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WORK IN PROGRESS: PROCEED WITH CAUTION

Primary Producer Access to Gene Technology

House of Representatives

Standing Committee on Primary Industries and Regional Services

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Mr Griffin and Dr Washer were appointed to the committee for the purposes of the inquiry into primary producer access to gene technology.

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Terms of reference

The House of Representatives Standing Committee on Primary Industries and Regional Services will inquire into and report on the following areas, with particular emphasis on the capacity of small and medium sized enterprises to access the benefits of gene technology:

- the future value and importance of genetically modified varieties;
- the ability for producers to compete using traditionally available varieties;
- the commercialisation and marketing of agricultural and livestock production varieties;
- the cost to producers of new varieties;
- other impediments to the utilisation of new varieties by small producers;
- assistance to small producers to develop new varieties and the protection of the rights of independent breeders, in relation to genetically modified organisms;
- the appropriateness of current variety protection rights, administrative arrangements and legislation, in relation to genetically modified organisms; and
- opportunities to educate the community of the benefits of gene technology.

Referred by the Minister for Agriculture, Fisheries and Forestry on 30 March 1999.

List of abbreviations

AAA	Agrifood Alliance Australia
ABA	Australian Biotechnology Association
ABARE	Australian Bureau of Agricultural and Resource Economics
ABB	Australian Barley Board
AFFA	Agriculture, Fisheries and Forestry Australia
AFGC	Australian Food and Grocery Council
AGN	Australian GeneEthics Network
ANZFA	Australia New Zealand Food Authority
ANZFSC	Australia New Zealand Food Standards Council
AQIS	Australian Quarantine Inspection Service
BA	Biotechnology Australia
BMA	British Medical Association
Bt	Plant variety with a gene inserted from a bacterium *(Bacillus thuringiensis*) that, by producing a toxin, makes the variety resistant to certain insect pests.
CAMBIA	Center for the Application of Molecular Biology to International Agriculture

CLIMA	Centre for Legumes in Mediterranean Agriculture
COMET	Commercialising Emerging Technologies
CRC	cooperative research centre
CRCA	Cooperative Research Centres Association
CSD	Cotton Seed Distributors Ltd
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DHAC	Department of Health and Aged Care
DNA	deoxyribose nucleic acid
EA	Environment Australia
EPRs	end point royalties
FAO	Food and Agriculture Organization of the United Nations
GCA	Grains Council of Australia
GEO	genetically engineered organism
GM	genetically modified
GMAC	Genetic Manipulation Advisory Committee
GMO	genetically modified organism
GRDC	Grains Research and Development Corporation
GTCCG	Gene Technology Community Consultative Group
GTEC	Gene Technology Ethics Committee
GTTAC	Gene Technology Technical Advisory Committee
GTR	Gene Technology Regulator
HSCA	Heritage Seed Curators Australia
IIF	Innovation Investment Fund
Ingard®	Monsanto's Australian Bt cotton variety

IOGTR	Interim Office of the Gene Technology Regulator
IP	intellectual property
IPCRC	Intellectual Property and Competition Review Committee
NFF	National Farmers' Federation
NRA	National Registration Authority
NSW	New South Wales
OECD	Organisation for Economic Co-operation and Development
OFA	Organic Federation of Australia
OGTR	Office of the Gene Technology Regulator
PBR Act	Plant Breeders' Rights Act
PBRs	plant breeders' rights
PDF	Pooled Development Fund
RDC	research and development corporation
R&D	research and development
SCARM	Standing Committee on Agriculture and Resource Management
TRIPS	Agreement on Trade Related Aspects of Intellectual Property Rights
UK	United Kingdom
USA	United States of America
WHO	World Health Organization
WTO	World Trade Organization

List of recommendations

1

Introduction

Biotechnology in agricultural development

1.1 From the start of human history, new technologies have played a key role in the development of agriculture. The introduction of mechanical tools, such as tractors and harvesting machinery, marked the first of the more recent revolutions in agricultural practice. The industrialisation of agricultural production intensified when chemical fertilisers, pesticides and herbicides became available. The application of these substances resulted in dramatic rises in farm productivity. The third revolution, which promises further gains in productivity, as well as greater environmental sustainability, is based on biotechnology.[1]

1.2 Several factors have contributed to the pursuit of biotechnology as a source of solutions to agricultural problems. The cost of oil rose in the 1970s and is rising again now. As many agrochemicals are oil based, higher oil prices have increased the costs of farm inputs. Since the 1970s it has also been clear that incremental improvements from the application of chemical fertilisers to American crops has decreased, and the effectiveness of pesticides and herbicides has declined. In addition, widespread concern has arisen about the impact of agricultural chemicals on the environment. Biotechnology is seen by some as offering a means of addressing these issues.[2]

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1 R Pistorius & J van Wijk, *The Exploitation of Plant Genetic Information: Political Strategies in Crop Development*, CABI Publishing, Wallingford, UK, 1999, pp. 106-7.

2 R Pistorius & J van Wijk, *The Exploitation of Plant Genetic Information: Political Strategies in Crop Development*, CABI Publishing, Wallingford, UK, 1999, p. 107.

1.3 At the same time as the above events unfolded, understanding of the structure and operation of genes grew to the point where genes could be manipulated, as Box 1.1 describes. At this point, breeding new varieties of crops and livestock more quickly than by conventional means became a reality. The range of characteristics that can be bred into living organisms has been extended too; gene technology allows greater possibilities for the transfer of genetic material between closely related species, as well as between those more distantly related. As a result, varieties can be 'custom designed' to suit particular primary producer, consumer or environmental requirements, and contribute to increased agricultural productivity and sustainability.

1.4 The usefulness of genetic manipulation in agriculture is demonstrated by the rapid uptake in several countries of genetically modified (GM) crops. Between 1996 and 1998, the area planted worldwide for commercial GM crop production increased more than 15 times to 27.8 million hectares.[3]

1.5 Consumer and environmental concerns in several countries are slowing the rate of uptake of GM crops and may even stop it in some cases. The Tesco supermarket chain in the UK, for example, has announced that it will not buy fruit and vegetables from suppliers who have previously grown GM crops on the same sites.[4] A survey of US farmers carried out in February 2000 indicated that they will plant 16 per cent less GM corn this year than last year.[5] Notwithstanding the recent lack of consumer confidence in GM food and consequent reduction in plantings, it has been expected that GM crops will eventually be very widely grown.

1.6 To mid 1999, only three genetically modified organisms (GMOs) had received approval for commercial use in Australia. Of these, only one, Bt cotton, is a significant commercial crop; the other two are varieties of carnations. By comparison with their major competitors, Australian primary producers have access to far fewer GM crop varieties, giving rise to fears that Australia's competitiveness in world markets will suffer. Various causes have been identified for Australia's slow uptake of GM crops, and suggestions made about how they might be addressed. There is, in addition, a strong desire that Australian expertise in genetic

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3 C James, *Global Review of Commercialized Transgenic Crops: 1998*, The International Service for the Acquisition of Agri-biotech Applications Briefs no. 8, Ithaca, New York, 1998, p. iii. This statistic excludes China as only tentative estimates of the area planted to GM crops there are available.

4 J Meikle, 'GM ban is extended by Tesco', *News Unlimited Special Reports*, 7 January 2000, http://www.guardianunlimited.co.uk/gmdebate/Story/0,2763,119632,00.html, accessed 15 May 2000.

5 M Kriz, 'Global food fight', *National Journal*, vol. 32, March 2000, p. 689.

manipulation be harnessed to benefit Australian farmers and generate a financial return to Australians.

Box 1.1 What is gene technology and how is it used?

All living things are made up of cells. All cells contain genes, which determine the physical characteristics of an organism. The building blocks of genes are composed of DNA. While DNA is the same across all species, the variety of ways it can be put together creates the difference between species and individual organisms. On average, plants contain around 22,000 genes, and animals can have up to 50,000.

Gene technology includes a range of techniques that can control, modify or delete particular characteristics of an organism, and transfer desired traits from one species to another. These processes give rise to plants, animals and other organisms that are referred to as genetically modified, genetically engineered or genetically manipulated. The term 'transgenic' describes plants or animals which have a new gene inserted into them.

Not every gene in an organism is active, and only the genes which are expressed are responsible for the characteristics of an organism. Much of the research undertaken in gene technology concentrates on activating or suppressing the expression of genes known to cause particular traits.

Desired traits can be transferred to different species through a number of methods. For example, a desired gene can be introduced into a plant cell using bacteria or a virus to which it is susceptible. Genes can also be transferred into cells using a gene gun, which shoots the DNA through the cell wall.

The main uses of gene technology lead to the same output as conventional breeding programs, but with greater speed and precision; for example:

- genetic markers easily and rapidly identify the presence of a particular gene, and helps with the selection of lines with desired characteristics; and
- gene transfers from near relative species can be done faster and more easily through this technology than by conventional means.

Other uses of gene technology produce results that cannot be achieved through conventional breeding, including accessing desired traits through gene transfers from unrelated species.

Source: Australian Academy of Science, http://science.org.au/nova/009/009box01.htm, accessed 11 May 2000; Biotechnology Australia, http://www.isr.gov.au/ba/Biotechnology/definition.html, accessed 11 April 2000; CSIRO, Submission no. 56, p. 5 and http://genetech.csiro.au/what.htm, accessed 3 April 2000 ; Nugrain, Submission no. 25, p. 8.

The committee's inquiry

1.7 It was in the context of the global and domestic situation sketched in the last section that the committee's inquiry into primary producer access to gene technology originated. The then Minister for Agriculture, Fisheries and Forestry, the Hon Mark Vaile, MP, referred the inquiry to the committee on 30 March 1999. The inquiry's terms of reference provide that the committee will inquire into and report on the following areas, with particular emphasis on the capacity of small and medium sized enterprises to access the benefits of gene technology:

- the future value and importance of genetically modified varieties;
- the ability for producers to compete using traditionally available varieties;
- the commercialisation and marketing of agricultural and livestock production varieties;
- the cost to producers of new varieties;
- other impediments to the utilisation of new varieties by small producers;
- assistance to small producers to develop new varieties and the protection of the rights of independent breeders, in relation to genetically modified organisms;
- the appropriateness of current variety protection rights, administrative arrangements and legislation, in relation to genetically modified organisms; and
- opportunities to educate the community of the benefits of gene technology.

1.8 The committee advertised the inquiry in capital city newspapers, the Financial Review, the Weekend Australian, rural publications in each state, the New Scientist and Australian Grain. In addition, information about the inquiry and requests for submissions were sent to state premiers, territory chief ministers, and Commonwealth ministers and departmental secretaries with an interest in the inquiry topic. Also approached to make submissions were organisations representing scientists, business and primary producers; research and development

(R&D) organisations; the food industry; life science and seed companies; academics; and environmental groups. Eighty-seven submissions and seven exhibits were received; they are listed in Appendix A.

1.9 Public hearings were held in Canberra, Perth, and Melbourne with the groups listed in Appendix B. The committee also held private discussions in Western Australia with a group including officers of Agriculture Western Australia, and individual gene technology researchers, farmers, seed suppliers and handlers, and organisations representing them. Briefings were provided to the committee in Canberra on intellectual property (IP), Biotechnology Australia's (BA) public awareness program, the regulation of gene technology, and the view of the field as seen by gene technology businesses. The committee was provided with a hands on insight into genetic manipulation during a visit to the Center for the Application of Molecular Biology to International Agriculture (CAMBIA).

1.10 The committee's inquiry is not the first parliamentary inquiry into this topic. In 1992, the House of Representatives Standing Committee on Industry, Science and Technology reported on the results of its investigation into the development, use and release into the environment of GMOs.[6] That inquiry covered many of the same issues that this current inquiry has grappled with.

The structure of the report

1.11 Each of the report chapters that follow deals with a major factor that influences primary producers' access to gene technology. Chapter 2 describes the benefits that result, or may in the future result, from the use of genetic modification. It also catalogues the risks that have been identified, or may arise, from growing GMOs.

1.12 Chapter 3 deals with consumer attitudes to genetic manipulation which influence the market for GMOs and affect producer readiness to replace conventional varieties with their GM counterparts. This chapter also examines the ways in which public understanding of the issues surrounding the use of GMOs can be enhanced. In Chapter 4, the committee looks at the scope for the continued use of traditional varieties by Australian producers in the context of uncertainty about the relative costs and benefits of using GMOs.

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6 House of Representatives Standing Committee on Industry, Science and Technology, *Genetic Manipulation: The Threat or the Glory?*, AGPS, Canberra, 1992.

1.13 Chapter 5 examines the research effort on which Australia's access to gene technology is based. Growers' access to the technology may depend on the commercialisation of Australian research, or it may involve arrangements for bringing overseas technology to Australia. Chapters 6 and 7 consider two important underpinning elements of the commercialisation process and ongoing use of GMOs: the protection of IP (Chapter 6) and regulation of their use (Chapter 7).

1.14 Readers will notice that the report is written largely in relation to crops rather than livestock. This reflects the relative progress that has been made in these two fields, even though the first application of gene technology to animals occurred only a year or two after its first application to plants. It has, however, proved harder to develop GM livestock than GM crops. This is partly due to the difficulty of inserting genes into eggs.[7] The committee is aware that cloning may be a more effective way of making transgenic livestock but that topic is beyond the scope of this inquiry. Nevertheless, many of the issues raised in this report in relation to crops apply equally to livestock.

7 O. Mayo, 'Animals', *Gene Technology and Food*, National Science & Industry Forum Report, Australian Academy of Science, April 1999, p. 5.

2

Benefits and risks of gene technology in agriculture

Introduction

2.1 Using biotechnology can be seen as extending earlier methods of plant and animal breeding which date back many thousands of years (Table 2.1).[1] The technology obtains results more rapidly, is more precise, and gives access to a broader genetic base than traditional breeding techniques. These are the features that recommend its use so powerfully to plant and animal breeders. It provides an important tool when integrated with traditional breeding approaches.

2.2 The precision that gene technology offers is possible because the exact segment of a chromosome that determines a desired trait can be identified. With this capacity, traditional breeding programs can be fast tracked by locating seeds or offspring at an early stage, through gene marker technology, and breeding only from them. The Cattle Council of Australia commented on the dramatic increases in precision of genetic improvement that is possible as a result.[2] In addition, genes can be removed from one organism and inserted into another.

2.3 Transgenesis, in which genes are moved from one species or organism to another, allows beneficial genes from any source to be transferred to other species or organisms. The Cooperative Research Centre (CRC) for Tropical Plant Pathology pointed out that, while conventional breeding programs have improved the pest and disease resistance of Australian crops, there

1 C Hudson, 'How industry adopts new technology', *Gene Technology and Food*, National Science & Industry Forum Report, Australian Academy of Science, April 1999, p. 12; Nugrain, Submission no. 25, p. 6.

2 Cattle Council of Australia, Submission no. 20, p. 3.

are some problems against which the natural germplasm of these crops lacks resistance. Examples of such problems are lack of resistance to:

- the fungus, Sclerotinia, in sunflowers;
- to Aschochyta blight in field peas; and
- to Rhizoctonia root rot in wheat.

The only way in which resistance can be given to such crops is through transgenesis.[3]

Table 2.1 Plant improvement using selection and breeding – historical perspective

Year	World population (m)	Development
8000BC	5	Cereals and pulses domesticated
2000BC	50	Rice, potato, oats, soybean, grape, cotton, banana domesticated
1583	500	Sexuality in plants described
1742		First company devoted to plant breeding and new varieties
1799		First cereal hybrid described
1900		Maize hybrid breeding: Mendel recognised
1927		X-rays used for mutation breeding
1983	5000	First use of gene technology for plants
1999	6000	50m hectares of genetically altered plants

Source *T J Higgins, 'Plants', Gene Technology and Food, Australian Academy of Science, April 1999, p. 4.*

2.4 Another way in which gene technology will eventually contribute to improving plant and animal varieties is by switching on genes for desired traits that are present in the genome but not currently expressed.[4] Conversely, it should be possible to switch off genes that produce undesirable traits.

2.5 Several examples were provided to the committee of the shorter time to commercial release for GM compared with traditional varieties of crops. Experience in the grains industry is that the time is reduced from 8-13 to 3-8 years.[5] The Dairy Research and Development Corporation estimated that there could be a 30 per cent reduction in time to 3-4 years to commercialisation for pasture plants.[6] The Australian Food and Grocery Council (AFGC) claimed that 'traditional breeding techniques stand to be

3 Cooperative Research Centre for Tropical Plant Pathology, Submission no. 21, p. 1.

4 B J Feder, 'New method of altering plants is aimed at sidestepping critics', *The New York Times Science*, 29 February 2000, p. D3.

5 AWB Ltd, Submission no. 66, p. 3; Grains Council of Australia, Submission no. 65, p. 9; Nugrain, Submission no. 25, p. 6.

6 Dairy Research and Development Corporation, Submission no. 15, p. 2.

eclipsed by the speed of development, and commercial impact, of new plant and animal varieties produced using gene technology'.[7]

2.6 However, Novartis sounded a warning note, pointing out that using gene technology does not necessarily reduce the time taken to develop new products. It can even increase the time needed because the genetic manipulation is complementary to field breeding work, not a substitute for it.[8]

2.7 In addition, although biotechnology has been claimed as an extension of earlier breeding techniques, some of its applications are different. Transgenesis, for example, has not been possible before, and may present new, unfamiliar risks.

> Almost certainly the majority (perhaps all) of the genetic modifications currently brought about using gene technology would never have occurred naturally. It is therefore inaccurate to state that gene technology simply enables what was previously done, to be achieved more efficiently and with more precision.[9]

Benefits

2.8 Many benefits have been identified from the use of GMOs in agriculture. The majority of submissions to the inquiry listed benefits, which are summarised below. Some of these benefits are proven but many more are still on the drawing board. They are expected to emerge but depend on the successful development of the relevant GMOs.

2.9 With gene technology, it is, or will be, possible to breed crop and animal varieties which:

- are better suited to specific, different environments;
- are more efficient at converting nutritional inputs into outputs;
- are more disease and pest resistant;
- are able to withstand herbicides;

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7 Australian Food and Grocery Council, Submission no. 59, p. 4

8 Novartis, Submission no. 26, pp. 5-6. Novartis is a Swiss based life sciences company which has health as well as agribusiness interests. Its seed division is one of the largest seed companies in the world with a turnover of US$900 million in 1998. (K ten Kate & S A Laird, *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-sharing*, Earthscan, London, 1999, pp. 122-3).

9 Environment Australia, Submission no. 82, pp. 9-10.

- are more productive, in addition to any increases in productivity due to the previous four points;
- will have better keeping qualities;
- will have better processing qualities; and
- be more healthy.

2.10 The characteristics of agricultural GMOs listed above are expected to bring benefits that can be divided, broadly speaking, into those for the farmer, the economy, the environment, the consumer and world food supplies.

Grower benefits

2.11 For the farmer, the main attractions of GM crops at present are the promises of increased productivity and lower input costs. Disease and pest resistant crops need less spraying; similarly, animals with better resistance to disease and pests require less care. As a result, the significant input costs of chemicals, labour and energy are reduced. With herbicide tolerant crops, better control of weeds enhances productivity. It would be possible to make better use of the land with animals better suited to local conditions and climate, and crops better suited to local growing conditions, for example, by being more tolerant of drought, salt or acid. Fertiliser costs could be reduced with crop varieties able to make better use of soil nutrients or to fix nitrogen. Growers improve their marketing options by offering the processor and consumer food of improved quality.[10]

2.12 Some of the types of crops described in the last paragraph are already in use and their usefulness has been demonstrated. In its submission to the inquiry, the National Farmers' Federation (NFF) mentioned a 33 per cent drop in overall herbicide use with herbicide tolerant soybeans in the USA. Herbicide tolerant canola in Canada showed improved quality and a 10-20 per cent yield increase over conventional varieties.[11] Australian experience with Bt cotton is that insecticide use dropped by 40-50 per cent. This has been accompanied by better survival of beneficial predators and parasites, and has reduced the likelihood of contamination of cattle on neighbouring properties with endosulphan which in previous years led to their rejection by export markets.[12]

10 Australian Biotechnology Association, Submission no. 39. pp. 4-5; Australian Sugar Industry, Submission no. 64, p. 5; National Farmers' Federation, Submission no. 36, p. 3; Nugrain, Submission no. 25, p. 8; Western Australian State Agricultural Biotechnology Centre, Submission no. 10, p. 1.

11 National Farmers' Federation, Submission no. 36, p. 3.

12 Cotton Research and Development Corporation, Submission no. 27, p. 3; Transcript of evidence, 18 October 1999, p. 202.

2.13 The benefits of GM crops to farmers are apparent from the rapid uptake of GM crops in the last few years, as indicated in paragraph 1.4. According to the International Service for the Acquisition of Agri-biotech Applications, by the end of 1998, GM crops had been approved for planting and commercialisation in 17 different countries. They comprised 56 varieties of about 13 different crops, of which squash, corn, canola, cotton and tomato were most widely grown.[13] GM crops have been taken up in the USA much faster than any previous technology,[14] and are also being grown in other countries, notably Argentina and Canada. In mid 1999, when submissions to the inquiry were made, projections for future plantings all showed 'massive' increases,[15] with promises of substantial profits.

2.14 Gene technology offers new possibilities to growers in the form of new products from existing species. It is possible, for example, that plants may eventually be modified to produce industrial chemicals.[16] Trees might be bred that yield timber with properties characteristic of timber substitutes like steel, aluminium, concrete and plastic.[17] A further benefit to farmers comes from the use of gene technology to control pest animal species and exotic weeds.[18]

Benefits to the national economy

2.15 Efficient crop production is essential for the international competitiveness of Australian agriculture. Eighty per cent of agricultural produce is exported each year; in 1998 agricultural exports earned $27 billion.[19] For some crops, such as grains, Australia is an important provider on the world scene. It has 15 per cent of the world wheat trade and, in 1997-98, grains exports earned about a quarter ($5.1 billion) of its farm export earnings.[20] Cotton, sugar and wine are also important export crops.[21]

2.16 Up to this point, Australia's cropping sector has maintained its position in world markets by continual improvements in yield, input costs and product quality.[22] There is evidence, however, that improvements in yields

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13 C James, *Global Review of Commercialized Transgenic Crops: 1998*, The International Service for the Acquisition of Agri-biotech Applications Briefs no. 8, Ithaca, New York, 1998, pp. 2, 3.

14 Cooperative Research Centres Association, Submission no. 40, p. 5.

15 Novartis, Submission no. 26, p. 3.

16 CSIRO, Submission no. 56, p. 2; Grains Council of Australia, Submission no. 65, p. 9.

17 Forest and Wood Products Research and Development Corporation, Submission no. 34, p. 4.

18 CSIRO, Submission no. 56, p. 2.

19 National Farmers' Federation, Submission no. 36, p. 2.

20 Grains Research and Development Corporation, Submission no. 47, p. 4.

21 ABARE, FARMSTATS Australia, March 2000.

22 Grains Council of Australia, Submission no. 65, p. 9; Grains Research and Development Corporation, Submission no. 47, p. 4; Nugrain, Submission no. 25, p. 1.

in Australia have been lagging behind overseas improvements or, in the case of sugar, have plateaued. With access to gene technology, the improvements will come faster and from a broader genetic base. If the resulting varieties are not adopted by, or are not available to, Australian farmers but are with respect to farmers overseas, the profitability of cropping will further decrease for Australians.[23] Access to biotechnology in agriculture is therefore seen as vital to Australia's success as a nation.[24] While access to biotechnology may not be essential in the present climate of negative sentiment towards GMOs, this sentiment may erode and Australian farmers may then find they are at a disadvantage compared with their competitors.[25]

2.17 Another avenue for the economic advancement of Australia is the exploitation of the country's genetic resources. Australia is one of the mega diverse continents of the world and has many endemic species. Its biological resources are relatively unexplored and a potentially rich resource of genes and bioproducts of commercial value.

World food supplies

2.18 The world's population is expected to grow substantially and become increasingly urbanised in the next few decades, giving rise to increased demand for food. AWB, for example, estimated that world wheat consumption will have grown by 38 per cent on current levels by 2020.[26] There is concern about how the growing demand for food will be met. Some see GM crops as a means of improving food security, and helping to meet long term global demands for food which traditional approaches to agriculture cannot.[27]

2.19 Others, however, have challenged the view that GM crops will help to feed the world. They see current and projected food shortages as the result of 'complex social, political and economic forces', for which other solutions are needed.[28] The Organic Federation of Australia (OFA) claimed that the

23 Australian Raw Sugar Industry, Submission no. 64, p. 4; Nugrain, Submission no. 25, p. 1.

24 Agrifood Alliance Australia, Submission no. 37, p. 2; National Farmers' Federation, Submission no. 36, p. 2; NSW Farmers' Association, Submission no. 38, p. 2; Waratah Seed Co., Submission no. 23, p. 1.

25 M Foster, 'Market implications: genetically modified crops', *OUTLOOK 2000*, ABARE, Canberra, 2000, p. 191.

26 AWB Ltd, Submission no. 66, pp. 2-3.

27 International Federation of Agricultural Producers quoted by the National Farmers' Federation, Submission no. 36, p. 5; Novartis, Submission no. 26, p. 2; NSW Farmers' Association, Submission no. 38, p. 2; Nugrain, Submission no. 25, p. 7.

28 National Genetic Awareness Alliance, Submission no. 54, p. 3.

problem is not one of inadequate food supplies, but of poverty and landlessness.[29]

Environmental benefits

2.20 According to CSIRO:

> There are already domestic and international indications of environmental benefits from less pesticide use (as in the case of Bt cotton) and replacement of rather potent herbicides with more benign herbicides for herbicide tolerant crops … [30]

The health risk to farming communities from exposure to these chemicals is thereby reduced, and the presence of these chemicals in the air, soil, ground water and runoff is diminished.[31]

2.21 Use of herbicides rather than tillage reduces soil erosion and degradation.[32] Reduced tillage also increases the organic matter and decreases the loss of carbon from the soil. By retaining carbon in the soil, global warming caused by the release of carbon dioxide from the soil is lessened.[33]

2.22 The NSW Farmers' Association claimed that GMOs provide the only means by which crop yields can be increased while reducing the chemical dependence of agriculture.[34] Novartis had a similar view; it commented that:

> Genetically modified crops … are a crucial tool through which we are trying to reduce the reliance of agriculture on non-sustainable resources (such as the inefficient use of pesticides and fertilisers, and the potentially degrading effects of mechanical weeding) and replace them with biological knowledge, packaged in the seed.[35]

2.23 Another possible environmental benefit is that GM crops, through allowing more efficient use of cropped land, will reduce the pressure for land clearing, thereby maintaining native vegetation and biodiversity.[36] Furthermore, if better quality timber can be produced that is able to

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29 Organic Federation of Australia, Submission no 24, p. 5.

30 CSIRO, Submission no. 56, p. 2.

31 Centre for Weed Management Systems, Submission no. 9, p. 2; Western Australian State Agricultural Biotechnology Centre, Submission no. 10, p. 1.

32 Centre for Weed Management Systems, Submission no. 9, p. 2; Mr Brendan Doyle, Submission no. 3, p. 2; Nugrain, Submission no. 25, p. 7.

33 Centre for Weed Management Systems, Submission no. 9, p. 2.

34 NSW Farmers' Association, Submission no. 38, p. 2.

35 Novartis, Submission no. 26, p. 3.

36 Western Australian State Agricultural Biotechnology Centre, Submission no. 10, p. 1.

substitute for such substances as aluminium and concrete, great savings will be possible on energy costs and greenhouse gas emissions.[37]

Consumer benefits

2.24 Gene technology offers the possibilities of making many improvements to the plant and animal food we eat. Taste, texture, appearance, consistency, keeping qualities and nutritional value are all likely to be targeted for upgrade.[38] Of these characteristics, the most significant improvements will be to nutritional quality. Among the changes suggested in submissions to the inquiry were altered fat, protein and vitamin content, the development of designer oils and starches, the removal of allergens and the reduction of anti nutritional factors.[39]

> The technology may be able to provide nutrients that will overcome deficiencies and reduce the risk of specific diseases. Varying the structure of key molecules can lead to variations in the content, and health effects, of food. Key molecules include:
>
> - natural antioxidants, which play a role in atherosclerosis and cancer
> - resistant starches, important in gut health and colon cancer
> - fatty acids, important in cardiovascular disease.[40]

2.25 Foods containing vaccines, antibodies and novel protective products are forecast.[41] Plants may be developed as 'bioreactors', producing pharmaceuticals and pharmacologically active compounds.[42] Work on pharming in animals is under way overseas, for example, producing human pharmaceuticals in milk.[43] GM animals may also become a source of organs and tissues for transplantation into humans, and serve as models for the study of human diseases.[44]

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37 Forest and Wood Products Research and Development Corporation, Submission no. 34, p. 4.

38 Australian Biotechnology Association, Submission no. 39, p. 4; CSIRO, Submission no. 56, p. 2; National Farmers' Federation, Submission no. 36, p. 4; Nugrain, Submission no. 25, p. 7.

39 Australian Biotechnology Association, Submission no. 39, p. 4; Cooperative Research Centres Association, Submission no. 40, p. 5; Grains Council of Australia, Submission no. 65, p. 9; National Farmers' Federation, Submission no. 36, p. 4; Western Australian State Agricultural Biotechnology Centre, Submission no. 10, p. 1.

40 R Head, 'The implications for nutrition', *Gene Technology and Food*, National Science & Industry Forum Report, Australian Academy of Science, April 1999, p. 8.

41 CSIRO, Submission no. 56, p. 2; Nugrain, Submission no. 25, p. 7.

42 Western Australian State Agricultural Biotechnology Centre, Submission no. 10, p. 1.

43 Pharming is the production of drugs and other medically important substances in the milk of transgenic domesticated animals.

44 O. Mayo, 'Animals', *Gene Technology and Food*, National Science & Industry Forum Report, Australian Academy of Science, April 1999, p. 5.

2.26 Plant and animal fibres, such as wool and cotton, are also being targeted for improvement.[45]

Other benefits

2.27 Food processors will benefit from gene technology with improvements to the processing characteristics of food. For example, barley with better malting qualities and changed enzyme activity is a possible development.[46] Processing may also become more efficient, productive and environmentally friendly.[47]

2.28 It will also be possible to improve pasture quality, as well as the quality of animal feed; amino acid content and digestibility could be increased and antinutritional compounds reduced.[48]

Conclusions about benefits

2.29 The committee is aware that crops with improved input traits (herbicide tolerance, and insecticide and virus resistance) have so far dominated the market. Improved output (consumer) traits are yet to be widely seen although, at the time of writing its submission in June 1999, Nugrain expected that modified oils would be on the market soon.[49] Furthermore, Novartis suggested that, in the second half of the next decade, the focus for gene technology will be on products offering a direct benefit to the consumer.[50]

2.30 The committee recognises that the benefits of using GMOs in agriculture are not yet widely apparent. As Nugrain pointed out, 'a feature of many new technologies is often the long time lag between their initial emergence and their measurable impact'. Evidence of the benefits that are expected in areas such as improved health and life expectancy will take some time to accumulate.[51]

2.31 In addition, early projections of gains from biotechnology have been 'overly enthusiastic'.[52] A case in point is provided by Bt cotton crops in

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45 Cooperative Research Centre for Premium Quality Wool, Submission no. 52, p. 1.

46 Nugrain, Submission no. 25, p. 7; Western Australian State Agricultural Biotechnology Centre, Submission no. 10, p. 1.

47 Australian Food and Grocery Council, Submission no. 59, p. 4.

48 Ag-Seed Research, Submission no. 31, p. 7; Cooperative Research Centres Association, Submission no. 40, p. 5; The Veterinary Manufacturers and Distributors Association, submission no. 76, p. 7.

49 Nugrain, Submission no. 25, p. 8.

50 Novartis, Submission no. 26, p. 4.

51 Nugrain, Submission no. 25, p. 7.

52 Nugrain, Submission no. 25, p. 7.

Australia, as detailed in Box 2.1. A number of other problems have been identified or foreseen in the use of GMOs, as discussed in the next section of this chapter.

Box 2.1 Bt cotton in Australia: have the gains been as great as expected?

Recent reports have shown that the Bt cotton grown in Australia (Ingard®) requires 40-50 per cent less pesticides than conventional crops and, on average, costs $91 less per hectare to produce. Ingard® cotton crop sites contain more beneficial predators and parasites, and are less harmful to the surrounding environment than conventional crops.

However, the success of Ingard® cotton in Australia varies within and between fields, farms, regions, varieties, and seasons. This variability cannot be fully explained. Evidence on cost effectiveness is not clear, and may depend on the success of the crop. A recent report has shown that some Ingard® cotton crops have cost Australian farmers up to $1200 per hectare to produce while others gained an overall profit of $850 per hectare.

While Bt cotton requires less pesticide than conventional cotton, there is some evidence that pesticide applications are increasing. US laboratory studies indicate pest resistance to Bt cotton may be developing five to ten times faster than expected, and the Cotton Research and Development Corporation has found that Bt cotton is not as effective against Australian *Helicoverpa spp.* as it is against American species.

Source: Cotton Research and Development Corporation, Submission no. 27, p. 4; T Long, Report on the Economic Performance of Ingard Cotton for the 1998-99 Season, 1999, p. 9.

Risks and disadvantages

2.32 Several submissions to the inquiry warned of the risks attached to using GMOs. The risks identified were seen as impacting on the environment, health, social and economic conditions, and the developing countries. There are also ethical concerns surrounding the use of genetic manipulation, particularly transgenesis.

2.33 At the root of many of the concerns is the nature of gene technology. The claim that it is a precise process for which the outcomes can be predicted has been questioned. In a statement issued in April 1999, a group of scientists from a number of different countries expressed the view that:

> The technology is driven by an outmoded, genetic determinist science that supposes organisms are determined simply by

> constant, unchanging genes that can be arbitrarily manipulated to serve our needs; whereas scientific findings accumulated over the past twenty years have invalidated every assumption of genetic determinism. The new genetics is compelling us to an ecological, holistic perspective, especially where genes are concerned. The genes are not constant and unchanging, but fluid and dynamic, responding to the physiology of the organism and the external environment, and require a stable, balanced ecology to maintain stability.[53]

Environmental impacts

2.34 A number of negative environmental impacts from using GMOs were raised with the committee during the inquiry. These impacts are summarised in Box 2.2.

2.35 In the view of critics of the use of gene technology such as the Australian GeneEthics Network (AGN), these impacts will add to all the other destructive influences visited on the environment by modern industrial, chemical farming. They will contribute to ecosystem disruption and species extinction, and cause genetic and further chemical pollution.[54]

2.36 Boxes 2.3 and 2.4 examine the risks that have been identified from herbicide tolerant crops and Bt cotton grown in Australia, and detail the measures that have been developed to minimise these risks.

2.37 The committee recognises, as CSIRO pointed out that:

> There are still many unanswered questions about ecological impacts of current GMO technologies, an example being the impact of Bt cotton trash on soil micro organisms. These questions need to be addressed to assuage possible community concerns. A case in point was the laboratory finding of mortality of Monarch butterfly larvae being fed pollen of Bt corn, reported in *Nature* in May [1999].[55]

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53 'World scientists' statement: Calling for a moratorium on GM crops and ban on patents', Quoted by the Natural Law Party, Submission no. 45, p. 7. This statement was issued during the 1999 meeting on the UN Convention on Biodiversity held in Cartegena, Columbia to consider the Biosafety Protocol. It was issued by 125 scientists from 24 different countries; the number of signatories had risen to 310 scientists from 36 countries by 18 April 2000 (Institute of Science in Society, http://www.i-sis.org, accessed 31 May 2000).

54 Australian GeneEthics Network, Submission no. 71, pp. 4, 6.

55 CSIRO, Submission no. 56, pp. 6-7.

Box 2.2 Summary of negative environmental impacts of GM crops mentioned in submissions to the inquiry

- Herbicide tolerant GM plants allow more extensive use of herbicides than is possible with conventional varieties. This is already happening and may contribute to a loss of diversity among all forms of life on the land, and in water and soil near the GM plants.
- Herbicide tolerant crop plants are more likely to escape into the wild.
- Pollen drift from herbicide tolerant crops to related wild species, for example of canola, could result in the development of 'super weeds'; this has already happened in a limited number of cases.
- Bt is present all the time in GM crops compared with its more occasional presence when used as a spray; it is feared that the continuous presence of the pesticide will lead to a more rapid build up of pest resistance and greater damage to non target and beneficial insects.
- If crop plants are developed that are better suited to marginal agricultural environments, further clearing of native vegetation and losses of biodiversity may occur.
- If terminator technology were to be used, terminator genes might be spread to other organisms and cause species extinction.
- GM crops are grown, like other modern crops, as monocultures. Monocultures are fragile, unstable and the antithesis of sustainability because they are extractive and rely on intensive, expensive inputs.

Source: Australian GeneEthics Network, Submission no. 71, pp. 4-5, 6; Go Mark Food Systems, Submission no. 33, p. 12; Heritage Seed Curators Australia, Submission no. 30, pp. 5-6; Mr Arnold Ward, Submission no. 41, pp. 6, 11-12, 17-18; National Genetic Awareness Alliance, Submission no. 54, p. 5; Organic Federation of Australia, Submission no. 24, p. 3; Supplementary submission no. 73, pp. 1-2.

Box 2.3 Environmental risks of growing herbicide tolerant crops in Australia

There are a number of environmental issues arising from the use of herbicide tolerant crops, none of which are exclusive to GM varieties. The environmental impacts of both GM and conventionally bred herbicide tolerant crops are similar, and with both the impacts may not be realised for a long period of time.

Overuse or misuse of herbicides on herbicide tolerant crops can have a number of environmental effects:

- weed species may develop resistance and become 'superweeds', which might only be controlled with potentially harmful herbicides;
- plants which were previously not significant weed species may become new or worse weeds; and
- the environment may be exposed to greater amounts of harmful chemicals, therefore increasing loss of biodiversity in the surrounding region.

In addition, herbicide tolerant crops may become weedy in other agricultural systems or non-farming areas.

Integrated Weed Management reduces reliance on herbicides and so reduces the risk of the above impacts. It must be coupled with early detection of herbicide tolerant weeds to more effectively manage and minimise potential negative impacts.

Another way in which herbicide tolerant crops may impact on the environment is through cross pollination with closely related species. If the trait for herbicide tolerance is transferred to wild populations, it may promote the development of weediness in those species.

Concerns about the spread of GM material from GM to non GM crops by cross pollination have been addressed by the Genetic Manipulation Advisory Committee (GMAC) through establishing buffer zones around GM crops to minimise this risk. While the extent of buffer zones around a GM crop is determined on a case by case basis, buffer zones around GM canola crops are generally 400 metres. However, a report released last year by the John Innes Centre in the UK found that pollen from GM canola crops can be carried up to 15 km by bees and 160 km by wind.

Source: Australian GeneEthics Network, Supplementary submission no. 85, p. 4; Environment Australia, Submission no. 82, p. 12 and attachment B; National Association for Sustainable Agriculture, Submission no. 74, p. 1.

Box 2.4 Environmental risks of growing Bt cotton in Australia

Concerns have been raised about the possibility of Bt cotton cross-pollinating with conventional cotton or with similar species in the wild. However, research by the CSIRO has shown that a genetic block prevents the transfer of genes from agricultural cotton to similar wild species. Additionally, cotton is naturally self-pollinating, and the possibility of outcrossing to other areas is minimal.

Pest insects can develop resistance to the Bt gene, which may cause unforeseen consequences to the surrounding natural environment. GMAC and the National Registration Authority (NRA) have developed a refuge strategy, which recommends that no more than 30 per cent of a crop be planted with Bt cotton. The interbreeding of resistant and susceptible pests slows the development of resistance.

The effects of Bt cotton on non-target insects, birds and mammals in the surrounding natural environment are not fully known, and may have an adverse effect on regional biodiversity. Researchers in Europe and the USA have recently shown that the Bt gene has the potential to affect at least two insect species apart from the target species.

Other environmental concerns include:

- the build-up of Bt endotoxins in the surrounding soil;
- the possible build-up of Bt in the food chain;
- possible gene transfer and recombination, creating new pathogenic organisms and biological changes to non-target species; and
- effects on neighbouring farms that grow crops with similar pest complexes.

While a number of submissions recognise these concerns, little information has been provided to the committee on measures developed to minimise possible risks associated with these other concerns.

Source: Australian GeneEthics Network, Supplementary submission no. 85, pp. 5-6 and attachment 3; Transcript of evidence, 18 October, 1999, pp. 201, 203, 210; CSIRO, http://genetech.csiro.au/debate.htm, accessed 5 May 2000; Submission no. 56, p. 6.

2.38 According to Environment Australia (EA):

> The novelty of GMOs, the fact they will continue to reproduce after release, the complexity of natural environments and ecosystem processes, and the unknown evolutionary fate of

> inserted genes, all contribute to the difficulties of predicting environmental impacts.[56]

In addition, 'any long-term adverse environmental effects of GMOs may not be known or detected for many years, decades, centuries, or much longer (for example, on evolutionary timescales)'.[57]

Health impacts

2.39 Several concerns were expressed to the committee about the health impacts of consuming GM foods. The points put forward are summarised below.[58]

- Allergies to soybeans are reported to have increased in the UK since the introduction of soybeans from GM varieties.
- It is feared that antibiotic resistant marker genes, which are used in conjunction with other genes to track the transfer of the latter from one organism to another, might be transferred to bacteria that cause serious disease. Similarly, virus particles inserted to confer virus resistance may undergo recombination with others in the environment or in the alimentary tract and produce new pathogens.
- With herbicide tolerant crops, increased use of herbicides is possible; some herbicides, such as glyphosate, are known to have adverse effects on human health. Glyphosate also changes the oestrogen content of soy beans.

2.40 Some aspects of the system for testing the safety of food were queried in submissions to the inquiry. The testing of GM food for safety relies on establishing whether it is substantially equivalent to its conventional counterpart. If it is, no further tests are necessary. Only substantially different foods are exhaustively tested. The use of substantial equivalence as the basis for a test of safety was queried during the inquiry. Doubts have also been cast on the accuracy of substantial equivalence tests, for example those carried out with GM soybeans.[59] It is claimed that some of the testing carried out has been very scant.[60]

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56 Environment Australia, Submission no. 82, p. 2.

57 Environment Australia, Submission no. 82, p. 18.

58 Australian GeneEthics Network, Submission no. 71, p. 5; Heritage Seed Curators Australia, Submission no. 30, p. 8; Mr Robert Anderson (member of the Physicians and Scientists for Responsible Application of Science and Technology), Submission no. 4, Attachment pp. 1- 3; Mr Arnold Ward, Submission no. 41, pp. 12-13; National Association for Sustainable Agriculture, Submission no. 74, pp. 3-4; Organic Federation of Australia, Submission no. 24, p. 4.

59 Natural Law Party, Submission no. 45, p. 11.

60 Organic Federation of Australia, Submission no. 24, p. 4.

2.41 Two recent reports have examined the health impacts of GM foods and found no major safety concerns with their use. The US National Research Council, the research arm of the National Academy of Sciences, reached this conclusion for foods derived from pest resistant GM crops.[61] Four hundred participants at an OECD conference agreed unanimously that 'no peer-reviewed scientific article has yet appeared which reports adverse effects on human health as a consequence of eating GM food'.[62]

2.42 Attention is also being paid to the methods used to assess food safety; the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) will shortly hold a meeting to evaluate the appropriateness of current approaches to food testing, which were established in international meetings held about 10 years ago.

Social and economic impacts

2.43 One of the criticisms made of GM crops is the failure of the promise of higher yields to materialise on a number of occasions. Dr Charles Benbrook, for example, reported inferior performance for GM soybeans grown in trials in the USA.[63] In the case of Ingard® cotton grown in Australia, the results of trials on small plots were not always parallelled when larger acreages were grown (Box 2.1). Furthermore, substantial GM crop failures have occurred occasionally in the USA, for example with Bt and Roundup Ready cotton. Information provided to the committee suggested that some of these crop failures may have resulted from insufficient testing of new varieties before they were released on to the market and inadequate understanding of crop physiology and ecology.[64]

2.44 A report to ABARE's Outlook 2000 conference commented on the fact that agronomic and profit performances of some GM crops 'contrast somewhat with the rapid adoption rates'. It drew attention to several reviews that concluded that the yields and input use of GM crops have been:

> … somewhat mixed with the herbicide tolerant crops but generally favourable with insect resistant ones. The profit performances of

61 Committee on Genetically Modified Pest-Protected Plants, Board on Agriculture and Natural Resources, National Research Council, *Genetically Modified Pest-Protected Plants: Science and Regulation*, National Academy Press, Washington DC, 2000, p. 9.

62 *GM Food Safety: Facts, Uncertainties, and Assessments: Rapporteurs' Summary*, The OECD Edinburgh Conference on the Scientific and Health Aspects of Genetically Modified Foods, March 2000, p. 2.

63 C Benbrook, *Evidence of the Magnitude and Consequences of the Roundup Ready Soybean Yield Drag from University-Based Varietal Trials in 1998*, Ag BioTech InfoNet Technical Paper no. 1, July 1999, p. 1. Dr Benbrook is a consultant on environmental, food safety and pest management issues. His paper reports the results of over 8,200 university based soybean varietal trials carried out in the US.

64 Mr Arnold Ward, Submission no. 41, pp. 13-16.

> these crops are even more mixed once the fees that are payable to the owners of these technologies (through seed costs) are taken into account.[65]

2.45 While GM crops may produce lower yields compared with their conventional counterparts,[66] this must be considered in the context of growers' outgoings on other farming inputs, such as control chemicals, which may be reduced.[67] Some growers prefer to use GM crops even if there is no financial benefit to them, because of the environmental benefits.

2.46 Another drawback to using gene technology in agriculture is its likely impact on farm incomes and rural communities. Biotechnology is seen as the latest driver in the industrialisation of agriculture, which has led to falling prices for agricultural products and has squeezed farmers off the land. It is feared that the use of GMOs will further exacerbate these trends.[68] So too might the dominance of a few multinational companies over key gene technologies which gives them the capacity to extract premium prices for GMOs. This issue is discussed further in Chapter 5. Monopoly control of GM crops will also continue the world wide trend of decreasing agricultural biodiversity and reduce the genetic stores from which future crop varieties might be developed.[69]

2.47 News that Monsanto had started work on a 'terminator gene', which will prevent GM plants from producing viable seeds, has also been widely discussed. Saving the seed from one harvest to plant for the next is a farming practice of great antiquity. It will be stopped by the terminator gene and farmers will be forced to purchase new seed each season. Although Monsanto has indicated that it has no intention of using terminator technology in its seed, serious fears have been expressed about the impact of such a system on farmers, especially in the developing world.[70] As discussed in Chapter 6, there is an alternative to using terminator technology to protect the IP in GM varieties without producing non viable seed.

2.48 Another economic influence feared from the introduction of GM crops is the spread of introduced genes into organic or non GM crops growing nearby. For farmers who wish to certify their produce as not containing

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65 M Foster, 'Market implications: genetically modified crops', *OUTLOOK 2000*, ABARE, Canberra, 2000, p. 184.

66 J Grellman, Transcript of evidence, 18 October 1999, p. 204; Mr Wayne Hancock, Submission no. 6, Attachment pp. 139-40.

67 T Long, *Report on the Economic Performance of Ingard Cotton for the 1998-99 Season, 1999*, p. 6.

68 Heritage Seed Curators Australia, Submission no. 30, p. 10; Mr Alan Griffiths, Submission no. 22, p. 3; Organic Federation of Australia, Submission no. 24, p. 4.

69 Australian GeneEthics Network, Submission no. 71, p. 4.

70 National Association of Sustainable Agriculture Australia, Submission no. 74, p. 3.

any foreign genetic material, GM crops represent a serious threat to their economic future.[71] Organic farmers may also suffer if pest resistance to Bt increases.

> … a spray of last resort to organic farmers, that of Bt, is under threat as resistance will be encouraged by wide spread plantings of Bt crops. Early studies in the US are showing that this fear is being realised.[72]

Avoiding and controlling risks

2.49 There are varying views on how these risks and disadvantages should be addressed. At one extreme in the range of attitudes on this subject is the view that there is a very good chance that few of the risks will eventuate and, if they do, they probably can, and will, be addressed. Others are less sanguine about the outcome of using GMOs in agriculture. At least some of the untoward consequences of releasing GMOs into the environment are likely to be irreversible.[73] In so far as GMOs are capable of self replication, it may be difficult to recapture them once they have been released.

2.50 Several submissions to the inquiry took the more alarmist view of the impact of GMOs. They pointed out that time is needed to observe what their long term health and environmental effects will be.[74] As a British report on GM food observed, 'there are all sorts of things that we don't know that we don't know'. Under these circumstances, it is appropriate to invoke the precautionary principle.[75] This principle states, that 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.

2.51 A moratorium on the growing of GM crops was proposed by several organisations.[76] It was suggested that the moratorium should continue for anything from five to 20-50 years, to allow adequate research to be carried out on health and environmental impacts.[77] In addition, consensus should

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71 Organic Federation of Australia, Submission no. 24, p. 6; Supplementary submission no. 73, p. 1.

72 Organic Federation of Australia, Submission no. 24, p. 3.

73 British Medical Association, *The Impact of Genetic Modification on Agriculture, Food and Health: An Interim Statement*, May 1999, p. 12.

74 Ms Lyssa, Submission no. 5, p. 1; Organic Federation of Australia, Submission no. 24, p. 3.

75 *The Politics of GM Food: Risk, Science & Public Trust*, Economic & Social Research Council, Special Briefing No. 5, October 1999, p. 5.

76 For example, the Public Health Association of Australia, Submission no. 57, p. 1.

77 Heritage Seed Curators Australia, Submission no. 30, p. 1; National Genetic Awareness Alliance, Submission no. 54, p. 1; Organic Federation of Australia, Submission no. 24, p. 4.

be obtained among scientific and health professionals on the safety of GMO use before they are released.[78] The National Genetic Awareness Alliance also suggested an assessment of the social and economic impact of gene technology on primary producers.[79]

2.52 In connection with the proposals outlined in the last paragraph, the committee's attention was drawn to recommendations on GMOs made by the British Medical Association (BMA) and by 125 world scientists from 24 countries. These groups took a cautious approach, calling for a 'moratorium on further environmental releases of transgenic crops, food and animal-feed products for at least 5 years'.[80] The BMA also believed that 'any conclusion upon the safety of introducing GM materials into the UK is premature as there is insufficient evidence to inform the decision making process at present'.[81] The Australian Medical Association also considered that 'the jury is still out on the benefits and risks of GM foods on public health and the environment'.[82]

2.53 In 1998, the Royal Society (London) reported its view of further work that it deemed necessary to ensure the safety of GM crops. It warned that the impacts of GM plants should not be considered in isolation, but should be judged in comparison with the impact of managing conventional crops. The recommendations it made included:

- monitoring for the transfer of genes from GM crops to wild relatives and non GM crops;
- review of the recommended isolation distances for plantings of GM crops and other methods of minimising gene transfer;
- replacement of antibiotic resistant gene markers by alternatives and, until alternatives are available, the removal of the marker at an early stage in the development of the GM variety;
- work on the impact of pest resistant plants on beneficial insects, the development of resistance among target insects, and methods of minimising these risks;
- monitoring the impact of greater herbicide use with herbicide tolerant crops;

78 Go Mark Food Systems, Submission no. 33, p. 3.

79 National Genetic Awareness Alliance, Submission no. 54, p. 2.

80 'World scientists' statement calling for a moratorium on GM crops and ban on patents', Quoted by the Natural Law Party, Submission no. 45, p. 6.

81 British Medical Association, *The Impact of Genetic Modification on Agriculture, Food and Health: An Interim Statement*, May 1999, p. 2.

82 Australian Medical Association, 'Ministers' decision positive but: the AMA will be vigilant on details', Media release, 4 August 1999.

- research on virus resistant plants;
- research on the need for long term feeding studies designed test for allergenicity and toxicity; and
- the provision of advice to growers about crop management and rotation.[83]

2.54 According to the BMA, there is also a need to considerably strengthen disease surveillance systems 'to deal with the potential emergence of new diseases associated with GM material which will be obscure and difficult to diagnose'.[84]

Ethical concerns

2.55 Disquiet about the use of gene technology in agriculture reflects in part people's reaction to the new and unexpected and their coming to terms with its implications for how they and their society live. One of the main concerns centres on the perceived unnaturalness of genetic engineering which involves transferring genes between species that do not normally interbreed, particularly when human genes are involved. Such processes are seen by some as violating fundamental natural processes. Heritage Seed Curators Australia (HSCA) drew the committee's attention to HRH Prince Charles' statement that these activities should not be meddled with; they should be left to God.[85]

2.56 The committee is aware that this viewpoint has been challenged by others. For example, Richard Dworkin asked what was wrong with 'playing God' if it enabled us to resist natural catastrophes.[86] Others, such as the Nuffield Council on Bioethics, have suggested that it would, in fact, be unethical not to develop GMOs if they will contribute to alleviating world hunger.[87]

2.57 In addition, from a scientific point of view, the outcomes of genetic manipulation may seem no stranger than naturally occurring phenomena. For example:

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83 The Royal Society, 'Genetically modified plants for food use', 1998, http://www.royalsoc.ac.uk/st_pol40.htm, accessed 12 July 1999.

84 British Medical Association, *The Impact of Genetic Modification on Agriculture, Food and Health: An Interim Statement*, May 1999, p. 13.

85 Heritage Seed Curators Australia, Submission no. 30, p. 4.

86 R Dworkin, 'Playing God', *Prospect*, no. 41, May 1999, p. 40.

87 *Genetically Modified Crops: The Ethical and Social Issues*, Nuffield Council on Bioethics, London, May 1999, p. xv.

> Plants can make haemoglobin, which is usually seen as an animal product. The deep sea dragonfish can make chlorophyll, which is usually associated with green plants. Nature is pretty good at moving genes around and recycling them around. There is nothing that we can do which matches what nature has already done.[88]

The Academy of Science commented that 'it is virtually impossible to decide what is "natural" and what is not after some 10,000 years of plant and animal improvement by humans'.[89]

2.58 HSCA claimed that 'the moral and ethical aspects of developing and using this technology have not been examined at all' and pointed out that 'it is important to consider whether the development of GE organisms offends the religious & moral sensitivities of Australian people'.[90] The consensus conference on gene technology in the food chain held in March 1999 recommended the inclusion of an ethicist in the formulation of major decisions regarding GMO policies.[91] In the drafting of the Gene Technology Bill, this point was recognised and an ethics committee is proposed to advise the ministerial council overseeing the operation of the Office of the Gene Technology Regulator (OGTR).

Conclusions

2.59 The committee is of the opinion that applying gene technology to agriculture can benefit farmers, consumers and the Australian environment and economy.

2.60 The committee realises that there is a range of GMOs; their differing biological characteristics mean that each class of GMO presents a different type and level of risk. It is therefore appropriate that each GMO is considered for use in the light of its own particular characteristics. The risks presented by some may justify a moratorium on them until their nature is better understood, and others can be considered for release promptly. The committee does not believe that there is a case for a complete moratorium on all GMOs. The important point is that each GMO

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88 O. Mayo, 'Animals', *Gene Technology and Food*, National Science & Industry Forum Report, Australian Academy of Science, April 1999, p. 5.

89 Australian Academy of Science, Submission no. 62, p. 1.

90 Heritage Seed Curators Australia, Submission no. 30, pp. 1, 4.

91 *First Australian Consensus Conference: Gene Technology in the Food Chain: Lay Panel Report*, Canberra, March 1999, p. 6.

is examined with care before being used. This matter is discussed further in Chapter 7.

2.61 In the early stages of the development and use of any new technology, the extent and nature of the benefits and risks are not fully known and can only be guessed at. It may be that the AFGC will be proved right in judging that the controlled use of biotechnology 'does not introduce new or additional unmanageable risk factors'.[92] Others, however, are not so sure.

2.62 It is only through extended use and careful monitoring that benefits and risks can be accurately gauged and consensus established on the appropriateness of the technology's use. Until then, extreme claims about the positive and negative aspects of the technology cannot be countered adequately. These claims can, however, help to drive the process of assessing the benefits and risks. The committee considers that the use of gene technology in agriculture is currently at the stage of needing much more work before the benefits and risks of using GMOs are well established. Only then will the best means of maximising benefits and avoiding or minimising risks be better understood.

2.63 The committee is aware that:

- environmental research is carried out by applicants before applying to regulatory bodies for the use and release of GMOs; and
- successful applicants may be required to monitor and report on environmental impacts after commercial release of GMOs.

GM foods that are substantially different from their conventional counterparts also undergo extensive examination before being approved for sale.

2.64 In addition to this research that is specific to the particular GMO under consideration, more general work may also be needed. The committee is aware that CSIRO is developing a multidisciplinary project to provide information and models that will help to understand the effects of GMOs at the landscape scale and their implications for farm management practices. This work will identify the best means of assessing risks and feed into the decision making of regulators.

2.65 ABARE staff have made the economic assessments of GMO crop prospects for Australia which were referred to earlier in this chapter. Consumer reaction will impact on acceptance of GM products and needs to be researched. In this context, AGN recommended a 'full economic

92 Australian Food and Grocery Council, Submission no. 59, p. 5.

assessment of the potential benefits and costs to Australian producers and the whole nation, of a variety of production options'.[93]

2.66 The committee is convinced that research as described above is essential. It believes that more is needed to better establish the nature and extent of the health, environmental and economic benefits and risks posed by agricultural GMOs and their development and options for addressing them. While it is appropriate for those who wish to use GMOs to fund some of this research, there may be occasions, for example, as discussed in Chapter 7, when more fundamental research is required and government funding is appropriate. It is important, with the current level of concern about the safety of GMOs that government is seen to be actively pursuing the public interest by supporting research into, and assessment and management of, the benefits and risks associated with their use.

Recommendation 1

2.67 **The committee recommends the continued use of gene technology, but only with stringent regulation, constant and cautious monitoring, and public reporting.**

Recommendation 2

2.68 **The committee recommends that the Commonwealth government increase funding for research into the potential benefits and risks (environmental, health, social, economic and ethical) presented by genetically modified organisms.**

2.69 The committee envisages that this research and monitoring will be carried out, or commissioned by agencies such as the Australia New Zealand Food Authority (ANZFA), CSIRO, EA, the OGTR and the National Registration Authority (NRA). For example, one of the functions of the Gene Technology Regulator (GTR) is to commission research into risk assessment. The committee believes that suggestions about research topics should be sourced more widely than simply from scientists and public servants within these organisations.

93 Australian GeneEthics Network, Submission no. 71, p. 6.

2.70 As some of the points raised in earlier sections of this chapter have demonstrated, there are concerns to understand how gene technology fits into a broader context. At one level, it is important to see gene technology as just one of the approaches that will contribute to an efficient, sustainable agricultural sector. Avcare, for example, emphasised that, 'in addition to gene technology, conventional breeding, traditional pest control methods, prescription farming and permaculture approaches will all contribute to produce the best outcome for Australia's primary producers'.[94]

2.71 The committee is aware that very large sums of money have been directed towards gene technology both in Australia and overseas. It is concerned that this funding does not crowd out assistance for other approaches to improving agricultural and environmental sustainability.

Recommendation 3

2.72 **The committee recommends that the Commonwealth government ensure that funding for research into improving agricultural productivity and sustainability is allocated equitably across all areas of research.**

2.73 Others have suggested taking an even wider view to assessing where gene technology fits in. The ultimate concern is for rural sustainability that includes protecting employment, communities and the environment.[95] The challenge is to establish the role that gene technology has in this vision.

94 Avcare, Submission no. 61, p. 4.

95 *The Politics of GM Food: Risk, Science & Public Trust*, Economic & Social Research Council, Special Briefing No. 5, October 1999, p. 16.

3

Understanding genetically modified organisms

Introduction

3.1 Gene technology, particularly GM foods, has had a high media profile worldwide. The committee has received evidence that lack of information, conflicting news reports and negative perceptions of multinational companies have generated concern among members of the public.[1] Many consumers feel that ethical and cultural values have not been considered, and an overwhelming number of submissions from both sides of the debate stated the urgent need to educate both consumers and producers about gene technology.[2]

> The GM debate has been so controversial not least because of the deep cultural significance of food and the changes that genetic engineering promises to bring culturally and socially. Our evidence shows that many people [in the UK] are increasingly unwilling simply to accept such revolutionary changes without a genuine debate about the options society faces.[3]

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1 For example, Agrifood Alliance Australia, Submission no. 37, p. 6; Australia and New Zealand Food Authority, Submission no. 63, pp. 4-5; Australian Barley Board, Submission no. 60, p. 11; Grains Council of Australia, Submission no. 65, p. 17; Mr Brendan Doyle, Submission no. 3, pp. 3, 4; Nugrain, Submission no. 25, p. 12; Office of Fair Trading, Queensland, Submission no. 13, p. 1.

2 For example, National Farmers' Federation, Submission no. 36, p. 18; Queensland Fruit and Vegetable Growers, Submission no. 42, p. 4; The Veterinary Manufacturers and Distributors Association, Submission no. 76, p. 3.

3 *The Politics of GM Food: Risk, Science & Public Trust*, Economic & Social Research Council, Special Briefing No. 5, October 1999, p. 20.

3.2 There are benefits and risks associated with gene technology, and there is a need to provide balanced information about them in an open and credible manner. Particular emphasis needs to be placed on addressing consumer concerns associated with risk, and how these risks are dealt with in the regulatory framework.

3.3 This chapter focuses on consumer concerns about gene technology and addresses the following issues:

- the role of education;
- the perception of risk;
- the provision of information; and
- education strategies.

Benefits and risks are discussed in greater detail in Chapter 2.

The role of education

3.4 Consumer concerns about food safety, environmental safety and ethics have impeded acceptance of gene technology in Australia. The Australian Biotechnology Association (ABA) considered that, by providing factual information about the benefits and risks of gene technology, consumers will be able to make an informed, rational choice about the application of the technology.

> A better informed community is better able to make more informed decisions on the benefit and risks associated with the application of biotechnology and less likely to be influenced by scaremongers.[4]

3.5 Lack of consumer confidence in gene technology and the government authorities responsible for its regulation have generated public feelings of distrust and suspicion. Animated Biomedical Productions pointed out that secrecy by government and industry groups will only serve to increase these feelings. It considered that 'nothing undermines confidence more than the impression that those "in the know" regarding gene technology are keeping the knowledge, and its attendant risks, to themselves'.[5] Lack of trust can be a major impediment to consumer acceptance of gene technology. A survey of 18 to 25 year olds found that:

4 Australian Biotechnology Association, Submission no. 39, p. 8.

5 Animated Biomedical Productions, Submission no. 1, p. 2.

> They trust very few people. It was really quite a striking finding. They think everyone either can be or is being bought. That is a real issue that I think the government regulators need to recognise and in some way … address. Until the public trusts ANZFA, GMAC and IOGTR [Interim Office of the Gene Technology Regulator], there always will be this distrust of the technology.[6]

3.6 A number of submissions considered that public acceptance of gene technology is vital to its successful application within the Australian market.[7]

> The most significant impediment to the utilisation of genetically modified varieties by primary producers could be the rejection of genetically modified food products by consumers. If this occurs, there will be no consumer demand and no market for GM foods and therefore no market for GM agricultural products.[8]

Box 3.1 illustrates the impact of consumer sentiment on GM food.

3.7 Avcare considered that there is a need to provide balanced, factual information to the public, and both Avcare and Queensland's Office of Fair Trading highlighted the need for the community to participate in the decision making process.[9] Effective consumer participation in decision making is only possible if good information is available to all involved. Information is also crucial to consultative processes such as those established to develop the new legislation, and to provide input to the GTR's decisions.

Awareness and attitudes

3.8 Public awareness campaigns need to target the right information at the right audience. Background research needs to identify the levels of education that are needed, what information the community wants and how to provide appropriate information effectively. The Australian United Fresh Fruit and Vegetable Association pointed out that:

> Any education campaign has to begin with the consumer. What is their concern? How strong is this concern? What do they want? How can these concerns be addressed?[10]

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6 Agrifood Alliance Australia, Transcript of evidence, 29 September 1999, p. 189.

7 For example, Australian Barley Board, Submission no. 60, p. 4; Australian Biotechnology Association, Submission no. 39, pp. 8-9.

8 South Australian government, Submission no. 81, p. 5.

9 Avcare, Submission no. 61, pp. 6, 7; Office of Fair Trading, Queensland, Submission no. 13, p. 1.

10 Australian United Fresh Fruit and Vegetable Association, Submission no. 58, p. 4.

Box 3.1 Genetically modified tomato paste in the UK

In 1996, the supermarket chain Sainsbury's introduced a GM tomato puree in the UK. The tomato had a higher solids content than conventional varieties, which reduced the manufacturing costs involved in the production of foods like tomato paste. This reduction in costs was passed on to the consumer, so the GM product was cheaper than conventional products. In 1996, the GM paste was outselling conventional paste by a ratio of 2:1.

Sainsbury's aimed to be as open and transparent about the GM paste as possible, and in 1995 it made a press announcement about the paste's anticipated release. It ensured that its staff could provide customers with information, and produced an in-store leaflet about the product. The product was clearly labelled as GM.

Late 1997 through 1998 saw a growing concern in the UK about GM foods. During 1998, sales of the GM paste declined until it was selling at a ratio of 1:1 with conventional past. After Christmas 1998 when media coverage of GM issues increased, sales dropped to a very low level until Sainsbury's found that it was no longer economically viable to sell the product. At present, in response to consumer concerns, Sainsbury's has eliminated all GM ingredients from its products.

Source: British House of Commons Select Committee on Science and Technology, Scientific Advisory System: Genetically Modified Foods, Minutes of Evidence, http://www.parliament.the-stationery-office.co.uk/pa/cmselect/cmsctech/286/9042104.htm, *accessed 15 May 2000;* http://www.parliament.the-stationery-office.co.uk/pa/cmselect/cmsctech/286/9042105.htm, *accessed 15 May 2000.*

Levels of awareness and acceptability

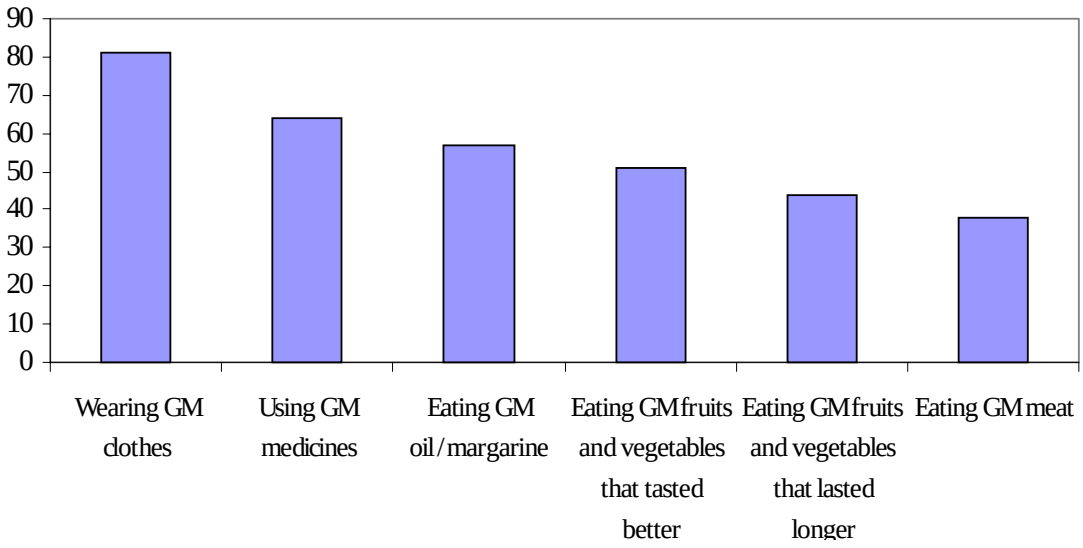
3.9 Several surveys on attitudes towards GM foods have been conducted. These surveys have provided information about public perceptions of gene technology and the reasons for those perceptions.

> A number of processes have gone on in the past, and several are going on now, to try to get an appropriate handle on what the level of consumer concern is, what the level of consumer information should be and to what extent there is misinformation affecting people's perceptions.[11]

11 Agriculture, Fisheries and Forestry Australia, Transcript of evidence, 20 September 1999, p. 150.

3.10 A survey commissioned by BA found that, while 92 per cent of participants had heard of the term 'genetic engineering', levels of awareness of its applications varied considerably (24–80 per cent).[12] The acceptability of gene technology differed depending on how the technology was used. Medical uses were the most acceptable, and manipulation of animals least acceptable. The nature of a particular GM product appears to determine public acceptance of GMOs (see Figure 3.1).

Figure 3.1 Percentage of people who would use GM products



Source: Yann Campbell, Hoare and Wheeler, Public attitudes towards biotechnology, p. 6, http://www.isr.gov.au/ba/WhatsNew/ychw.pdf, accessed 5 May 2000

3.11 A postal survey undertaken by CSIRO regarding public attitudes to genetic engineering and food found that:

- those who could define genetic engineering thought it had something to do with altering genes, mutation or cloning,
- 47 per cent of men thought the technology would make [life] better, compared to only 24 per cent of women,
- 70 per cent thought citizens had a role in decisions about technology,
- Only 20 per cent felt that the risks of genetic engineering had been exaggerated.[13]

12 Yann, Campbell, Hoare, Wheeler, *Public attitudes towards biotechnology*, pp. 2, 4-5, http://www.isr.gov.au/ba/WhatsNew/ychw.pdf, accessed 5 May 2000.

13 National Farmers' Federation, Submission no. 36, p. 19.

3.12 In a survey reported to a forum on transnational agri-food systems, participants were generally concerned about the risks of GMOs. Seventy six per cent considered that the accidental release of these organisms would cause environmental damage and 52 per cent considered that eating GM foods would have long term health effects (either positive or negative). Fifty two per cent felt that the risks of genetic engineering would outweigh the benefits. It was also found that 93 per cent of participants supported government control of GM foods, as well as consultation with consumers before the release of such foods.[14]

Risk perception

3.13 Consumer perceptions of risks associated with gene technology and their attitudes towards those risks can have a great impact on acceptance of the technology. Brendan Doyle of the University of New England's Rural Development Centre pointed out that attitudes can be founded on ethical as well as scientific reasoning. Social values and distrust of organisations can also be extremely important.[15] A recent report by the House of Lords stated that:

> Some issues currently treated by decision-makers as scientific issues in fact involve many other factors besides science. Framing the problem wrongly by excluding moral, social, ethical and other concerns invites hostility.[16]

3.14 Scientific perceptions of risk are based on identifying and characterising hazards, and determining the probability of their occurrence and possible consequences. Consumers, however, tend to focus on the consequences for them personally should the risk materialise and are less concerned with scientific perceptions of risk.[17]

> What the public finds acceptable often fails to correspond with the objective risks as understood by science. This may relate to the degree to which individuals feel in control and able to make their own choices.[18]

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14 J Norton, G Wood & G Lawrence, 'Public Acceptance of Genetically Engineered Food', Paper presented at the Forum on Critical Issues in Transnational Agri-food Systems, Queensland University of Technology, Brisbane, 1998.

15 Mr Brendan Doyle, Submission no. 3, p. 3.

16 House of Lords Select Committee on Science and Technology, Third Report, *Science and Society*, www.publications.parliament.uk/pa/ld199900/ldselect/ldsctech/38/3802.htm, accessed 3 April 2000.

17 Agriculture, Fisheries and Forestry Australia, Submission no. 77, p. 14.

18 House of Lords Select Committee on Science and Technology, Third Report, *Science and Society*, www.publications.parliament.uk/pa/ld199900/ldselect/ldsctech/38/3802.htm, accessed 3 April 2000.

3.15 Individuals' perceptions of risk vary according to the possibility of that risk affecting themselves, their families and their communities. The acceptability of that risk is weighed up according to the benefits the consumer will receive. **Medical applications are regarded as the most acceptable use of gene technology because individuals can see a direct benefit to themselves.**[19] **Similarly, consumers are more willing to wear wool from a GM sheep than consume that sheep's meat; they perceive a lower potential risk from wearing than from eating a GMO** (Figure 3.1).

3.16 The NFF believes that one of the barriers to consumer acceptance of gene technology is that there is little discernible benefit to consumers in the products on the shelves.[20] Presently, most of the benefits are gained by producers.

3.17 Another factor that affects acceptance of risk is the extent to which a choice exists over whether to take the risk or not. People are more prepared to take risks if they feel that they have a degree of control over them.[21] Labelling gene technology products, particularly GM foods, places the choice directly in the hands of the consumer. Brendan Doyle considered that 'consumers might also place value on having the right to be informed about the composition of processed foods they purchase'.[22]

3.18 The survey reported at the forum on transnational agri-food systems found 86-91 per cent of consumers felt that GM foods should be labelled. In addition, approximately 60-65 per cent considered that GM products which were not for consumption, such as the blue rose, or sheep genetically engineered for wool, should also be labelled.[23]

Addressing risk perceptions

3.19 Consumers have identified concerns over the safety of GM products and how this could possibly affect them. They have also identified information about the ethical and social aspects of the technology as important.[24]

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19 Agriculture, Fisheries and Forestry Australia, Submission no. 77, p. 14.

20 National Farmers' Federation, Submission no. 36, p. 17.

21 A Kellow, 'Risk assessment and decision-making for genetically modified foods', *IPA Biotechnology Backgrounder*, no. 1, October 1999, p. 3.

22 Mr Brendan Doyle, Submission no. 3, p. 3.

23 J Norton, G Wood & G Lawrence, 'Public Acceptance of Genetically Engineered Food', Paper presented at the Forum on Critical Issues in Transnational Agri-food Systems, Queensland University of Technology, Brisbane, 1998.

24 *First Australian Consensus Conference: Gene Technology in the Food Chain: Lay Panel Report*, Canberra, March 1999, p. 6.

3.20 AFFA pointed out that the technology should not be considered on a purely scientific level, and identified ethical, social economic and environmental concerns as important.[25] The Australian United Fresh Fruit and Vegetable Association outlined its experiences of addressing consumer concerns:

> It is not a scientific debate – it is an emotional one in which the consumer has genuine concerns. The fruit and vegetable industry has been through this issue with agricultural chemicals and residues. It was not until all consumer concerns were recognised that any headway on solving the various issues could be made.[26]

As a select committee of the House of Lords pointed out, public attitudes and values need to be recognised, respected and weighed along with scientific and other factors.[27]

3.21 The committee feels that, to be fully effective, an information campaign should acknowledge the value that consumers place on environmental, economic, ethical and social considerations, and address them. The government funded public awareness campaign, which is described later in this chapter, must pay attention to these issues.

Recommendation 4

3.22 **The committee recommends that all public education campaigns funded by the Commonwealth government recognise and address the environmental, economic, cultural, ethical and social concerns of the consumer.**

Provision of information

3.23 Information such as that presented in the two previous sections is useful in designing public awareness campaigns. It assists with the choice of material to be presented and the manner in which it is provided. Several submissions to the inquiry commented specifically on these matters,

25 Agriculture, Fisheries and Forestry Australia, Submission no. 77, p. 15.

26 The Australian United Fresh Fruit and Vegetable Association, Submission no. 58, pp. 3-4.

27 House of Lords Select Committee on Science and Technology, Third Report, *Science and Society*, www.publications.parliament.uk/pa/ld199900/ldselect/ldsctech/38/3802.htm, accessed 3 April 2000.

emphasising the importance of unbiased, open and credible information.[28] Some submissions called for information about all aspects of the technology to be made available.[29] Others stressed the particular need for information relating to:

- general aspects of gene technology;[30]
- the benefits and risks of gene technology;[31] and
- how the regulation of gene technology addresses the risks posed by its use.[32]

3.24 The first Australian consensus conference on dealing with gene technology in the food chain identified detailed scientific information about the technology as less important than understanding how the technology could be used and the consequences of its use.[33] As AFFA pointed out:

> Public information campaigns on gene technology tend to focus on making the public familiar with the intricacies of the technology and reducing the opposition to the technology by reducing the 'unknown'. Several experiences have shown this tactic not to work; it often strengthens peoples' opinions, both in support of and opposition to the technology … [34]

Notwithstanding these points, the committee believes that it is important that information continue to be available about developments in gene technology and detail past, current and future projects.

3.25 AFFA suggested that there is a need to listen to consumers, as well as provide them with information.[35] CSIRO agreed and considered that 'it is critical to involve all stakeholders and engage [in] an informed and public debate seeking to resolve issues rather than just creating conflict and polarisation'.[36] The Grains Research and Development Corporation

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28 For example, Avcare, Submission no. 61, p. 11; Interim Office of the Gene Technology Regulator, Submission no. 78, p. 16; The National Association for Sustainable Agriculture, Submission no. 74, p. 2.

29 For example, Mr Wayne Hancock, Submission no. 6, p. 6; Western Australian government, Submission no. 48, p. 6.

30 Australia and New Zealand Food Authority, Submission no. 63, p. 5.

31 Australia and New Zealand Food Authority, Submission no. 63, p. 5; Dairy Research and Development Corporation, Submission no. 15, p. 7.

32 Australia and New Zealand Food Authority, Submission no. 63, p. 5.

33 Agriculture, Fisheries and Forestry Australia, Submission no 77, p. 15.

34 Agriculture, Fisheries and Forestry Australia, Submission no 77, p. 15.

35 Agriculture, Fisheries and Forestry Australia, Submission no. 77, p. 15.

36 CSIRO, Submission no. 56, p. 6.

(GRDC) stated that lessons learnt during the consensus conference may assist in formulating an open approach to education.[37]

3.26 Agrifood Alliance Australia (AAA) also pointed out the significance of having advice available from trustworthy sources.

> Consumers are not interested in being "educated about" or "preached to" about the benefits or risks of new innovation and technologies. Rather, the community requires access to quality information and advice from a body which they trust on which to base their choices.[38]

3.27 In this context, providing information about how the regulatory system operates and how it reaches its decisions are important, as discussed in Chapter 7. Novartis commented with respect to the role and nature of its regulatory processes that the government needs to communicate and:

> … act to ensure that they are viewed credibly by consumers. It is particularly critical that government is active in communicating the credibility of systems that assess the safety to the environment and human health of genetically modified crops. It is apparent that at present, the need for concerns about safety to be addressed far outstrips other issues.[39]

Education strategies

3.28 BA is currently the leading government agency responsible for providing information on gene technology to the public. BA carries out this task as part of its role of ensuring that, 'consistent with safeguarding human health and ensuring environmental protection, Australia captures the benefits of biotechnology for the Australian community, industry and the environment'. BA was established in 1999 as the focal point for the policy measures needed to facilitate the development of biotechnology. It reports to a ministerial council comprising the Ministers for Industry, Science and Resources; Agriculture, Fisheries and Forestry; Education, Training and Youth Affairs; the Environment and Heritage; and Health and Aged Care. In addition to raising public awareness about biotechnology, BA is:

- developing a national biotechnology strategy;
- supporting training for developers and managers of IP; and

37 Grains Research and Development Corporation, Submission no. 47, p. 16.

38 Agrifood Alliance Australia, Submission no. 37, p. 6.

39 Novartis Australia, Submission no. 26, p. 9.

- securing better access to genetic resources and gene collections.[40]

3.29 In the 1999-2000 budget, BA received funding to conduct a public awareness campaign over two years; the 2000-2001 budget provides $3 million for this purpose. BA has so far provided information through public forums and debates, conferences and seminars, the media, the internet, and its telephone hotline. Among the fact sheets that it has produced is a brochure about GM foods that has been distributed through major supermarket chains in Australia.[41] An information kit for secondary school teachers is being developed. BA also plays an important role in coordinating information provided by the regulatory agencies and CSIRO.[42]

3.30 Several submissions identified ways of providing information to the public. These included:

- fact sheets and pamphlets;[43]
- media and the internet;[44]
- labelling;[45]
- consensus conferences and public forums;[46] and
- field days.[47]

3.31 Fact sheets and pamphlets are published by a number of government, industry and community bodies. The ABA, for example, supports the need to inform the community regarding gene technology, and has produced 12 pamphlets describing gene technology and its applications.[48] Fact sheets are also produced by CSIRO, ANZFA, the Therapeutic Goods Administration, and a number of biotechnology companies.

3.32 A number of submissions expressed concern about the portrayal of gene technology in the media, both through traditional sources and through the

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40 Biotechnology Australia, 'Biotechnology - a framework for the future'.

41 Department of Industry, Science and Resources, Submission no. 84, p. 2.

42 Biotechnology Australia, http://www.isr.gov.au/ba/Biotechnology/consultation.html, accessed 5 April 2000.

43 For example, Australian Biotechnology Association, Submission no. 39, p. 8; Interim Office of the Gene Technology Regulator, Submission no. 78, p. 16; The Veterinary Manufacturers and Distributors Association, Submission no. 76, pp. 2, 11.

44 For example, Australian Academy of Science, Submission no. 62, p. 4; Australian Barley Board, Submission no. 60, p. 11; Dr Brian Booth, Submission no. 7, p. 6.

45 For example, NSW Farmers' Association, Submission no. 38, p. 2.

46 For example, Heritage Seed Curators Australia, Submission no. 30, p. 2; Organic Federation of Australia, Submission no. 24, p. 2.

47 Mr Mal and Ms Nancy Robinson, Submission no. 18, p. 2.

48 Australian Biotechnology Association, http://www.aba.asn.au, accessed 14 April 2000.

internet.[49] The availability of balanced, factual information on which the media can draw is therefore important. As an increasingly important media tool, the internet provides better opportunities for the public to be fully informed than before.[50] In a recent survey, the internet was cited as the preferred source of information about biotechnology.[51] Many of the pamphlets and fact sheets mentioned above are available on the internet.[52]

3.33 The committee is aware of the large amount of useful information available on government internet sites. It understands, however, that some of these sites are less user friendly and intuitive than others, and not all are updated regularly. Among the regulators, ANZFA's site and that of the Interim Office of the Gene Technology Regulator (IOGTR) suffered from some of these problems at the time that the committee's report was being prepared. The committee believes that these faults could and should be quickly rectified.

Recommendation 5

3.34 **The committee recommends that government agencies, especially the Interim Office of the Gene Technology Regulator and the Australia New Zealand Food Authority, review the design of their internet sites to ensure they are user friendly.**

Sites should lay out clearly what they contain, be easily navigable, and present readily understood information which is updated regularly.

49 For example Australian Raw Sugar Industry, Submission no. 64, p. 7; National Farmers' Federation, Submission no. 36, p. 17; Nugrain, Submission no. 25, p. 12.

50 Australian Academy of Science, Submission no. 62, p. 4.

51 Yann, Campbell, Hoare, Wheeler, *Public attitudes towards biotechnology*, p. 7, http://www.isr.gov.au/ba/WhatsNew/ychw.pdf, accessed 5 May 2000.

52 For example, CSIRO, http://www.genetech.csiro.au; Therapeutic Goods Administration for access to the IOGTR's web site, http://www.health.gov.au/tga/genetech.htm; Australia New Zealand Food Authority, http://www.anzfa.gov.au; Monsanto, http://www.monsanto.com.au/sitemap/fact/default.htm; Biotechnology Australia, http://www.isr.gov.au/ba.

Recommendation 6

3.35 **The committee recommends that Biotechnology Australia, in its role as the coordinator of information about gene technology provided by government departments, monitor the efficiency and effectiveness with which material is presented.**

Biotechnology Australia should regularly publicise all information from the Gene Technology Regulator, including information about the regulator's role and function.

3.36 Labelling of GM products is another way of providing information to the public and may help to increase consumer confidence.[53] The lay panel report from the consensus conference recommended that all GM foods, regardless of where modification occurs, should be labelled to allow free and informed consumer choice.[54] Many submissions to the inquiry supported labelling for the same reason.[55]

3.37 The lay panel recognised the difficulties associated with labelling.[56] From a regulatory perspective, labelling is highly complex and has the potential to be misleading. Information that is provided on a label could be interpreted in a number of ways by consumers, including that GM products are unsafe.

3.38 Consensus conferences and public forums are useful in raising awareness of gene technology issues. The Consensus Conference on Gene Technology in the Food Chain was aimed at assisting citizens to participate in an informed way in the debate and to contribute to developing public policy in this area. It brought together members of the community and participants from both sides of the gene technology debate, and culminated in a report to the government by a lay panel of 14 members.[57]

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53 Australian Biotechnology Association, Submission no. 39, p. 8.

54 *First Australian Consensus Conference: Gene Technology in the Food Chain: Lay Panel Report*, Canberra, March 1999, p. 8.

55 For example, Heritage Seed Curators Australia, Submission no. 30, p. 9; Mr Alan Griffiths, Submission no. 22, p. 1.

56 *First Australian Consensus Conference: Gene Technology in the Food Chain: Lay Panel Report*, Canberra, March 1999, p. 8.

57 C Renouf, 'Rebirthing democracy: the experience of the first Australian consensus conference', *Consuming Interest*, Autumn 1999, p. 17.

3.39 The consensus conference was generally received positively by all involved, and was well covered by the media. In a review of the conference, the GRDC found that there was broad support for the conference, and concluded that:

> The consensus conference bolstered support for and helped lock in a number of the decisions in the May 1999 budget announcements. The credibility of the Consensus conference is enhanced by the fact that Ministers have chosen to publicly attribute influence to the Lay Panel's Report in arriving at these decisions.

However, they also stated that:

> Overall our conclusion is that the CC [consensus conference] process has not significantly softened or ameliorated the polarisation of beliefs and positions in relation to genetic engineering in the food chain; if anything it may have entrenched this polarisation, at least between the 'fundamentalists' on either side.[58]

3.40 Public forums also received support in submissions to the inquiry.[59] They are useful in disseminating information and can also be used to elicit responses from different interest groups that can feed into policy formation. An example of this process is the series of public meetings held by the IOGTR in all states during February and March 2000 to encourage public comment on the draft Commonwealth Gene Technology Bill 2000.[60] A series of one day forums is being organised by BA to raise awareness of the issues surrounding GM crops. They will be held in rural areas over the next year, and comprise presentations and panel discussions involving regulators, organic and GM farmers, scientists and economists.

3.41 Field days and seminars were listed by farmers as the two most effective ways of delivering information on gene technology.[61] The response to a series of gene technology workshops held in regional areas of Western Australia was extremely positive, with all participants indicating that they

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58 A Crombie & C Drucker, *The First Australian Consensus Conference: Gene Technology in the Food Chain: Evaluation: Phase 2 Report*, February 2000, p. vi.

59 Heritage Seed Curators Australia, Submission no. 30, p. 2; Organic Federation of Australia, Submission no. 24, p. 2.

60 Therapeutic Goods Administration, http://www.health.gov.au/tga/gene/genetech/consult.htm, accessed 30 March 2000.

61 Orima Research, *Summary of the Survey of Farmers Perceptions on Genetically Modified Foods,* Agrifood Alliance Australia, November 1999.

would recommend the workshop to other people interested in gene technology in agriculture.[62]

3.42 Other ways of providing information have included hypotheticals,[63] public lectures and telephone hotlines.[64] A recent survey has found that 32 per cent of respondents would call an 1800 number for more information.[65] CSIRO and BA have both established telephone hotlines to answer public inquiries regarding gene technology.

3.43 The committee believes that the range of sources of information about gene technology that is available, and the different forms in which it is presented, will assist in taking the information to as many people as possible. The committee regards it as important to monitor, as time passes:

- changes in attitudes towards, and awareness of, biotechnology; and
- the effectiveness of the different forms of communication in conveying information.

With this information, future public awareness campaigns can be fine tuned.

The role of government and industry

Government

3.44 There are, as Novartis pointed out, a range of stakeholders with differing information needs. Under these circumstances, it is entirely appropriate for community education to be shared by a number of different government and industry parties.[66]

3.45 A key issue identified in a number of submissions is the lack of trust consumers have in government agencies, and the fear of monopoly and control by overseas multinational companies.[67] **The challenge for government in particular is thus to ensure that information is provided in an open manner, and by a body which is not only independent but seen to be independent.**

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62 J Gibbs, 'Agriculture and gene technology - the bread and butter issues', Report prepared on a workshop initiative by the Centre for Legumes in Mediterranean Agriculture Education Program and CY-O'Connor Campus of TAFE, Northam, Western Australia, 1999, p. 1.

63 Western Australian State Agricultural Biotechnology Centre, Submission no. 10, Attachment.

64 CSIRO gene technology, http://www.genetech.csiro.au, accessed 15 April 2000; Department of Industry, Science and Resources, Submission no. 84, p. 2.

65 Department of Industry, Science and Resources, 'Consumers after more balanced information on GM foods', Media release, May 5 2000.

66 Novartis, Submission no. 26, p. 9.

67 For example, Mr Russell McGilton, Submission no. 51, p. 1; Mr Arnold Ward, Submission no. 41, p.20.

3.46 A survey commissioned by BA showed that the public currently places more trust in CSIRO than in other government or industry bodies.[68] However, as CSIRO has strong research ties with a number of biotechnology companies, in the long term it may not be perceived as unbiased and impartial.

3.47 The committee believes that, if BA is to be a credible source of information, it must not only be seen to be independent, but must also be independent. The committee is therefore concerned that the framework, within which BA operates, does not provide it with the necessary independence to be seen to be providing unbiased information. The committee therefore recommends that BA become a statutory authority. The status of a statutory authority would place BA at arms' length from ministerial control while still being accountable to the Parliament and subject to audit by the Auditor-General.

Recommendation 7

3.48 **The committee recommends that Biotechnology Australia be made a statutory authority.**

Recommendation 8

3.49 **The committee recommends that the Commonwealth government, through Biotechnology Australia:**

- **monitor understanding and awareness of biotechnology; and**
- **assess the effectiveness of its current public awareness campaign and the need for additional information.**

68 Yann, Campbell, Hoare, Wheeler, *Public attitudes towards biotechnology*, p. 7, http://www.isr.gov.au/ba/WhatsNew/ychw.pdf, accessed 5 May 2000.

Recommendation 9

3.50 **The committee recommends that information provided by Commonwealth agencies about gene technology:**

- **detail the independence, transparency and accountability of the regulatory processes;**
- **give equal prominence to information about the risks and benefits; and**
- **detail how the regulation of gene technology is able to avoid or minimise risk.**

3.51 The committee believes that the level of public awareness of regulatory bodies in Australia is very low. This contrasts with the situation in the USA where 'the average consumer … knows more about the FDA [Food and Drug Administration] than the average Australian consumer does about ANZFA'.[69] The committee believes that the greater acceptance of GMOs in the USA than in Australia may have been associated with greater knowledge of regulation in that country. The committee recognises that some information about regulation of gene technology in Australia is already available and welcomes this. The committee believes that, if recommendations in this chapter are implemented, the public will be in a better position to find out about gene technology and its regulation than they are at present.

3.52 The committee also considers that providing lists of other sources of information or internet links to other sites is a helpful way of enabling the public to follow up particular concerns. It is the committee's view that access to information presenting different points of view is likely to reduce the sceptics' impression that they are being told only one side of the story. The committee is aware that most government internet sites link to others, including industry, overseas and consumer groups.[70]

69 CSIRO, Transcript of evidence, 18 October 1999, p. 212.

70 For example, the Department of Health and Aged Care, http://www.health.gov.au/tga/gene/genetech/purpose.htm, accessed 9 May 2000.

Industry

3.53 Several of the bigger businesses involved with gene technology provide information about the technology and its use, for example, Monsanto.[71] In other cases, businesses have combined to make information available, as in the case of AAA, which comprises farmers, industry and R&D organisations.[72] Another source of information is the Food Science Bureau which was established in 1999 by the AFGC. There is an important role for food manufacturers and retailers in the provision of information to the public, as Novartis pointed out.[73]

> It has been Novartis' experience that communication to consumers closer to the point of sale, that is, through food manufacturers and retailers, may be more effective than communication from seed companies.[74]

3.54 The Food Science Bureau is currently funded solely by the AFGC. It aims to provide consumers with access to independent, credible, science-based information about biotechnology, and to encourage accurate and balanced discussion of food and food technology issues. The AFGC has 170 members who come from organic, conventional and gene technology industries. The council believes that it is an impartial body because it is driven by consumer choice, irrespective of industry and government views on gene technology.

> We do not consider ourselves in a position to promote or defend this technology *per se*. Our responsibility lies in pursuing a market conducive to innovation and a market conducive to independent commercial decisions about investment in the development and about the application of this technology in food and grocery products.[75]

71 Monsanto's, http://www.monsanto.com.au, accessed 20 April 2000.

72 Agrifood Alliance Australia, http://www.afaa.com.au/papers.htm, accessed 7 May 2000.

73 Novartis Australia, Submission no. 26, p. 9.

74 Novartis Australia, Submission no. 26, p. 9.

75 Australian Food and Grocery Council, Transcript of evidence, 30 August 1999, p. 114.

4

The competitiveness of traditional crops

Introduction

4.1 The relative competitiveness of traditional and GM crops will be determined by the benefits and risks of growing them, and how primary producers and the market weigh up these benefits and risks. The interactions of consumer and producer views that determine preferences for GM produce are illustrated in four scenarios shown in Table 4.1.

Table 4.1 Factors influencing the uptake of GM crops

	Benefits to producers	
Benefits to consumers	**Yes**	**No**
Yes	Higher quality, cheaper to produce – rapid uptake Example: better tasting strawberry resistant to berry rot	Consumer benefit but same or higher production costs – uptake depends on farmers' market judgement Example: product with high antioxidant levels
No	No different to conventional food but producers benefit – uptake depends on consumer attitudes to GMOs Example: pest and disease resistant and herbicide tolerant varieties	Not considered for uptake

Source: Centre for Legumes in Mediterranean Agriculture, Submission no. 14, pp. 1-3; Cooperative Research Centres Association, Submission no. 40, pp. 6-7.

Negative views

4.2 Most submissions to the inquiry took the view that the economic and environmental advantages provided by GM crops would ensure that they were adopted increasingly. The Cooperative Research Centres Association (CRCA) stated that 'it is generally accepted that, in time, traditional varieties will not be competitive, in the same way that old varieties produced conventionally are no longer competitive'.[1] The Academy of Science took a similar view:

> In the longer-term, it seems likely that most agriculturally important organisms will be genetically manipulated in some sense or another, just as they have been manipulated in conventional breeding systems.[2]

4.3 In the face of declining world prices for primary produce, the lower costs of production anticipated from GM crops are seen as strong incentives for adopting them. With future research expected to yield more products of better quality than traditional crops do, it is likely that GM varieties will be more competitive than conventional varieties, and will be essential for maintaining competitiveness, for example, in the grains industry.[3] The gap in performance between the two types of crops is expected to increase over time.[4] Furthermore, non GM varieties may eventually prove to have higher production costs and higher pesticide residues, and to be less environmentally friendly.[5]

4.4 Representatives of the food industry told a national science and industry forum in 1999 that 'the horse has already bolted',[6] and 'there is an inevitability to gene technology … the issue is not whether there will be this technology, rather when'.[7] The Queensland government agreed:

> The economic and environmental benefits of gene technology to primary production have been so obvious that most industries now acknowledge that it [is] not a question of if they will take up this technology but when.[8]

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1 Cooperative Research Centres Association, Submission no. 40, p. 5.

2 Academy of Science, Submission no. 62, p. 2.

3 Grains Research and Development Corporation, Submission no. 47, p. 6.

4 Novartis, Submission no. 26, pp. 4-5.

5 Cooperative Research Centre for Tropical Plant Pathology, Submission no. 21, p. 2; Western Australian State Agricultural Biotechnology Centre, Submission no. 10, p. 2.

6 Professor Hudson of Goodman Fielder, 'How industry adopts new technology', *National Science & Industry Forum Report*, Australian Academy of Science, April 1999, p. 8.

7 M H Hooke, 'The food industry as honest broker', *National Science & Industry Forum Report*, Australian Academy of Science, April 1999, p. 2.

8 Queensland government, Submission no. 79, p. 1.

4.5 It was also suggested to the committee that control of the seed market by the life sciences companies that own GM varieties and the alliances between these companies and others in the food chain might result in farmers being forced into growing GM crops.[9] If this were to eventuate, the choice of growing non GM food for the mainstream market could be limited.

4.6 Notwithstanding these views, it was generally recognised that a market for traditional varieties will continue to exist, just like the market for organic produce.[10] Some submissions to the inquiry indicated that this market was expected to be small and to shrink over time,[11] unless a major catastrophe with GM varieties occurred.[12] The ABA suggested that:

> On a small scale, some producers might be able to establish niche markets for premium-priced organic / non-genetically modified foods, but this is likely to be a minor component of the national agri-business industry.[13]

Positive views

4.7 Other submissions painted a more positive future for traditional crops, at least in the short term. Some conventionally bred varieties offer equal value to GM varieties, as AgrEvo pointed out:

> Despite over 75% of Canada's canola market utilising herbicide tolerant varieties, derived from both genetic modification and traditional plant breeding, 9 new conventional varieties were introduced into the market place in 1999.[14]

4.8 Furthermore, in some cases, the use of GM crops may be restricted by regulation, for example, to minimise the development of pest resistance. The area of cotton that may be planted to Bt cotton, for example, is limited to 30 per cent of the total area. In addition, as discussed in Chapter 5, the market for minor crops may not be sufficiently large to attract the development of GM varieties and traditional varieties will continue in use. Another factor that might favour the retention of traditional varieties by

9 The O'Hallorans, Submission no. 17, p. 3.

10 CSIRO, Submission no. 56, p. 3.

11 Australian Food and Grocery Council, Submission no. 59, pp. 8-9; Queensland Fruit and Vegetable Growers, Submission no. 42, p. 2; Queensland government, Submission no. 79, p. 2; South Australian government, Submission no. 81, p. 5.

12 Cooperative Research Centre for Tropical Plant Pathology, Submission no. 21, p. 2.

13 Australian Biotechnology Association, Submission no. 39, p. 5.

14 AgrEvo, Submission no. 55, p. 3.

reducing the attractiveness of using GM varieties is better development of integrated approaches to crop management.[15]

4.9 It is clear that consumer sentiment will also affect the demand for non GM food, and this has altered since the middle of last year when most of the submissions summarised above were written. Many consumers are now wary about GM products. If GM foods were labelled, consumers might well show their preference for non GM foods.

4.10 Several submissions drew attention to incidents that reflected negative consumer sentiment towards GM foods in European markets to which Australia exports:

- some European food processors and supermarket chains are excluding GM ingredients from their brands; and
- a shipment of North American corn chips was rejected when the chips were found to contain foreign genetic material.[16]

In addition, Asian markets, especially that in Japan, are showing signs of consumer resistance to GM food.

4.11 As the Australian Barley Board (ABB) pointed out, 'if consumers are divided on the GMO issue then markets for GMO free products should be available to the producers'.[17] The Victorian government conceded that:

> It is now evident that consumer acceptance of GM varieties in some markets will be slow in coming and, in some cases, substantial markets can be expected to develop in the short term for products which are 'certified' as being non-GM.[18]

4.12 There is already some evidence that this is happening. In January 1999, the largest orders ever for non GM canola were placed with Australian suppliers.[19] In addition, AWB was reported recently as having received requests for certified non GM wheat.[20] It has been possible to guarantee that virtually all Australian produce is non GM because GM cotton is the only GM crop commercially grown in Australia and then in only certain parts of the country. These circumstances have enabled Australian produce to be cheaply and easily certified as non GM, and gives Australian producers a marketing advantage over competitors from countries where GM crops are grown.

15 Mr Wayne Hancock, Submission no. 6, p. 3.

16 Go Mark Food Systems, Submission no. 33, pp. 14-15; Organic Federation of Australia, Submission no. 24, p. 6.

17 Australian Barley Board, Submission no. 60, p. 6.

18 Victorian government, Submission no. 67, p. 2.

19 NSW Grains Board, quoted by Go Mark Food Systems, Submission no. 33, p. 16.

20 J Madden, 'Farmers face GM dilemma', *The Australian*, 1 April 2000, p. 22.

4.13 In addition, organic practices preclude the use of GMOs and are expected to continue to do so for the foreseeable future. Non GM varieties will therefore be in demand in the context of the organic market as well as simply for their non GM status. The Queensland government predicted that 'substantial markets in Europe and Japan, together with niche markets in many other countries (Australia and the USA included), will ensure the viability of "organic" enterprises'.[21]

4.14 AGN suggested that:

> A potentially lucrative, definitely sustainable, food industry based on growing domestic and export markets for conventional / organic produce is available. The GE-free options (conventional / organic) are growing strongly and could absorb all our production.[22]

The price premiums for non GM food could be 10-40 per cent higher than for conventional crops.[23]

4.15 However, as the NFF observed, the size of the markets for non GM food remains to be seen.[24] Market signals are uncertain, with the size and duration of these markets depending on public rejection of GMO produce. CSIRO suggested that consumer distrust may subside once confidence in the regulatory systems in Europe is restored and a more rational approach to the technology develops.[25]

4.16 Another view is that the mixed market signals 'may be more about trade than technology'.[26] Professor Aynsley Kellow from the University of Tasmania pointed out that 'the GMOs debate has provided less efficient European producers of beef, soybeans and so on with an opportunity to try to nobble their more efficient US competitors'.[27] The existence of the market for non GM produce is well recognised by Australia's trading competitors and competition will be fierce.[28]

4.17 A further problem for the non GM industry was suggested by the Australian Academy of Science which predicted that 'over time it will become more difficult for producers to escape the use of GM material at

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21 Queensland government, Submission no. 79, p. 2.

22 Australian GeneEthics Network, Submission no. 71, pp. 5-6.

23 Organic Federation of Australia, Submission no. 24, p. 7.

24 National Farmers' Federation, Submission no. 36, p. 5.

25 CSIRO, Submission no. 56, p. 3.

26 Agriculture Western Australia, Transcript of evidence, 27 July 1999, p. 10.

27 A Kellow, 'Risk assessment and decision-making for genetically modified foods', *IPA Biotechnology Backgrounder*, No. 1, October 1999, p. 9.

28 Queensland government, Submission no. 79, p. 2.

some point in the production chain'.[29] Quite apart from the possibility of escape of GM material into non GM crops which is one of the main concerns at present, other GM material is already in use. For example:

> Many vaccines and other products are produced by gene technology, and as use of these become widespread, they will be difficult to avoid. For example, if it were a requirement that all poultry required immunisation against a particular virus and the most effective vaccine was a gene technology-derived vaccine, most poultry would then be produced by a GMO-influenced route.[30]

GM free farming

Ensuring non GM status

4.18 GM free farmers need to satisfy the demands of consumers who do not wish to eat GM foods. Organic farmers face the same requirement as the definition of organic food is that it is not GM. Up to now, as noted above, Australian produce has been certifiable as non GM because very few GMOs are grown in the country. However, large trials of GM canola were conducted in most states during the 1999-2000 season, raising fears that GM pollen may have spread to non GM canola growing nearby. The issue for organic, non GM farmers, and for others who wish to have the choice of which type of variety they plant, is therefore how to ensure the integrity of their crops.

4.19 There are several possible approaches to preserving the identity of non GM crops. A short term solution is to institute a moratorium on the use of GM crops, preserving the status quo and the present basis on which the non GM status of crops is certified. Taking advantage of Australia's clean green image which is associated with its isolation:[31]

> We can choose to fully take advantage of this opportunity that will benefit Australia and allow us time to research the impacts of GE food. It will necessitate Australia saying no to any further commercial releases of GE foods.[32]

29 Australian Academy of Science, Submission no. 62, p. 2.

30 CSIRO, Submission no. 56, p. 3.

31 National Association of Sustainable Agriculture Australia, Submission no. 74, p. 3.

32 Organic Federation of Australia, Submission no. 24, p. 7

AGN claimed that the market acceptability of Australia's non GM produce 'will be severely compromised or lost completely if Australia adopts GEOs'.[33] Noting consumer concerns in Australia's export markets, Ian Donges, President of the NFF, recently supported the need for delay in embarking on 'full-scale production' of GM crops.[34]

4.20 Another option for separating GM and non GM crops that has been suggested recently is to declare certain areas of the country as non GM. Recent media reports indicated that pressures were mounting for such a move in Tasmania and certain local government areas in Western Australia.[35] The Gene Technology Bill does not include an explicit opt out clause, because such a clause would raise constitutional problems and breach Australia's obligations under international agreements. However, state and territory land management powers may allow for certain areas to be declared GM free.[36]

4.21 Where both GM and non GM crops are grown in close proximity or in successive harvests, a number of measures will need to be in place to ensure the status of crops is maintained. OFA listed a number of requirements that it saw as necessary. It stated in this context that:

> The Organic Industry in Australia believes it is important to clearly and urgently state the minimum conditions whereby our industry will be protected and able to prosper in the face of widespread production of genetically engineered crops.[37]

4.22 The conditions nominated by OFA included:

- environmental impact assessments before GMOs are released;
- establishing appropriate buffer zones;
- monitoring of such matters as adherence to the conditions imposed on growing GM crops;
- rapid response by a regulatory authority to 'an environmental or economic hazard';
- 'a quality management system approach … from paddock to plate, certified, audited and regulated';

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33 Australian GeneEthics Network, Submission no. 71, p. 6.

34 D McKenzie, 'No rush for genes mix', *The Weekly Times*, 5 April 2000, p. 5.

35 'Council calls for genetic crop ban', *The Western Australian*, 20 March 2000, p. 5; A Barbeliuk, 'Protests modify genetic push', *The Hobart Mercury*, 21 April 2000, p. 9.

36 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, p. 288.

37 Organic Federation of Australia, Supplementary submission no. 73, p. 1.

- mandatory notification of the planting of GM crops; and
- establishing liability for economic and environmental damage and a compensation fund.[38]

Conclusions

4.23 The committee is aware of the current strength of the market for non GM produce. Very different estimates have been made of the time for which this strong demand will endure; they range from two or three years to 20.[39] Even if demand does drop, it is firmly expected that a niche market for non GM (and organic) produce will remain.

4.24 The committee views support for this market as important. In Chapter 2, it recommended that the Commonwealth government ensure its funding for gene technology does not crowd out funding for other effective means of promoting agricultural productivity and sustainability. In light of the increasing demand for non GM (and organic) produce, this is one of the sectors that must not be disadvantaged by competition for funding for GMOs.

4.25 The committee received several submissions that called for greater government assistance for organic farming, as well as for non GM farming. The submissions suggested that this assistance should be directed to, among other issues, certification.[40] By comparison with research on GM crops and by comparison with some other countries, such as Denmark, organic farming in Australia receives very little funding.[41]

4.26 The committee recognises the importance of ensuring the integrity of non GM and organic crops. However, as discussed in Chapter 2, it does not favour a blanket moratorium on the use of GMOs. It will therefore be very important to establish a strong, well researched regulatory regime, dealing with such issues as those listed by OFA above. The committee discusses these matters in more detail in Chapter 7 and makes a number of recommendations.

38 Organic Federation of Australia, Supplementary submission no. 73, pp. 2-3.

39 Two to three years was estimated by Ian Donges of the NFF, quoted by D McKenzie, 'No rush for genes mix', *The Weekly Times*, 5 April 2000, p. 5; 20 years was predicted on the basis of Danish research.

40 Australian GeneEthics Network, Submission no. 71, p. 11; Go Mark Food Systems, Submission no. 33, p. 3; Heritage Seed Curators Australia, Submission no. 30, p. 2; Mr Anderson, Submission no. 4, p. 1; Ms Lyssa, Submission no. 5, p. 2; Organic Federation of Australia, Submission no. 24, p. 2; Transcript of evidence, 13 August 1999, p. 70.

41 Australian GeneEthics Network, Submission no. 71, p. 6; Organic Federation of Australia, Submission no. 24, p. 7.

4.27 With respect to the option of declaring certain areas of Australia GM free, the committee considers that this will be a matter for state and local authorities. The integrity of the crops growing in these areas will, however, be safeguarded by the Commonwealth government's regulatory regime for GMOs wherever they are grown near non GM crops. The issue of certifying the non GM status of agricultural produce is discussed further in Chapter 7.

5

Research, development and commercialisation

Introduction

5.1 The gene technology and its products that are available in Australia are sourced from both Australian and overseas research. This chapter examines Australia's research performance in this field, the commercialisation of its gene technology research, and Australians' access to overseas gene technology.

Research and development in agricultural gene technology

Research in Australia

5.2 It is not known precisely how much agricultural gene technology research is carried out in Australia, although expenditure in this area is estimated to be around $100 million a year. According to Agriculture, Fisheries and Forestry Australia (AFFA), most of Australia's gene technology research is performed by the public sector. In relation to Commonwealth funding, for example, CSIRO spent $40 million on gene technology research in 1998. In mid 1997, funding from nine rural research and development corporations (RDCs) was supporting 88 gene technology projects to the value of about $12 million per annum. RDC funds are derived from both industry levies and AFFA and, according to the Rural R&D Chairs Committee, it is not uncommon for individual RDCs to allocate about 20 per cent of their

budgets to gene technology.[1] CRCs also perform gene technology research with a mix of public and private sector funding.

5.3 By contrast, private sector expenditure by about 20 small companies probably amounted to $8-15 million per year.[2] Subsidiaries of multinational firms, such as Monsanto and AgrEvo, also conduct work in Australia. A survey commissioned by the NFF in 1998 found that, by comparison with other countries' performance in agricultural biotechnology, 'Australia does … appear to lag in industry funded research which is focussed on commercial outcomes.[3]

5.4 In 1999 there were 86 sites registered with GMAC to conduct contained genetic manipulation research in Australia. These sites were in universities, medical facilities, companies, CSIRO and state departments of agriculture,[4] and included laboratories devoted to medical as well as agricultural research.

5.5 Gene technology research funded by RDCs includes pasture improvement; animal feeds; animal breeding, health and nutrition; food processing; and enhanced product characteristics.[5] CSIRO is using gene technology with crops and fruits (peas, potatoes, sugar, grapes, barley and wheat), to improve eucalypts for wood and paper production, to control animal disease and to improve productivity (fish and seafood, sheep, pigs, cattle and poultry).[6]

Funding for research

5.6 Public funding for agricultural gene technology research is provided by both state and the Commonwealth governments. The Commonwealth government contributes funds to CSIRO, the rural RDCs and CRCs.

5.7 Several submissions to the inquiry called for continued strong government support for rural R&D, including for biotechnology. For example, the Grains Council of Australia (GCA) pointed out that, in the absence of government funding, there would be under investment in R&D, and large external benefits to the community and opportunities for pursuing national interest objectives would be lost. It drew attention to a 1991 study by the GRDC of the benefits of GRDC research. This study indicated that

1 Agriculture, Fisheries and Forestry Australia, Submission no. 77, p. 4; Rural R&D Chairs Committee, Submission no. 49, p. 2.

2 Agriculture, Fisheries and Forestry Australia, Submission no. 77, p. 4.

3 National Farmers' Federation, Submission no. 36, p. 7.

4 Agriculture, Fisheries and Forestry Australia, Submission no. 77, p. 4.

5 Agriculture, Fisheries and Forestry Australia, Submission no. 77, p. 4.

6 CSIRO, 'Gene technology in Australia', http://www.csiro.au/pubgenesite/research/index.htm, accessed 28 April 2000.

returns on individual projects varied from 34 to 561 per cent; the overall benefit:cost ratio was 19:1.[7]

5.8 The case for government support is particularly strong where an industry is characterised by many small firms, as in the grains industry, and the cost of the research is high, as it is for biotechnology. Indeed, the GCA argued in its 1999 submission to this inquiry that the Commonwealth government should increase its contribution beyond the present 0.5 per cent of the gross value of production.[8] However, the GRDC is currently very well endowed financially and expects increasing income from royalties in coming years. Other RDCs are less well off.[9]

5.9 A further argument for government funding is that it enables the development of gene technologies that give Australia bargaining power to access technologies held by other parties. For this reason, the CRC for Tropical Plant Pathology called for substantial funding for gene technology research in public institutions, preferably in partnership with Australian or overseas private interests.[10]

5.10 A case for government support for research funding was also put to the committee in relation to so called 'minor' crops that are important to Australian farmers but not grown widely around the world. The fear here is that overseas owners of gene technologies will be uninterested in making the technologies available for use with these crops.[11] As many Australian crops are minor crops, 'this makes Australia vulnerable to being shut out from access to this technology for many of its crops'.[12] The same may prove true for peripheral livestock breeds. To circumvent this problem for crops, 'it is important to maintain our own germplasm and research capacity and capability to insert critical genes into varieties of importance to Australian agriculture'.[13]

5.11 For minor crops, Avcare suggested that:

> It is possible in the future, that appropriate minor use programs such as those being developed for agricultural chemicals will need to be determined for applications of gene technology that are not currently supported by global priorities.[14]

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7 Grains Council of Australia, Submission no. 65, pp. 6-7.

8 Grains Council of Australia, Submission no. 65, pp. 7-8.

9 P Hemphill, 'Grains funds boom', *Weekly Times (Vic)*, 19 April 2000, pp. 1-2.

10 Cooperative Research Centre for Tropical Plant Pathology, Submission no. 21, p. 3.

11 National Farmers' Federation, Submission no. 36, p. 10.

12 Western Australian government, Submission no. 48, p. 2.

13 CSIRO, Submission no. 56, p. 5.

14 Avcare, Submission no. 61, p. 6.

In some fields, work is unlikely to be carried out unless it is done in Australia.[15] The NSW Farmers' Association suggested that:

> One can … conclude from a study of market share that public breeding programmes will be obligatory for smaller crop species, such as Durum wheat or for specialised varieties to meet particularly difficult conditions. The tonnages grown may not be adequate to support a fully commercial breeding program which will be particularly true in the case of a new crop.[16]

5.12 The NFF recommended that the government should:

> … encourage opportunities in Australia for commercialisation of biotechnology traits that may be of little interest to multi national companies but have significant market value both domestically and possibly to other countries. Such investment will help to ensure Australian agriculture has access to biotechnology products.[17]

5.13 From the points discussed in the preceding paragraphs, it is clear that gene technology is significant nationally but expensive. For these reasons, the committee concludes that it deserves government funding. It is important that a coordinated strategic approach is taken here, as the Western Australian government suggested.[18] Identifying emerging strengths, setting priorities and pursuing a more coordinated research focus should be goals in such a strategy.[19] Aquaculture, for example, was brought to the committee's attention as an 'important emerging primary industry sector based on small to medium sized businesses', the benefits from which 'are not widely recognised'.[20] The committee believes that support for such industries will promote innovation of the kind needed for Australia to maintain its international competitiveness.

15 Cooperative Research Centre for Premium Quality Wool, Submission no. 52, pp. 1-2.

16 NSW Farmers' Association, Submission no. 38, p. 6.

17 National Farmers' Federation, Submission no. 36, p. 10.

18 Western Australian government, Submission no. 48, p. 2.

19 Innovation Summit, Resource and Infrastructure Consolidation and Cooperation Working Group, Executive summary, Melbourne, 9-11 February 2000, pp. 7-8.

20 Victorian government, Submission no. 67, p. 1.

Recommendation 10

5.14 **The committee recommends that Agriculture, Fisheries and Forestry Australia develop a strategy for Commonwealth funding to facilitate and encourage the innovative use of gene technology in the development of commercially viable, emerging industries in agriculture, fisheries and forestry.**

This strategy should be drawn up in consultation with state and territory agriculture departments and the private sector.

5.15 This strategy will be developed in the context of a much larger role for the private sector than has been the case up to now. The committee was told that even greater commercial involvement can be expected in the future,[21] in what is a world wide trend occasioned by the lack of public resources.[22] The Western Australian State Agricultural Biotechnology Centre predicted that 'plant breeding of cereals [in Australia] will be 100% privatised within 5-7 years'.[23]

5.16 Accepting that private sector involvement in gene technology R&D will increase, the focus of attention turns to what role governments should play in this environment. It was suggested to the committee that government support for scientific R&D, including biotechnology, should focus on such elements as a strong fundamental research base, major cutting edge facilities and stimulating cluster development.[24] The GRDC, for example, has proposed that government should provide the infrastructure and the research personnel to operate it, while industry pays for projects carried out using the infrastructure and personnel.[25] Recommendations made in a major review of the future needs for health and medical research touched on similar matters: a coherent approach to

21 Cooperative Research Centres Association, Submission no. 40, p. 9; Grain Biotechnology Australia, Submission no. 68, p. 2.

22 'Collaborations essential for food in the developing world', *Nature*, vol 401, 28 October 1999, p. 829; National Farmers' Federation, Submission no. 36, p. 11.

23 Western Australian State Agricultural Biotechnology Centre, Submission no. 10, p. 2.

24 Cotton Research and Development Corporation, Submission no. 27, pp. 7-8; *Developing Australia's Biotechnology Future: Discussion Paper*, September 1999, Biotechnology Australia, pp. 24-5; Innovation Summit, Resource and Infrastructure Consolidation and Cooperation Working Group, Executive summary, Melbourne, 9-11 February 2000, pp. 7-8.

25 Grains Research and Development Corporation, 'Business-like GRDC wants more value for research dollar', Media release, 5 April 2000.

infrastructure funding, increased support for research, and fostering of geographic clusters of biotechnology and research organisations.[26]

5.17 Providing government support for the basic infrastructure needed for gene technology and its application was seen as more appropriate than funding for specific projects. Some of the advantages of this approach are:

- preventing confusion over the ownership of IP;
- allaying public concern over the use of government funds; and
- ensuring that 'a threshold level of activity exists'.[27]

5.18 The committee considers that, in addition to targeted funding for commercial and emerging sectors, the government should contribute to the basic research that underpins the application of gene technology to agriculture. Such research is vitally important as the basis for further R&D and to provide opportunities for commercialisation by Australian companies. It also gives Australian businesses easier access to IP than if they have to rely on foreign owned IP, and something with which to bargain when negotiating access to other people's technologies.

5.19 The committee is aware that substantial funding for biotechnology research ($250 million annually) is already provided by the Commonwealth government.[28] The committee considers that this research is essential and support for it should continue. It also believes that greater input to this research should be provided by the private sector, possibly through research partnerships.

Recommendation 11

5.20 **The committee recommends that the Commonwealth government:**

- **continue to contribute funding for the basic gene technology research required for applications to agriculture, fisheries and forestry; and**
- **seek more involvement, possibly through partnerships, of private sector involvement in this research.**

26 *The Virtuous Cycle: Working Together for Health and Medical Research: Health and Medical Research Strategic Review*, 1999, pp. 3, 7.

27 Ag-Seed Research, Submission no. 31, p. 10.

28 Senator Nick Minchin, *Senate Hansard*, 11 May 2000, p. 13770.

Utilising publicly funded research

5.21 There are several trends in gene technology R&D that impact on primary producer access to publicly funded gene technology, or are likely to do so.

- Publicly funded plant breeders are being encouraged to aggressively protect their IP and maximise the return on the public's investment in it.
- Alliances are being formed between public and private sector organisations to research, develop and commercialise GMOs.

5.22 Several submissions to the inquiry noted these trends with some concern.[29] They emphasised that the outcome of publicly funded research must be readily available in Australia. Grain Biotechnology Australia, for example, suggested that IP developed at taxpayer expense or through grower levy funds should be made available on a competitive basis to Australian companies or multinationals with a clear R&D commitment in Australia.[30] Frontier Seeds called for publicly funded IP to remain in Australia for commercialisation by Australian companies, and the Western Australian government stressed the importance of mechanisms to ensure that it is available to other publicly funded Australian scientists at a reasonable cost and with minimum restrictions.[31] The CRCA indicated that publicly available technology should be freely used by the public and small plant breeders.[32]

5.23 There was concern that primary producers should not fund research and then be called on to pay further for the fruits of that research.[33] The NFF stated that it would be 'unpalatable' to Australian farmers to pay significant premiums to benefit from gene technology 'when the initial research has been publicly or industry funded, sold to a multi-national and then brought back to Australia'.[34]

5.24 Publicly funded R&D organisations must make difficult decisions about the way in which they make their output available to others. Some of the dilemmas that face them are described in detail in the chapter dealing with IP protection (Chapter 6). Organisations such as CSIRO and the GRDC have developed policies to address this issue. The GRDC's first objective is to optimise economic benefits to the grains industry and the nation as a whole while CSIRO, when licensing its IP overseas, ensures

29 For example, NSW Farmers' Association, Submission no. 38, p. 3.

30 Grain Biotechnology Australia, Submission no. 68, p. 4.

31 Western Australian government, Submission no. 48, p. 2; Frontier Seeds, Submission no. 32, p. 2.

32 Cooperative Research Centres Association, Submission no. 40, p. 9.

33 NSW Farmers' Association, Submission no. 38, p. 7.

34 National Farmers' Federation, Submission no. 36, p. 10.

that Australian interests are not disadvantaged.[35] In a 1999 paper published by BA, it was suggested that the guiding principle in such cases must be to maximise the commercial benefits to Australia. At the same time, consideration must be given to creating wealth and new jobs and providing benefits to health, the community and the environment.[36]

5.25 Some research grants are currently provided on the condition that approval is obtained if the resultant IP is licensed or sold.[37] However, the implementation of the guiding principle set out above becomes more difficult when the research being commercialised has been carried out in joint ventures,[38] and it can hamper further use of the research.[39] At a private meeting in Perth, the committee was told about several multinational companies that avoid any involvement in joint projects with the public sector.

5.26 BA's discussion paper suggested that 'a review of the existing arrangements to encourage the maximisation of benefit from publicly funded R&D might be warranted'.[40] The NFF made a similar point, calling for a joint industry-government investigation of the barriers to the commercialisation of publicly funded biotechnology research.[41]

5.27 The committee believes that it is very important to get the right balance between providing incentives for commercialisation and giving benefits to growers and all Australians from public investment in agricultural biotechnology research. The committee recognises that finding the balance between these two goals can be difficult. The committee understands that some publicly funded bodies have been more successful than others in finding this balance, and urges all such bodies to examine carefully the full implications of their policies.

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35 CSIRO, Transcript of evidence, 18 October 1999, p. 218; Grains Research and Development Corporation, Submission no. 47, p. 7.

36 *Developing Australia's Biotechnology Future: Discussion Paper*, September 1999, Biotechnology Australia, p. 26.

37 *Developing Australia's Biotechnology Future: Discussion Paper*, September 1999, Biotechnology Australia, p. 26.

38 Grains Research and Development Corporation, Submission no. 47, p. 8; NSW Farmers' Association, Submission no. 38, p. 6.

39 In private meetings with staff from CAMBIA and Uniquest, the committee heard of the extent to which insistence on control by some R&D corporations has stymied commercialisation.

40 *Developing Australia's Biotechnology Future: Discussion Paper*, September 1999, Biotechnology Australia, p. 26.

41 National Farmers' Federation, Submission no. 36, p. 21.

Recommendation 12

5.28 **The committee recommends that the Commonwealth government review the current arrangements in place regarding gene technology research and ownership of intellectual property to ensure maximum commercial benefit for Australian industry.**

5.29 The committee also considers that a parallel investigation carried out by RDCs could result in improved practices and recommends accordingly. Among those who should be involved in this process is the Rural R&D Chairs Committee, which comprises the chairs and managing/executive directors of all RDCs and deals with matters of common interest.[42]

Recommendation 13

5.30 **The committee recommends that, in conjunction with the review proposed in Recommendation 12:**

- **each research and development corporation review its practices in relation to commercialisation and ownership of intellectual property to maximise benefits to Australian industry; and**
- **the committee of the chairs and managing directors of the rural research and development corporations, in conjunction with Agriculture, Fisheries and Forestry Australia and industry, take a lead role in assessing and disseminating best practice arrangements.**

Australian breeding programs

5.31 The germplasm developed in Australian breeding programs is the outcome of many years of crossing and selection, and is well adapted to our climatic, soil and disease characteristics. It is the basis for developing new varieties for use here by both Australian and overseas businesses. It is, in fact, one of Australia's bargaining chips in accessing gene technologies from overseas. As the New South Wales government pointed out:

42 Rural R&D Chairs Committee, Submission no. 49, p. 2.

> If an overseas company wanted to begin plant breeding using gene technology in Australia, it would save a great deal of time and effort if it could gain access to the advanced breeding lines of our breeding programs. … This has happened in several instances eg. Bt cotton and 'Round up Ready' canola.[43]

The development of Ingard® cotton is described in Box 5.1. Another example of such an arrangement was described by the Victorian government. Its Department of Natural Resources and Environment, Monsanto, the GRDC and other collaborators are providing the germplasm, facilities and expertise needed to develop glyphosate tolerant canola varieties.[44]

Box 5.1 The development of Ingard® cotton in Australia

Ingard® cotton was first grown commercially in Australia in 1996. Ingard® refers to cotton varieties that carry genes from the bacteria *Bacillus thuringiensis* which produces an insecticidal protein toxin known as Bt. It was developed from the US GM cotton Bollgard®. The Ingard® gene technology is owned by Monsanto and has been incorporated into Australian cotton varieties by CSIRO and Deltapine researchers. The transformed material has been commercialised by Cotton Seed Distributors (CSD) and Deltapine. Monsanto's agreements with CSD and Deltapine cover the development and marketing of the seed, but allow Monsanto to independently negotiate contracts with growers over the sale of Ingard®'s insect protein.

Source: Australian Biotechnology Association, Submission no. 39, p. 4; Cotton Research and Development Corporation, Submission no. 27, p. 4; Monsanto Australia, Submission no. 44, p. 2.

5.32 The committee heard that some of Australia's plant breeding programs are less than fully efficient. For example, at a private meeting with Western Australian businesses, the committee was told that the nine wheat breeding programs in the country should contract to three to reduce the replication of effort and improve their efficiency. Ag-Seed Research and the Western Australian government made similar points about decreasing the number of programs.[45] Another concern is that these programs tend to have a strong state focus; a wider focus would be more appropriate.

43 New South Wales government, Submission no. 72, p. 11.

44 Victorian government, Submission no. 67, p. 4.

45 Ag-Seed Research, Submission no. 31, p. 10; Western Australian government, Transcript of evidence, 27 July 1999, p. 4.

5.33 The committee believes that it is critical that Australian farmers are served by the best programs possible. It suggests that the Commonwealth government should facilitate the process of ensuring that efficient breeding programs exist.

Recommendation 14

5.34 **The committee recommends that the Commonwealth government, in conjunction with state and territory governments and the private sector:**

- **review the efficiency and effectiveness of plant breeding programs in Australia;**
- **identify ways of improving them; and**
- **promote their adoption, particularly where Commonwealth funding is provided.**

Recommendation 15

5.35 **The committee recommends that the Commonwealth government, in conjunction with state and territory governments and the private sector, consider the benefits of amalgamating some of the existing plant breeding programs.**

5.36 Successful commercialisation of gene technology requires the pairing of the right technology with the right germplasm.[46] In this connection, concern has been expressed about the wide scale buying out of seed companies by the major gene technology corporations.

> A disadvantage of this trend is that seed companies become captive to their new owner's biotechnology and may not have the freedom to choose what may be better technology from other suppliers. Certainly the ability to 'mix and match' various desirable traits from different sources will be curtailed.[47]

5.37 CSD made the same point: 'the ability to commercialise traits from other entities is therefore limited, which may in fact be somewhat limiting to grower benefit in the end'.[48] The Cotton Research and Development

46 Cotton Research and Development Corporation, Submission no. 27, p. 5.

47 Cotton Research and Development Corporation, Submission no. 27, pp. 5-6.

48 Cotton Seed Distributors Ltd, Transcript of evidence, 18 October 1999, p. 235.

Corporation suggested that Australian farmers' access to GM seed would be improved if seed companies and distribution remained in Australian, and preferably growers', hands.[49] The committee appreciates the concerns of Australian growers on this point, but does not believe that there is a role for government in this matter, beyond what might be determined by competition law.

5.38 Breeding programs often draw on the holdings of plant genetic resource centres. In the case of the grains industry, there are seven centres in Australia which cover winter cereals, temperate and tropical forage crops, medicago, tropical and temperate field crops, and indigenous wild relatives of crops. The centres are operated by CSIRO and all state agriculture departments except Tasmania. They provide accessions on demand and obtain appropriate accessions that may be valuable to Australian agriculture.[50]

5.39 At a private meeting with Western Australian grain growers, the committee was told that the germplasm relevant to that industry was likely to be well maintained. There were concerns, however, that what are now publicly held collections could be sold. The committee is aware that New Zealand's germplasm centre has been privatised, and a review is being carried out into the role and functions of Australia's collections by the Standing Committee on Agriculture and Resource Management (SCARM).

5.40 The committee recognises that the future of these centres is a matter for the states that operate them, but would be concerned if the centres were sold into private hands. The committee believes that there is a role here for the Commonwealth government to develop a national policy with state and territory governments and industry for the maintenance and accessibility of the germplasm.

Recommendation 16

5.41 **The committee recommends that the Commonwealth government, together with state and territory governments and industry, develop a policy for maintaining Australia's germplasm collections and continuing to make them accessible.**

49 Cotton Research and Development Corporation, Submission no. 27, p. 7.

50 Grains Research and Development Corporation, Submission no. 47, pp. 13-14.

5.42 Some of the germplasm to which Australian researchers have access comes from international collections, for example, the International Maize and Wheat Improvement Center in Mexico and the International Rice Research Institute at Manila in the Philippines. It is important that these centres continue to receive support.[51] However, the environment in which they are operating has changed in recent years.

5.43 An international instrument on genetic resources, the Food and Agriculture Organization's (FAO) International Undertaking on Plant Genetic Resources, recognised plant genetic resources for food and agriculture as the common heritage of mankind. It provided for free exchange of such material between countries. According to the GRDC, the Convention on Biological Diversity, which came into force in 1993, has changed the focus here in a way that could be detrimental. The convention recognises national sovereignty over genetic resources and provides for access to them only on the basis of mutually agreed, informed consent. The FAO's Plant Genetic Commission has been working for several years to 'harmonise' the International Undertaking on Plant Genetic Resources with the Convention on Biological Diversity, but has been unsuccessful to date because of opposition from some third world countries.[52]

5.44 The GRDC feared that 'increased competition for valuable genetic material and decreasing government aid for international research agencies may reduce Australia's access to genetic material in the future'.[53] It claimed that:

> It is likely that the interests and concerns of Australian agriculture are not being given sufficient weight relative to the interest of overseas conservation and indigenous groups in developing the Australian negotiating position for this international instrument. The current situation in Australia is unsatisfactory from the point of view of the agricultural industries. This issue should be a high priority for the … Biotechnology Australia program.[54]

5.45 The committee supports the need for access by Australian growers to the best germplasm from international sources. It believes that it is important for the Australian government's contribution to the existence of the international centres, through organisations such as the Australian Centre for International Agricultural Research, to continue.

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51 Heritage Seed Curators Australia, Submission no. 30, p. 2.

52 Grains Research and Development Corporation Submission no. 47, p. 14.

53 Grains Research and Development Corporation Submission no. 47, p. 13.

54 Grains Research and Development Corporation Submission no. 47, p. 14.

Recommendation 17

5.46 **The committee recommends that the Commonwealth government continue to contribute to the operation of the international germplasm centres.**

5.47 The committee acknowledges concerns about access to the international germplasm collections. However, it is aware that the same international agreements that may limit this access will also enable Australia to benefit from access by overseas interests to Australia's own natural resources.

Recommendation 18

5.48 **The committee recommends that the Commonwealth government:**

- **play a major role in international negotiations to harmonise the International Undertaking on Plant Genetic Resources with the Convention on Biological Diversity; and**
- **take a position that balances the interests of those who wish to import genetic resources from overseas with maximising Australia's benefit from its native genetic resources.**

Access to native genetic resources

5.49 The Australian continent is biologically mega diverse. Its biological resources represent a source of genetic potential that will become increasingly important. Access to this resource is being developed at a policy and regulatory level as part of BA's program, as EA pointed out. The ownership of biological resources is being clarified, a national system of biological resource centres accelerated, and industry access to the documentation of biological resources improved.[55] An inquiry into some of these matters is under way at present and will advise on their implementation through regulations under the *Environment Protection and Biodiversity Conservation Act 1999*. The inquiry will be completed by 30 June 2000.[56]

55 Environment Australia, Submission no. 82, pp. 23-4.

56 Senator the Hon. Robert Hill, Minister for the Environment and Heritage, 'Inquiry to examine access to biological resources', Media release, 22 December 1999.

Commercialisation

5.50 Many studies over the last few decades have investigated Australia's record of R&D and the commercialisation of the fruits of this R&D. There has been general agreement that, in a number of fields, Australia's research has been of a high standard, if not of world class quality. Australia's record in agricultural biotechnology research was described to the committee as 'strong',[57] and its position as being 'at the forefront of genetic manipulation leading to improved breeds of cattle and sheep and crop varieties'.[58]

5.51 However, Australia has been generally less successful in bringing its innovations on to the market than it has been in conducting the underlying research and preliminary development. Australian research has frequently been commercialised overseas, and has then been imported back into this country. As a result, few of the benefits have gone to Australian companies. Within this general context, the committee expected that it would find evidence of a similar situation in the commercialisation of Australian agricultural gene technology.

5.52 Successfully commercialising the results of gene technology research depends on a number of factors.

- Firstly, the IP produced by the research must be protected and that protection enforced. Access to any IP that is owned by other people must be negotiated. These are complex tasks and can be costly. They are discussed further in Chapter 6.
- Secondly, the GM products of the research must satisfy local regulatory requirements for local commercial release, and meet the requirements of export destinations when exported. Until recently, the regulatory pathway to commercial release of GMOs in Australia was unclear and represented a deterrent to commercialisation. Requirements for labelling GM foods will also have implications for the cost of providing GM food to the market. These requirements have not yet been decided. The regulation of GMOs is covered in Chapter 7.
- Thirdly, access to capital is needed to meet the costs of:
  - ⇒ the original research, or getting access to it;
  - ⇒ IP protection;
  - ⇒ meeting regulatory requirements; and

57 National Farmers' Association, Submission no. 36, p. 7.

58 Australian Biotechnology Association, Submission no. 39, p. 5.

⇒ commercial production of the GMO. The sums required are very considerable.

- Lastly, a market for GMOs depends on consumer acceptance which is not yet forthcoming from all sections of the community. Chapter 3 deals with consumer attitudes to GMOs.

5.53 With the cost of research, IP protection and enforcement, and meeting regulatory requirements, the process of commercialising gene technology research is clearly an expensive business. The commercialisation and marketing of agricultural and livestock production varieties is complex, cumbersome and costly.[59] According to Novartis:

> It is generally more expensive to develop genetically modified varieties and bring them to market than conventional varieties, because of the additional research and development work and additional regulatory requirements.[60]

These regulatory requirements may include the implementation of post release management plans and monitoring environmental impacts.[61]

5.54 The expense entailed in bringing research to the market may be beyond the capacity of many Australian firms. For example, Ag-Seed Research suggested that:

> … any program developing gene technology products, will need to spend at least $400,000 p.a. and desirably around $1m p.a. on relevant R&D. Ag-Seed Research itself currently spends $1.5m p.a. on oilseed brassica development, and we are only now commencing to develop GMO-based canola.[62]

BA's discussion paper on biotechnology revealed that:

> The cost of developing a biotechnology application or product from laboratory bench through to market release is generally prohibitive for most Australian firms unless they work in partnership with companies or obtain financing from overseas.[63]

5.55 In addition, one of the characteristics of Australia's industrial scene is that there are few locally owned agricultural input suppliers. As a result:

> When Australian researchers make a commercially valuable discovery, there may not be a local firm able and willing to

59 Australian Barley Board Submission no. 60, p. 7; CSIRO, Submission no. 56, p. 3.

60 Novartis, Submission no. 26, p. 5.

61 Victorian government, Submission no. 67, p. 3.

62 Ag-Seed Research, Submission no. 31, p. 9.

63 *Developing Australia's Biotechnology Future: Discussion Paper*, September 1999, Biotechnology Australia, p. 27.

> complete the development and bring the product to market, or with the international infrastructure to sell it effectively worldwide and thereby maximise the return.[64]

Forming alliances, which is discussed in the next section, is a recent development that overcomes some of these problems.

5.56 Start up companies and industry bodies were also identified to the committee in private meetings as possible means of commercialising R&D. However, in some industries it is not easy for those involved in R&D to identify the most relevant industry body to approach when seeking to commercialise their work.

Licensing, joint ventures and strategic alliances

5.57 Under the circumstances outlined in the last section, Australian researchers frequently choose to commercialise their discoveries by licensing their technologies to companies overseas. Alternatively, they seek to use them as bargaining chips to negotiate access for Australian interests to overseas owned technologies. As the CRC for Tropical Plant Pathology pointed out:

> Most genetically modified crop plants require a combination of several gene technologies to be successful. … In modern biotechnology there is a considerable amount of cross-licensing where technologies are exchanged for mutual commercial gain. This means that Australian research institutes that have valuable intellectual property in gene technologies may be able to trade licenses for these technologies for access to other valuable gene technologies controlled by companies outside Australia. This is particularly important to obtain access to the enabling technologies. This would mean that the small Australian producer and breeder can access all the required licenses for Australian developed technologies plus the required enabling technologies controlled by overseas companies.[65]

5.58 According to a survey of 90 companies by Ernst & Young, Australian biotechnology companies are very active in licensing activities. Licences were most frequently acquired from overseas; Australian universities were the second most frequent source.[66] In a private meeting with the committee, CAMBIA's chairman, Dr Richard Jefferson, warned that, if in-licensing is very widely practised, Australia might become no more than a

64 Agriculture, Fisheries and Forestry Australia, Submission no. 77, pp. 5-6.

65 Cooperative Research Centre for Tropical Plant Pathology, Submission no. 21, p. 3.

66 V Santer, 'Intellectual property and patent issues', in Ernst & Young, *Australian Biotechnology Report 1999*, Commonwealth of Australia, 1999, pp. 35-6.

contract research agency and lose its inventive capability. With out-licensing, the downsides are the financial cost and the potential for loss of control.

5.59 One of the points stressed in several submissions was that companies entering into licensing arrangements should ensure that they negotiate the rights to export their products. Since much of our produce is exported and the cost of bringing GM varieties to market are considerable, rights to overseas export of the products of gene technology must not be compromised.[67] It was therefore disappointing that CSD was excluded by Monsanto from selling its transgenic cotton seed in the international market.[68]

5.60 The GCA pointed out that, despite the difficulties, there are many cases where there is little alternative for Australian companies but to enter into arrangements with multinational companies in order to be able to effectively develop and market their gene technology IP. If the Australian grains industry is to remain internationally competitive, 'Australian companies will have no choice but to enter into joint ventures with the large multinational players if gene technology products are to be developed effectively in Australia'.[69] Other witnesses to the inquiry made a similar point.[70]

5.61 Several examples of strategic alliances were brought to the committee's attention. They include Graingene which is described in Box 5.2. In another strategic alliance, CSIRO has patented a gene that controls the browning process in many fruits and vegetables. The gene has been licensed to Zeneca for worldwide use in bananas. The contract requires Zeneca to make these new bananas available to Australian growers as soon as they are available in the marketplace, and on terms that are at least as favourable as anywhere else in the world.[71]

67 Australian Raw Sugar Industry, Submission no. 64, p. 10; Western Australian government, Submission no. 48, p. 2.

68 CSIRO, Submission no. 56, p. 21.

69 Grains Council of Australia, Submission no. 65, p. 12.

70 Cooperative Research Centres Association, Submission no. 40, p. 9; Western Australian State Biotechnology Centre, Submission no. 10, p. 2.

71 Avcare, Submission no. 61, p. 6.

Box 5.2 Graingene

Australia is utilising strategic alliances with multinational companies to gain entry into global agribusiness. Without access to IP generated by these companies, Australian growers may be put at a significant disadvantage. Graingene is an example of such an alliance.

Graingene was formed in April 1999 and is a joint venture between AWB, CSIRO and the GRDC. Graingene aims to carry out plant biotechnology research, generate IP, create commercialisation opportunities for Australian grains, and enhance Australia's investment capability in new technologies.

It is anticipated that Graingene will generate strong linkages between plant breeding and advances in biotechnology, have a strong negotiating capability, a powerful IP position, improve access to key technologies, and develop a wide range of international marketing opportunities.

Graingene's research programs include:

- genomics;
- new breeding and production specification technologies;
- yield increase and performance traits;
- resistance to pests and diseases;
- crop nutrition and abiotic stress; and
- product quality.

It is envisaged that Australian and international research organisations and companies will be invited to participate in the alliance through involvement in individual research projects.

Source: Agriculture, Fisheries and Forestry Australia, Submission to the Innovation Summit, http://www.isr.gov.au/industry/summit/reference/sectoral/index.html, *accessed 27 April 2000; AWB Ltd, Submission no. 66, pp. ii,* 6; *Grains Research and Development Corporation, Submission no. 47, p.8.*

5.62 To form effective strategic alliances or develop alternative technologies, a strong national capability is needed. If Australia is not well served in this respect, 'it runs the risk of becoming relegated to being a marginal, dependent player in this key research field'.[72] Other submissions to the inquiry stressed the importance of such arrangements, underpinned by a strong local capability in gene technology.[73] The committee has already made a recommendation earlier in this chapter about funding to provide a strong national R&D capacity in gene technology

5.63 Domination of gene technology by a few large firms could result in the extraction of monopoly rents or restricted access to this technology for Australians. This situation is likely to be exacerbated by further rationalisation of the sector as further international mergers and acquisitions occur.[74]

> The major multinational corporations have Australian subsidiaries that now control much of the gene technology intellectual property in Australia. These subsidiaries are increasingly looking to enter into joint ventures with smaller Australian companies. …
>
> Any difficulties that arise in relation to dealings and arrangements between Australian companies and multinationals could have the potential to both restrict Australia's access to internationally developed gene technologies and also to hinder the marketing of Australian developed intellectual property.[75]

The Centre for Legumes in Mediterranean Agriculture (CLIMA) suggested that, by their actions, multinational companies were acting to reduce competition for their core species 'by ensuring that access to IP is not made available to potentially competing species'.[76]

5.64 From other input to the inquiry, however, the committee learnt that such fears were considered by some to be exaggerated or unfounded.[77] Furthermore, some of the reluctance of multinational companies to make their technology available may relate to regulatory hurdles, liability concerns and uncertainty over IP issues.[78]

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72 Grains Research and Development Corporation Submission no. 47, p. 9.

73 Victorian government, Submission no. 67, p. 3; Western Australian government, Submission no. 48, p. 2.

74 Grains Council of Australia, Submission no. 65, p. 11.

75 Grains Council of Australia, Submission no. 65, p. 12.

76 Centre for Legumes in Mediterranean Agriculture, Submission no. 14, p. 4.

77 Grain Biotechnology Australia, Submission no. 68, p. 4.

78 Western Australian government, Submission no. 48, p. 2.

Investment in commercialisation

5.65 According to Dr Brooke of Rothschild Bioscience Managers, 'the great financing challenge for Australian biotechnology companies is bridging the gap between world class commercialisable primary science and listing on the public market'. Finance for commercialising research can be sourced from government sources, corporate deals, private investors (angels), public markets, and venture capital, or a combination of these.[79] A particular impediment is the lack of venture capital for early stage developments.[80]

5.66 Recognising these problems, the government charged BA with developing a national strategy for biotechnology which will ensure that Australia captures the benefits from applying biotechnology in medicine, agriculture and the environment. In September 1999, BA put out an issues paper to focus attention on the priority issues, which included the financial aspects of commercialisation. The National Biotechnology Strategy has been developed on the basis of extensive consultation with stakeholders.[81] It will be announced soon.

Tax incentives

5.67 Given that gene technology is a high risk undertaking, it is not surprising that submissions to the inquiry called for incentives to encourage its use and development. Australia's tax regime was seen as failing to provide an adequate stimulus to private investment in R&D. Ag-Seed Research emphasised the importance of 'tax incentives along the lines of:

- minimum 150% claims for R&D expenditure; and
- accelerated depreciation on capital items, together with export incentives'.[82]

Others also made these points.[83]

5.68 A group meeting at the Innovation Summit held in Melbourne in February 2000 concluded that the R&D tax concession had been a primary incentive for innovation and should be retained on a long term basis. The group was concerned, however, at the erosion of the concession in light of reduction

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79 G Brooke, 'Overview of venture financing in Australia', in Ernst & Young, *Australian Biotechnology Report*, Commonwealth of Australia, 1999, p. 22.

80 *Developing Australia's Biotechnology Future: Discussion Paper*, September 1999, Biotechnology Australia, p. 28.

81 Biotechnology Australia, 'Biotechnology - framework for the future', http://www.isr.gov.au/ba/framework.html, accessed 1 June 2000.

82 Ag-Seed Research, Submission no. 31, p. 9.

83 For example, participants at the committee's private meeting in Perth.

in the company tax rate and suggested that increasing the concession should be considered.[84]

5.69 The absence of a viable venture capital market in Australia has been attributed to an income tax system that is not conducive to risk taking,[85] particularly our capital gains tax regime.[86] The Wills report on health and medical research made the same point.[87] The NFF went into some detail on this matter:

> The Australian capital gains tax system discriminates again risky investments because of its asymmetric treatment of losses and gains. Realised capital gains are taxed immediately as income, whereas realised capital losses can only be carried forward and offset against current or future capital gains. …
>
> Many OECD countries, and most of Australia's trading competitors, allow taxpayers to offset current years losses against the tax paid in the previous three years. Compared to carry-forward tax losses, the carry-back of losses provides the firm with cash-flow when it is losing money, rather than lower taxes when the firm returns to profitability.
>
> Similarly, many OECD countries provide a more generous capital gains regime than Australia. In particular, the UK 'stepped rate' proposals appear to provide a model that Australia could well emulate.[88]

5.70 The comments summarised above were made before recent changes to business taxes following the government's review of business taxation. The changes make Australia's tax regime more competitive with those overseas. They include lowering the company and capital gains tax rates for Australian businesses, and exempting Australian superannuation and overseas pension funds from capital gains tax. Such changes are expected to attract major investments.[89]

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84 'National Innovation Summit' Melbourne, 9-11 February 2000, pp. 4-5, http://www.isr.gov.au/industry/summit/ois/communique.doc, accessed 7 March 2000.

85 Dr Brian Booth, Submission no. 7, p. 7.

86 Agriculture, Fisheries and Forestry Agriculture, Submission no. 77, p. 6.

87 *The Virtuous Cycle: Working Together for Health and Medical Research: Health and Medical Research Strategic Review*, 1999, p. 7.

88 National Farmers' Federation, Submission no. 36, pp. 11-12.

89 Biotechnology Australia, 'Biotechnology and innovation in Australia', Submission to the Innovation Summit, February 2000, p. 10; K Hardy, 'Tax issues in the biotechnology industry', in Ernst & Young, *Australian Biotechnology Report 1999*, Commonwealth of Australia, 1999, p. 46.

5.71 A number of other suggestions for providing incentives for investment in innovative projects came to the committee's attention. Participants at the Innovation Summit noted that greater incentives are provided for investment in established public companies than in loss making start up ventures. They recommended the use of a sliding scale capital gains tax regime that is only applicable to investments in innovation based companies, as happens in the UK.[90] BA also proposed that additional incentives be considered for investment in unlisted, local start up and early phase ventures.[91]

5.72 The committee welcomes the incentives to investment in biotechnology that are expected to flow from the changes to business tax arrangements. It considers, however, that the extent to which investment is stimulated must be monitored so that further measures can be pursued if needed to provide further stimulus.

Recommendation 19

5.73 **The committee recommends that the Commonwealth government:**

- **monitor the impact of the new business tax arrangements on the level of investment in biotechnology; and**
- **implement further changes to taxation arrangements if further stimulus to invest is needed.**

5.74 From the evidence before it, the committee identified two areas which should be paid particular attention in relation to encouraging investment in commercialising biotechnology R&D. They are the apparent erosion of the R&D concession because of the reduction in company tax rates and the need for more support for the early stages of commercialisation. The committee considers that, if these matters are not addressed by the National Biotechnology Strategy, they should be reviewed in conjunction with the monitoring of the impact of the new business tax arrangements proposed above.

90 'National Innovation Summit' Melbourne, 9-11 February 2000, p. 9, http://www.isr.gov.au/industry/summit/ois/communique.doc, accessed 7 March 2000.

91 Biotechnology Australia, 'Biotechnology and innovation in Australia', Submission to the Innovation Summit, February 2000, p. 10.

Grant incentives

5.75 Until the announcement in the last budget, there were no programs dedicated to commercialising biotechnology research. There were, however, a number of Commonwealth programs that support the commercialisation of research in general. The 2000-2001 budget changes this situation; it provides an extra $20 million for assistance to the early stages of commercialising biotechnology.[92]

5.76 The existing programs open to gene technology businesses are described below.[93]

- The R&D Start program provides grants and loans of up to 50 per cent of total expenditure over three years, predominantly to start up companies which are unlikely to be profitable in the early years.
- The Commercialising Emerging Technologies (COMET) program is providing $30 million over three years to mentor individuals and companies through the pre-seed stage of commercialisation.
- The Innovation Investment Fund (IIF) provides access to government funds through five licensed venture capital firms. Funds are available at the rate of two to one for investment in the early stages of a technology venture. It is expected that between $500,000 and $3 million will be given to each investment, with a total Commonwealth allocation of $230 million.
- Pooled Development Funds (PDFs) are investment companies that receive a concessional 15 per cent tax rate for equity investments in growing small companies, including high technology start-ups, with less than $50 million of total assets at the time of investment. Capital gains from sales of shares in PDFs are free from capital gains tax. Dividends paid by PDFs are exempt from income tax and dividend withholding tax.

92 Sen the Hon Nick Minchin, '$4.5 billion record level for science and technology' Media release, 11 May 2000.

93 *Budget Papers: Budget 2000-2001: Budget Papers No. 2: Budget Measures Part II: Expense Measures: Industry, Science and Resources*; K Hardy, 'Tax issues in the biotechnology industry', in Ernst & Young, *Australian Biotechnology Report 1999*, Commonwealth of Australia, 1999, p. 47; Senator the Hon Nick Minchin, 'Budget 2000-2001: Empowering industry to invest in innovation and grow', Media release, 9 May 2000.

- The Technology Diffusion Program assists industry and researchers to access and adopt new and leading-edge technologies developed in Australia or overseas. $101.8 million is available over four years for this program. In the 2000-2001 budget, $6.6 million were reallocated from this program to the National Biotechnology Strategy.[94]

5.77 R&D Start, IFF and PDFs were assessed by Dr Brooke as having drawn significant resources to seed and early stage ventures with the assistance of experienced venture capital investors. With improvements to the tax system and better skills in the management of early stage biotechnology companies, there is promise of more successful commercialisation of Australian biotechnology. Participants at the Innovation Summit suggested that the IIF and PDF programs be expanded.[95]

5.78 The committee is aware of some criticisms of these schemes. The Wills report commented on the fact that government programs tend to change frequently and unpredictably, and some involve government committees or public servants picking winners. It also made the point that 'support for biotechnology, with its long time frames and compliance work is rare despite the potentially high rewards'.[96] The review suggested the effectiveness of PDFs and the IIF in raising capital for biotechnology should be reviewed after the reform of the business tax system. If the schemes are found to be wanting, alternatives should be explored.[97]

5.79 A further suggestion was for additional assistance at earlier stages in the process of R&D and commercialisation than most of the above schemes cover.[98] While the COMET program goes some way to filling the gap here, it is insufficient. Overseas experience suggests that an incubator program is useful in providing the necessary expertise, particularly in cases where public sector researchers are involved in setting up spin off companies. A working group at the Innovation Summit proposed the urgent establishment of an incubator program for biotechnology, like the one already in place in Australia for information technology.[99]

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94 G Brooke, 'Overview of venture financing in Australia', in Ernst & Young, *Australian Biotechnology Report 1999*, Commonwealth of Australia, 1999, p. 23.

95 'National Innovation Summit' Melbourne, 9-11 February 2000, p. 9, http://www.isr.gov.au/industry/summit/ois/communique.doc, accessed 7 March 2000.

96 *The Virtuous Cycle: Working Together for Health and Medical Research: Health and Medical Research Strategic Review*, 1999, pp. 152-3.

97 *The Virtuous Cycle: Working Together for Health and Medical Research: Health and Medical Research Strategic Review*, 1999, p. 156.

98 *The Virtuous Cycle: Working Together for Health and Medical Research: Health and Medical Research Strategic Review*, 1999, p. 156.

99 Innovation Summit, Resource and Infrastructure Consolidation and Cooperation Working Group, Executive summary, Melbourne, 9-11 February 2000, p. 6.

5.80 The committee believes that the Commonwealth government should continue to support successful grant schemes. It agrees with the suggestion reported above that the operation of the existing schemes should be reviewed after the impact of business tax reform can be established. Such a review should take into account the particularly long time frames associated with the commercialisation of biotechnological applications. The committee considers that this review should be linked with that of the taxation arrangements proposed in Recommendation 19.

Recommendation 20

5.81 **The committee recommends that, when reviewing the impact of the new business tax arrangements on the level of investment in biotechnology, the Commonwealth government also review:**

- **the contribution of grant programs and the 125 per cent tax concession for research and development; and**
- **the need for more support, through grants and taxation measures, for investment in the early stages of commercialisation.**

5.82 The committee is aware of the value of incubator centres in promoting innovative projects at early stages in their development. It believes that an incubator program would be of great assistance in stimulating the application of biotechnology to agriculture and recommends that such a program be established.

Recommendation 21

5.83 **The committee recommends that the Commonwealth government fund a specific incubator program to assist the application of biotechnology to agriculture.**

Marketing

5.84 A feature of the agricultural sector is the growing vertical integration of the supply chain that might eventually result in a direct linkage between seed suppliers and consumers' plates. AgrEvo commented on this trend.

> The entry of traditional crop protection companies into seed production and biotechnology has created new opportunities and outlook on the commercialisation and marketing of the products of gene technology. AgrEvo can draw upon its experience as a leader in crop protection products and agronomic sales support to assist in the successful introduction of these products in the near future. Relationships with distributors and farmers and quality assurance systems … are easily applicable to new seed and technology products.[100]

Nugrain is also entering the gene technology business. Nugrain is an Australian conglomerate formed from a supplier of farming inputs (Nufarm), the nation's four largest bulk grain handlers (Vicgrain, GrainCorp, SACBH and CBH), and a leading rural merchandise business (Wesfarmers Dalgety).

5.85 The introduction of GM livestock to growers is also expected to be favoured by the structure of the industry.

> Because of the pyramidal breeding structure of most extensive livestock industries, and the vertical integration of the intensive industries, commercialisation and marketing of genetic improvements, once these are covered by a satisfactory regulatory mechanism, should be relatively straightforward assuming that issues like animal welfare, ethics etc are appropriately dealt with. Producers of genetically enhanced livestock … will licence the genetically enhanced animals to major breeders, who will spread them out to commercial producers and multipliers.[101]

> … in general, the structure of our livestock industry will preclude the introduction of elaborate, restrictive mechanisms.[102]

5.86 Large multinational companies with strong IP positions in gene technology have power over the market through their links down the supply chain. Concern was expressed to the committee about the power of

100 AgrEvo, Submission no. 55, p. 3.

101 CSIRO, Submission no. 56, p. 4.

102 CSIRO, Submission no. 56, p. 5.

these companies to prevent farm saving of seeds through the use of terminator technology, to require the use of specific inputs, and to dictate the varieties grown under contract to retailers.[103] The Australian United Fresh Fruit and Vegetable Association, for example, expected market domination by larger companies 'probably working with large retail chains, which restrict grower access to varieties and pesticides and will ensure premium prices will be paid for seed'.[104] AGN pointed out that 'this ability to monopolise agricultural inputs has never been so complete before. It represents significant departure from traditional farming practices'.[105]

5.87 However, Monsanto's experience with the introduction of Ingard® cotton illustrates some of the difficulties that may be associated with marketing a GM variety. Cost, limited technical support, and the absence of 'real compensation' for poor performance were among the issues that were of concern to Ingard® cotton growers.[106]

Skills

5.88 The growth of the biotechnology industry is expected to be rapid. It is estimated that around 5,000 more highly skilled and qualified people will be required in the field by 2005.[107]

Research skills

5.89 AFFA's submission to the inquiry drew together information about Australia's scientific skills base in agricultural biotechnology, and expressed concern that there were 'potential deficiencies in the skills base of our researchers'. A survey by SCARM found that shortages of senior experienced staff were becoming apparent. This situation reflected several recent developments.

- Bearing in mind that 90 per cent of agricultural research is performed by the public sector, the restructuring of public administration has had a particular impact on the number of agricultural research workers employed. For example, the number employed by Commonwealth and

103 Mr Wayne Hancock, Submission no. 6, p. 4; Mr Griffiths, Submission no. 22, p. 4; Queensland Fruit and Vegetable Growers, Submission no. 42, p. 3; The O'Hallorans, Submission no. 17, pp. 2-3.

104 Australian United Fresh Fruit and Vegetable Association, Submission no. 58, p. 2.

105 GeneEthics Network, Submission no. 71, p. 8.

106 Mr Wayne Hancock, Submission no. 6, p. 4.

107 *Developing Australia's Biotechnology Future: Discussion Paper*, September 1999, Biotechnology Australia, p. 35.

state governments and in higher education fell by nearly 14 per cent between 1992-93 and 1994-95.

- There is a strong overseas demand for gene technologists, particularly in medicine and pharmaceuticals. Given that their skills are not peculiar to a particular discipline, they can move easily out of agricultural research into other fields.[108]

5.90 It is important for Australia to have an adequate number of researchers with appropriate research skills, and support for them must be provided. If it is not, the skills will not be maintained or will go overseas.[109] Strategies to develop biotechnological expertise are being developed. For example, BA recognised that researchers are needed who will operate successfully in transdisciplinary research; producing such researchers requires creative university courses. These researchers will also need opportunities to interact with top researchers overseas.[110]

Business and management skills

5.91 It is widely recognised that management skills in gene technology are not of a high enough standard in the research and business community in Australia. The South Australian government claimed that:

> … researchers and traditional industry funders (R&D Corporations) are required to be more conversant and proficient in the development, protection and commercialisation of intellectual property as well as be more professional in forming strategic and commercial business alliances.[111]

Conversely, there is a shortage in the venture capital funds of 'dedicated expertise able to fully understand the complexities of biotechnology investment'.[112]

5.92 In Ernst and Young's survey of 90 companies, skilled human resources and access to smart capital (money plus management expertise) were among the top four issues nominated as needing to be addressed when successfully commercialising biotechnology.[113]

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108 Agriculture, Fisheries and Forestry Australia, Submission no. 77, p. 5.

109 Cooperative Research Centre for Premium Quality Wool, Submission no. 52, p. 2.

110 *Developing Australia's Biotechnology Future: Discussion Paper*, September 1999, Biotechnology Australia, p. 36.

111 South Australian government, Submission no. 81, p. 11.

112 G Brooke, 'Overview of venture financing in Australia', in Ernst & Young, *Australian Biotechnology Report 1999*, Commonwealth of Australia, 1999, p. 26.

113 Ernst & Young, *Australian Biotechnology Report 1999*, Commonwealth of Australia, 1999, p. 45.

5.93 BA's discussion paper addressed the types of training needed to meet the demands of a developing biotechnology industry. For example, researchers must be exposed to commercial issues and Master of Business graduates to basic science concepts.[114] The COMET program acknowledges this and supports management skills training for individuals in companies at the early stages of commercialising R&D.[115] Training in IP issues is also needed,[116] and is dealt with in more detail in Chapter 6.

5.94 More broadly, a fundamental change in culture and thinking of Australians will be required if they are to become more entrepreneurial.[117]

5.95 The committee views the development and maintenance of Australians' research, business and management skills as essential to the effective use of biotechnology in agriculture. It is aware of initiatives to improve the skill levels of those already involved in biotechnology research and the industry and to increase the number of skilled people. The committee considers that it is important for these initiatives to be maintained and expanded if needed.

Recommendation 22

5.96 **The committee recommends that the Commonwealth government continue to fund programs for increasing the numbers of people and the levels of skills in:**

- **biotechnology research; and**
- **the business and management issues involved in the commercial use of the research.**

114 *Developing Australia's Biotechnology Future: Discussion Paper*, September 1999, Biotechnology Australia, p. 36.

115 Senator the Hon Nick Minchin, 'Budget 2000-2001: Empowering industry to invest in innovation and grow', Media release, 9 May 2000.

116 Australian Barley Board, Submission no. 60, p. 8; Cotton Seed Distributors Ltd, Transcript of evidence, 18 October 1999, p. 237.

117 'National Innovation Summit' Melbourne, 9-11 February 2000, http://www.isr.gov.au/industry/summit/ois/communique.doc, accessed 7 March 2000.

Cost of GM varieties

5.97 It is clear that GM varieties must be priced to recover, within a reasonable period of time, the expenses incurred in bringing them to market. At the same time, the pricing structure should be such as to provide profit to growers as well as other players in the production chain.

5.98 There was no consensus, however, on whether GM seeds would be more or less expensive than conventional varieties. AgrEvo anticipated that the cost of its GM canola seeds would be comparable to that for non GM seed.[118] On the other hand, the cost of GM seed could be expected to be generally higher than for conventional seed because of the expense involved in developing and commercialising gene technology products.[119] The view most often expressed to the committee was that prices would be higher.

5.99 Novartis explained that:

> Seeds are typically priced at a level that recognises the added benefits to the farmer, such as more efficient chemical usage, increased yield and reduced effort/time. Thus, while producers pay a premium for the seeds, this is more than offset by the reduced cost of the other inputs required to bring the crop to harvest. Thus producers can expect a higher profit from the crop.[120]

5.100 It was suggested to the committee that the cost of GM seeds would be determined by the market, especially when the genetic enhancement was carried out in Australia.[121] If there is no advantage to growers in using GM varieties, they will continue to purchase conventional varieties, and there will be pressures on the suppliers of GM seed to keep prices low. If, on the other hand, a GM variety is demonstrably superior, it will command a higher price.[122] The cost of gene technology will be what the market can bear.[123]

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118 AgrEvo, Submission no. 55, p. 3.

119 Grains Council of Australia, Submission no. 65, p. 11; New South Wales government, Submission no. 72, p. 12; Novartis, Submission no. 26, p. 7.

120 Novartis, Submission no. 26, p. 7.

121 CSIRO, Submission no. 56, p. 4; Victorian government, Submission no. 67, p. 3.

122 Centre for Legumes in Mediterranean Agriculture, Submission no. 14, p. 4; Dairy Research and Development Corporation, Submission no. 15, p. 5.

123 Dr Brian Booth, Submission no. 7, p. 4; Waratah Seed Co., Submission no. 23, p. 2.

5.101 The Queensland government pointed to 'the Monsanto experience' with Bt cotton where, it claimed:

> … the cost is not related so much to the cost of production but on what the market will bear. This can be alleviated to a major extent through support for competitive endeavours, particularly by public programs.[124]

However, public subsidy of research is diminishing and prices are expected to rise as a result.[125]

5.102 Fears were expressed to the committee that, in this situation, the few multinational companies that own many of the key gene technologies would charge premium prices. In the absence of competition, costs are likely to be even higher. This appeared to be the case with Bt cotton in Australia, as described in Box 5.3.

5.103 The committee appreciates the fears of those who anticipate that multinationals will charge exorbitant prices for GMOs. It is aware, however, of suggestions from others, like CSIRO and the Australian Academy of Science, that the opportunity to exact unusually high profits will be limited, given the competitive nature of production of all commodities.[126]

124 Queensland government, Submission no. 79, p. 3.

125 South Australian government, Submission no. 81, p. 12.

126 Australian Academy of Science, Submission no. 62, p. 1; CSIRO, Submission no. 56, p. 4.

Box 5.3 Ingard® cotton seed price

When Monsanto introduced Ingard® cotton in 1996, it set the price of seed at $245 per hectare, which was considerably more than was charged for Monsanto's Bt cotton in the USA. The Ingard® price was based on the assumption that Ingard® cotton would reduce the insecticide sprays used to control *Helicoverpa spp.* by 90 per cent. However, in response to concerns raised by the cotton industry, Monsanto also included a value guarantee. The guarantee included a rebate if the Ingard® crop planted by the farmer did not provide $245 worth of value in reduced sprays when compared with a conventional cotton crop grown on the same property.

Ingard® cotton's performance in Australia has been far less impressive than was expected. It has reduced *Helicoverpa* sprays by 40 – 50 percent, instead of the predicted 90 per cent. Dr William Blowes, a technical director at Monsanto Australia, estimated that $2-3 million dollars was rebated to farmers through this scheme.

At the end of the second year of the scheme the cotton industry asked Monsanto to adopt a lowest possible price strategy that reflected value to most cotton growers, while allowing Monsanto a reasonable return on investment. As a result, the cost was reduced to a net purchase price of $155 per hectare.

Ingard® cotton is not particularly profitable when compared with other technologies. Monsanto Australia does not expect to make a positive return on the technology until 2001, and Monsanto Co. USA will not recoup the development costs for biotechnology research for some considerable time after that.

Within Australia, almost all modified genes and the processes used to transfer them are patented by multinational seed companies. Many of these companies have the potential to create monopolies and produce false markets. For example, because there is currently only one supplier of GM cotton in Australia, the price of GM cotton seed may not reflect the true value of the product. However, the CRCA considered that the price of the seed will always be competitive or it will not succeed in the Australian market.

Source: Australian Biotechnology Association, Submission no. 39, p. 6; Cooperative Research Centres Association, Submission no. 40, pp. 8-9; Cotton Seed Distributors Transcript of evidence, 18 October 1999, pp. 235-6; Monsanto Australia Ltd, Submission no. 44, pp. 2-4; Transcript of evidence, 18 October 1999, p. 231.

5.104 One way in which the owners of gene technology recover costs from growers of GM crops is through licences. Under this arrangement, growers pay a licence fee, in addition to paying the organisation that bred and marketed the seed.[127] End point royalties (EPRs) are another avenue for recouping costs, with growers making payments to the seed supplier at the time of harvest. With EPRs, companies are more able to effectively derive ownership of varieties and the technology used to develop them. This provides:

> … the incentive for increased investment in new varieties and technologies, orderly and structured distribution and expansion of production and more effective alignment of production to markets, with subsequent greater market share and price premiums with a flow back to the producer.[128]

5.105 To capture EPRs, closed loop marketing licences are sometimes used. They involve exclusive seed and grain marketing rights and payment of royalties on sales of both seed and grain. Such arrangements are seen as anticompetitive, and likely to restrict marketing choices and infrastructures.[129] Issues relating to EPRs are discussed further in Chapter 6.

5.106 In addition to the cost of purchasing GM seed, the grower will encounter other costs associated with regulatory requirements relating to management and monitoring of the crop and, in some circumstances, the need to segregate GM from non GM produce.

Issues for small producers

5.107 Among the terms of reference for the inquiry is one that tasks the committee with examining the impact of gene technology on small producers. In general, the impacts on them are no different in kind from those facing all producers, although they may be felt more intensely, as would be the effect of many new technologies.

5.108 According to Avcare, Australia's system for IP protection gives small producers the same opportunities to capture value from their IP as large corporations or government funded institutions.[130] Even small producers could gain access to the necessary technologies through cross licensing

127 Novartis, Submission no. 26, pp. 7-8.

128 South Australian government, Submission no. 81, p. 12.

129 Grains Council of Australia, Submission no. 65, p. 10; NSW Farmers' Association, Submission no. 38, p. 10; Victorian government, Submission no. 67, p. 2.

130 Avcare, Submission no. 61, p. 5.

arrangements or other forms of association,[131] develop new varieties from varieties containing GM traits, and successfully protect them under the Plant Breeders' Rights (PBR) Act.[132]

5.109 However, small producers do not have the resources to compete with major plant breeding companies. They have neither the financial capability nor the expertise to deal with relevant IP, regulatory and management issues.[133] The Dairy Research and Development Corporation considered that it is:

> … increasingly unrealistic that small producers will be able to grow and supply new varieties of pasture seed (traditional or genetically enhanced) given the extent of investment in technology and infrastructure necessary to achieve a critical mass for a financially viable enterprise.[134]

AgrEvo agreed with this view:

> The development of GM varieties is expensive due to the global regulatory and product stewardship responsibilities that come with them. This makes it difficult to support widespread access or development of novel varieties by small players.[135]

5.110 Among those who addressed the issue, there was little support for assistance targeted specifically at small producers.[136] The Victorian government pointed out that growers and both the Commonwealth and state governments already contribute to gene technology R&D. The committee is concerned about the role for small producers in the development of gene technology. An appropriate form of assistance for them would be through the incubator program.

5.111 The committee believes that small producers may be able to carry out breeding work with varieties containing GM material. The committee noted CSIRO's suggestion that 'the most effective and specific assistance to small producers and independent breeders would be educational in the

131 Cooperative Research Centre for Tropical Plant Pathology, Submission no. 21, p. 3.

132 Victorian government, Submission no. 67, p. 4.

133 Cooperative Research Centres Association, Submission no. 40, p. 9; CSIRO, Submission no. 56, p. 6; Queensland Fruit & Vegetable Growers, Submission no. 42, p. 3; Western Australian State Agricultural Biotechnology Centre, Submission no. 10, p. 2.

134 Dairy Research and Development Corporation, Submission no. 15, p. 5.

135 AgrEvo, Submission no. 55, p. 4.

136 Ag-Seed Research, Submission no. 31, p. 9; New South Wales government, Submission no. 72, p. 12; South Australian government, Submission no. 81, p. 13; Victorian government, Submission no. 67, p. 4.

form of sharing knowledge about how to position Australia and manage … relationships' with the larger players in the field.[137]

5.112 The committee identified a number of other aspects of using GM crops as being of particular significance for small producers. They are summarised in the following points.[138]

- Regulatory requirements could be problematic, for example, if big buffer areas around crops were required.
- The task of segregating GM and non GM produce is likely to be more burdensome for smaller than for larger producers, as will that of dealing with liability for any untoward outcomes of growing GMOs.
- It may be more difficult for small producers to acquire sufficient knowledge about the benefits and drawbacks of GMOs to make informed decisions about their use.

Recommendation 23

5.113 **The committee recommends that Biotechnology Australia, in conjunction with other agencies, develop and deliver educational programs and materials targeted at small producers and breeders.**

These programs and materials should cover:

- **the business and intellectual property issues relating to the breeding of agricultural genetically modified organisms; and**
- **the practical aspects of using genetically modified organisms in agriculture.**

137 CSIRO, Submission no. 56, p. 6.

138 Cotton Research and Development Corporation, Submission no. 27, p. 7; CSIRO, Submission no. 56, p. 5; NSW Farmers' Association, Submission no. 38, p. 8; Western Australian government, Submission no. 48, p. 3.

6

Intellectual property

Introduction

6.1 The protection of IP is fundamental to the commercial development of gene technology. A strong IP system allows local organisations to protect their property and negotiate effectively with the large multinational companies. It also stimulates further innovation and encourages overseas owners of IP useful to Australian producers to make their IP available here.

6.2 There was general support among submissions to the inquiry for the system of IP protection in Australia.[1] A strong IP regime was seen as critical for farmers' access to gene technology.[2] Others suggested it should be strengthened.[3]

6.3 IP protection for GMOs in Australia relies largely on patent law and plant breeders' rights (PBRs). Other forms of protection exist, such as trade secrets, private know how agreements, and technologies that restrict the use of the GMOs to which they have been applied, like hybridisation and terminator and verminator technologies.[4]

6.4 Australia's IP regime is consistent with the international agreements to which we are party, notably the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and the International Convention for the Protection of New

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1 For example, Avcare, Submission no. 61, p. 7.

2 Agrifood Alliance Australia, Submission no. 37, p. 4; National Farmers' Federation, Submission no. 36, p. 15.

3 Australian Biotechnology Association, Submission no. 39, p. 7.

4 Terminator technology produces sterile seeds and verminator technology ensures that growers have to use particular proprietary chemicals.

Varieties of Plants. Under TRIPS, Australia is obliged to provide certain minimum IP rights, covering matters such as:

- the scope of patentable subject matter;
- exceptions to patents rights, including compulsory licensing;
- the protection of undisclosed information, including regulatory test data; and
- measures to control anti competitive licensing.

Within this general framework, there is scope for individual countries to fashion their regimes to meet local requirements.[5]

6.5 Australia's IP protection regime is similar to those of our trading partners.[6] Not only is it broadly compatible with the regimes of most other countries, its enforcement practices are 'at least on par with most advanced economies'.[7]

> … if Australian protection regimes were to be significantly out of step with our major trading partners, it would likely make us a less desirable market for innovation than our overseas competitors. Without protection, Australian innovators will not develop and manufacture the latest innovations for the domestic and export markets.[8]

6.6 The challenge for governments is to establish arrangements which on the one hand provide sufficient incentive for innovators to develop new products, but on the other hand avoid promoting monopolies which restrict innovation and extract 'above normal' returns.[9] **Getting the right balance between these two requirements is critical to the commercial development of gene technology.**

Patents

6.7 Patents are designed to encourage innovation by providing the innovator with the exclusive right to commercialise his or her invention for a set period of time, usually 20 years. In return, the patent holder makes

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5 Department of Foreign Affairs and Trade, Submission no. 70, pp. 4, 5; IP Australia, Submission no. 35, pp. 1, 2.

6 IP Australia, Submission no. 35, p. 1.

7 Intellectual Property & Competition Review Committee, *Issues Paper*, September, 1999, p. 7.

8 IP Australia, Submission no. 35, p. 3.

9 New South Wales government, Submission no. 72, p. 9.

available the details of the patented invention for publication, thereby increasing public knowledge and encouraging further innovation.[10]

The Australian patent system

6.8 Under the *Patents Law 1990,* all technologies may be patented with the exception of 'human beings and the biological processes for their generation' and 'an invention the use of which would be contrary to law'. IP Australia's submission listed the range of patentable inventions involving genetic manipulation found in Australian patent applications. They include:

- synthetic genes or DNA sequences;
- mutant forms and fragments of gene sequences;
- the DNA coding sequence for a gene (in either the isolated or recombinant form);
- the protein expressed by the gene;
- vectors (such as plasmids or bacteriophage vectors or viruses) containing the gene;
- methods of transformation using the gene;
- host cells carrying the gene;
- higher plants / animals carrying the gene; and
- organisms for expression of the gene (making the protein from the DNA) which may be bacterial, yeast, viral; plant or animal cell cultures; or higher plants or animals *per se*.[11]

Stimulating commercialisation

6.9 AFFA commented that extending patentability to biotechnology had stimulated greater private sector involvement than previously because it improved investors' ability to capture the benefits of their investment. The patent owner of a gene, for example, can control not only which species the gene is inserted into, but also the countries to which the end product is exported. Through the issue of licences, patent holders can divide up the world market. The flurry of mergers and take over activity attests to the commercial gains possible from IP in biotechnology.[12]

10 IP Australia, Submission no. 35, p. 1.

11 IP Australia, Submission no. 35, pp. 1-2.

12 Agriculture, Fisheries and Forestry Australia, Submission no. 77, pp. 18, 20.

6.10 Patented IP can thus be indispensable in attracting commercial investment.[13] Because of the long pathway to commercial release, patent protection is vital if investors are to recover their costs. The status and strength of patent protection are some of the first elements that bankers, venture capitalists, financial analysts and potential large partners will investigate when considering investing in a biotechnology project.[14]

6.11 Agricultural industries that have been identified as particularly likely to be assisted by a strong patent system for protecting their biotechnology IP include wine, cheese, cotton and wildflowers. Many others also stand to gain from it in the longer term.[15]

Limiting access to technologies

6.12 While stimulating innovation and commercialisation, patenting has limited the dissemination of information, access to material, and cooperation among researchers as IP owners release technologies only where it fits in with their global strategies. The owners also control tightly the commercial release of technologies (as discussed in Chapter 5).[16] BA suggested that this was likely to be a particular problem for Australian agriculture.[17] Examples of Australian interests being denied access to needed technologies are given in Box 6.1. The owners of patents on seeds can also interfere with traditional farm saving of seed.[18]

13 *Developing Australia's Biotechnology Future: Discussion Paper*, September 1999, Biotechnology Australia, p. 26.

14 V Santer, 'Intellectual property and patent issues', in *Australian Biotechnology Report 1999*, Ernst & Young, p. 33.

15 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, p. 45.

16 P French, *Biotechnology in Australia*, Federation of Australian Scientific and Technological Societies, Occasional Paper Series, No 1, January 1999, section 6; Cotton Seed Distributors Ltd, Transcript of evidence, 18 October 1999, p. 240.

17 *Developing Australia's Biotechnology Future: Discussion Paper*, September 1999, Biotechnology Australia, p. 26.

18 National Genetic Awareness Alliance, Submission no. 54, p. 4.

Box 6.1 Examples of technologies to which Australian companies were refused access

Two gene cotton

To achieve better pest control, and to reduce the risk of resistance building in cotton pests, scientists advocate the rapid development of two gene technology. The two gene variety P2 has been tested recently in Australia, and has been found by CSIRO to be more effective against *Helicoverpa spp.* than the single gene Ingard® cotton. Growers were expecting this variety to be released commercially in the next two years, but in June 1999, Monsanto decided against releasing it, arguing that the P2 gene depressed cotton yields.

Monsanto will concentrate on developing another series of two gene Bt cottons which will delay the introduction of these varieties by a further two or three years. Monsanto argues that, because P2 depresses cotton yields, it is a faulty product and commercialisation poses a significant corporate risk.

The Australian Cotton Growers Research Association stated that the industry fought hard to introduce the two gene technology, and was prepared to accept the yield losses because of the technology's importance to the future sustainability of the industry. CSIRO expressed disappointment that the product was withdrawn, arguing that Australian breeders had nearly overcome reduced yield through regular breeding.

> We – the industry, the cotton seed distributors company and CSIRO – have all looked into whether or not we could have the Monsanto company completely indemnified against damage, and our lawyers say that that is possible.

Herbicide tolerant lupin

CLIMA has developed a herbicide tolerant lupin for use in Australian farming systems. A gene was used in its development that was the property of AgrEvo (now known as Aventis). The work was completed with the knowledge and support of AgrEvo. In November 1998, CLIMA submitted an application to GMAC for the general release of the variety, and renewed negotiations with AgrEvo for commercial access to the use of the gene in the lupin. At present, CLIMA has been unable to secure commercial rights for the gene.

Source: Centre for Legumes in Mediterranean Agriculture, http://www.clima.uwa.edu.au/research/nes06.html, accessed 5 May 2000; New South Wales government, Submission no. 72, p. 13; Private meeting in Perth with local stakeholders, 27 July 1999; Stakeholders in the cotton industry, Transcript of evidence, 18 October 1999, pp. 204-5, 221-2, 238, 240.

6.13 Furthermore, as IP Australia pointed out:

> It is important not to think of patents as a "monopoly" in the everyday meaning of conferring absolute market dominance since there are normally alternative substitutes. … Rather, it is a "temporary exclusive right" to only part of the commercialisation process … [19]

6.14 Others have suggested, however, that markets are not contestable in the long run, if the original innovator can perpetuate the market advantage beyond the initial property right. This may be the case with the market for transgenic seeds where a small number of big companies own key patents for the basic enabling techniques for the genetic manipulation of organisms.[20] Asker and Stoeckel pointed out that:

> It is difficult for the patents owned by these firms to be challenged, as they are large players in the market with considerable resources. These large resources mean that they are willing to defend and pursue legal challenges. Anecdotal evidence suggests that these firms cross-license technology so that, within this group of large players, there is little incentive to challenge property rights.

In addition:

> By limiting access to enabling technologies, large firms guarantee that they will have ownership of the next stage in the development of enabling technology since they are in a position to control existing research.[21]

6.15 Asker and Stoeckel concluded that:

- only time will tell if these monopolies will persist; and
- it is better to characterise markets as contestable in the long term because there are few examples of perpetuating monopolies, other than those operated with government assistance.[22]

The Department of Foreign Affairs and Trade acknowledged that 'there is considerable international debate about the role of IP rights in promoting and limiting access to the benefits of gene technology'.[23]

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19 IP Australia, Submission no. 35, p. 4.

20 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, pp. 16-17.

21 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, p. 17.

22 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, p. 19.

6.16 The committee is concerned that the stimulus that a strong patent system can give to innovation may be threatened by the power of monopolies to perpetuate their market positions beyond the patent period. In addition to damaging innovation, monopolies obviously are also economically damaging to other industries. The committee is aware that two major reviews of competition law are proceeding, which will identify changes that are needed to it.[24]

Cost and complexity

6.17 According to AFFA, it can cost $500,000 to gain full patent protection for a discovery, and double that per year to protect the patent from illegal use or challenge.[25] BA's discussion paper estimated that less than half this amount would be required to obtain and protect patents in an appropriate range of countries.[26] Much smaller amounts were also quoted as typical in private meetings that the committee held with people involved in businesses using GMOs.

6.18 The costs incurred in enforcing patents include legal fees, lost time assembling information, the chance of having to meet the other party's costs, stress and bad publicity. Litigation is extremely expensive in part because of the need to employ specialised lawyers.[27] By international standards, however, relatively few Australian biotechnology firms were engaged in litigation in 1999.[28]

6.19 A general problem facing any business interested in enforcing its IP rights was identified by the Advisory Council on Industrial Property. The committee reported 'substantial uncertainty' facing businesses that were considering whether to enforce their IP rights. Not only were cost and time issues of concern, so were uncertainty in legal proceedings, questions about the validity of patents and fear of abuse of the system by large players to the detriment of smaller players.[29] One view of the international scene was that 'no part of the tale is straightforward, and no one's rights

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23 Department of Foreign Affairs and Trade, Submission no. 70, pp. 5-6.

24 The reviews are by the Intellectual Property and Competition Committee and the National Competition Council. The latter is examining sections 51(2) and 51(3) of the *Trade Practices Act 1974*.

25 Agriculture, Fisheries and Forestry Australia, Submission no. 77, p 18.

26 *Developing Australia's Biotechnology Future: Discussion Paper*, September 1999, Biotechnology Australia, p. 26.

27 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, p. 27.

28 V Santer, 'Intellectual property and patent issues', in *Australian Biotechnology Report 1999*, Ernst & Young, p. 35.

29 Advisory Council on Industrial Property, *Review of Enforcement of Industrial Property Rights*, quoted by the Intellectual Property & Review Committee, *Issues Paper*, September, 1999, p. 27.

are clearly defined in the shifting nexus of international legal protection, fast-paced technological developments, and changing business alliances'.[30]

6.20 Those wishing to use other's technologies can also face considerable expense and complexity. From its experience of licensing-in GM traits for commercial use, CSD singled out two aspects for comment. One related to the difficulty of identifying 'whom do we licence from and what do we licence?'[31] The difficulty arises from the fact that there are frequently many patents involved in a single technology, and the ownership of each must be discovered and addressed. In addition, ownership of particular patents may be under dispute.

> … really a lot of people do not know who owns what. In the middle of last year, there were 42 patent cases going on in corn. There was an estimate of $US100 million to $US150 million being spent on legal fees and the clarification of who had freedom to operate commercially with corn. Some of those have probably been sold, but there would probably be in excess of 30 patent issues currently being fought globally in corn.[32]

6.21 A second factor that contributes to the high cost and complexity of accessing gene technology is the need to deal with other legal systems.

> … the governing law of an agreement … is often not Australian law, which then predisposes you to know everything about New York law or Delaware law, and this adds to the cost, complexity and representation.[33]

6.22 Much of the cost and complexity discussed in this section reflects the way in which the patent system operates internationally. Actions that the Australian government can take to ameliorate this situation are therefore somewhat limited. However, a more uniform system of patents in different countries would simplify their use and help to reduce costs and complexity; Australia can support international moves in this direction, as discussed later in the chapter. Another way in which the Australian government can assist is by providing training in the use of patents so that the complexity inherent in the system is more easily dealt with. This issue is also covered in more detail later.

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30 S Shulman, *Owning the Future*, Houghton Mifflin Company, New York, 1999, p. 92.

31 Cotton Seed Distributors Ltd, Transcript of evidence, 18 October 1999, p. 235.

32 Cotton Seed Distributors Ltd, Transcript of evidence, 18 October 1999, p. 238.

33 Cotton Seed Distributors Ltd, Transcript of evidence, 18 October 1999, p. 235.

Practices in issuing patents

6.23 Patents are issued for inventions that are new, non obvious and useful. A more detailed definition of a patent, with particular relevance to GMOs is given by IP Australia.

> A patent is granted for an invention that is an innovative idea which provides a practical solution to a technological problem. In this context, a patent would only be granted for subject matter which meets all the following tests:
>
> - involves the technical intervention of a technologist applying their inventive ingenuity to produce something distinguishable from the natural source material. (A patent cannot be granted for a mere discovery of biological material);
> - is new in the sense of not previously being publicly available. That is, a patent cannot be granted for materials in their naturally occurring state or for materials which have previously been made publicly available [in Australia or overseas];
> - has been fully described in the sense that sufficient information is provided to allow the technologist to make the product or perform the process without having to resort to invention;
> - has a demonstrated industrial use. The use to which the invention is to be put, for example, for the treatment of human diseases such as cancer or multiple sclerosis, must also be fully described. This means that there must be an actual use for an invention rather than speculation as to future uses.

A further criterion exists for biological inventions; they must be repeatable.[34]

6.24 How these criteria have been interpreted in issuing patents for biotechnology in Australia has been the subject of comment in several recent papers, as well as in some of the input to the committee's inquiry. For example, Dr Charles Lawson suggested that:

- the hurdle for inventiveness, non obviousness and novelty and the grant of a patent has been set too low; and
- the breadth of coverage of patents is too wide, leaving very little room for further invention.[35]

6.25 Others have also commented on the problems caused by broad patents. Combined with the similarity of commercially important genes across many species, broad patents have contributed to the dominance of the

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34 IP Australia, 'Australian patents for: Microorganisms; Cell lines; Hybridomas; Related biological materials and their use; & Genetically manipulated organisms', November 1998, pp. 2, 3-4.

35 Dr Charles Lawson, Submission no. 19, p. 1.

owners of these patents. This may be a situation that needs to be remedied.[36] Uniquest drew attention to the drawbacks of broad patents.

- They are more likely to be challenged which raises the cost of enforcing them.
- Potentially valuable lines of research or applications may be abandoned because of the risk of infringement.
- Additional expense is incurred if a user needs to seek clarification from the patent owner, and must pay licence fees which ought not to have been required had the patent been properly granted.
- Potential patentees decide the rigour of the system is too low to justify seeking protection in Australia.[37]

However, it has been suggested that the broadness of the patents is 'transitory, reflecting the immaturity of those technologies currently being developed'.[38]

6.26 The rigour of examination of patent applications was called into question in private meetings that the committee held with gene technology businesses. Participants in these meetings claimed that Australian patent examination is weak by comparison with that carried out in the USA and European countries. They told the committee that:

- a patent was issued by IP Australia after one day's examination when it took four years for US authorities to issue a patent and longer in Europe; and
- in another case, inadequate examination was carried out by IP Australia and a broader patent issued than in the USA. As a result of the limitations imposed on the patent in the USA, researchers in that country will be able to design around the patent and innovate while Australian researchers will not.

Others referred to weakness in the Australian patent system as well.[39]

6.27 The Intellectual Property and Competition Review Committee (IPCRC) was set up to assist with the implementation of the National Competition Policy in relation to IP protection. In an interim report, the IPCRC examined a number of matters concerning the issuing of patents, and

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36 *Developing Australia's Biotechnology Future: Discussion Paper*, September 1999, Biotechnology Australia, pp. 26, 27.

37 Uniquest, Submission no. 29 to the Intellectual Property & Competition Review, p. 6.

38 Department of Industry, Science and Resources, Submission no. 34 to the Intellectual Property & Competition Review, p. 23.

39 Intellectual Property & Competition Review Committee, *Interim Report*, April 2000, p. 50.

some of its observations reinforce the evidence received by the committee. The IPCRC's conclusions and proposals, based on the submissions which it received, have been put forward for further public discussion and are summarised here.

- The threshold for the issue of a standard patent should be 'no less than the highest threshold set by any of the countries with which we conduct substantial technology trade';[40]
- In relation to the threshold tests for granting patents:
  - ⇒ The current basis for assessing the industrial or technical nature of patents applied for is flexible and adapts well to new and rapidly evolving technologies. It serves the purpose of the patent system better than any firm definition of what constitutes a patentable invention.[41]
  - ⇒ Mere discoveries, such as identifying a gene sequence, should continue to be excluded from patentable subject matter. Only the applications of these discoveries should be patentable. Guidelines may be needed to assist in making this distinction.[42]
  - ⇒ The test for inventiveness used in Australia appears to be more lenient than those used in some other countries; the threshold for inventiveness should be raised.[43]
  - ⇒ It is possible that there would be a better balance between the interests of IP owners and users if the objectives of the Patent Act emphasised that the long term interests of end users should be the predominant consideration in granting patents. Such a requirement would serve to balance the greater lobbying power possessed by IP owners compared with that of end users.[44]
- With respect to the administration of the patent system:
  - ⇒ Rigorous screening of patent applications is needed to ensure that those that are granted are 'strong, certain and enforceable'.[45]
  - ⇒ A more stringent test for granting patents is suggested which will improve their certainty and validity.[46]

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40 Intellectual Property & Competition Review Committee, *Interim Report*, April 2000, p. 38.

41 Intellectual Property & Competition Review Committee, *Interim Report*, April 2000, pp. 40-1.

42 Intellectual Property & Competition Review Committee, *Interim Report*, April 2000, pp. 43-4.

43 Intellectual Property & Competition Review Committee, *Interim Report*, April 2000, p. 46. See also: J Revesz, *Trade-Related Aspects of Intellectual Property Rights*, Productivity Commission Staff Research Paper, AGPS, Canberra, 1999, p. 29.

44 Intellectual Property & Competition Review Committee, *Interim Report*, April 2000, pp. 47-8.

45 Intellectual Property & Competition Review Committee, *Interim Report*, April 2000, p. 50.

46 Intellectual Property & Competition Review Committee, *Interim Report*, April 2000, p. 52.

⇒ A small office like IP Australia cannot hope to have the level of expertise that much larger overseas offices have. The quality of patent examination in Australia might be improved through more use of, and cooperation with, overseas patent offices. The work of patent examiners might also be assisted by requiring applicants to provide a wider range of relevant information than they do at present.[47]

6.28 The committee believes that a strong patent system that issues clear, valid patents to biotechnological inventions will benefit Australian agriculture. From the small amount of evidence it received and the findings of other reviews, the committee recognises that there are a number of improvements needed.

6.29 The committee favours narrower, more stringently examined patents issued over higher thresholds than at present. It believes that changing the Patent Act's objectives to emphasise more firmly the long term interests of end users would help to inhibit the emergence of persistent monopolies. The monopoly power of the multinational life science, agrichemical companies was a recurring theme of the inquiry. The committee wishes to ensure that the highest level of protection is provided to Australian IP.

Recommendation 24

6.30 **The committee recommends that IP Australia:**

- **avoid issuing broad patents;**
- **raise the thresholds for granting patents so that they are equivalent to the highest set by overseas countries; and**
- **screen patent applications more rigorously.**

47 Intellectual Property & Competition Review Committee, *Interim Report*, April 2000, pp. 52-3.

Recommendation 25

6.31 **The committee recommends that the *Patent Act 1990* be amended:**

- **to give effect to the changes proposed in Recommendation 24; and**
- **to clarify that the long term interests of end users are as important as the rights of intellectual property owners to benefit from their investment in that intellectual property.**

6.32 The committee also believes that IP Australia's staff must be assisted to carry out their work as efficiently and effectively as possible. The suggestion that IP Australia might share skills with overseas patent offices seems to be one that is worth pursuing. It also appears logical to the committee to require maximum assistance from patent applicants by way of providing relevant information to IP Australia.

Recommendation 26

6.33 **The committee recommends that IP Australia develop and implement mechanisms for sharing skills with other patent offices.**

6.34 One of the issues brought to the committee's attention concerned the ongoing debate about whether gene sequences should be regarded as scientific discoveries, which are not patentable, or technological innovations, which are.[48] The committee is aware that there are those who argue that gene sequences should be patentable. For example, in a submission to the IPCRC, Uniquest argued that gene sequences and the proteins they encode are no different from the patentable biologically active chemical entities used in crop protection as pesticides and herbicides. Failure to patent genetic sequences might inhibit biotechnological innovation.[49] Avcare mounted a similar argument,[50] but this view has been challenged.[51]

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48 Intellectual Property & Competition Review Committee, *Interim Report*, April 2000, pp. 42-3; Revesz, *Trade-Related Aspects of Intellectual Property Rights*, Productivity Commission Staff Research Paper, AGPS, Canberra, 1999, p. 12.

49 Uniquest, Submission no. 29 to the Intellectual Property & Competition Review, p. 4.

6.35 On the other hand, others object to the patenting of all genetic material, particularly food plants, on a number of grounds. Their objections are summarised below.[52]

- There are moral and spiritual objections to treating life as a commodity. It is inappropriate to draw on precedents developed to serve other industries.
- Food plants are not owned by one group of people but are part of our human heritage from the past.
- If they belong to anyone, it is to their traditional owners, whose rights have been ignored when plants such as the Neem tree and Basmati rice have been patented. This is biopiracy.
- Patents on the genetic material of food plants put these plants under the control of private corporations. When private firms gain exclusive control over the IP needed to grow the food on which we rely for survival, they will effectively own the future, determining the direction and shape of agricultural development and the types of food available.

6.36 The committee believes that the current practice in Australia of regarding the identification of genetic sequences as mere discoveries meets some of the objections of those opposing patents on living organisms, while still encouraging innovation. The committee is aware the IPCRC reached a similar conclusion in its interim report, and is seeking to more clearly define the distinction between discovery and invention.[53]

Time limits on patents

6.37 The term of patents on agricultural biotechnology is 20 years, in keeping with the minimum requirement imposed by TRIPS. It is possible that a longer patent period is needed to make sure that the cost of bringing GMOs to the market can be recouped. There is often only eight to ten years left on patents after commercial release.[54]

6.38 Pharmaceutical patents can be extended to 25 years, in recognition of the delays that regulatory requirements may impose on commercialisation. A similar case can be made for lengthening the patent period for

50 Avcare, Submission no. 42 to the Intellectual Property & Competition Review, p. 26.

51 Dr Charles Lawson, Submission no. 19, p. 2.

52 Australian GeneEthics Network, Submission no. 71, p. 11; National Genetic Awareness Alliance, Submission no. 54, p. 4; S Shulman, *Owning the Future*, Houghton Mifflin Company, New York, 1999, pp. 87, 99-100.

53 Intellectual Property & Competition Review Committee, *Interim Report*, April 2000, pp. 43-4.

54 Dr Brian Booth, Submission no. 7, p. 2.

biotechnology innovations.[55] However, the committee is aware that others believe that there is insufficient evidence to justify either a shortening or lengthening of the patent term.[56]

6.39 The New South Wales government asked:

> … whether the time limit applying to patent protection should be standardised in terms of years, or should relate to the period of time required for innovators to derive a 'normal' return on their investment.[57]

It appears to the committee that the latter course would introduce an extra degree of complexity to the patent system that is not justified.

Impact of patents on agricultural biotechnology R&D

6.40 As discussed in Chapter 5, much of Australia's agricultural R&D is carried out by publicly funded bodies with obligations to make their IP widely available. By contrast, the R&D carried out by private firms is unambiguously owned by them and used for their own financial benefit. Consequently, they are more likely to be responsive to the innovation incentive provided by patent protection than are publicly funded R&D bodies.

6.41 If the international IP regime is strengthened, as some anticipate it will be (see below), the property rights that attach to intellectual endeavour will become more widely acknowledged. Under these circumstances, the incentive effects of the patent system are likely to increase. Asker and Stoeckel predicted that the impact of this on Australian R&D will depend on the relative mix of 'private' and 'public' R&D in the country. They pointed out that:

> … the high proportion of public R&D in agriculture tends to suggest that agricultural industry is unlikely to be in a position to be able to extract the maximum benefit from the rewards and incentives offered by a patent system.[58]

The committee received confirmation that this is happening, as detailed in Chapter 5.

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55 Avcare, Submission no. 42 to the Intellectual Property & Competition Review, p. 25; Department of Industry, Science and Resources, Submission no. 34 to the Intellectual Property & Competition Review, p. 24.

56 Dr Charles Lawson, Submission no. 19, p. 3; J Revesz, *Trade-Related Aspects of Intellectual Property Rights*, Productivity Commission Staff Research Paper, AGPS, Canberra, 1999, p. 26.

57 New South Wales government, Submission no. 72, p. 9.

58 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, pp. 38-9.

6.42 Asker and Stoeckel described the dilemmas facing publicly funded R&D organisations in relation to how they manage their IP.

> Who should the returns of R&D, which can be realised through the patent, be distributed to? If the organisation keeps the funds, this suggests there is less need for external funding, but which funding body should reduce its contribution? If the returns are transferred to industry, how is it done? If the organisation is giving returns to industry, why is the taxpayer, in effect, subsidising a virtually private firm?
>
> In this instance, the solution seems to be to set up the organisation according to the normal model of corporate governance with industry and the government having the same position as shareholders. However, this begs the question why is the government involved in what is now a private organisation?[59]

6.43 Because the commercial exploitation of IP by an R&D organisation may not be consistent with its mission and purpose, it raises complex issues, which Asker and Stoeckel described thus:

> A public R&D organisation, typically in agriculture, operates to benefit a collection of small producers. The organisation conducts research that is intended to benefit all producers. To reap the rewards afforded by the property rights IP law gives, the public R&D organisation should sell its IP to the very firms that the IP was created to benefit. This does not seem a problem except where the purpose of the R&D organisation is to give an R&D subsidy to the industry. The price involved in selling the R&D may offset the subsidy intended to be created.
>
> The R&D organisation is also bound by the fact that it cannot just give away its IP to the industry that it is trying to benefit. If it does this, the members of the industry may sell the IP to others. In this way, the organisation may get next to no benefit from owning IP. This would mean obtaining a patent would be too costly when compared with the benefit.[60]

6.44 The committee considered user views of the dilemmas facing publicly funded R&D organisations in Chapter 5. It recommended a review of the arrangements used by these organisations to make their output available to others. It suggested that best practice be identified and information disseminated.

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59 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, p. 40.

60 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, p. 40.

6.45 A further factor that might inhibit innovation in public institutions is that their researchers are less likely to receive rewards for their innovations than their counterparts in the private sector. The committee was told in private meetings that this was a problem that needs to be addressed. The committee agrees.

6.46 The committee believes that acknowledging and rewarding researchers when their innovations lead to commercial success is important in stimulating a commercial focus for research. Rewards also help to retain Australian researchers in this country and attract skilled people from overseas.

Recommendation 27

6.47 **The committee recommends that research institutions that receive Commonwealth funding and do not at present acknowledge and reward their researchers for innovative output that leads to commercial success, be required to do so as a condition of receiving public funding.**

Plant breeders' rights

6.48 The *Plant Breeders' Rights Act 1994* permits developers of plant varieties to benefit commercially from their work in developing those varieties. At the same time, it allows access to new plant varieties for public and private uses, such as further improving them. PBRs do not extend to genes and the processes for manipulating them, but they do cover GM varieties. PBRs represent a reasonably easy and inexpensive method to protect all new varieties, and are potentially available to the breeders of all varieties, regardless of size. Further information about PBRs is provided in Appendix C.

6.49 There remain unresolved issues relating to the current framework for protecting PBRs. Three problems were identified:

- farm saving of seed which is prevalent, for example, in the grains industry;
- the difficulty experienced by owners of variety rights in recouping their financial outlays; and

- the absence of benefit to the owners of rights to varieties that are subsequently genetically modified.

End point royalties

6.50 Producers saving seed for future sowing limit the collection of seed royalties and therefore the return to the developer of the variety. This situation can be rectified by collecting EPRs on grain produced or on processed products of the grain. The committee is aware that there are difficulties in collecting EPRs. The ABB suggested that the collection of EPRs is difficult in deregulated markets unless closed loop marketing is used. Although public breeding institutions have not favoured closed loop marketing to date, the ABB saw a place for it in the market development of a variety and giving a return to breeders.[61] The CRCA suggested that, with the withdrawal of government funds for plant breeding activities, the collection of EPRs will be essential to maintain the standard of Australia's crop varieties.[62]

6.51 EPRs have been under discussion by the grains industry. At one stage, consideration was given to the possibility that EPRs might be collected by AFFA's Levies Management Unit at cost to the owner of the variety.[63] However, EPRs are now recognised as a purely commercial arrangement between producers and breeders, supported by contract law. The basis for collecting EPRs will be clearer in the light of work being undertaken at present in relation to the PBR Act. The committee supports amendments to the act to clarify and facilitate the commercial relationship between breeders and producers.

Genetic manipulation of protected varieties

6.52 The New South Wales government expressed concerns that PBRs allow protected varieties to be used for genetic manipulation in breeding programs and research without reference to the original owner of the variety.[64] The Western Australian government also believed that the PBR Act may not adequately recognise the efforts of the first breeder of the variety. It suggested that 'advances in biotechnology are allowing rapid insertion of important genes into well established PBR varieties that may devalue the rights of the breeder of the first variety'.[65]

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61 Australian Barley Board, Submission no. 60, p. 7.

62 Cooperative Research Centres Association, Submission no. 40, p. 9.

63 For example, NSW Farmers' Association, Submission no. 38, p. 10.

64 New South Wales government, Submission no. 72, p. 10.

65 Agriculture Western Australia, Submission no. 48, p. 4.

6.53 The Australian Raw Sugar Industry illustrated the disadvantage it would suffer under the current legislation.

> Our concern is that a variety developed by the industry and paid for through the BSES [Bureau of Sugar Experiment Stations] research levy could be transformed with a single gene which adds one distinct characteristic (e.g. herbicide resistance). Under current legislation, the organisation creating this transformed variety can claim PVR [Plant Variety Rights], while the original plant breeder that provided all of the other useful genes in the variety has no further claim.[66]

The sugar industry claimed that failure to protect the IP of the original breeder is contrary to the International Convention for the Protection of New Varieties of Plants and to Australia's best interests.

> This provision would mean that large multinational companies can obtain access to PVR protected varieties, transform them, and then charge growers for using the variety even though an industry's own organisation bred the original variety.[67]

6.54 Furthermore, the holders of varieties under PBR 'stand to have their better varieties genetically modified and then patented without any royalties accruing to the original PBR holder in the longer term'.[68] The sugar industry recommended that the PBR Act be changed to take into account the rights of the initial breeder of varieties which are subsequently genetically transformed.[69]

6.55 The committee understands that the PBR Act:

- recognises the major contribution of the first variety by allowing joint control of the derived variety, where the incremental improvement produced by a subsequent breeder is minor; but
- allows the breeder of the derived variety to market the new variety without reference to the breeder of the first variety, where the improvement on the first variety is large.[70]

It appears from the arguments put to the committee that most submissions were based on the premise that genetic modification of varieties would *per se* produce 'large' improvements.

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66 Australian Raw Sugar Industry, Submission no. 64, p. 12.

67 Australian Raw Sugar Industry, Submission no. 64, p. 12.

68 NSW Farmers' Association, Submission no. 38, p. 3.

69 Australian Raw Sugar Industry, Submission no. 64, p. 12.

70 Agriculture, Fisheries and Forestry Australia, Submission no. 77, p. 19.

6.56 There are attractions in the suggestion that the first breeders' rights should be strengthened, but this is likely to inhibit the production of new varieties from existing ones, as well as increase the price of new varieties to growers.[71] The committee concludes that it would not be in the interests of Australian agriculture overall to change the current arrangements.

International arrangements

6.57 Internationally consistent IP laws are to Australia's advantage.[72] They facilitate international trade and investment by eliminating official barriers to these activities and by reducing the transaction costs facing exporters and importers.[73] Support for similar, synchronised laws among nations was expressed in submissions to the inquiry, for example, by the NSW Farmers' Association.[74]

6.58 As indicated at the start of this chapter, Australia's regime for IP protection is comparable to those of its trading partners. However, Australia currently provides stronger protection for biological innovations than other countries in the world, with the possible exception of the USA and Japan. A paper by a Productivity Commission staff member suggested that Australia's IP protection 'goes much beyond' the minimum requirements imposed by TRIPS. Under these circumstances, lowering Australian standards to maximise gains to Australia might be advisable unless Australian standards are adopted globally.[75] Asker and Stoeckel, in their report on IP in agricultural trade, advocated the latter course: negotiating to strengthen TRIPS' minimum requirements to mirror Australia's domestic law.[76]

6.59 The committee is aware that globalisation is putting pressure on nations not only to strengthen their IP laws but also to harmonise them.[77] TRIPS is currently under review, and any revision of Article 27.3(B), which covers the patenting of biological material, will be relevant here. Some of the issues likely to be considered in this context are:

- clarification of the current wording of Article 27.3(B);

71 Agriculture, Fisheries and Forestry Australia, Submission no. 77, p. 18.

72 Department of Foreign Affairs and Trade, Submission no. 70, p. 5.

73 Intellectual Property & Competition Review Committee, *Issues Paper*, September, 1999, p. 7.

74 NSW Farmers' Association, Submission no. 38, p. 9.

75 J Revesz, *Trade-Related Aspects of Intellectual Property Rights*, Productivity Commission Staff Research Paper, AGPS, Canberra, 1999, pp. 31-2.

76 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, p. 35.

77 Agriculture, Fisheries and Forestry Australia, Submission no. 77, p. 22.

- increased compliance with existing obligations by developing countries; and
- mandatory protection of bioengineering innovations above the microorganism level.[78]

6.60 It has been suggested that all these developments would be in Australia's interests as they would clarify the application of patent law to biotechnology, provide more uniform protection and increase compliance. Stronger IP regimes in developing countries would give greater certainty to Australian companies doing business in those countries.[79] Developing countries, concerned about such matters as farmers' rights, are likely to oppose such moves, however.[80]

6.61 The committee believes that the Commonwealth government's position in negotiations over changes to TRIPS should be to strengthen the international IP regime.

Recommendation 28

6.62 **The committee recommends that, in international negotiations, the Commonwealth government support the strengthening of the provisions of the Agreement on Trade Related Aspects of Intellectual Property and assist in establishing stronger intellectual property systems in developing countries in Asia.**

Alternative means of protecting intellectual property

6.63 Most submissions to the inquiry saw patents as the best way of protecting IP in biotechnology. The New South Wales government drew attention to the views of SCARM's High Level Working Group on Gene Technology; the group regarded patents as the preferred instrument for

78 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, pp. xiv, 8; J Revesz, *Trade-Related Aspects of Intellectual Property Rights*, Productivity Commission Staff Research Paper, AGPS, Canberra, 1999, p. 95.

79 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, pp. 32, 34, 37.

80 J Revesz, *Trade-Related Aspects of Intellectual Property Rights*, Productivity Commission Staff Research Paper, AGPS, Canberra, 1999, p. 94.

commercialising innovations derived from gene technology. Australian patent law provides the necessary legal and commercial protection.[81]

6.64 However, according to the Queensland government:

> The rate of innovation should be considered in determining appropriate mechanisms for protection of intellectual property. The emergence of genomics is accelerating the rate of discovery and application to an extent that may render many patents redundant. Perhaps the cost of patent filings may not be warranted in many cases, relying instead on trade secrecy — particularly for innovations directed specifically at Australian production and marketing systems.[82]

6.65 The importance of trade secrets has increased in recent years 'because the pace of incremental innovations in dynamic sectors … has rendered patent protection less relevant'. Trade secrets may be protected by contracts, but may also rely on legal injunctions and, more usually, common law remedies for breaches of confidence. They are effective in limiting the loss of commercially significant information to competitors. However, they also inhibit further innovation and the transfer of technologies because, unlike patents, no information about the secret is disclosed and no time limit applies.[83]

6.66 Biotechnological methods of protecting IP have also been proposed, most notably terminator technology. An outcry accompanied the first revelation that a patent on that terminology had been acquired. Inserting terminator genes into a variety that would render it sterile was seen as unacceptable. Terminator technology would prevent farm saving of seed, which would be particularly disadvantageous for poor farmers, and enable the genes' owners to extract monopoly rents. Monsanto subsequently gave an undertaking not to release terminator technology.

6.67 More subtle biotechnological approaches to limiting the use of GMOs are theoretically possible, however. Turning off the GM trait after the first generation while maintaining the organism's viability would be a solution to the objections raised to terminator technology.

6.68 The Queensland government proposed that alternatives to patents and PBRs should be considered in the context of a review of the appropriateness of the Australia's IP system for the innovators and users

81 New South Wales government, Submission no. 72, p. 9.

82 Queensland government, Submission no. 79, p. 5.

83 B Bailey, *New Ideas, Old Laws: Copyright, Patents, Trade Marks and Designs, and How to Avoid Plagiarism*, Department of the Parliamentary Library, Background Paper 12, 1995-96, p. 10; J Revesz, *Trade-Related Aspects of Intellectual Property Rights*, Productivity Commission Staff Research Paper, AGPS, Canberra, 1999, pp. 23-4.

of biotechnology.[84] The committee is not convinced that such an inquiry is necessary. It understands that trade secrets will be used where they benefit the IP's owner, for example, if the product using the IP cannot be easily reverse engineered or is likely to become obsolete very quickly. With other products, patents will provide more effective protection. Similarly, the committee expects that biotechnological protection of IP will be employed where appropriate.

Managing intellectual property

Intellectual property skills

6.69 IP is expected to grow in significance to Australian agriculture as global competition increases. This trend will be driven by:

- continuing falls in commodity prices as yields rise, particularly in the developing world; and
- life style and attitudinal change among consumers in favour of products of higher, more consistent quality and greater diversity.[85]

In this context:

> Product differentiation and innovation are likely to be increasingly important to agricultural industries in the future. As competition in world markets continues to intensify, the greatest advantage may accrue to those producers who use intellectual property (IP) to the greatest advantage.[86]

6.70 In this context, the committee was concerned to hear from many witnesses to the inquiry that the level of skills in, and understanding of, IP is inadequate.[87] According to BA:

> Lack of appropriate intellectual property protection and management strategies has led to the loss of commercialisation opportunities for a number of key Australian innovations. These losses can be far greater than the costs of obtaining intellectual property rights. Therefore, it is important that firms and researchers have a good understanding of how to strategically

84 Queensland government, Submission no. 79, p. 5.

85 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, p. 1.

86 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, p. xi.

87 Grains Research and Development Corporation, Submission no. 47, p. 15.

> manage their intellectual property, for example, when to patent or trade mark, and in which countries, and when to rely on other strategies.[88]

6.71 In private meetings with gene technology businesses, it was stressed to the committee that IP considerations must be a part of any project from the very beginning. The nature of this relationship and the activities that need attention at each stage of the process of bringing research findings to the market are illustrated in Figure 6.1.

6.72 The first step in a project's design is to make sure that the results of any research planned are not already other people's property and therefore unavailable for commercialisation.[89] Freedom to operate must be addressed at a global level.[90] Twenty-one per cent of the 90 Australian companies surveyed by Ernst & Young in 1999 had at some time abandoned an important biotechnology project because further work was blocked by IP rights held by another organisation. This may reflect an inadequate level of due diligence before undertaking a project,[91] and indicates the need for better in house understanding of IP issues and use of specialist advice.

6.73 In addition to carrying out one's own research, it is usually necessary to license-in some of the technology needed. Because many pieces of technology are required to produce a GMO, it is highly likely that all projects will involve locating the owners of the relevant technologies and negotiating rights to use them. The GRDC reported that research priorities can shift dramatically when access to, and the costs of, any prerequisite IP are considered.[92]

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88 *Developing Australia's Biotechnology Future: Discussion Paper*, September 1999, Biotechnology Australia, p. 26.

89 Cooperative Centre for Tropical Plant Pathology, Submission no. 21, p. 4.

90 Avcare, Submission no. 61, p. 6.

91 V Santer, 'Intellectual property and patent issues', in *Australian Biotechnology Report 1999*, Ernst & Young, p. 35.

92 Grains Research and Development Corporation, Submission no. 47, p. 15.

Figure 6.1. Diagram to show the IP issues that need to be addressed at each stage in R & D

	research	development	commercial
R & D:	•set objectives •identify milestones •develop strategies •experiment, repeat, review	•extrapolate to other systems •verify stability of outcomes •select best prototype •optimise performance	•seek partners •negotiate agreements •establish legal framework

IP issues:	•ensure not already done •locate relevant 3rd party rights •decide whether to make or buy •protect IP as it arises	•monitor 3rd party positions •negotiate at appropriate time •formulate IP protection strategies •continue prosecution	•maintain rights •prosecute infringers •monitor competitors

Source: Dr Carol Nottenburg, Center for the Application of Molecular Biology to International Agriculture

6.74 There are alternative approaches to licensing but they involve very wise, well informed decision making. They include:

- ignoring other people's rights and risk challenges from them – this may be a risk worth taking when a patent is near the end of its term; and
- challenging the validity of a patent but this can be a very costly undertaking, US$500,000 as a minimum.

6.75 Smart implementation of IP rights is crucial to the successful use of IP. A firm's decision to enforce its IP rights is often a complicated strategic commercial decision. Mismanaged, IP is liable to impose considerable costs on an organisation and erode any benefit IP may have brought.[93]

6.76 IP cases require highly specialised lawyers, involve very complicated factual detail and are concerned with a body of law that, in relation to biotechnology, is still being developed at a rapid rate.

> Similarly, other firms may anticipate that an IP owner will not choose to enforce their IP rights. It may be apparent that the gains from enforcement do not outweigh the costs, particularly as a patent comes close to the end of its term. … The owner may have been better off licensing their IP in the early stages of the patent, and getting some profits from other firms, rather than finding themselves helpless in the face of patent violation.[94]

6.77 Several elements were identified to the committee as necessary to improve the management of IP in Australia: education, resources to assist decision making, and an environment that enables the most to be gained from Australian IP. A number of initiatives have been taken to provide training and resources.

- BA is running IP management awareness seminars, producing a CD-ROM on IP management and developing a professional training course on the same topic;[95]
- CAMBIA is establishing an informatics centre, funded by the Rockefeller Foundation, to enhance the ability of public sector and small to medium sized businesses to use biotechnology for crops. The centre will provide internet access to IP databases, as well as business and strategic advice.

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93 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, pp. 7, 27-8.

94 J Asker & A Stoeckel, *Intellectual Property in Agricultural Trade*, Rural Industries Research and Development Corporation, 1999, p. 7.

95 Department of Industry, Science and Resources, Submission no. 84, p. 2.

- The establishment of the Australian Centre for Intellectual Property in Agriculture at the Australian National University was announced in March 2000. It is being set up with funding from the university, the GRDC and the Commonwealth government. Biologists and lawyers will work together to provide education and training and, through partnerships with other centres such as CAMBIA, develop a national network in IP law and policy. The centre's activities will target industry, professionals in the field, students, farmers and the public.[96]
- In recent years IP Australia has undertaken 'major marketing and awareness-raising activities … to ensure that businesses effectively use the IP rights available to them by law'.[97] With BA, it is providing information about IP protection through its web site and CDs, and training and other materials for small and medium businesses, schools and universities.

6.78 Other suggestions have also been made. From CSD came the idea that it would be useful to help those who need access to key technologies to develop relationships with the owners of these technologies.[98] It would also be useful to provide a framework for research and industry groups to network and share IP management skills with legal, commercial, and patent experts.[99]

6.79 The importance of providing resources of this kind was underlined by the Department of Industry, Science and Resources' comment in relation to doing business overseas that:

> … a number of government programs are in place to assist firms (particularly small and medium enterprises) in gaining access to information about other countries' requirements. … but there is little available information on overseas intellectual property systems. For example, Austrade can provide exporters with considerable information about the United States' food, automotive, and engineering markets, but has no comparable level of information on the United States' intellectual property system.[100]

6.80 The committee appreciates that R&D is now being commercialised in an environment where there is a much greater emphasis than before on

96 Professor John Lovett (GRDC) and Professor Michael Cooper (ANU), 'New centre for intellectual property in agriculture at ANU', Media release; Professor John Hearn, Interview on ABC radio, Canberra 2CN, 7 March 2000.

97 IP Australia, *1999 Corporate Report*, p. 29.

98 Cotton Seed Distributors Ltd, Transcript of evidence, 18 October 1999, p. 237.

99 Prime Minister's Science, Engineering and Innovation Council quoted by P French, *Biotechnology in Australia*, FASTS Occasional Paper Series, No 1, January 1999, section 6.

100 Department of Industry, Science and Resources, Submission no. 34 to the Intellectual Property & Competition Review, p. 12.

exploiting IP and extracting commercial returns from it. It recognises the need to upgrade the national skills and resources in IP protection, and supports the initiatives that are being taken to improve them. The committee believes that the success of these initiatives should be monitored so that they can be fine tuned quickly in the light of experience.

Recommendation 29

6.81 **The committee recommends that the effectiveness of the initiatives to upgrade the level and volume of intellectual property skills in Australia be monitored, reviewed, and improved when gaps in required skills are identified.**

A national intellectual property strategy

6.82 The committee was told that a national strategy to invest in agricultural biotechnology IP should be developed. Such a strategy should aim to reduce Australian growers' input costs and increase their productivity. It should also minimise Australia's exposure to overseas IP and provide Australian businesses with commercial leverage.[101]

6.83 The committee is aware that one of the issues to be addressed by the National Biotechnology Strategy is the management of IP in Australia. The committee supports this initiative, and understands that the strategy will be announced shortly.

101 National Farmers' Federation, Submission no. 36, p. 13; Western Australian government, Submission no. 48, p. 2.

7

Regulation

Introduction

7.1 Regulation of GMOs has been established to protect human health and the environment from risks that may arise from the use of GMOs, while at the same time assisting organisations developing and selling GMOs by indicating clearly what is required of these organisations. In terms of primary producer access to gene technology, there are several regulatory processes of significance:

- those that govern their release for commercial use by farmers;
- those that assess food safety and impose labelling requirements, for example, for GM content; and
- international agreements, such as the Biosafety Protocol.

Regulating GMOs

7.2 Changes are being made to the system that regulates GMOs in Australia. It is expected that the Gene Technology Bill will be introduced into Parliament in the near future with a view to new arrangements coming into force in January 2001. **The committee believes that the bill's provisions must ensure that a more comprehensive, independent and rigorous regulatory system for GMOs is established than exists at present.** The need for an improved regulatory regime stems from three developments as gene technology has expanded:

- an increasing number of GMOs that are not directly regulated by the existing agencies, for example, herbicide tolerant crops;

- more crops reaching the stage at which their proponents are likely to apply for their commercial release; and
- community and industry expectations.[1]

Current legislative arrangements[2]

7.3 At present, there is no single regulatory body for GMOs; a number of different agencies are involved. The nature of each GMO determines which agency (or agencies) is (are) responsible for regulating it.

- Food is regulated under the *Australia New Zealand Food Authority Act 1991*, which is administered by ANZFA and accompanying state and territory legislation. ANZFA alone among regulatory agencies administers a standard specific to GMOs; the other agencies assess, or would assess, GM products in the same way as any other product.
- Therapeutic goods are controlled by the *Therapeutic Goods Administration Act 1989*, which is administered by the Therapeutic Goods Administration.
- Agricultural and veterinary chemicals fall under the *Agricultural and Veterinary Chemicals Code Act 1994*, which is administered by the NRA and accompanying state and territory legislation. The NRA was involved in regulating the release of Ingard® cotton, on the grounds that the genetic modification of the cotton plants had caused the plants to produce a pesticide. It would also be involved with respect to herbicide tolerant crops in so far as it would need to approve the use of the relevant herbicide to take into account that the crop was modified.[3]
- Industrial chemicals are covered by the *Industrial Chemicals (Notification and Assessment) Act 1989*, which is administered by the National Occupational Health and Safety Commission and accompanying state and territory legislation.
- Imports and exports are regulated by the *Quarantine Act 1908*, the *Imported Food Control Act 1992*, and the *Export Control Act 1982*, which are administered by the Australian Quarantine and Inspection Service (AQIS). Imports and exports are also regulated by wildlife protection legislation administered by EA.

1 *Explanatory Guide to the Draft Commonwealth Gene Technology Bill 2000*, December 1999, p. 5.

2 Information in this and following sections of the chapter draw on Submission no. 78 from the Interim Office of the Gene Technology Regulator.

3 Grains Research and Development Corporation, Submission no. 47, p. 12.

7.4 GMAC oversees all research work in Australia involving the use of GMOs and genetic modification techniques. It scrutinises all stages in the development of GMOs from proposals for research through to their general release into the environment. GMAC's work underpins all the regulatory arrangements described above.

Interim arrangements

7.5 Since the inquiry was announced at the end of March 1999, changes to the regulatory system have been introduced. In May 1999, interim arrangements were put in place while legislation to change the current system was developed with community and state and territory government input. The IOGTR was established in the Department of Health and Aged Care (DHAC), and GMAC was moved to that department from the Department of Industry, Science and Resources. Until the new legislative controls are in place, the Minister for Health and Aged Care will make decisions, in consultation with other ministers as appropriate, on the general release of GMOs.

7.6 The IOGTR is part of the Therapeutic Goods Administration of DHAC, and is responsible for:

- regulating all aspects of the development, production and use of GMOs and their products, where no existing regulatory body has responsibility;
- working with other regulatory bodies to ensure the consistent application of standards and to harmonise genetic safety assessments across all systems of regulation; and
- undertaking or commissioning research in risk assessment.

IOGTR's position in the health portfolio places it at arms length from industry programs, and reflects the government's view that protecting the environment and the public's health and safety are the paramount concerns.

7.7 Other aspects of the interim arrangements also contribute to making the regulatory process more transparent, accountable and rigorous.

- GMAC's operations are being revised, for example, to include more public input, more publicly available information and a broader basis for GMO risk assessment than at present. Both biosafety and agricultural sustainability must be considered.
- Contracts and agreements will be finalised between the government and proponents of commercial releases of GMOs to provide for greater assurance of compliance with the conditions imposed on releases.

Regulating agricultural GMOs

Deficiencies

7.8 This section summarises views expressed in submissions and during public hearings. It should be remembered, however, that most of the input to the inquiry was made before the draft Gene Technology Bill was released in December 1999, and some of it before the interim arrangements were put in place in May 1999.

7.9 There was general agreement that the regulatory regime that was in place in early 1999 was deficient. State governments, industry, and groups engaged in R&D complained that the lack of a clear regulatory pathway was hampering the introduction of GM varieties.[4] Uncertainty was a disincentive both to innovation in Australia, to exporters and to overseas corporations that were considering bringing their products to the Australian market.[5] The Victorian government commented that:

> In the absence of a regulatory system in Australia which provides a clearly defined pathway to the market, gene technology owners face high costs and high risks of failure. …
>
> Until an effective regulatory system is in place, gene technology owners will not be able to invest with any certainty in the infrastructure needed to commercialise GM varieties.[6]

7.10 An example of the difficulties encountered in the face of regulatory deficiencies was provided to the committee by CSIRO. CSIRO's submission described how new regulatory requirements involving the NRA were developed in response to an application for the commercial release of Bt cotton. The submission continued:

> At the time it caused some degree of uncertainty and costs to meet newly developed NRA regulatory requirements but nevertheless provided a pathway by which the entire new cropping system could be introduced, monitored and managed in the field.

In addition, at that time, 'similar arrangements [were] not in place … for introducing new genes to confer resistance to plant diseases such as rust, nematodes, scald, etc or indeed when breeding herbicide tolerant crops'.[7]

4 For example, New South Wales government, Submission no. 72, p. 8.

5 Queensland government, Submission no. 79, p. 4.

6 Victorian government, Submission no. 67, p. 3.

7 CSIRO, Submission no. 56, pp. 3-4.

7.11 Nor are they in place for approving GM livestock.[8] CSIRO recounted its experience with GM pigs:

> Bresagen produced a line of commercially viable pigs with enhanced growth hormone production with the advantage that the pigs grew faster for a given amount of food, putting on more muscle and less fat. Because there was no regulatory agency prepared to approve the use of these animals for human consumption and declare the technology safe, Bunge has slaughtered all the pigs and the germplasm is in existence as semen (and perhaps ova) stored in liquid nitrogen. It is highly likely that this technology will go overseas. It is not the inability of the Australian company that produced the pigs to commercialise them but the lack of a regulatory pathway that has caused the problem.[9]

7.12 Regulatory deficiencies slowed assessment and release of varieties submitted for approval.[10] They were seen as likely to become a more critical issue in the future. The committee is aware that the time taken to gain regulatory approval was among the three most frequently mentioned hurdles in commercialising biotechnology in Australia, according to 90 companies surveyed by Ernst and Young.[11] Regulatory delays increased the cost of bringing GMOs to market and contributed to regulation, along with IP, being key cost items in producing GM varieties. The impact of delays on cost is particularly significant, given that regulatory costs can amount to $50-100 million.[12] The application of gene technology to minor crops was particularly likely to be affected by regulatory costs.[13]

7.13 Others found Australia's regulation of GMOs defective for different reasons.[14]

- Compliance with guidelines developed by GMAC and SCARM[15] is voluntary. Independent verification of compliance with these

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8 Academy of Science, Submission no. 62, p. 3.

9 CSIRO, Submission no. 56, Attachment 2, p. 17.

10 National Farmers' Federation, Submission no. 36, p. 2.

11 Ernst & Young, *Australian Biotechnology Report*, Commonwealth of Australia, 1999, p. 45.

12 Cotton Seed Distributors Ltd, Transcript of evidence, 18 October 1999, p. 236.

13 Centre for Legumes in Mediterranean Agriculture, Submission no. 14, p. 4; Cooperative Research Centres Association, Submission no. 40, p. 8; Grain Biotechnology Australia, Submission no. 68, p. 4.

14 Australian GeneEthics Network, Submission no. 71, p. 12; Organic Federation of Australia, Submission no. 24, p. 5; Supplementary submission no. 73, p. 3; Senator Stott-Despoja, Submission no. 28, pp. 6-7.

15 Genetic Manipulation Advisory Committee, *Guidelines for the Deliberate Release of Genetically Manipulated Organisms*, April 1998; Working Group of the Standing Committee on Agriculture

guidelines is not carried out, for example, in relation to refugia among Bt cotton crops. GMAC lacks the statutory power to enforce its decisions, and no penalties are applied to persons who fail to observe the guidelines.

- Both GMAC and the institutional biosafety committees that oversee the implementation of GMAC guidelines in individual companies and institutions are dominated by proponents of gene technology. These groups operate without adequate accountability.
- The buffer zones around GM crops are insufficient to protect organic and GM free crops growing nearby.

7.14 Several witnesses to the inquiry welcomed the establishment of the IOGTR, and supported the changes made under the interim arrangements.[16] Others, while approving the changes, regretted the slow pace at which they were being introduced.[17] The NFF commented that 'we are behind the US and Europe in establishing a regulatory framework'.[18] AAA claimed that:

> … Roundup Ready cotton was about to get its final approval through the previous process; but with the introduction of the Interim Office of the Gene Technology Regulator, that has been set back a year.[19]

7.15 The siting of the OGTR in DHAC was seen as reassuring to those anxious to ensure that the health impacts of GMOs are adequately regulated. However, users of gene technology in agriculture were concerned that their interests might not be given sufficient attention.[20] Mechanisms by which the interests of primary producers could be brought to the regulator's attention were discussed in submissions to the inquiry.[21] For example, regular consultation by DHAC with Commonwealth, state and territory agriculture agencies and CSIRO, among others, was recommended by the New South Wales government.[22]

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and Resource Management, *Good Agricultural Practice Guidelines for the Use of Genetically Modified Plants*, March 1999.

16 Australian Barley Board, Submission no. 60, p. 9; Australian Biotechnology Association, Submission no. 39, p. 8; CSIRO, Submission no. 56, p. 4; industry participants at a private meeting held in Perth in July 1999; Western Australian government, Submission no. 48, p. 5.

17 Agrifood Alliance, Submission no. 37, p. 5.

18 National Farmers' Federation, Submission no. 36, p. 15.

19 Agrifood Alliance Australia, Transcript of evidence, 29 September 1999, p. 192.

20 Grains Council of Australia, Transcript of evidence, 30 August 1999, p. 134.

21 Grains Council of Australia, Submission no. 65, p. 4; CSIRO, Submission no. 56, p. 4.

22 New South Wales government, Submission no. 72, p. 9.

7.16 **The committee believes that it is entirely appropriate for the OGTR to be in the health portfolio, given the level of concern about the possible risks that GMOs pose.** Furthermore, the committee feels that those who suggested meetings between government agricultural agencies and DHAC are missing the point that the GTR is to be an independent statutory office holder. **It is vitally important in establishing public trust in the regulatory system that the regulator is seen to be free of commercial pressures.**

7.17 The committee was very concerned to hear allegations earlier this year that Aventis' (formerly AgrEvo) trials of herbicide tolerant canola in the Mount Gambier area of South Australia had breached GMAC guidelines. It is even more worried by the manner in which the IOGTR has investigated the alleged breaches, in particular its tardiness in completing its investigation. The IOGTR began its examination of the allegations on 24 March 2000[23] and, as at 18 May, the results of this examination had not even been forwarded to the Minister for Health and Aged Care,[24] let alone been publicly released.

7.18 The committee is of the view that the alleged breaches would have been much less likely to have occurred if stringent, transparent regulatory processes, such as those described in the next sections of this chapter, had been in place. The committee is unanimous in believing that rigorous, independent regulatory processes must be instituted as quickly as possible. A more prompt, open, transparent approach must be taken to breaches of guidelines. It is essential that the OGTR act much more efficiently and effectively than the IOGTR has been able to if it is to reassure the Australian people that their interests are being strenuously protected. If this does not happen, public confidence in GMOs and their regulation will be badly prejudiced.

Characteristics of the ideal regulatory system

7.19 The type of regulatory system that is needed was described in many submissions to the inquiry. The importance of getting it right was also stressed. This was seen as critical to public acceptance of GMOs in agriculture and food, as well as to commercialising new inventions.[25] For example, with respect to cotton, CSIRO emphasised that:

23 Interim Office of the Gene Technology Regulator, Exhibit no. 7, p. p. 1.

24 Interim Office of the Gene Technology Regulator, covering letter to Supplementary submission no. 87.

25 AgrEvo, Submission no. 55, p. 4; CSIRO, Submission, no. 56, p. 1.

> This technology is critically important for the future of the industry, and if it is mismanaged it will go the same way as the chemical insecticides and we will waste it.[26]

7.20 Regulation should be comprehensive, clear, rigorous, impartial, independent, objective, transparent, accountable, and put in place as soon as possible.[27] Clarity depends on having in place such elements as defined and documented processes, accepted standards and codes, clear data requirements, and assessment reports.[28] Independent, impartial assessments could be assured by:

- basing assessments on replicable findings only; and
- requiring the same type of peer review of the research evidence submitted by commercial companies to the regulatory bodies as is applied to published research.[29]

A comprehensive, rigorous regime would also require post approval monitoring of compliance with the conditions imposed on those using GMOs and effective sanctions to maximise compliance.[30]

7.21 The regulatory regime must provide confidence to the community that their health and the environment are being adequately protected while, at the same time, giving industry and farmers certainty about the requirements imposed on them.[31] These requirements should be the minimum to effectively and efficiently ensure health and environmental safety.[32]

7.22 Another view put to the committee was that government also has a clear responsibility to regulate to protect the organic and GM free food industries from 'contamination' by GMOs. Such measures as wider buffer

26 CSIRO, Transcript of evidence, 18 October 1999, pp. 207-8.

27 For example, Agriculture, Fisheries and Forestry Australia, Submission no. 77, p. 1; Agrifood Alliance Australia, Submission no. 37, p. 4; Australian Biotechnology Association, Submission no. 39, p. 6; Australian Food and Grocery Council, Submission no. 59, p. 6; Dairy Research and Development Corporation, Submission no. 15, p. 7; Grain Biotechnology Australia, Submission no. 68, p. 5; National Association for Sustainable Agriculture, Australia, Submission no. 74, p. 2; New South Wales government, Submission no. 72, pp. 8, 13; Organic Federation of Australia, Supplementary submission no. 73, p. 3.

28 Environment Australia, Submission no. 82, p. 16.

29 'BMA response to Chief Medical and Scientific Officers' review of GM foods and health', Media release, 21 May 1999; *First Australian Consensus Conference: Gene Technology in the Food Chain: Lay Panel Report*, Canberra, March 1999, p. 4; Environment Australia, Submission no. 82, p. 16; A Kellow, 'Risk assessment and decision-making for genetically modified foods', *IPA Biotechnology Backgrounder*, no. 1, October 1999, p 4.

30 Organic Federation of Australia, Supplementary submission no. 73, p. 3.

31 Australian Food and Grocery Council, Submission no. 59, p. 10; Avcare, Submission no. 61, p. 7.

32 Australian Food and Grocery Council, Submission no. 59, p. 3.

zones and mandatory reporting of GM crops to local farmers and local, state and regional management authorities were supported.[33]

7.23 Consultation with the public is an important element of regulating gene technology.[34] OFA suggested that:

> Decision-making must include representation from all stakeholders, whereby the needs of consumer, government, science, environmental, health, social, ethical and industry interests are all EQUALLY met.[35]

7.24 In addition, a national, coordinated approach is needed, with flexibility to adjust to rapid changes in the fields of plant breeding and gene technology.[36] The separate elements of the regulatory system, which are described at the start of this chapter, must be fully integrated into the regulatory regime and consistency of approach established across these elements. Duplication must be avoided.[37]

7.25 Furthermore, the system should be internationally competitive,[38] and regulatory clearances harmonised at a global level.[39] If Australia's regulations are consistent with our international obligations and recognised internationally, we will not be seen as erecting non trade barriers nor will we encourage other countries to do likewise.[40]

The case by case, scientifically based approach

7.26 There was one point on which a difference of opinion among witnesses existed in relation to the type of regulatory system needed. It was the extent to which a science-based, case by case approach to regulating GMOs is desirable. Such an approach received support from organisations such as the AFGC, the NFF, representatives of the cotton industry, and the Veterinary Manufacturers and Distributors Association.[41]

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33 Organic Federation of Australia, Supplementary submission no. 73, p. 3.

34 Australian Biotechnology Association, Submission no. 39, p. 6; National Association for Sustainable Agriculture, Australia, Submission no. 74, p. 2; National Genetic Awareness Alliance, Submission no. 54, p. 3.

35 Organic Federation of Australia, Submission no. 24, p. 5.

36 Western Australian government, Submission no. 48, pp. 4-5.

37 Australian Barley Board, Submission no. 60, p. 2; Grains Council of Australia, Submission no. 65, p. 16.

38 Grains Council of Australia, Submission no. 65, p. 16.

39 Avcare, Submission no. 61, p. 7.

40 Australian Barley Board, Submission no. 60, p. 2; National Farmers' Federation, Submission no. 36, p. 15.

41 Representatives of the Australian cotton industry, Transcript of evidence, 18 October 1999, pp. 207, 208; National Farmers' Federation, Submission no. 36, p. 15; The Veterinary Manufacturers and Distributors Association, Submission no. 76, p. 8.

7.27 Others, however, had reservations about it.[42] The consensus conference on gene technology in the food chain held in March 1999 suggested that 'decisions by any regulatory body should take into account more than just science'.[43] Professor Kellow pointed out that risk assessment of GM foods requires 'careful analysis of the best available science, an understanding of the social and psychological factors which will inevitably intrude into the process, and careful policy analysis'. He suggested that, in addition to science, statistics, ethics, economics, sociology, political science and the views of the public must all be involved.[44]

7.28 A British study commented on the narrow remit of regulators and called for broader consideration of the issues relating to the introduction of GM crops and food.[45] This study outlined the limitations of the scientific method and saw it as being ill equipped to tackle the diffuse effects of new technologies. The study also drew attention to the fact that:

> Scientific judgements on risks and uncertainties are underpinned and framed by unavoidably subjective assumptions about the nature, magnitude and relative importance of these uncertainties. These "framing assumptions" can have an overwhelming effect on the results obtained in risk assessments.
>
> … in any given context, more than one set of assumptions may be equally reasonable in appraisal. … The adoption of any particular set of framing assumptions in risk assessment must therefore be justified … in terms of factors such as:
>
> - the legitimacy of the institution making the justification;
> - the degree of democratic accountability to which the institution is subjected; and
> - the ethical acceptability of the assumptions adopted.[46]

7.29 A strong argument was mounted for reliance on a precautionary approach in assessing risks. This is a commonsense attitude to guide action but can be misused. Professor Kellow pointed out that, as everything is capable of

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42 Senator Stott-Despoja, Submission no. 28, p. 7.

43 *First Australian Consensus Conference: Gene Technology in the Food Chain:: Lay Panel Report*, Canberra, March 1999, p. 4.

44 A Kellow, 'Risk assessment and decision-making for genetically modified foods', *IPA Biotechnology Backgrounder*, no. 1, October 1999, pp. 5, 7.

45 *The Politics of GM Food: Risk, Science & Public Trust*, Economic & Social Research Council, Special Briefing No. 5, October 1999, p. 10.

46 *The Politics of GM Food: Risk, Science & Public Trust*, Economic & Social Research Council, Special Briefing No. 5, October 1999, p. 7.

causing harm under some circumstances, it is important that the precautionary principle not be misused. [47] EA suggested that:

> The precautionary principle has particular application to GMOs. Not only could direct damage be serious, but ongoing and extensive because of irreversibility. Once released freely to the environment, a living organism, or a novel gene that has transferred to an unintended host, cannot be 'recalled'. A cautious and conservative approach to risk should be followed where there is insufficient scientific confidence of safety. Successful application of the principle will mean that Australia avoids expensive failures.[48]

7.30 Concerns have been raised that the overall impact of the technology on agriculture and the environment and the long term effects of GMOs may be missed by relying on a case by case approach to regulation. The Royal Society (London) recommended the establishment in the UK of 'an over-arching body or "super-regulator" … to span departmental responsibilities and have an ongoing role to monitor the wider issues associated with the development of GM plants'.[49] The Nuffield Council on Bioethics made a similar recommendation for an independent biotechnology advisory committee 'to consider within a broad remit, the scientific and ethical issues together with the public values associated with GM crops'.[50]

Gene Technology Bill

7.31 The committee was advised by the IOGTR that the Gene Technology Bill will address many of the points listed above, as well as other concerns about the use of GMOs in agriculture which are covered in Chapter 2. The Bill has been developed on the basis of extensive consultation with state and territory government officials, existing regulators, Commonwealth agencies, and a very broad range of non government stakeholders (industry, primary producers, environmental and consumer groups and the R&D sector). A discussion paper was issued by the Commonwealth and State Consultative Group on Gene Technology in October 1999. Taking account of comments made on this paper, a draft version of the bill and an explanatory guide were circulated in December 1999.

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47 A Kellow, 'Risk assessment and decision-making for genetically modified foods', *IPA Biotechnology Backgrounder*, no. 1, October 1999, p. 6.

48 Environment Australia, Submission no. 82, p. 9.

49 The Royal Society, 'Genetically modified plants for food use', 1998, http://www.royalsoc.ac.uk/st_pol40.htm, accessed 12 July 1999.

50 *Genetically Modified Crops: The Ethical and Social Issues*, Nuffield Council on Bioethics, London, May 1999, p. xv.

Consultations on the draft legislation were held in February and early March 2000.

7.32 The bill has not yet been introduced into Parliament, so the final details are not yet known. However, the policy underpinning the legislation is, as advised by the IOGTR:

- to protect public health and safety and the environment;
- to be based on scientific assessment of risks along with consideration of broader issues of national interest and ethics;
- to operate in conjunction with existing regulators and avoid unnecessary duplication;
- to be nationally consistent, efficient and effective;
- to be characterised by transparent and accountable decision making;
- to rely on extensive stakeholder and community involvement; and
- to provide a streamlined and efficient pathway for industry.[51]

7.33 The IOGTR advised the committee that many of the deficiencies noted above have been addressed. The regulatory regime possesses many of the needed characteristics of a best practice system, as listed above. The IOGTR claimed that the governance structure proposed in the new legislation, which is shown in Figure 7.1, reflects good regulatory practice, as seen in other Australian regulatory bodies.[52]

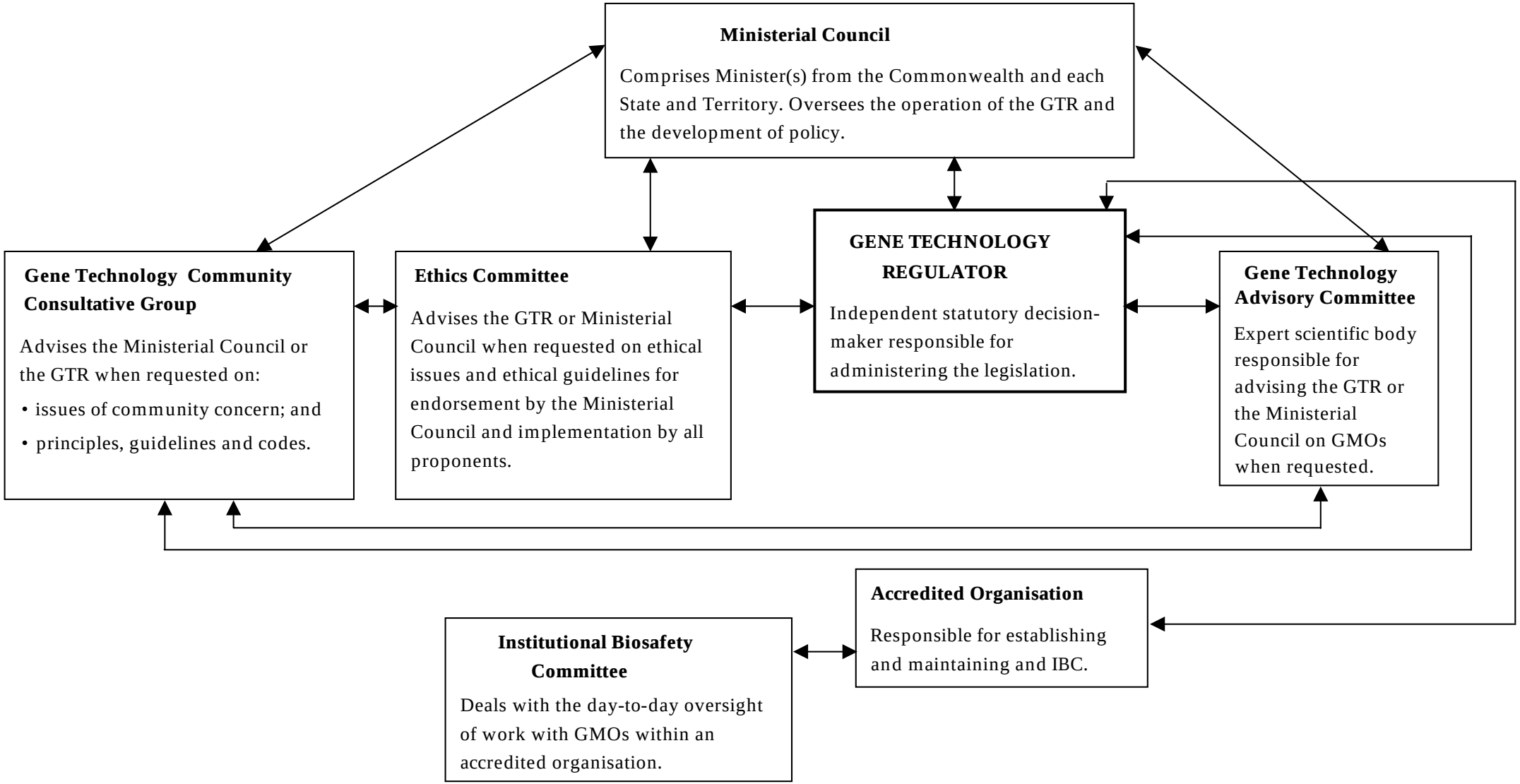
- Comprehensiveness - it covers all GMOs and GM products, from the start of laboratory work onwards, and covers the entire life cycle, including trash and offspring.[53]

51 Office of the Gene Technology Regulator, Exhibit no. 6, p. 2.

52 Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, pp. 6-7.

53 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, p. 270.

Figure 7.1 Proposed governance structure for gene technology regulation*



**Note: it is proposed that all committees and groups have some overlapping membership with the other committees and groups.*

Source: Department of Health and Aged Care, http://www.health.gov.au/tga/gene/genetech/generegs.pdf, accessed 30 March 2000; Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, pp. 5, 10, 11, 13.

- Transparency, clarity and accountability:
  - ⇒ notifications about field trials will contain a high level of information, omitting only commercial in confidence material; tight criteria will be applied to assess confidentiality;[54]
  - ⇒ information will be provided in the Gazette, on the internet, in newspapers and by direct mail to interested persons and local governments in affected areas; regulations may require notification or consultation with neighbouring property owners;[55]
  - ⇒ both detailed scientific information and information in plain English will be available;[56]
  - ⇒ applications and draft determinations for the general release of GMOs will be released for public comment;[57]
  - ⇒ guidelines will spell out in detail the requirements for risk assessment;[58] and
  - ⇒ the GTR will report on monitoring activities and suspected breaches of the Act in its annual report to Parliament.[59]
- Independence and impartiality:
  - ⇒ the GTR will be a statutory office holder responsible for the day to day administration of the office; he / she will not be 'subject to direction from anyone in relation to whether or not a particular application for a GMO licence is issued or refused or the condition to which a particular GMO licence is subject';[60]
  - ⇒ the GTR is not inherently pro gene technology; he / she will focus on risks and not on cost / benefit analysis; economic or trade issues could not 'under any circumstances' override environment or human health concerns;[61]

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54 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, pp. 271, 276-7.

55 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, pp. 276, 278.

56 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, p. 274.

57 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, p. 271.

58 Interim Office of the Gene Technology Regulator Supplementary submission no. 87, p. 23.

59 Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, p. 18.

60 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, p. 284; Supplementary submission no. 87, p. 9.

61 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, p. 280; Supplementary submission no. 87, p. 16.

- ⇒ members of GMAC's replacement, the Gene Technology Technical Advisory Committee (GTTAC) will be subject to stringent conflict of interest and disclosure of interest provisions;[62] and
- ⇒ appeals against decisions may be made through reviews carried out internally, by the Administrative Appeals Tribunal, by the Federal Court under the *Administrative Decisions (Judicial Review) Act 1977*, and by the Ombudsman.[63]

- Objectivity - scientific assessment of risk will be continued by GTTAC, which will comprise 20 members with expertise in molecular biology, plant and animal genetics, public health and environmental systems. It will also be able to call on expert advisers.[64]

- Compliance:
  - ⇒ compliance will be encouraged by clean up orders and heavy penalties;[65] and
  - ⇒ a number of monitoring mechanisms will be established: the licence holder will be required to report the results of his/her monitoring activities to the GTR, and the GTR will independently monitor compliance, and appoint inspectors to carry out planned and unplanned inspections, including when breaches of licence conditions are suspected.[66]

- Effectiveness and efficiency:
  - ⇒ by categorising and regulating each GMO according to the level of risk that it presents, the regulatory burden is minimised to an appropriate level (see Appendix D);[67]
  - ⇒ the GTR will, at any time, be able to review any GMO approval and to add or vary conditions of its use;[68]
  - ⇒ evaluating a GMO's risk characteristics after obtaining experience with its use allows for that GMO's reclassification and the removal of

62 Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, p. 8.

63 Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, p. 21.

64 Interim Office of the Gene Technology Regulator, Exhibit no. 6, p. 5; Supplementary submission no. 87, pp. 10-11.

65 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, pp. 266, 270.

66 Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, p. 18.

67 Interim Office of the Gene Technology Regulator Proof transcript of evidence, 5 April 2000, pp. 263, 272.

68 Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, p. 18.

the requirement to licence, if risks have not been identified; such GMOs will be placed on a register;[69] and

⇒ the IOGTR will lead work on harmonising regulatory processes among existing regulatory agencies.[70]

- Consultation:
  - ⇒ community input will be possible in relation to applications for general release of GMOs, as indicated above;
  - ⇒ the Gene Technology Ethics Committee (GTEC) will conduct public consultations when developing guidelines;[71] and
  - ⇒ the members of the Gene Technology Community Consultative Group (GTCCG), with their experience with gene technology research and community impacts, and consumer, environmental, public health, primary producer, industry and local government issues, will provide advice to the Ministerial Council, as shown in Figure 7.1.[72]
- A nationally coordinated approach - it is expected that an intergovernmental agreement will be reached by the Commonwealth and state and territory governments, and complementary legislation may be enacted.[73]
- Protection for the organic and non GM industries – acting on a broad definition of the environment, the GTR will be able to set conditions to limit contamination of non GM by GM crops and punish breaches. The bill defines the environment as including 'ecosystems and their constituent parts, and natural and physical resources, and the qualities and characteristics of locations, places and areas'.[74]
- Ethical concerns - the 12 members of the GTEC Committee will advise the GTR and the Ministerial Council on ethical issues and guidelines, which will underpin the regulatory scheme. The guidelines 'would come in through the bottom of the system', for implementation by institutional biosafety committees in each institution using GMOs, so that 'any researchers undertaking work would have to observe those

69 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, p. 273.

70 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, p. 265.

71 Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, p. 14.

72 Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, p. 12.

73 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, pp. 266, 268.

74 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, pp. 265-6.

ethical guidelines'. The committee will be modelled on the Australian Health Ethics Committee which is established under the National Health and Medical Research Council legislation in relation to human health. Its members will have a range of skills and experience and will be able to access other experts.[75]

7.34 The committee is aware that a requirement for the GTR to report annually to the Parliament has been proposed for the new legislation. The GTR's reports would include, among other matters, information about monitoring activities and suspected breaches of guidelines. The committee believes that the transparency of the regulator's operations would be improved if he/she reported more frequently than annually for the first three years of the OGTR's existence.

Recommendation 30

7.35 **The committee recommends that the Office of the Gene Technology Regulator report to the Parliament at least quarterly for the first three years of its existence.**

7.36 Other legislation will support the objectives of the gene technology legislation. An amendment to the *Environment Protection and Biodiversity Conservation Act 1999* has been foreshadowed which will allow for environmental impact assessment before GMOs are released into the open environment.[76]

Issues of concern

Cost recovery

7.37 The proposal to recover the full costs of regulating GMOs was received with concern by primary producers.[77] In addition, the GRDC argued that industry should not fund the implementation of regulation for GMOs; it suggested that Commonwealth and state government resources should be

75 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, pp. 282-3; Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, p. 14.

76 Environment Australia, Submission no. 82, p. 23.

77 Grain Biotechnology Australia, Submission no. 68, p. 4; Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, p. 262.

provided for this task 'commensurate with the potential loss to the competitiveness of Australia's agricultural sector'.[78]

7.38 The IOGTR reported to the committee that it will not be possible to fully cost the regulatory system until:

- the legislation has been passed by the Commonwealth government and regulations developed;
- model state legislation is drafted; and
- the Gene Technology Inter-Governmental Agreement has been signed.

An independent analysis of costs will then be conducted.[79]

7.39 The committee agrees with the view that industry should not fund the setting up of the regulatory system. The committee recognises that adding to regulatory costs by charging users may act as a deterrent to the use of biotechnology.

Keeping an eye on the wider picture

7.40 Another issue raised earlier in this chapter concerns the limitations of the case by case approach to regulation. The committee feels that such an approach is entirely appropriate for governing the use and release of individual GMOs. As discussed above, however, it has been suggested that this approach may well miss some of the broader impacts of introducing GMOs.

7.41 The committee is aware that the gene technology legislation will establish a community consultative group and an ethics committee, whose members will possess expertise in such matters as:

- health, environmental and applied ethics, law, religious practices, and animal health and welfare for the ethics committee; and
- consumer, environmental, primary producer, industry and local government issues on the consultative group.[80]

In addition, the membership of GTTAC will be wider than GMAC's and will represent 'a balance of reductionist and holistic approaches'.[81] The committee believes that these bodies will be able to provide input to the regulatory process about the more diffuse impacts of introducing GMOs.

78 Grains Research and Development Corporation, Submission no. 47, p. 13.

79 Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, p. 20.

80 Interim Office of the Gene Technology Regulator, Exhibit no. 6, p. 5.

81 Interim Office of the Gene Technology Regulator, Exhibit no. 6, p. 5.

7.42 In Chapter 2, the committee referred to proposals in the UK to address this issue by the appointment of a super regulator or an independent biotechnology advisory committee. The Royal Society envisaged that the super regulator's functions would include such activities as:

- review mechanisms by which GM crop plants could be monitored in the environment and make recommendations for long term monitoring of their impact on ecosystems;
- review available methods for minimising gene transfer and make recommendations regarding further research;
- review the appropriateness of current arrangements and recommend changes relating to:
  - ⇒ testing for allergenicity and toxicity of GMOs; and
  - ⇒ managing herbicide tolerant and pest resistant crops; and
- consider the effects of GM crops in comparison with the effects of current agricultural practices in general on ecosystems and the environment as a whole.[82]

7.43 The committee considers that the three advisory committees (GTTAC, GTEC and GTCCG) will possess the expertise to assess the broader impacts of GMOs. As Figure 7.1 shows, these committees' relationships with the GTR and the Ministerial Council provide opportunities for the wider picture to be brought to the attention of ministers and the regulator. The committee believes that the GTR should take account of the more diffuse impacts of GMOs when issuing licences, with responsibility for bringing forward relevant information about these impacts resting with GTTAC, GTEC and GTCCG.

Regulating GM food safety

7.44 Farmers' decisions about growing GM crops or livestock will be influenced by the domestic and international standards required of the food derived from their produce. In January this year, the European Union approved new rules requiring food companies to label products containing more than one per cent of GM food. These rules came into effect in February and apply to domestically produced and imported food. They are the strictest in the world. Japan and South Korea, among others, are also reported to be moving to introduce GM food labelling.

82 The Royal Society, 'Genetically modified plants for food use', 1998, http://www.royalsoc.ac.uk/st_pol40.htm, accessed 12 July 1999.

7.45 In Australia, the existing standard for labelling for GM content (Standard A18) requires all GM commodities:

- to go through a pre market safety assessment; and
- to be labelled if they contain new and altered genetic material and/or are significantly different from conventionally produced food in terms of nutritional quality, composition, allergenicity or end use

7.46 This standard is under review by the Australia New Zealand Food Standards Council (ANZFSC), which comprises the health ministers of the states and territories and the Australian and New Zealand governments. In August 1999, the council agreed to extend labelling requirements to all foods produced using gene technology, and in October a draft standard was released for public comment. The council will consider the matter at a meeting in July.

7.47 The move to improve the labelling of GM food is being driven by consumer concerns about their safety. Notwithstanding the fact that ANZFA carries out pre market safety assessments on all food released for sale, ANZFSC acknowledges that consumers who do not want to eat GM food should be able to make that choice.

7.48 International food standards are set by the Codex Alimentarius Commission, which is a subsidiary body of the FAO and the WHO. At present there is no Codex Alimentarius standard for labelling the GM content of food which might provide a guide to national food regulators.[83] Furthermore, it is unclear what position the commission will adopt.[84] Once an international standard is in place, however, Australia may be restricted in how stringently it can regulate.

7.49 Under two international agreements to which it is party,[85] Australia may not regulate more stringently in terms of trade restrictions than the standards set down in the Codex Alimentarius. More stringent regulation is allowed only if:

- there is a strong, scientifically based concern that a food product could threaten human, plant or animal health or survival; and

83 I. Lindenmayer, 'Regulating genetically modified food', speech prepared for the APEC Technomart III Conference, Queensland, November 1999, p. 7, http://www.anzfa.gov.au/documents/sp008_99.asp, accessed 11 February 2000.

84 Australia New Zealand Food Authority, Transcript of evidence, 8 March 2000, p. 253.

85 The Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement on Technical Barriers to Trade.

- there are justifiable concerns in relation to national security, environmental protection, or deceptive trade practices.[86]

For this reason, ANZFA brought to the attention of the WTO its Standard A18 which regulates GM foods.[87]

Costs imposed by labelling

7.50 Mandatory labelling will impose significant additional costs on suppliers of GMOs. It has been estimated, for example, that to identity preserve grain would add 5-15 per cent to delivery costs in world markets.[88]

7.51 A study commissioned last year by ANZFA made preliminary estimates of the cost that might be involved for the entire Australian food industry. Reporting on the basis of a limited analysis that used a highest cost scenario and was carried out within a short time frame, the study found that:

- the cost to industry would be six per cent in the first year and three per cent per annum thereafter;
- prices could rise between 5 and 15 per cent, depending on the content of GM food; and
- regulatory costs would be between $7 million and $150 million per annum, depending on the rigorousness of the regime instituted.[89]

7.52 The study also suggested that, if full mandatory labelling was not required, costs could be reduced. For example, cost reductions of about 80 per cent would be possible if labelling was not required for refined ingredients, minor ingredients, food additives, processing aids and flavourings.[90]

7.53 After considering this study, ANZFSC requested a more thorough analysis of the costs to the food industry of labelling GM food. Press reports indicate that the costs are unlikely to be as high as the first study suggested, and industry could be expected to absorb the full cost without

86 I Lindenmayer, 'Regulating genetically modified food', speech prepared for the APEC Technomart III Conference, Queensland, November 1999, p. 3, http://www.anzfa.gov.au/documents/sp008_99.asp, accessed 11 February 2000.

87 Australia New Zealand Food Authority, *Statement of reasons: Proposal P97 for Recommending Standard A18 - Foods Produced Using Gene Technology*, February 1998.

88 M Foster, 'Market implications: genetically modified crops', *OUTLOOK 2000*, ABARE, Canberra, 2000, p. 186.

89 KPMG, *Report on the Compliance Costs facing Industry and Government Regulators in relation to Labelling Genetically Modified Foods*, October 1999, pp. 20, 27.

90 KPMG, *Report on the Compliance Costs facing Industry and Government Regulators in relation to Labelling Genetically Modified Foods*, October 1999, pp. 26-7.

having to pass it on to consumers.[91] However, it is the view of the committee, based on past experience, that such costs are inevitably passed on.

7.54 The GCA reported to the committee that it was extremely concerned about the decision by the Australian and New Zealand Health Ministers to significantly strengthen the labelling requirements for GM foods. This decision, and the new labelling proposals being considered by ANZFA, 'have the potential to significantly restrict the benefits that the biotechnology revolution can bring to the industry'.[92] AWB felt that the commercial cost impositions of a requirement for grain segregation would prohibit it from trading in GM grain markets.[93]

7.55 The committee recognises that labelling will impose costs on producers and may well deter them from growing GMOs. However, the committee is aware of the public's concern about the introduction of GMOs and the wish of many people to be able to choose to eat non GM food. Labelling the GM content of food provides people with the information they need to make choices; not labelling might be interpreted as an attempt to deny choice and to profit from an unknowing public. The committee believes that, on balance, the public's trust in the regulation of GM food safety is most likely to be engendered by meeting the demand for information. The committee therefore supports a practical regime of labelling for GM foods that provides useful information to the consumer.

7.56 The committee believes that, when a revised standard for the labelling of GM foods is implemented, a survey should be conducted to assess:

- the use made by the public of label information; and
- the public's views on the usefulness of the information provided.

Such a study would allow the information supplied to be adjusted to the public's needs.

91 J Macken, 'GM food labelling talks delayed', *Financial Review*, 10 May 2000, p. 7.

92 Grains Council of Australia, Submission no. 65, p. 14.

93 AWB Ltd, Submission no. 66, p. ii.

Recommendation 31

7.57 **The committee recommends that, if and when a revised standard for labelling genetically modified foods is instituted, the Australia New Zealand Food Authority evaluate:**

- **the use made by the public of label information; and**
- **the public's views on the usefulness of the information provided.**

Segregation and identity preservation

7.58 Providing information about the GM content of food for labelling purposes will impose requirements on growers. This will be particularly the case where both GM and non GM crops are grown at the same time and / or in the same place. Growers will need to carefully segregate GM and non GM crops, and track the identity of both from paddock to the market.

7.59 If both GM and non GM crops are grown in close proximity to one another or on the same ground in successive harvests, it will be necessary to establish crop practices that will minimise contamination of the two types of crops and produce from one another. The main sources of contamination of crops are seeds and pollen. Non GM farmers and / or GM crop producers will therefore need to ensure that their crops are isolated from one another by an appropriate distance or barrier to reduce pollen transfer if the crop flowers. To reduce seed mixing, shared equipment will need to be cleaned and enough time allowed for viable seed to disappear from the soil before non GM crops are grown on land previously used for GM crops. Responsibility for isolating crops will need to be decided before appropriate measures can be implemented.[94]

7.60 The requirements for ensuring that non GM crops are not contaminated in the field by foreign genetic material from GM crops will be established and monitored by the GTR.[95] Management practices have long been followed in the seed industry to ensure seed purity, and these provide a model for the type of arrangement that might be established to

94 John Innes Centre, 'Gene transfer from genetically modified crops', http://www.jic.bbsrc.ac.uk, accessed 5 September, 1999.

95 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, pp. 265-6.

maintaining the integrity of non GM crops in the field. One of the factors that will influence the exact nature of the management practices needed will be the threshold of GM material that will be allowed in certified non GM produce. In addition, measures must be established to confirm compliance. It should be noted that testing may be difficult and expensive.[96]

7.61 The committee is aware that work is being carried out to establish appropriate management practices for growing and marketing GM crops. For example, a study has been commissioned by the Rural Industries Research and Development Corporation which will produce a guide for farmers, consultants and extension specialists. It will detail farm and resource management issues and strategies associated with growing GM plants and marketing the resulting products.[97]

7.62 Australia already has experience in segregating and preserving the identity of some of its produce.[98] According to AFFA, 'our grain industries, for example, are way ahead of the rest of the world in terms of identity preservation that we are doing with traditional crops'.[99] For such industries, experience with identity preservation could simply be extended to GM and non GM crops. Other industries will need to develop the necessary skills, and there will be costs associated with setting up the necessary infrastructure, management practices and recording systems. AFFA suggested that:

> As more GMO products emerge, both within Australia and overseas, the onus on segregation may well become one of the biggest challenges that not only government but also industry have in order to market.[100]

7.63 The committee was pleased to learn that work is being carried out to establish management strategies for growing GM crops. It is also aware that provision was made in the last budget for an assessment of the requirements and costs involved in segregating GM products and

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96 I Lindenmayer, 'Regulating genetically modified food', speech prepared for the APEC Technomart III Conference, Queensland, November 1999, p. 5, http://www.anzfa.gov.au/documents/sp008_99.asp, accessed 11 February 2000.

97 Rural Industries Research and Development Corporation, 'Management strategies associated with growing and marketing genetically modified plants', http://www.rirdc.gov.au/genplants.html, accessed 14 April 2000.

98 Grains Council of Australia, Transcript of evidence, 30 August 1999, p. 136.

99 Agriculture, Fisheries and Forestry, Transcript of evidence, 20 September 1999, p. 147.

100 Agriculture, Fisheries and Forestry, Transcript of evidence, 20 September 1999, p. 147.

ensuring these products can be traced through to their origins. $3.65 million is being provided over four years for this purpose.[101]

7.64 A system for certifying the GM status of produce for domestic consumption does not exist. With respect to exports, however, AQIS has been able to certify exports as GM free, because very little GM produce is grown commercially in Australia. AQIS told the committee that:

> … we have been approached by a number of countries to ensure that our shipments are free of GMOs. As there had been no commercial releases of GMOs in Australia, we were confident that shipments did not contain GMOs. As things such as canola are commercialised further … AQIS will not be as comfortable doing that.[102]

7.65 AFFA reported to the committee that it is discussing segregation and identity preservation with industry, and could play a role in auditing and certifying the GM status of food for export. However, AQIS will require 'extremely good documentation' to carry out these tasks.[103] With respect to other elements of a system for segregating and certifying the GM content of food, the majority view put to the IOGTR during its consultations on the draft Gene Technology Bill was that:

> … the Gene Technology Regulator should not impose conditions that require segregation, accreditation, and certification of crops for export. People very much saw this as a market issue … [104]

7.66 The committee endorses the role foreshadowed for the GTR in setting conditions to prevent contamination of non GM (and organic) crops and policing compliance with the conditions.[105] There is also a place for government support for the development of some of the broad parameters relating to segregation and certification. However, for any other tasks, the committee believes that the non GM food industry should develop and operate its own standards and systems, as the organic industry has done.

7.67 With respect to certified GM and non GM crops destined for export, the committee believes that AQIS should provide the same type of services to these industries as it does when certifying organic produce for export.

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101 Hon Warren Truss, Minister for Agriculture, Fisheries and Forestry, 'New technologies for Australian agriculture',Media release, 9 May 2000.

102 Agriculture, Fisheries and Forestry, Transcript of evidence, 20 September 1999, p. 146.

103 Agriculture, Fisheries and Forestry, Transcript of evidence, 20 September 1999, p. 147.

104 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, p. 287.

105 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, pp. 265-6.

Recommendation 32

7.68 **The committee recommends that the Australian Quarantine and Inspection Service certify both non genetically modified and genetically modified produce for export.**

Regulating the international movement of GMOs

7.69 The import of GMOs into Australia is overseen by AQIS. A recent quarantine proclamation provides for the evaluation of novel pest and disease risks posed by imported GMOs. An imported GMO is also controlled under the new interim arrangements of the IOGTR and by other relevant existing regulators in the same way as domestic GMOs.[106]

7.70 The Biosafety Protocol of the Convention on Biological Diversity deals with the international movement of GMOs. Its objective is:

> … the safe transfer, handling and use of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.[107]

The protocol was agreed to in January 2000 by 130 countries. It is open for signature until 4 June 2001, and will come into force after 50 countries have ratified it.

7.71 The protocol requires exporters to get permission from the importing country before shipping, for the first time, GMOs that are destined to be released into the environment. Nations may bar the import of GMOs on scientific grounds, even if the evidence is incomplete. Permission to import is not required for produce that is intended for food, feed or processing. However, it must be labelled as including, or possibly including, GM material. In addition, an internet based biosafety clearing house will be set up; it will facilitate the sharing of technical data and help to establish the scientific basis for decisions on imports.

106 Evironment Australia, Submission no. 82, p. 25.

107 *Convention on Biodiversity, Draft Cartegena Protocol on Biodiversity*, United Nations Environment Program, 28 January 2000.

7.72 The United Nations Environment Program affirmed that, under the agreement reached over the Biosafety Protocol:

> … the Protocol and the WTO are to be mutually supportive; at the same time, the Protocol is not to affect the rights and obligations of governments under any existing international agreements.[108]

However, the protocol is premised on a precautionary approach, while decisions under trade law require 'sufficient scientific evidence'. It appears that the provisions of the protocol and WTO agreements conflict with one another.

7.73 The NFF's president, Ian Donges, claimed that the Biosafety Protocol had the potential to unduly restrict international trade in GM commodities intended for direct use as food, feed, or for further processing. He suggested that it would be possible for nations to rely on the precautionary principle to cloak politically motivated decisions. In practice, this would introduce uncertainty into international trade and a bias against new products and new technologies which Australian farmers need to remain globally competitive.[109]

7.74 The committee supports the thrust of the Biosafety Protocol in so far as it will contribute to the careful use of GMOs. It is concerned, however, about:

- the apparent lack of clarity introduced by the Biosafety Protocol to the rules of international trade; and
- the potential for its misuse.

Both these features are likely to deter trade in GM produce. The committee believes that Australia must play an active part in negotiating the details of implementing the Biosafety Protocol and help to clarify the apparent contradictions of the protocol and existing WTO arrangements.

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108 United Nations Environment Program, 'Global treaty adopted on genetically modified organisms',Media release, 29 January 2000, http://www.biodiv.org/PRESS/PR-2000-01-28-BIOSAFETY.HTML, accessed 11 April 2000.

109 National Farmers' Federation, 'New gene treaty has hidden dangers for world trade', Media release, 3 February 2000.

Recommendation 33

7.75 **The committee recommends that the Commonwealth government, together with industry representatives, play an active part in negotiations to implement the Biosafety Protocol in such a way that:**

- **apparent contradictions between the protocol and World Trade Organization arrangements are clarified and addressed; and**
- **Australia's interests in freely trading genetically modified organisms are maximised, without jeopardising public safety.**

Risk assessment and management

7.76 Concerns about the deficiencies of the current regulatory system were discussed earlier in this chapter. Some of these concerns centred on the rigour of the risk assessment on which approvals are based and management strategies put in place to contain risks. Recognising that assessing and managing risk are the key planks in any regulatory system, EA pointed out that:

> Assessment involves identifying hazards, analysing exposures and probabilities, evaluating impacts, characterising risks, and recommending management measures. Risk management is not only the implementation of management recommendations arising from the risk assessment process, but also the monitoring of implementation and impacts. This monitoring is essential for 'closing the regulatory loop', that is informing subsequent risk assessment and development of management measures. This makes regulation effective and avoids unnecessary regulation.[110]

7.77 Under the interim arrangements currently in place, GMAC examines the risks posed by each application to public health, the environment, or the sustainability of agricultural systems. GMAC takes into account the consequences of any adverse effect, the likelihood of its occurring, and the possibility of reducing the risk to an acceptable level. In the course of developing its view, GMAC draws on many different sources of information, including the applicant, experts, information from overseas and in the literature, environmental assessment, and input from the public

110 Environment Australia, Submission no. 82, p. 15.

and other agencies. GMAC must also address any concerns raised by environmental assessments carried out by EA.[111]

7.78 The committee understands that, under the new legislation, applicants would be required to provide the GTR with information about:

- the GMO's parent organism;
- its characteristics;
- its new traits, including its stability;
- any health impacts it may have;
- details of the proposed release, including information about the receiving environment and the impact of the GMO on that environment;
- potential environmental impacts;
- proposed monitoring techniques;
- methods or procedures to minimise the spread of the GMO; and
- contingency planning in the case of any unexpected effects of the GMO.

With applications for the release of a GMO for commercial production, the applicant would also have to provide information about previous field trials, including any impacts on the native Australian flora and fauna.[112]

7.79 If it appears that the GMO will have a significant environmental impact, the GTR would call for public submissions about the risks and their management, as well as consult other government agencies.
A comprehensive risk assessment and risk management plan would be prepared on the basis of the OGTR's own literature and independent research and advice from GTTAC; state, territory and local governments; EA and state environmental protection agencies; health agencies; and the public. The assessment and plan would be released for further comment before being finalised.[113]

7.80 The arrangements described above are more rigorous than those that were previously in place. It is anticipated that the new legislation will come into effect on 3 January 2001.

111 Interim Office of the Gene Technology Regulator, Submission no. 78, pp. 27-31.

112 Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, pp. 22-3.

113 Interim Office of the Gene Technology Regulator, Supplementary submission no. 87, pp. 23-4.

7.81 Several submissions to the inquiry commented on the high standard of the work carried out by GMAC. It was EA's view that:

> In Australia, a responsible and professional approach to the development and deployment of agricultural GMOs has always been taken, under the control of the Commonwealth Genetic Manipulation Advisory Committee (GMAC) and existing statutory regulators.[114]

The Western Australian government saw GMAC as comprising 'probably the best set of skill and expertise in the gene technology regulation arena in Australia'.[115] CSIRO told the committee that, without doubt, GMAC's standards 'would be certainly equivalent to the highest standards in the world'.[116]

7.82 The fact that only three GM plant varieties are grown commercially in Australia so far indicates that Australian regulatory authorities have taken a more cautious approach to them than have other countries. Complaints about delays in approving GM crops also suggest that regulators have a careful attitude to their responsibilities.

7.83 The management strategy developed for Bt cotton is an example of the careful approach of both growers and the NRA. The strategy is designed to minimise the likelihood of Bt resistance developing among cotton pests and imposes a 30 per cent limit on the area planted to Ingard® cotton.[117] By contrast:

> In the United States, the introduction of transgenic cotton has been less regulated than we have had. There is no cap and also their resistance management requirements are much less stringent than we have in place. There are parts of the US cotton belt, particularly in the delta and the mid-south states like Mississippi and Alabama, where a very high proportion of the cotton that is grown is transgenic—up to 96 per cent of the cotton area might be transgenic.[118]

The committee is aware that moves are now being made in the USA to introduce more stringent regulation of GMOs than has existed up to this point.

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114 Environment Australia, Submission no. 82, p. 10.

115 Western Australian government, Submission no. 48, p. 5.

116 CSIRO, Transcript of evidence, 18 October 1999, p. 208.

117 Australian Cotton Growers Research Association Inc., Submission no. 80, p. 2.

118 Australian Cotton Cooperative Research Centre, Transcript of evidence, 18 October 1999, p. 217.

7.84 GMAC's performance has been criticised by others because there have been 16 breaches over the last 15 years of the conditions that GMAC had recommended for the conduct of trials.[119] The IOGTR commented that:

> There have been very few recorded breaches of the GMAC Guidelines (or those of GMAC's predecessors) over the past fifteen years (when formal record-keeping commenced) – and none which warranted GMAC's intervention to the extent of causing the research to cease. Most incidents reported to GMAC have involved either minor accidents, such as needle-stick injuries, rather than breaches of the Guidelines, or did not involve a release into the environment. In all cases, appropriate action was taken and there were no significant hazards identified to the environment or the community.[120]

7.85 More recent criticism of GMAC's performance relates to its approval of field trials of GM herbicide tolerant canola. OFA brought these trials to the committee's attention, and claimed that the acreage grown far exceeded that needed for agronomic trials and was being used to bulk up seed for export and commercial gain.[121]

7.86 The committee believes that GMAC's cautious approach to commercial releases is essential and should be continued by it and its successor, GTTAC.

Recommendation 34

7.87 **The committee recommends that the Genetic Manipulation Advisory Committee and its successor, the Gene Technology Technical Advisory Committee, continue to take a cautious approach to approving the use of genetically modified agricultural organisms.**

119 Australian GeneEthics Network, Submission no. 71, pp. 12-13.

120 Interim Office of the Gene Technology Regulator, Submission no. 78, p. 7.

121 Organic Federation of Australia, Transcript of evidence, 13 August 1999, p. 60.

Issues in risk assessment and management

Knowledge and skills base

7.88 From its experience with the introduction of exotic species and their development as noxious weeds and pests, Australian authorities have learnt that:

> The lesson is to manage risks through early detection and improved methods of monitoring. There will be a need to develop and implement the best ways to effectively monitor impacts, and to specify responsibilities and contingency plans.[122]

7.89 Monitoring may need to be widespread and include agricultural and natural ecosystems outside the area in which the GMO is deployed. This is necessary because environmental impacts vary regionally and cannot be predicted from small field trials, as monitoring in the USA has shown. Information gained from monitoring feeds into regular reviews and revision of risk management measures.[123]

7.90 EA suggested that:

> Risk management for GMOs will probably require some new specific methods for detection of impacts, and methodologies for measuring impact. For example, field diagnostic kits or bio-monitoring systems may need to be developed to detect and track transgene flow. Specific adverse effects reporting systems, and perhaps some new infrastructure, will need to be established to monitor for invasiveness, detect novel herbicide tolerance, or detect insects resistant to pesticides.[124]

7.91 The knowledge base on which risk assessment depends is likely to be deficient for many classes of GMOs; data will need to be assembled while the GMOs are being developed. EA suggested that the research needed could be funded by the proponent but:

> … some of the knowledge base needed for adequate risk assessment is not GMO-specific and the information required is more strategic and fundamental (for example basic knowledge about recombination among viruses in co-infected hosts). In other cases, there is market failure for generating the necessary knowledge, for example where the proponent is a government agency developing a GMO for a public good. These are probably

122 Environment Australia, Submission no. 82, p. 18.

123 Environment Australia, Submission no. 82, pp. 18-19.

124 Environment Australia, Submission no. 82, p. 18.

> valid community service obligations, requiring government support.[125]

7.92 In Chapters 2 and 5, the committee discussed the need for Commonwealth assistance for research into gene technology. The committee accepts the argument that the Commonwealth government has a responsibility to support the basic research that underpins effective regulation of GMOs. The committee has already recommended that the Commonwealth government provide more funding for research into the risks associated with the use of GMOs by farmers (see Recommendation 2).

Arrangements for risk assessment

7.93 According to EA, best practice risk assessment requires two elements. The first is 'access [to] whatever experts and sources best meet the needs of accurately determining the nature and likelihood of impacts arising from the action being assessed'. The second element are the assessors who are:

> … independent persons who have no active interest in promoting gene technology and who do not represent any specific interest group. The need for neutrality is a prime reason for separating provision of expert advice (which will inform risk assessment) from independent risk assessment itself, in the regulatory path. The community expects neutrality.[126]

7.94 The current arrangements for risk assessment are primarily based on a committee of part-time assessors comprising GMAC, and will be continued under the new legislation by GTTAC. EA expressed doubts about:

> … whether such a system will be able to meet all aspects of the risk assessment challenge for the OGTR … There needs, therefore, to be debate about whether the future regulatory scheme for GMOs in Australia should rely on a standing expert committee as the focus for risk assessment.[127]

EA pointed out that 'there are few, if any, developed countries that rely on a standing expert committee as the focus for risk assessment of GMOs'.[128]

125 Environment Australia, Submission no. 82, p. 17.
126 Environment Australia, Submission no. 82, p. 21.
127 Environment Australia, Submission no. 82, p. 22.
128 Environment Australia, Submission no. 82, p. 21.

7.95 EA suggested that:

> … the new OGTR should build on the existing GMAC 'experts committee' system for regulation of agricultural GMOs at the contained research phase. The GTAC could also provide independent expert advice on non-contained proposals, but the OGTR should build primarily on the risk assessment expertise already in the Commonwealth (for existing regulatory systems) for assessment of releases into the open environment (including field trials).[129]

7.96 An AgrEvo employee told the committee in August 1999 that:

> It is my personal belief that the government capacity building needs to happen in a big way in the next 12 months. If you look at the number of people employed in the Canadian government system and the fact that they do all of their evaluations in-house and that expertise has been developed in-house, that is extremely important to the credibility of their system. That would be particularly valuable to the Australian system. I would like to see a lot more experts working within the government departments ... [130]

An alternative, according to EA, would be to use 'accredited, independent, professional risk assessment consultants'.[131]

7.97 CSIRO also pointed out that it is important for Australia to have the capacity to answer the questions raised when they emerge and to build that capacity into its normal risk assessment processes.[132]

7.98 The committee is concerned by suggestions that there may be insufficient in-house capacity in government agencies to deal adequately with the risk assessment task. The committee considers that the arrangements for risk assessment that will be developed under the new legislation must be the best possible. It believes that, if GTTAC's capacity is stretched in the future, it should be augmented, including, where appropriate, by independent risk assessment consultants.

129 Environment Australia, Submission no. 82, p. 22.

130 AgrEvo, Transcript of evidence, 13 August 1999, p. 47.

131 Environment Australia, Submission no. 82, p. 21.

132 CSIRO, Submission no. 56, p. 7.

Recommendation 35

7.99 **The committee recommends that the Commonwealth government:**

- **ensure that there is sufficient in house capacity in the Gene Technology Technical Advisory Committee to provide timely and effective risk assessment of genetically modified organisms;**
- **give it the authority to coopt independent expertise when required; and**
- **make these assessments public.**

Regulating all novel and genetically modified organisms

7.100 As EA pointed out, many of the risks posed by GMOs are unrelated to their GM status. For example, all herbicide tolerant crops will tend to pose similar issues for risk management, irrespective of whether they were conventionally bred or genetically engineered (see Box 2.3).[133] The committee's attention was drawn to a canola variety which is highly tolerant to the herbicide triazine that was bred traditionally and is grown in Western Australia. It is not subject to environmental regulations to minimise risks although it could have the same impacts as GM herbicide tolerant varieties which are regulated.

7.101 AgrEvo also pointed out the anomalies of concentrating on GMOs alone, suggesting that it is more appropriate to focus on the product rather than on the process by which it is generated.

> In Australia, GMAC captures only those crops derived by recombinant DNA processes, thereby excluding those crops with novel traits (especially herbicide tolerance) derived by irradiation methods or conventional breeding – and therefore subject to similar environmental management issues. In this context, GMACs requirements for GMOs are restrictive including site selection, management and monitoring.[134]

7.102 The committee considers that it is inappropriate to impose different requirements on crops solely on the basis of the process by which they were derived. In Canada, all herbicide tolerant crops are defined as plants

133 Environment Australia, Submission no. 82, p. 19.

134 AgrEvo, Submission no. 55, pp. 3-4.

with novel traits and as such are evaluated for environmental and feed safety.[135] The committee believes that a similar arrangement should apply in Australia.

Recommendation 36

7.103 **The committee recommends that all novel crops, whether bred by conventional means or by gene technology, should be assessed and regulated for their impact on the environment and human and animal health.**

Liability and insurance

7.104 The definition of organic produce includes a requirement that it not contain GM elements. It is therefore important for organic farmers that, if their crops are contaminated by GM products, they can seek compensation for the damage done. The reverse situation might also occur in the future, for example, if GM crops are developed for specific nutritional qualities; they might be contaminated by neighbouring organic or non GM crops. The organic industry noted that litigation involving GMOs is occurring overseas,[136] and urged the establishment of 'strong enforceable liability regimes'.[137]

7.105 The question of where the liability would rest if GM contamination occurred was debated in several submissions. The National Genetic Awareness Alliance argued for the 'polluter pays' principle.[138] Others suggested that liability could lie with:

- the developer of the GMO, including the owner of plant variety rights;
- government bodies that approved the release of the GMO; and/or
- businesses engaged in producing and growing GMOs, including the farmer and seed supplier.[139]

135 AgrEvo, Submission no. 55, pp 3-4.

136 National Association for Sustainable Agriculture, Australia, Submission no. 74, p. 3.

137 Australian GeneEthics Network, Transcript of evidence, 13 August 1999, p. 77.

138 National Genetic Awareness Alliance, Submission no. 54, p. 4.

139 Heritage Seed Curators Australia, Submission no. 30, p. 2; National Association for Sustainable Agriculture, Australia, Submission no. 74, p. 3; Organic Federation of Australia, Supplementary submission no. 73, p. 2.

7.106 Specific legislation relating to liability for the risks posed by gene technology does not exist, nor has liability been tested in the courts. Common law provides a means for redressing problems arising from GMOs. Remedies might also be sought through environmental protection and pollution control legislation, and legislation relating to wild animals and abnormally dangerous activities. Liability in relation to food would be caught under the Trade Practices Act.[140]

7.107 The AGN suggested that:

> Given clear threats to environment and human health, it would be prudent to require a fidelity bond as the Spanish government has done, or place a tax on GE organisms to fund damage mitigation research and clean-up.[141]

OFA supported the establishment of a compensation fund, to which organic farmers could apply 'immediately they suffer a financial loss as a result of contamination'.[142] Another suggestion was for companies wishing to commercially release GM products to pay 'a substantial licence fee to government to support insurance against risk'.[143]

7.108 The gene technology legislation addresses the issues of liability and compensation. It provides for criminal penalties for breach of the legislation and gives the GTR the power to require that a problem be rectified when the legislation has been breached. A bond can also be imposed under the licence conditions for particular GMOs.[144] However:

> If a third party wanted to bring an action in relation to contamination, their recourse would be through common law trespass, negligence, and nuisance—actions of that nature. The legislation does not establish a compensation fund per se … [145]

It is the committee's view that this is an appropriate arrangement.

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140 Advice provided by the Environmental Defenders Office, Tasmania to the National Association of Sustainable Agriculture Australia, dated 25 October 1999, pp. 2-3; T L'Estrange, T Spender & J Baartz, *GeneCom 98 – Gene technology in the community*, Allen Allen & Hemsley, December 1998, http://www.allens.com.au/wnew/whatscon2.htm, accessed 12 May 1999.

141 Australian GeneEthics Network, Submission no. 71, p. 7.

142 Organic Federation of Australia, Submission no. 73, p. 2.

143 *First Australian Consensus Conference: Gene Technology in the Food Chain:: Lay Panel Report*, Canberra, March 1999, p. 3.

144 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, pp. 266, 269.

145 Interim Office of the Gene Technology Regulator, Proof transcript of evidence, 5 April 2000, p. 266.

7.109 The Insurance Council of Australia reported that most insurers and reinsurers have not yet reached a clearly defined position on insuring gene technology companies because the nature and size of the exposure to losses are not clear. Furthermore, genetic engineering has an extremely diversified risk profile, and any damage or injury may not show up until a lengthy period has elapsed. Class actions for serial and latent claims would present a problem for the insurance industry, as would the substantial costs that might be required to defend politically targeted policy holders.[146]

7.110 Any cover offered is likely to be restricted and leave a large gap between the cover on offer and the level of coverage required. Alternatives to traditional insurance have been sought in tailor made hedging instruments financed jointly by the policy holder and the insurer or reinsurer.[147]

7.111 The committee believes, however, that the best form of insurance is to provide the OGTR with sufficient funding and independence to discharge the duties envisaged for it, as described earlier in this chapter.

Recommendation 37

7.112 **The committee recommends that the Commonwealth government ensure that:**

- **the independent status of the Gene Technology Regulator is clearly prescribed in the new gene technology legislation;**
- **sufficient funding is provided to enable him/her to fully discharge his/her duties; and**
- **the Gene Technology Regulator is publicly accountable.**

Fran Bailey, MP
Committee Chair

7 June 2000

146 Insurance Council of Australia, Submission no. 83, pp. 1-2.

147 Insurance Council of Australia, Submission no. 83, p. 2.

Dissenting Report—Peter Andren MP

Introduction

From the outset I was uncomfortable with the terms of reference for this inquiry.

I agree with Mr Robert Phelps, Director, Australian GeneEthics Network in evidence to the Inquiry:

> "*... we felt that the terms of reference made the assumption that gene technology would proceed and that it undoubtedly had benefits. We simply wanted to make the point that, in the highly monopolised genetic engineering industry, we should not assume there would be benefits to society as a whole; that the benefits would principally accrue to transnational genetic engineering and chemical industrial companies; and that the rules on which this technology was going to be accessible to primary producers would be potentially so restrictive that it might reap them no benefits at all".*[1]

While there are obvious benefits from the application of biotechnology in the health sector, the jury is well and truly out in the agriculture and food sectors. Therefore, I do not support the broad conclusion in the committee's majority report that:

> *"The committee is of the opinion that applying gene technology to agriculture can benefit farmers, consumers and the Australian environment and economy".*[2]

I am not convinced of these benefits, and the more evidence I heard, the more I researched this matter through avenues other than the evidence presented, the more I became convinced any objective jury will be out for quite some years before any definitive "benefits" could possibly be measured.

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[1] Evidence to Committee, Melbourne 13th August 1999, p. 75

[2] Majority Report par. 2.59

I have no dispute with the good faith of those committee members who reached the conclusions and recommendations they did. In fact one cannot disagree with recommendations calling for the utmost caution in introducing genetic technology to the Australian landscape.

However, I believe there is a naïve acceptance that industry, science and government knows best, and the concerns of consumers, traditional farmers, organic growers, and other doubters can be overcome through proper "communications" campaigns and a regulatory process that has already displayed shortcomings elsewhere in the world.

I do not believe the case against genetic modification on ethical grounds has been satisfactorily addressed by the committee inquiry. Arguments that it would be unethical not to develop GMOs if they will contribute to alleviating world hunger or to help resist natural catastrophes are really a form of moral blackmail. This is especially so, given the emerging evidence that GMOs could one day indeed contribute to such catastrophes [3] and that forecasts of greatly increased production appear quite premature.[4]

Throughout the inquiry it was apparent to me that a lay committee of the Commonwealth Parliament (supplemented by one member with specialist GMO understanding, but worryingly with strong GM commercial interests) was ill-equipped to reach conclusions and recommendations on: *"the future value and importance of genetically modified varieties"* as required in the first term of reference.

The "Benefits" of Gene Technology

At par. 2.8 the majority report states the majority of submissions listed benefits from the use of GMOs. That is true. But the report suggests many of these benefits are proven. At par. 2.13 the report also contends: *"the benefits of GM crops to farmers are apparent from the rapid takeup of GM crops in the last few years"*.

I would challenge both contentions.

Monsanto for example: *"has already received permits for a threefold increase in herbicide residues on genetically engineered soybeans in Europe and the United States-up from 6 parts per million to 20 parts per million"*.[5]

In the case of Bt cotton, maize and potatoes (plants modifed with gene from bacterium *Bacillus thuringiensis* toxic to major pests): *"Bt resistance has already been*

[3] Majority Report par. 2.34 to 2.36 inclusive

[4] Majority Report par. 2.43

[5] Lappe` M. & Bailey B., *Against the Grain*, Common Courage Press, 1998, pp 75-6

noticed among some insect populations, and the U.S. Environment Protection Agency has predicted that most target insects could be resistant to Bt within 3 to 5 years".[6]

Importantly, the toxin may harm a wide range of insects including pollinating bees and beneficial insects further up the food chain.

Claims in par. 2.9 of the report that gene technology will make possible the breeding of animal or crop varieties which: *"are better suited to specific, different environments"* do not give due recognition to the downside.

The Organic Federation of Australia Inc. in evidence to the committee points out that drought resistant and salt tolerant plants may lead to weeds moving into areas where they have not previously been able to establish.

One wonders if development of salt tolerant species will be an incentive not to deal with the farming practices that created the salination.

World Food Supplies

A major selling point for GM products is the need to feed the world.

According to the United Nations' World Food Program:

> *"we are already producing one and a half times the amount of food needed to provide everyone in the world with an adequate and nutritional diet; yet one in seven people is suffering from hunger."*[7]

Gebre Egziabher, General Manager of the Environmental Protection Authority in Ethiopia says: *"There are still hungry people in Ethiopia, but they are hungry because they have no money. No longer because there is no food to buy".*[8]

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[6] EPA (US) Pesticide Fact Sheet 4/98

[7] Anderson L., *Genetic Engineering, Food, and Our Environment*, Green Books, UK, 2000, p.39

[8] *Splice* (Genetic Forum UK) Vol 4, issue 6, Aug/Sept 1998, p.4-5

Traditional and Organic Food Crops

Despite the evidence to the committee from the Australian Biotechnology Association that organic or non-genetically modified foods are only likely to be a "minor" component of the national agri-business industry, evidence suggests otherwise.

In fact the swing away from GM products in Europe, Japan and to a lesser degree the US, and the high premiums that are being paid for produce that is guaranteed GE-free, suggest traditionally grown crops (and more and more organically grown products) will enjoy a growing demand.

In this regard, it is imperative that Australian agriculture does not surrender its unique clean, green advantage. There are very clear benefits at the moment for Australia remaining GE free.

In January 1999 the largest shipment of canola ever exported from Australia was announced for processing plants in Europe. Australia was the only country to guarantee non-genetic canola. Canada on the other hand, lost major oilseed rape sales to Europe because 50% of its crop had been genetically engineered.[9] The potential for non-GE exports appears to be growing strongly.[10] In the UK, demand for organic products has accelerated since the GM debate began. At last reports 75% of the organic produce sold in the UK has to be imported.

The committee unfortunately deleted a draft recommendation asking the Commonwealth to continue to provide funding to the organic farming industry. Mr Robert Phelps, Director Australian GeneEthics Network, told the committee on Friday August 13th 1999 that the organisation had received $50,000 a year for four years to do public education, debate and discussion. But, "*when the Howard Government was elected we were not given any more money*". This at a time when public debate and the need for information on this crucial issue was escalating.

It is imperative the Commonwealth substantially increases funding to the organic farming industry and registered organisations promoting non GE products.

In an interview on ABC Director of the UK Soil Association Patrick Holden said:

> *" And those (GM) crops are so widely grown now, in both North and South America, that they have contaminated the non-GM crops and European consumers have said NO to GM foods and as a result farmers throughout North and South America are faced with a virtual block on the export of all*

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[9] Majority Report par. 4.12

[10] Anderson L., *Genetic Engineering, Food, and Our Environment*, Green Books UK, 2000, p.11

> *those commodity crops, and the implications of that can hardly be overstated".*[11]

Market Dominance

While it is fair to say much of the popular media have highlighted negative and confrontational aspects of the GM debate I think it is also fair to say the pro-GM debate is being driven by the major agro-vet and agro-chemical manufacturers.

A growing reliance by universities, CSIRO and individual researchers on corporate support, threatens the objectivity and independence of such research.

This in turn threatens to corrupt the advice given by scientists to national governments.

The Australian Government allocated $10 million in the 1999-2000 Budget to set up Biotechnology Australia, with a major role of promoting public acceptance of gene technology by funding GE proponents' materials. I am aware its leaflet distribution at supermarkets has been regarded in some quarters as heavily biased in favour of GE products.

In the UK the Biotech and Biological Research Council was headed up by the CEO of Zeneca until May 1999. There does not appear to be a willingness on the part of government in either country to fairly fund and disseminate the alternative point of view.

In fact one commentator argues that:

> *"if you want to understand 'objectivity' in the science and medicine of environment and health these days, the same advice applies as it does in politics: follow the money".*[12]

As well, Dr Egziabher from Ethiopia, speaking after the US veto of a Biosafety Protocol designed to regulate the trade and safety assessment of GEOs, said African countries were *"absolutely united"* in resisting US plans to *"decide what we eat".*[13]

The top five biotech companies (Astra-Zeneca, DuPont, Monsanto, Novartis and Aventis) account for virtually 100% of the market in transgenic seeds, also account for 60% of the global pesticide market and 23% of the commercial seed market.[14]

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[11] ABC "Background Briefing" April 30, 2000

[12] Montague P., "Follow the Money", *Rachel's Environment and Health Weekly*, No 581, 15 Jan 1998

[13] Lean G., "Third World Rejects G M Environment", *Independent on Sunday*, London 28th Feb 1999

[14] "Seedless in Seattle", Rural Advancement Foundation International, News Release 26 Nov 1999

The acquisition of seed companies has led to the dramatic shrinkage of the independent seed industry in industrialised countries[15] and monopolisation of genetically engineered crops. It has been claimed the narrowly controlled GE industry now dominates GE food supply from laboratory to dinner plate.

No such monopoly exists, for the moment, in organic or traditional agriculture, which still enjoys a huge market, a market that could grow rather than contract, depending on consumer demand for GM products.

Surveys have indicated a majority of Australian farmers and consumers prefer a non-GMO marketplace.[16] In fact it can be argued the more people learn about GE the less they like it.

The arrogance of using "terminator technology" to render seed sterile and prevent farm saving of seed only underlines what could fairly be described as the "agricultural imperialism" of the current GE industry. Monsanto only backed away from this technology (for the time being) in the face of a public outcry and the undeniable concerns of poor farmers.

Recommendation 6 of the majority report does not adequately address the need for balanced information on the positives and negatives of gene technology. In fact Biotechnology Australia's stated tasks are to promote biotechnology.

Environmental Benefits

There appears to be an acceptance of environmental benefits from GEOs, not only in the evidence presented to the Inquiry, but the conclusions drawn by the majority report.

However in par. 2.38 of the majority report Environment Australia gave evidence that:

> *"…the unknown evolutionary fate of inserted genes, all contribute to the difficulties of predicting environmental impacts".*

Yet in its conclusions at par. 2.59 the report says:

> *"The committee is of the opinion that applying gene technology to agriculture can benefit farmers, consumers and the Australian environment and economy".*

The impact on bio-diversity has not been adequately addressed throughout the inquiry or in the report's findings and recommendations.

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[15] Anderson L., *Genetic Engineering, Food, and Our Environment*, Green Books UK, 2000 p.103

[16] Ibid p.10

Rather than access to gene technology providing a "broader genetic base" there is strong evidence to suggest a dramatic narrowing of varieties. The so-called Green Revolution that persuaded farmers in the Third World to replace a multitude of indigenous crops with a few high-yielding varieties dependent on expensive inputs of fertilisers and chemicals has reportedly led to *"huge losses in genetic diversity"*.[17]

Indian farmers for instance are reported to have seen the number of rice varieties available to them reduced from 50,000 to just a few dozen over several decades. It is argued this would be further accelerated by monopoly control of GM seed varieties and the chemical regimes required for each crop.[18]

Paragraphs 2.34 to 2.38 of the majority report adequately complement the above concerns about the bio-diversity and environmental consequences from using GMOs.

Regulatory Regime

There is a wide disparity of views about the kind of "buffer zones" that should be put in place around GM trial crops. In addition, the impact of pollen transported by insects, or wind, is open to wild conjecture.

I am not convinced, despite evidence given to the Inquiry, that the Interim Office of Gene Technology Regulator (or its permanent successor) is, or will be, objective and impartial in its handling of regulatory matters.

I am most concerned at the contradictory evidence provided on the handling of the recent possible breach of GMAC (Genetic Manipulation Advisory Committee) conditions in the Mt Gambier region of South Australia. It is alleged GM Canola plants, part of a trial by the Aventis company, were dumped at an open commercial tip. The Interim Office of Gene Technology Regulator (IOGTR) is currently investigating the allegations, but the process has been rightly criticised in the majority report.[19]

From reports provided to the committee, I am not satisfied the IOGTR has managed this matter with anything like the openness required. I am also concerned the stated need for "commercial and security secrecy" in such trials has led to a GM crop-trial program that is unaccountable to the farming community and those other communities with a vital and legitimate interest in such trials.

I am also conscious of the widespread dismay at the lack of control mechanisms that enabled the recent completely unregulated importing, distribution and

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[17] Genetic Engineering, Food, and Our Environment. Luke Anderson. Green Books UK 2000, p.66

[18] Ibid, p.67

[19] Majority report par. 7.17

sowing of 13,000 hectares of GM modified canola in Great Britain, and an as yet unassessed planting of the same Canadian seed in France, Germany and Sweden.[20]

As recently as May this year the West Australian Primary Industries Minister Mr Monty House flagged the possibility of permanently banning the commercial production of genetically manipulated crops in WA, while the WA Farmers Federation President Kevin McMenemy said a two year moratorium on the commercial exploitation of GM crops would protect the image and quality of WA honey.[21]

Conclusion

While I have no dispute with most of the recommendations in the majority report, I do not believe we are able to conclusively say that the benefits of GM technology to Australian agriculture or Australian consumers will outweigh the potential detriments in the long term.

Reaching such a conclusion is premature, and has more to do with agricultural and economic domination by a few companies, with the support of a few governments, rather than on an objective assessment of possible benefits of GM against yet to be assessed costs, especially to smaller, less developed economies.

Rather than a mono-culture agriculture, Third World countries should be encouraged to restore the diversity of their agriculture.

Likewise Australia risks surrendering its unique "clean" agricultural status in a too hasty marriage to an unproven technology. Australia should be ultra-cautious in facilitating any genetic pollution of its agriculture and not give ground as it has in quarantine protection.

The moral and ethical aspects of developing and using GMO technology in food have not been properly debated within the community, a debate that requires far greater attention to the spiritual rather than scientific arguments.

The Australian Medical Association told the inquiry that: *"the jury is still out on the benefits and risks of genetically modified foods on public health and the environment".*[22]

The British Medical Association says starkly: *"there are all sorts of things that we don't know".*[23]

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[20] Mann S., "Growing Concern over Gene Crops", *Sydney Morning Herald*, 19 May 2000.

[21] Mallabone, M., "Gene ban sweet with the beekeepers", *The West Australian*, 20 May 2000

[22] Majority Report par 2.52

[23] Majority Report par 2.50

For these and those other reasons detailed in this minority report I would recommend:

There be a five year moratorium on the development of GMOs in Australia to enable adequate independent research to be carried out on health and environmental impacts and consumer demand.

Peter Andren,
Independent Member for Calare.
8th June 2000.

A

Appendix A- List of submissions and exhibits

Submissions

Number	Organisation
1	Animated Biomedical Productions
2	Dr Chris Blanchard
3	Mr Brendan Patrick Doyle
4	Mr Robert Anderson
5	Ms Alison Lyssa
6	Mr Wayne Hancock
7	Dr Brian Booth
8	The Cattlemen's Union of Australia Inc.
9	Cooperative Research Centre for Weed Management Systems
10	WA State Agricultural Biotechnology Centre, Murdoch University
11	NSW Farmers' Association, Tallimba Branch
12	D F Cook
13	Queensland Government: Office of Fair Trading, Department of Equity and Fair Trading
14	Centre for Legumes in Mediterranean Agriculture
15	Dairy Research and Development Corporation
16	Submission withdrawn

Number	Organisation
17	The O'Halloran Family
18	Mr Mal and Ms Nancy Robinson
19	Dr Charles Lawson
20	Cattle Council of Australia
21	Cooperative Research Centre for Tropical Plant Pathology
22	Mr Alan Griffiths
23	Waratah Seed Co. Ltd
24	Organic Federation of Australia Inc.
25	Nugrain Pty Ltd
26	Novartis Australia Pty Ltd
27	Cotton Research and Development Corporation
28	Senator Natasha Stott Despoja
29	Dr Chris Sotiropoulos
30	Heritage Seed Curators
31	Ag-Seed Research Pty Ltd
32	Frontier Seeds Pty Ltd
33	Go Mark Food Systems
34	Forest & Wood Products Research and Development Corporation
35	IP Australia
36	National Farmers' Federation Australia
37	Agrifood Alliance Australia
38	NSW Farmers' Association
39	Australian Biotechnology Association
40	Cooperative Research Centres Association Inc.
41	S A & M A Ward
42	Queensland Fruit & Vegetable Growers
43	Mr Doug McIver

Number	Organisation
44	Monsanto Australia Ltd
45	Natural Law Party
46	Ms Susan Stribling
47	Grains Research and Development Corporation
48	Western Australian Government
49	Rural R&D Chairs Committee
50	Tasmanian Government
51	Mr Russell McGilton
52	Cooperative Research Centre for Premium Quality Wool
53	Senator the Hon Nick Minchin, Minister for Industry, Science and Resources
54	National Genetic Awareness Alliance
55	AgrEvo Pty Ltd
56	CSIRO
57	Public Health Association of Australia Inc.
58	Australian United Fresh Fruit & Vegetable Association Ltd
59	Australian Food and Grocery Council
60	Australian Barley Board
61	Avcare Ltd
62	Australian Academy of Science
63	Australia New Zealand Food Authority
64	Australian Raw Sugar Industry
65	Grains Council of Australia
66	AWB Ltd
67	Victorian Government
68	Grain Biotechnology Australia Pty Ltd
69	Pastoralists and Graziers Association of WA Inc.

Number	Organisation
70	Department of Foreign Affairs and Trade
71	Australian GeneEthics Network
72	New South Wales Government
73	Organic Federation of Australia Inc. (supplementary to submission no 24)
74	The National Association for Sustainable Agriculture, Australia Ltd
75	Agritrade International Pty Ltd
76	The Veterinary Manufacturers and Distributors Association
77	Agriculture, Fisheries and Forestry Australia
78	Interim Office of the Gene Technology Regulator
79	Queensland Government
80	Australian Cotton Growers Research Association Inc.
81	South Australian Government
82	Environment Australia
83	Insurance Council of Australia Ltd
84	Department of Industry, Science and Resources
85	Australian GeneEthics Network (supplementary to submission no. 71)
86	Australian Quarantine and Inspection Service
87	Interim Office of the Gene Technology Regulator (supplementary to submission no. 78)

Exhibits

1 Various Genetic Manipulation Advisory Committee public information sheets detailing planned release proposals, dated from September 1997 to March 1999.

Documents presented by Mr Scott Kinnear at the public hearing in Melbourne, 13 August 1999.

2 Various correspondence, papers, information and news clippings.

Documents presented by Mr Bob Phelps at the public hearing in Melbourne, 13 August 1999.

3 J Alexandra, *Environmental Management Systems for Australian Agriculture – Issues and Opportunities*, April 1999.

Document presented by Mr Jason Alexandra at the public hearing in Melbourne, 13 August 1999.

4 Comments on article by B Hoyle, 'Canadian farmers seek compensation for "genetic pollution', *Nature Biotechnology*, vol. 17, August 1999.

Document provided by Heritage Seed Curators Australia at the public hearing in Canberra on 20 September 1999. Comments were provided as an excerpt from an email dated 17 August 1999.

5 Interim Office of the Gene Technology Regulator:

- Primary producer (and related) organisations that participated in public forums on the *Gene Technology Bill 2000*
- Submissions from primary producer (and related) organisations on the draft *Gene Technology Bill 2000*

Document provided at the public hearing in Canberra on 15 March 2000.

6 Interim Office of the Gene Technology Regulator, Transparencies shown at the public hearing in Canberra on 5 April 2000.

7 Interim Office of the Gene Technology Regulator, *Progress Report to the House of Representatives Standing Committee on Primary Industries and Regional Services: Possible Breaches of GMAC Conditions*, 19 April 2000.

B

Appendix B –List of public hearings, inspections and discussions

Public hearings

Tuesday, 27 July 1999 - Perth

Agriculture Western Australia

Ms Celia Cornwell, Manager Policy and Legislation, Agriculture

Mr Robert Delane, Executive Director, Agriculture Protection

Dr M Dracup, Senior Research Officer

Centre for Legumes in Mediterranean Agriculture

Dr Joanne Barton, Research Associate

Dr Nancy Longnecker, Coordinator, Education Program

Dr Penelope Smith, Lecturer

WA State Agricultural Biotechnology Centre, Murdoch University

Professor Mike Jones, Director

Friday, 13 August 1999 - Melbourne

AgrEvo Pty Ltd

Mrs Naomi Stevens, Regulatory Affairs Officer Crop Improvement

Australian GeneEthics Network

Mr Robert Phelps, Director

Department of Natural Resources and Environment, Victoria

Mr John Blackstock, Principal Analyst Plant Industries

Dr Bruce Kefford, Executive Director, Primary Industries

Nugrain Pty Ltd

Dr Michael Dalling, Research and Development Director, New Technologies

Organic Federation of Australia Inc.

Mr Jason Alexandra, Organic farmer and member

Mr Scott Kinnear, Chairperson

Monday, 30 August 1999 - Canberra

Australian Food and Grocery Council

Dr Geoffrey Annison, Scientific and Technical Officer

Mr Mitchell Hooke, Executive Director

CSIRO

Dr Mikael Hirsch, Principal Adviser, Natural Resources, Office of the Deputy Chief Executive,

Dr Chris Mallett, Deputy Chief Executive

Grains Council of Australia

Mr Jock Kreitals, Deputy Director

Mr Leigh Spencer, Research Officer

Grains Research and Development Corporation

Mr Steven Lack, Acting Managing Director

National Farmers' Federation

Dr Wendy Craik, Executive Director

Ms Anwen Lovett, Deputy Director, Environment

Monday, 20 September 1999 - Canberra

Agriculture, Fisheries and Forestry Australia

Ms Virginia Greville, Assistant Secretary, Biotechnology and R&D Policy Branch

Dr Simon Hearn, First Assistant Secretary, Portfolio Policy & International Division

Mr John Madden, Director, Science, Technology & Innovation Policy Section

Mr Paul Trushell, Policy Officer, Multilateral Team, Plant Quarantine Policy Branch, Policy & International Division, AQIS.

Mr Douglas Waterhouse, Registrar, Plant Breeders' Rights Office

Heritage Seed Curators Australia

Mr Bill Hankin, President

Wednesday, 29 September 1999 - Canberra

Agrifood Alliance Australia

Dr Wendy Craik, Executive Member

Mr Claude Gauchat

Dr Stephen Prowse, Executive Officer

Monday, 18 October 1999 - Canberra

Australian Cotton Co-operative Research Centre

Dr Gary Fitt, Chief Executive Officer

Australian Cotton Growers Research Association

Mr John Grellman, Immediate Past Chairman

Cotton Research & Development Corporation

Mr Bruce Pyke, Research and Extension Manager

Cotton Seed Distributors Ltd

Mr Graham Windeatt, Chief Executive Officer

CSIRO

Dr Danny Llewellyn, Principal Research Scientist

Dr Jim Peacock, Chief, Plant Industry

Monsanto Australia Ltd

Mr Brian Arnst, Public Affairs Manager

Dr William Blowes, Technical Director

Wednesday, 8 March 2000 - Canberra

Australia and New Zealand Food Authority

Dr Paul Brent, Food Product Standards

Dr Marion Healy, Chief Scientist

Mr Peter Liehne, General Manager, Food Product Standards

Mr Ian Lindenmayer, Managing Director

Wednesday, 15 March 2000 - Canberra

Department of Health and Aged Care

Mr Terry Slater, National Manager, Therapeutic Goods Administration

Interim Office of the Gene Technology Regulator

Ms Elizabeth Cain, Head, Department of Health and Aged Care

Dr Deborah Maguire, Scientific Adviser, Genetic Manipulation Advisory Committee Secretariat, Department of Health and Aged Care

Wednesday, 5 April 2000 - Canberra

Department of Health and Aged Care

Mr Terry Slater, National Manager, Therapeutic Goods Administration

Interim Office of the Gene Technology Regulator

Ms Elizabeth Cain, Head

Ms Andrea Matthews, Legal Consultant

Professor Jim Pittard, Chairman, Scientific Subcommittee, Genetic Manipulation Advisory Committee

Inspections and discussions

Perth – Tuesday, 27 July 1999

Meeting and discussions with representatives of:

Centre for Legumes in Mediterranean Agriculture

Council of Grain Grower Organisations

Export Grains Centre Ltd

Grain Biotechnology Australia Pty Ltd

National Association of Sustainable Agriculture Australia Ltd

Pastoralists & Graziers Association of WA Inc.

Seed Industry Association of Australia Ltd

The Grain Pool of Western Australia

WA Farmers' Federation

Western Australian State Agricultural Biotechnology Centre

Wesfarmers Dalgety

Canberra – Friday, 10 March 2000

Meeting and discussions with representatives of:

Center for the Application of Molecular Biology to International Agriculture (CAMBIA)

C

Appendix C - Plant breeders' rights

The *Plant Breeders Rights Act 1994 Act* was introduced to support the competitiveness and sustainability of Australian primary industries by encouraging investment in plant breeding; facilitating access to elite varieties from overseas; and speeding technology transfer.

The scope of protection granted by PBR focuses on the commercial use of a variety's propagative material and extends to the exclusive right to: produce or reproduce; condition for propagation; offer for sale; import or export; or stock the material for any of the previous purposes. In certain circumstances these rights can be extended:

- to include the harvested material or products obtained from harvested material if the grantee has not had reasonable opportunity to exercise their rights on the propagative material; and
- to another variety that has been essentially derived from the PBR variety (including other varieties that cannot be reproduced without the repeated use of the PBR variety).

Balanced against the rights granted to the owner of the new variety, certain rights are also allowed for public and private interests. These include:

- farm saved seed (the ability of farmers to save seed of a PBR variety to establish subsequent crops of that variety). It is important to note that patents do not include a similar provision;
- the right to use the variety as a food, food ingredient or fuel; or for any other purpose that does not involve reproduction (including the production of sprouts); and
- any act that is done privately for non-commercial purposes, experimentation or for the purpose of breeding other plant varieties.

PBR promotes producer access to new varieties by imposing important conditions. Grantees are required, within two years of the grant of PBR rights, to provide reasonable public access to the variety. Reasonable access is defined in terms of price, quality and quantity to meet market demands. Should reasonable public access not be provided, compulsory licenses can be issued for the production and sale of the variety. A compulsory license entitles the grantee to 'reasonable remuneration' consistent with the normal course of business.

Another condition of continuing PBR protection is access by breeders of other new varieties to the propagative material of a PBR variety for the purposes of testing and comparison.

PBR protection is available to varieties in all plant species, provided they satisfy the eligibility criteria of distinctiveness, uniformity and stability. Varieties covered include fungi and algae (but excluding bacteria, bacteriodes, mycoplasmas, viruses, viroids and bacteriophages). Protection lasts for 25 years in the case of trees and vines, and 20 years for other species.

Australia's PBR regime accords with the relevant convention of the International Union for the Protection of New Plant Varieties, and falls within the bounds of the World Trade Organisation's agreement on the Trade Related Aspects of Intellectual Property. Administration of the PBR schemes in all 44 UPOV member countries is similar, allowing a high degree of reciprocity.