animal feeding on Roundup ready soya beans or an animal feeding on conventional soya beans. This will be the difficulty facing the retailers if they decide to go GM free and use that as one of the stipulations: they could have two pieces of meat side by side and be making a GM free claim about one, but there will be no way either the enforcement agencies, in terms of making sure the label statements are correct, or, indeed, the consumers buying the products, will be able to tell whether the label statements are correct.[38]

2.65 Although there may be no evidence of genetically modified DNA being transferred from GM crops through the food chain, the public perception of this risk still exists.[39] The way in which consumer confidence in gene technology can be enhanced is examined in Chapter 3.

2.66 The Committee notes that there is significant disagreement about the nature and extent of the risks associated with genetic engineering. The approach that should be taken with respect to the regulation of GMOs in the light of the uncertainties and inconclusiveness about the potential risks of gene technology are discussed in Chapter 3 of this report under the section 'the precautionary principle'.

GMOs covered by the Gene Technology Bill 2000

2.67 Another issue raised during the inquiry was the way in which the Bill defines GMOs and gene technology. The definitions of gene technology and genetically modified organism contained in the Bill were referred to at the start of the chapter.

---

37 *Committee Hansard*, pp.403-4 (AFGC).

38 *Committee Hansard*, 25.08.00, pp.407-8 (AFGC).

39 *Committee Hansard*, 23.08.00, p.175 (GE-Free Tasmania).

2.68 Heritage Seed Curators expressed concern that regulations would be able to exclude organisms from the definition of a GMO under the Bill.[40] Friends of the Earth (Fitzroy) recommended that, in addition to the organisms specified as GMOs in the Bill, the following should be added:

> (d) any biological entity capable of replication or transfer of genetic information, and includes plants, animals, bacteria and all other kinds of micro-organisms, cell cultures (prokaryotic[41] or eukaryotic[42]) created and propagated as such, viruses, and plasmids[43] and other kinds of vectors, in which the genetic material has been altered in away that does not occur naturally, by means of cell or gene technology.[44]

2.69 One of the dangers in including a list of additional biological entities under the definition of GMO is that in providing such a prescriptive definition, the chance that something may slip through may increase because the definition is too specific.

2.70 Concerns were raised about the lack of regulation for stockfeed safety.[45] However, the Committee notes that the draft regulations, released on 25 August, declare that any GM product intended for use as a stockfeed is also a genetically modified organism.

2.71 Under the Gene Technology Bill, a GMO does not include:

- a human being who has undergone somatic cell[46] gene therapy; or
- an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be genetically modified organisms.

2.72 The draft regulations exempt a number of organisms listed from the Bill's definition of a GMO because they:

- give rise to organisms that can occur in nature;
- are commonly used in biology; and
- have a very long history of usage in Australia and overseas.[47]

---

40 Submission No.9, p.5 (Heritage Seed Curators Australia Inc).

41 Bacteria and their relatives.

42 Non-bacterial organisms, including plants and animals.

43 Circular DNA present in bacteria.

44 Submission No.51, p.2 (Friends of the Earth (Fitzroy)).

45 *Committee Hansard*, 22.08.00, p.122 (Aventis).

46 Cells of the body rather than ova or sperm.

47 A list of organisms not considered to be GMOs under the Gene Technology Bill is included in the draft regulations, p.3.

2.73 The IOGTR advised the Committee that having chosen to define gene technology in broad terms in the legislation, the exemptions in the regulations identify those techniques not generally considered to be 'gene technology' that may have unintentionally been covered by the Bill.[48]

48 Explanatory Guide to the Draft Commonwealth Gene Technology Regulations 2000, August 2000, p.19.