Inquiry into the Gene Technology Bill 2002

Report No. 2

Standing Committee on Health

December 2002

Legislative Assembly for the Australian Capital Territory

Committee membership

Ms Kerrie Tucker MLA, Chair

Ms Karin MacDonald MLA, Deputy Chair

Mr Brendan Smyth MLA

Secretary:	Ms Siobhán Leyne
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Administration:	Mrs Judy Moutia

Resolution of appointment

To examine matters related to hospitals, community, public and mental health, health promotion and disease prevention, disability services, drug and substance abuse and targeted health programs.

Terms of reference

The Committee will inquire into and report on the Gene Technology Bill 2002.

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Summary of recommendations

RECOMMENDATION 1

3.5. The Committee recommends that the Government make representations to the Gene Technology Ministerial Council to address the outstanding concerns raised in the report *A Cautionary tale: Fish don't lay tomatoes*.

RECOMMENDATION 2

3.10. The Committee recommends that the Government, as a matter of urgency, talk to the NSW Government about the concerns regarding cross-border GMO contamination and the potential liability of the NSW Government, should NSW allow environmental release of GMOs.

RECOMMENDATION 3

3.31. The Committee recommends that the ACT, for the purposes of marketing itself as a centre for research excellence and for promoting bio-business, assert its right under section 21(b) of the bill to declare itself GE-free. This moratorium should be reviewed five years after the enactment of this bill.

3.32. The Committee recommends that this include a moratorium on dealings with transgenic organisms, such as that in place in Tasmania, on:

- **all new commercial environmental releases of transgenic crops;**
- **environmental releases of transgenic animals and transgenic animal feed;**
- **trials in the open environment of transgenic food crops; and**
- **trials in the open environment of transgenic non-food crops where no test is available to detect the presence of the transgenic material.**

RECOMMENDATION 4

4.15. The Committee recommends that the Government make representations to the Ministerial Council to call on the Federal Government to move the responsibility for gene technology to the Prime Minister and Cabinet portfolio.

RECOMMENDATION 5

4.20. The Committee recommends the Government make representations to the Ministerial Council to require the OGTR to consider the economic and social impact of applications before granting licenses.

RECOMMENDATION 6

4.23. The Committee recommends that the Government make representations to the Ministerial Council to call on the Federal Government to urgently review the makeup of the Gene Technology Grains Committee to ensure that it has more equitable representation of the community, including farmers.

RECOMMENDATION 7

4.26. The Committee recommends that the Government lobby the Federal Government for an independent inquiry into farming practice, including the use of GM products.

RECOMMENDATION 8

4.29. The Committee recommends that the Government make representations to the Ministerial Council to ensure that all residents within a reasonable radius of field trial sites be informed in writing of the location and nature of the site and that the sites of field trials within the ACT be listed on the ACT Government website.

RECOMMENDATION 9

4.35. The Committee recommends that the Government make representations to the Ministerial Council for the OGTR to establish a standard application that requires risk assessments and management plans to be based on long-term studies undertaken in Australian conditions.

RECOMMENDATION 10

4.40. The Committee recommends that the Government make representations to the Ministerial Council that the GENHAZ process be a basic requirement for all license applicants to the OGTR.

RECOMMENDATION 11

4.44. The Committee recommends that the Government make representations to the Ministerial Council that the OGTR be involved in any future risk assessment processes it is invited to and that it puts in place processes to deal with any real or perceived conflicts of interest that may arise from this involvement.

RECOMMENDATION 12

4.50. The Committee recommends that the Government make representations to the Ministerial Council that the Gene Technology Regulator ensures an open and transparent process if changes to applications are accepted as minor. The Committee further recommends that the Government, through

the Ministerial Council investigate the potential for developing definitions of minor changes to applications.

RECOMMENDATION 13

4.56. The Committee recommends that section 72A be withdrawn from the ACT bill and replaced with a reference to the *Gene Technology (Licence Charges) Act 2000* or appropriate legislation be introduced amending the Gene Technology Bill 2002 to resolve the issue of a tax in subordinate legislation.

RECOMMENDATION 14

4.66. The Committee recommends that:

- **the ACT Government support the ongoing funding of the gene technology regulatory scheme through a cost-share arrangement between the Commonwealth, State and Territory Governments and at no stage should the OGTR be self-funding through application fees; and**

- **no moves should be made towards self-funding of the regulatory scheme until a public cost-benefit analysis of the implications of self-funding is undertaken.**

RECOMMENDATION 15

4.72. The Committee recommends that, in order to increase transparency, that the Government make representations to the Ministerial Council requiring the Gene Technology Regulator to report on those licenses with confidentiality clauses in a similar manner to that required in the *Public Access to Government Contracts Act 2000*.

RECOMMENDATION 16

4.79. The Committee recommends that the Government make representations to the Ministerial Council for the Regulator to work closely with the scientific community to encourage timely patent and GMO license applicants to ensure that neither the public nor intellectual property interests are compromised.

RECOMMENDATION 17

4.81. The Committee recommends that the Government make representations to the Ministerial Council to ensure that a clear policy is implemented regarding the timeframe for consideration and determination of all types of applications.

RECOMMENDATION 18

4.86. The Committee recommends that a formal appeals process be established and legislated so that non-applicants may appeal decisions which have the potential to seriously impact on the broader public interest or their personal or environmental health and safety or economic well-being.

RECOMMENDATION 19

4.95. The Committee recommends that Section 1 Part 4(a) be withdrawn from the Gene Technology Bill and replaced with the definition of the precautionary principle as named in the Environment Protection Act 1997 (ACT), Section 3 (2)(a). This definition should explicitly name the precautionary principle and not include a reference to cost-effectiveness.

RECOMMENDATION 20

4.102. The Committee recommends the Government make representations to the Ministerial Council to put in place a policy that the Gene Technology Regulator require all persons undertaking any dealings with GMOs to hold adequate insurance coverage.

RECOMMENDATION 21

4.111. The Committee recommends that the issue of liability and adequate insurance coverage be addressed as a matter of urgency and before any environmental release of GMOs occurs.

RECOMMENDATION 22

4.122. The Committee recommends that the Government make representations to the Ministerial Council to put a policy in place that ensures that the application of measures to protect health incorporate the World Health Organisation definition of health, including environmental health.

RECOMMENDATION 23

4.127. The Committee recommends that the Government make representations to the Ministerial Council to ensure that there is more community representation on the Gene Technology Ethics Committee.

RECOMMENDATION 24

4.129. The Committee recommends that the Government undertake a comprehensive survey of the perceptions about the safety and use of GMOs in the ACT and use these findings to undertake a comprehensive, unbiased education campaign to inform public debate during the proposed 5-year moratorium.

RECOMMENDATION 25

5.6. The Committee recommends that the Assembly pass the Gene Technology Bill 2002 with the proposed amendments recommended in this report.

1. Introduction

1.1. The Minister for Health introduced the Gene Technology Bill 2002 into the Assembly on 21 February 2002. It was referred to the Standing Committee on Health for inquiry on 7 March 2002.

1.2. This Bill was introduced to the Assembly following the signing of the intergovernmental agreement on gene technology (Gene Technology Agreement) by the then Chief Minister, Mr Gary Humphries MLA, in August 2001.

1.3. The Agreement, recognising the need for a co-operative national legislative scheme protecting the heath and safety of people and the environment, binds the ACT to introduce nationally consistent legislation within a scheme that is intended to provide a national regulatory system for the application of gene technologies.

1.4. In this report, the Committee has attempted to provide readers with a picture of gene technology – what it is and how it can be used, followed by a national and international overview. The report then discusses issues regarding the regulatory framework.

1.5. The Committee has serious concerns about the regulatory framework, for instance appeal rights, and the protection available to non-GM farmers from crop contamination by genetically modified products. These and the other issues raised in this report need to be addressed as a matter of priority.

1.6. Despite these concerns, the Committee is recommending that the Assembly pass the Gene Technology Bill 2002 with amendments as recommended throughout this report.

1.7. Currently the ACT is covered by the Commonwealth *Gene Technology Act 2000* and will continue to be until complementary legislation is passed. Passing this legislation will give the ACT some scope to regulate matters within its jurisdiction and otherwise influence policies by its representation on the Gene Technology Ministerial Council.

1.8. The Committee has also recommended that the ACT assert its right under the legislation to declare the Territory a GE-free zone, excluding research, to promote itself as a centre of excellence in biotechnology.

1.9. In doing so, researchers in the ACT can feel confident about their ongoing support, and the public can feel confident about their health and safety and that of the environment, at least until a stage when the debate is more advanced. The Committee feels that there is an absence of confidence at the moment.

1.10. Finally, the Committee would like to thank all those who made time to either make submissions, appear before the Committee, or otherwise assist in the Committee's inquiries.

Conduct of the inquiry

1.11. The purpose of this inquiry was not to inquire into the ethical concerns of using gene technology, but to recognise the existence of these concerns and ensure that the legislation and processes being put in place adequately address them.

1.12. The Committee is keenly aware that the impact of gene technology may not be felt until many years in the future and is cautious about dedicating land and environmental resources to experimental plantations. Given this, the Committee expanded the information sought under the terms of reference to include the following:

- The scope of activities involving gene technology in the ACT both now and in future;
- Ethical, environmental and public health issues relating to gene technology;
- The objectives and role of the ACT Government on the Gene Technology Ministerial Council and subordinate committees;
- The relationship between the ACT Government and the Office of the Gene Technology Regulator; and
- The extent of regulation necessary in the ACT.

1.13. Advertisements detailing the inquiry's terms of reference were placed in *The Canberra Times* and *The Chronicle* in May 2002. In addition, letters advising of the inquiry and inviting input were sent to organisations and individuals known to have an interest in the matter.

1.14. In response, the committee received 11 submissions and heard from eight witnesses at hearings. A list of submissions is at Appendix 1 and a list of witnesses who gave evidence at public hearings is at Appendix 2.

1.15. The Committee met with the following people in the ACT -

- Mr Tony Peacock, Manager, CRC for Biological Control of Pest Animals
- Mr David Dall, General Manager, PESTAT Pty Ltd

1.16. The Committee met with the following people outside of the ACT -

- Mr Bob Phelps, GeneEthics Network, Melbourne, VIC

The Committee meets in Melbourne at the GeneEthics Network offices.

1.17. Because of the extent of work that has been done at the Federal level and in several states many peak organisations were reluctant to respond to this inquiry, but through drawing on work done previously and through the submissions to this inquiry, the Committee was able to gain a comprehensive picture of the issues facing this piece of legislation.

2. What is Gene Technology?

Definitions

2.1. Gene technology is a term referring to a range of techniques for genetic investigation, analysis and change that depend on the direct manipulation of DNA, the material substance of heredity. It consists of tools and techniques scientists can use to study, identify or modify the genes of living organisms.

2.2. It is defined in the *Gene Technology Act 2000* (Cwth) Section 10 - Definitions:

> "… any technique for the modification of genes or other genetic material but does not include sexual reproduction, homologous recombination or any other techniques specified in the Regulations."[1]

2.3. In the context of the Gene Technology Bill 2002, gene technology refers to genetically modified organisms and the products derived from such organisms, such as food, agricultural and veterinary chemicals, industrial chemicals and therapeutic goods.

2.4. Genetic engineering bypasses the reproductive barriers that prevent genetic transfers between unrelated species, thus allowing transfer of genes from an organism of one species to another, completely unrelated species. Genetic engineering also includes methods of gene deletion and gene manipulation that are not possible using conventional breeding methods.

2.5. An organism which results from the use of genetic engineering is referred to as a genetically modified organism (GMO) and may be the result of a single modification or multiple manipulations changing multiple characteristics over generations.

2.6. The CSIRO refers to 'biotechnology as: "… the application of science, technology and innovation to produce new goods and services."[2]

Use of gene technology

2.7. Gene technology involves the use of 'genetic engineering' (GE) (also referred to as 'genetic modification' (GM)). These are interchangeable terms meaning the transfer of genes, or part of a gene, from one organism to another organism in ways that are not possible using conventional breeding methods.[3]

2.8. Selective breeding resulting in genetic modification, has been an intrinsic part of plant reproductive processes for centuries through traditional farming methods, although not to the degree possible today. In their policy document 4/02, the Royal Society states:

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[1] *Gene Technology Act 2000* (Cwth) Section 10 - Definitions
[2] CSIRO. June 2002: 4
[3] Royal Society, February 2002: 4; Stone et al. October 2002: 2.

> "Mankind has cultivated plants for thousands of years, during which time crop plants have continually been selected for improved yield, growth, disease resistance or food characteristics. The improvement of a plant species by 'conventional' techniques involves the selection for breeding purposes of certain plants that express desired characteristics. … Genetically modified plants differ from their conventional counterparts in that they are created by the deliberate insertion of specific genetic material using recombinant DNA technology. This technology may allow plant breeders to develop new varieties of crops at a faster rate than by conventional means, and it also allows the introduction of genetic material from other species, families or even kingdoms, which in many cases is not possible by conventional means. More specifically it allows the introduction of single genes and modification of a specific trait."[4]

2.9. This debate centres around GE which bypasses the natural barriers which would otherwise prevent any hybrid development, in particular the use of transgenes between totally unrelated species (plant to plant) and/or across kingdoms (bacteria to plant and animal to plant). In other words, it is genetic engineering that would not occur in nature or with conservative intervention but requires scientific human intervention at a DNA level.

2.10. This form of GE is used in plants for purposes such as incorporating herbicide and/or insect resistance, improving nutritional value and growth factors, and/or resistance to environmental factors such as salinity and drought. Research into the use of GE plants to produce industrial chemicals (such as bio-oil) and pharmaceuticals for human and veterinary use is currently underway.

2.11. GE is also used to transfer transgenes between organisms of the same species.

Environmental release

2.12. An environmental release refers to the authorisation to plant a crop in field (outside of enclosed space such as a greenhouse). This may be a contained release, such as for a field release trial, monitored for research purposes, or an un-contained release such as a full field planting for crop production.

2.13. The Gene Technology Bill 2002 states the following:

> A dealing with a GMO involves the ***intentional release of the GMO into the environment*** if the GMO is intentionally released into the open environment, whether or not it is released with provision for limiting the dissemination or persistence of the GMO or its genetic material in the environment.[5]

2.14. It is this matter which is of concern to the Committee. Without detailed investigation of the long-term impact on human health of GMOs in the food chain, it is reckless to irreversibly contaminate the environment with these products.

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[4] Ibid.
[5] Gene Technology Bill 2002 Part 2 Division 2.2 11

2.15. Until there have been peer reviewed and independent longitudinal studies addressing scientific, economic and social implications of the environmental release of GMOs, and a high level of consensus on these issues, the Committee feels that we should err on the side of caution. For more information regarding the precautionary principle, refer to Chapter 4.

2.16. The Committee is aware that there is a lack of consensus on the long-term safety of GMOs, although there is some agreement on the possible benefits that GE technology may bring.

2.17. The majority of global scientific and legislating communities, recommend a precautionary approach to GE, calling for ongoing and thorough research into all aspects and implications of the science.

2.18. An issue that was commented on in evidence by Dr. Mark Lonsdale of the CSIRO was that there is, in his opinion, still not enough data with which to be making decisions and discussing environmental risks[6].

2.19. This opinion was supported by Mr Scott Kinnear of the Organic Federation of Australia Inc. referring to a recent admission by Monsanto on this point:

> "Monsanto has recently admitted that the scant nutritional testing done on the roundup ready soy beans, was on laboratory soy beans that had not been exposed to the high levels of roundup that they would get in the field. Much of the testing appears to be on small numbers of rats (10 for Bt cotton) for a number of weeks."[7]

2.20. Also, the GeneEthics Network in its submission raised this same point:

> "The superseded, small-scale experimental evidence which is often accepted by the GTR as proof of the efficacy and safety of GE crops (the current canola applications for example) has in many cases only included conventional varieties which do not equate with GEOs in terms of environmental or agronomic performance."[8]

2.21. World-wide, governments have a responsibility to ensure that proponents of this technology substantiate a much greater burden of proof before environmental release than they currently hold.

2.22. Unfortunately, with the variation in world-wide standards, it will be difficult to impose an international regulatory system ensuring consistency in the burden of proof.

Benefits of gene technology

2.23. Proponents of gene technology have promoted many benefits of the use of gene technology.

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[6] Transcript of Evidence. 7 November 2002, p 42
[7] Exhibit 1, p 4
[8] Submission 8, p 3

2.24. The Government submission concurred with claims that gene technology provides a level of exactness in the development of genomic structures of plants that conventional techniques cannot possibly achieve.[9] This view is continually stated in documentation on the subject. For example:

> "The application of modern gene technology may offer producers several distinct advantages over traditional techniques. First, its use can result in easier, more precise and faster transfer of genetic material between living organisms. For some applications this can reduce the time required to successfully develop a new trait (ANZFA 1999). Second, modern gene technology use means that genetic material can be transferred between distantly related organisms or species that would not have been achievable using traditional breeding techniques (ANZFA 1999; OGTR 2002b)."[10]

> "GM enables a much more precise method of developing new plant varieties than conventional breeding by enabling single, well-characterised genes to be introduced. … Many scientists prescribe to the view that the GM process is simply a technologically advanced breeding tool that allows rapid and precise development of new varieties"[11]

2.25. The Government submission points out that development of GE agriculture may provide benefits to farming practices which include: reducing the use of pesticides and herbicides; more efficient use of veterinary and agricultural chemicals; reduction of farm worker exposure to chemicals and "savings in the energy inputs to farm production"[12], all of which should reduce costs to the farmer.

2.26. Some of these claims are not borne out by recent statistics reported by the Productivity Commission which found "that different studies look at different outcome measures"[13] making it difficult to obtain consistent benchmark data against which to measure economic gain or loss or increase or decrease in chemical use or yield.

2.27. There is some doubt as to the claims regarding reduction of chemical spraying resulting from planting of GM crops:

> "Bt cotton is the only crop for which claims of reduced spraying are clear. Analysts paint a mixed picture on the results of planting Roundup Ready soybeans. Bt corn and herbicide-tolerant cotton and corn have not resulted in clear reductions in the spraying of chemicals."[14]

2.28. Mr Graham Strong, in evidence to the Committee, expressed a number of reasons why insecticide use on farms could conceivably increase. These included: fear of contamination of a non-GE crop which would cause the entire crop to be

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[9] Submission 11, p. 12
[10] Stone et al., October 2002: 2
[11] Glover, 2002: 3
[12] Submission 11, p. 12
[13] Stone et al., October 2002: 12 – 13.
[14] http://www.colostate.edu/programs/lifesciences/TransgenicCrops/risks.html

rejected; concern about the possibility of GE volunteers from neighbouring farms; and resistance to herbicides being developed naturally. [15]

2.29. Mr Strong also stated that volunteer canola plants from an earlier planting germinated in his field of wheat up to 4 years later. Normal agricultural practice would be to use a herbicide such as Roundup to remove these volunteers along with other weeds from the crop. However, if the canola were to be a Bt variety (genetically engineered to be resistant to Roundup), then there would be a need to use expensive, stronger, more dangerous chemicals to remove the unwanted canola.[16]

2.30. Indeed, a canola crop in Tasmania has recently been destroyed because GM-canola has appeared five years after a trial was held at the site.[17]

2.31. The use of recombinant DNA techniques provide the opportunity to develop foods which optimise health more effectively than traditional hybrid-developed techniques.

> "The availability of recombinant DNA techniques provides the opportunity to develop foods that help optimize health status. The major difference with recombinant DNA techniques is the ability to introduce different nutrient profiles with greater speed and precision."[18]

2.32. Proposed benefits include rice varieties such as one which produces beta-carotene, one which decreases an undesirable component (glutelin) for sake brewing and another ("golden rice") "which is specifically designed to target Vitamin A deficiency, a cause of blindness among people living in developing countries."[19]

2.33. Proponents of GE claim that increased crop yield and/or nutrient value will provide a boost to food production in third world countries[20]. While the Committee accepts why potential benefits could be the case, there is not conclusive evidence to support this claim.

2.34. The review of statistical sources as analysed in the Productivity Commission paper demonstrates the problem of different findings in different reports regarding the yields, net returns, herbicide applications and weed control costs.[21] The increased cost of GM seeds due to purchase and technology fees may prove prohibitive to poorer farmers when coupled with the fact that they would not be able to collect seed for subsequent crops as per traditional practice.[22]

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[15] Uncorrected Proof Transcript of Evidence. 28 November 2002, p 7
[16] IBID., p 9
[17] Correspondence to Committee Office Research Officer from N. Ellis, Office of the Gene Technology Regulator, 10 December 2002
[18] World Health Organisation. June 2000: 8; and Royal Society, February 2002: 8.
[19] Ye, X., Al-Babili, S., Kloti, A., Zhang, J., Lucca, P., Beyer, P. and Potrykus, I. *Engineering the Provitamin A (b-carotene) Biosynthetic Pathway into (Carotenoid-Free) Rice Endosperm*. Science 287, 303-305 cited in FAO/WHO June 2000: 8
[20] "Gene technology alone, is not going to feed the millions of people in the developing world, however, it has the potential to give subsistence farmers access to crops that require less water and less pest and disease controls." Agrifood Awareness Australia: 13
[21] Stone et al. 2002: 12-13
[22] IBID., p. 10

2.35. Currently, research is being conducted into the use of crop plants to produce industry products such as bio-oil, and pharmaceuticals which provide disease immunity. AusBiotech Ltd, in their submission point out "At present the focus is on agricultural products and food but new microbially-based products are emerging, as are plant-based therapeutics."[23]

2.36. Research and development is also underway to develop salt- and drought-resistant strains.

2.37. Certainly if all of these claims were proved true, there could be great benefits for agriculture and industry, however the Committee recommends the use of a precautionary approach (for more information regarding the precautionary principle, refer to Chapter 4).

2.38. It is unacceptable to use unsubstantiated claims to inform public policy on genetic technology. Analysis of the economic impact resulting from the introduction of pharmaceutical and industrial biotech plants into the market needs to include cost-benefit.

Concerns about gene technology

2.39. There are a number of concerns raised about the safety of GM technology and processes. Many of these are complex and scientific, however the Committee has listed some of them here to give an idea of why caution and further research is advised.

Horizontal gene transfer and antibiotic resistance marker genes

2.40. Transgenic DNA in GMOs is designed and optimised to cross species barriers and is flanked by recombination sequences which enable the DNA to incorporate itself into the host genome. This may increase the likelihood that the transgenic DNA may break up and recombine with another host, resulting in unexpected consequences.[24] Although this happens, it may also be possible to develop mechanisms to prevent unintended transfer of transgene DNA.

2.41. Questions have been raised about the transference of transgenes to plants, animals and humans. In her report, Dr. Deborah Read states:

> "Horizontal gene transfer has been reported between distantly related bacteria and from bacteria to yeast, mammalian cells and plant cells.... almost any type of bacterium has the potential to transfer DNA to any other type of bacterium if it contains a broad host range gene transfer element. Although most ingested DNA is likely to be degraded and diluted in the human gastro-intestinal tract, natural transformation of gut epithelial cells or micro-organisms cannot be completely ruled out."[25]

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[23] Submission 2
[24] Ho, M. (2002). The Best Kept Secret of GM Crops. In *Science in society*.
[25] Read, 2000, p. 12

2.42. However, antibiotic resistance from GMOs is far less likely than from the common other uses of antibiotics in humans and animals. Dr Read goes on to state:

> "It is more likely that antibiotic resistance genes would be introduced into gut micro-organisms through transfer between naturally occurring ingested contaminating micro-organisms and gut micro-organisms than through transfer from DNA released during digestion of GM plant or animal material."

2.43. Horizontal gene transfer between plants is similarly unlikely but not impossible.

2.44. Antibiotic resistance marker genes are used to identify the section of genetic material that has been successfully implanted. The three classes of selectable marker genes are genes that confer resistance to antibiotics, or to herbicides, or are concerned with metabolic pathways.[26]

2.45. Biotechnologists use a limited range of these antibiotic resistance genes, some of which are antibiotics commonly used in human and/or veterinary pharmacology. Increased tolerance to antibiotics (those used as antibiotic marker genes in GE) is an issue of concern raised by Mr Kinnear:

> "The use of antibiotic resistant [sic] marker genes is dangerous and has drawn appropriate critical responses from medical and health associations around the world (British Medical Association)."[27]

2.46. The Food and Agriculture Organisation of the United Nations/World Health Organisation (FAO/WHO) June 2000 report in response to concerns over the use of antibiotic resistance marker genes, recommends the following:

> "The consultation encourages the use of alternative transformation technologies, if available and demonstrated to be safe, that do not result in antibiotic resistance genes in genetically modified foods. If further development of technology is required, additional research should be strongly encouraged."[28]

2.47. This concern was also raised in the Senate Community Affairs References Committee report on gene technology, see also Chapter 3.[29]

Health issues and allergies

2.48. Concerns have been raised that allergies may result from transgenic food crops[30]. These may result from either a known allergen being incorporated into a transgenic organism, or from an unforeseen protein combination, which results from a transgenic mutation.

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[26] IBID., p. 19
[27] Exhibit 1, p 4
[28] FAO/WHO, June 2000, p. 22
[29] Senate Committee, November 2000. 2.49 – 2.53
[30] Exhibit 1, p 4

2.49. These may either trigger allergies in people already prone to reaction, or may trigger allergies in previously non-allergic individuals.[31] The FAO/WHO recognised that this is a potential problem in their January 2001 report,

> "… a clear need exists to pay particular attention to allergenicity when assessing the safety of foods produced through genetic modification." In his opening statement to the consultation, Mr Jacque Vercueil "indicated that allergenicity was one of the most frequently asked questions in connection with the safety of genetically modified foods."[32]

Chemical resistance & 'superweeds'

2.50. 'Superweeds' are a result of outcrossing (or 'gene swapping') of genes from plants that are pest or/and herbicide resistant to weedy or wild varieties. The resulting superweed therefore gains a selective advantage over related native species and weeds, and can therefore decimate native species reducing biodiversity, or increase the level of 'weediness'.

2.51. Research in the US on GM sunflowers has found that this scenario occurs with outcrossed GM sunflowers.[33] The University of Lille in France has also reported gene swapping in sugar beets, which provided advantage to the outcrossed weed varieties.[34]

2.52. The Committee was told by a farmer in evidence that canola can out-cross to wild-radish (a native Australian weed). Therefore Roundup, traditionally used to eliminate wild-radish from any crop, will not be effective – leading to a greater use of more potent chemicals.[35]

Effects on non-GE farming

2.53. Non-GE crops can be inadvertently contaminated throughout the supply chain which negates their certification and makes them un-saleable to their market.

2.54. This contamination can happen in any range of ways, and this Committee heard and saw convincing evidence that it would be impossible to adequately clean farm equipment and other machinery used along the supply-chain. Canola volunteers can grow in fields up to seven years after the initial crop removal.[36]

2.55. Currently all Australian grain crops need certification that they are GE-free to be sold to certain markets. As there are no commercial-grown GE grain crops in this country yet, this is easy to achieve.

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[31] Royal Society, 2002, p. 7
[32] FAO, 2001, p. 5
[33] Research of Ohio State University's Professor Allison Snow. Available online: http://www.osu.edu/units/research/archive/sungene.htm. The research found that the outcrossed weeds were stronger, produced more seed and had the same bt resistance of the GM parent. This would give the outcrossed weeds a selective advantage in the wild.
[34] http://www.guardian.co.uk/gmdebate/Story/0,2763,774794,00.html
[35] Uncorrected proof transcript, 28 November 2002, p. 27
[36] Uncorrected proof transcript, 28 November 2002, p. 23

2.56. Should GE crops be allowed, the certification scheme could be onerous, especially for non-GE farmers. The additional costs imposed on these farmers could include: cost of barrier-zone crops; ensuring separation throughout the supply chain (from farming equipment to cargo ships) and the cost of continuous testing and monitoring of crops.

2.57. As the photo below illustrates, an ordinary wheat crop can be inadvertently mixed with canola (black seeds) through ordinary farming practice. If this were GE-canola, this wheat crop is at risk of losing certification to be sold in a market demanding non-GE product.

Figure 1 - Canola seeds scattered throughout a wheat sample. This is from a sample supplied by Mr Graham Strong (Exhibit 2).

2.58. GE farming risks reduced diversity in farming practices due to "the impact of contamination to traditional or organic crops in areas surrounding genetically modified crops"[37] and therefore less choice for both farmers and consumers.

2.59. Domination and manipulation of the seed supply market by biotechnology companies is a concern, which has often been raised[38], and to some degree borne out in the Productivity Commission's research paper:

[37] Submission 11, p. 13

> "… GM crops may also increase costs, most obviously in terms of seed price premiums and technology fees – estimated at up to 30 per cent for GM corn and soybeans (EC 2000). Requirements to purchase seed every year as part of contractual arrangements may also push annual seed purchase costs up."[39]

2.60. 'Terminator' technology results in seed which cannot be re-germinated. This means that farm-collected seed cannot be harvested for subsequent seasons imposing significant costs on the farmer who has to buy new seed each season.

2.61. Commercial environmental release of GE product also imposes costs of separation for the non-GE farmer. Although the GE-farmer may be responsible for separation zones the cost of separation will be a cost to all farmers as they try to ensure that contamination does not take place at any stage along the supply chain.

The 'unknown' factor and unintended effects

2.62. The 'unknown' factor is a concern raised in a significant amount of the research arguing against GMOs,[40] including the unpredictable nature of disposal of the waste products of gene technology, an issue raised in the government submission.[41] Ms Catherine Moore also raised it in her submission:

> "So far there is nothing to reassure us that this will be the case [GE organisms being proven safe], and the unknowns are far too numerous for us to feel confident about their introduction."[42]

2.63. Leakage of GM product into the soil which may in turn invade soil bacteria is a concern raised:

> "There are concerns that transgenic plants may leak different compounds than conventional plants do, as an unintended consequence of their changed DNA. Speculation that this may be happening leads to concern about whether the communities of micro-organisms living near transgenic plants may be affected. The interaction between plants and soil micro-organisms is very complex, with the micro-organisms that live around plant roots also leaking chemical compounds into the soil. … Attempts to discover whether transgenic plants are changing the soil environment, and whether they are changing it in good ways or bad ways, are hindered by our lack of basic scientific knowledge."[43]

2.64. As stated in the FAO/WHO Consultation: "In the future, genetic modifications of plants are likely to be more complex perhaps involving multiple between-species transfers and this may lead to an increased chance of unintended effects." They also state: "Due to the increased precision of genetic modification compared to

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[38] Senate Committee. (November 2001). 3.122, 3.123 , 3.124 & 3.125
[39] Stone et al, p. 10
[40] www.colostate.edu/programs/lifesciences/TransgenicCrops/riskl.html
[41] Submission 11, p. 13
[42] Submission 9
[43] http://www.colosate.edu/programs/lifesciences/TransgenicCrops/risks.html

conventional breeding, it may become easier to predict pathways likely to be influenced by unintended effects."[44]

2.65. In response, it has been argued by the Life Sciences Network and Agrifood Awareness Australia that "a genetically modified crop takes some eight to thirteen years to progress from a scientific research project to a commercial product", and that it is assessed on a "case-by-case basis, with a thorough and transparent risk assessment and risk management plan" [45].

2.66. The Committee acknowledges that development of a GM crop may be a lengthy process – but it is one that takes place largely in contained environments and does not agree that the length of this process in necessarily addresses these concerns or assures safety.

[44] WHO/FAO, June 2000, p. 6
[45] Submission 10, p. 3

3. Gene Technology in Australia

3.1. A considerable amount of work has been undertaken in Australia on the issue of gene technology. The Australian Senate referred the Gene Technology Bill 2000 (Cwth) to the Senate Community Affairs References Committee for inquiry. The resulting report, *A Cautionary Tale: Fish Don't Lay Tomatoes*[46], looked in detail at issues to do with the establishment of the Office of the Gene Technology Regulator (OGTR), and related committees, and the involvement of the States and Territories, and the general public in the scheme.

3.2. The Committee refers readers interested in the development of the complementary Commonwealth legislation to this report.

3.3. The report refers to the following issues (with page references) which have been of particular interest to the Committee:

- Application of the precautionary principle (p. 32);
- Consideration of Australia's bio-diversity and unique flora and fauna (p. 48);
- Ethical considerations (p. 51);
- Commercial-in-confidence provisions (p. 59);
- Public confidence in the scheme and gene technology (p. 74);
- Insurance coverage (p. 102);
- Licensing conditions and review (p. 107);
- Roles of the consultative group and committees of the [Interim] Office of the Gene Technology Regulator (p. 126); and
- Rights of third-parties to seek reviews of decisions (p. 140).

3.4. The Committee is concerned that important recommendations of the Senate committee were not addressed in the legislation, but are still of serious concern to the community and recommends that the Government, make representations to the Gene Technology Ministerial Council to look closely at addressing the concerns raised in the report *A Cautionary tale: Fish don't lay tomatoes*.

Recommendation 1

3.5. The Committee recommends that the Government make representations to the Gene Technology Ministerial Council to address the outstanding concerns raised in the report *A Cautionary tale: Fish don't lay tomatoes*.

[46] Senate Committee (November 2000)

State and Territory issues

3.6. Following the introduction of complementary State and Territory legislation the *Gene Technology Act 2000* (Cwth) will be wound back.

3.7. Even though this legislation is being implemented at a state level, environmental issues such as gene technology can not sit in isolation within the States and Territories as seed, pollen and animals do not respect state borders. Therefore, the Committee has outlined the current status of the corresponding legislation in each of the States and the Northern Territory.

3.8. As of November 2002, the **New South Wales** (NSW) legislation is stalled in the Upper House, the legislation having been referred to the Standing Committee on State Development for inquiry and this report is not expected until 31 December 2002.

3.9. Should NSW choose to allow environmental-release of GMOs, and the ACT choose to be GE-free, the ACT, being an island within NSW, and NSW Governments will have to look closely at issues of crop barriers and liability in the instance of contamination.

Recommendation 2

3.10. The Committee recommends that the Government, as a matter of urgency, talk to the NSW Government about the concerns regarding cross-border GMO contamination and the potential liability of the NSW Government, should NSW allow environmental release of GMOs.

3.11. The **Northern Territory** has a draft bill which will be a platform for discussion with stakeholders prior to finalisation. At the moment there is no timeframe set for presenting the bill.

3.12. The **Queensland** Government has enacted the *Gene Technology Act 2001* (QLD) with no additional restrictions and is allowing the decision to be GE-free or not to be made at a local farm level.

3.13. **South Australia** has passed the *Gene Technology Act 2001* (SA). The Act does not cover the issue of GM-free areas, if the Government decides to declare GM-free areas, this is expected to be done through custom legislation.

3.14. However, a Select Committee on Genetically Modified Organisms has been established charged to inquire into the following –

a) advice on how (within the established Commonwealth-State regulatory framework) South Australia can assess the impact of GM plant technology from the point of view of human health, environment and market access;

b) identify where the impact of GM plants might be different in South Australia compared with the rest of Australia and other countries, and advise on strategies that South Australia should adopt to address these differences;

c) review the relevant State, national and international reports and inquiries on GM plants and the major issues for South Australia in relation to human health, environmental safety and market access; and

d) advice on the means by which the South Australian community can be consulted and informed and their views consolidated in relation to GM plants.

3.15. This committee is to report within 12 months of 22 August 2002.[47]

3.16. The Committee feels that this report will be an important contribution to the debate regarding gene technology in Australia and urges the Government to pay close attention to its findings, particularly in regards to community consultation.

3.17. **Tasmania** has exercised its right under the *Gene Technology Act 2001* (Tas) to declare a moratorium on certain dealings with transgenic organisms. Namely:

- "All new commercial environmental releases of transgenic crops;
- Environmental releases of transgenic animals and transgenic animal feed;
- Trials in the open environment of transgenic food crops; and
- Trials in the open environment of transgenic non-food crops where no test is available to detect the presence of the transgenic material."[48]

3.18. Recognising how imperative it is that research takes place, it is permitted, with the OGTR regulating dealings. However, the Government applies additional strict conditions on research field trials, which are to be assessed on a case-by-case basis and are to ensure "adequate isolation, management and minimisation of any risk of gene flow into the environment".[49]

3.19. **Victoria** passed the *Gene Technology Act 2001*. This legislation mirrors the Commonwealth Act.

3.20. **Western Australia** has also referred the Gene Technology Bill 2001 (WA) to the Legislative Council's Environment and Public Affairs Committee for inquiry. This Committee is expected to report in June 2003.

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[47] Parliament of South Australia website, http://www.parliament.sa.gov.au/committees/committee.asp?doCmd=show&intID=65
[48] Department of Primary Industries, Water and Environment (Tasmania), July 2002: 6.
[49] IBID., p.23

Gene technology in the ACT

3.21. The application of gene technology legislation in the ACT primarily concerns the small-scale producers, animal feed and to a larger extent, research organisations.

3.22. The research that occurs in the ACT is in the form of small-scale agricultural research (in glasshouses or at research sites) or laboratory-based research. The Committee recognises the value of this research, but stresses the need for a strong regulatory system and well-resourced structures to ensure best practice and to prevent inappropriate release into the environment.

3.23. Those organisations currently authorised to undertake gene technology research in the ACT are: Australian National University (ANU), Centre for the Application of Molecular Biology to International Agriculture (CAMBIA), Commonwealth Scientific and Industrial Research Organisation (CSIRO), The Canberra Hospital, and the University of Canberra.[50]

3.24. All of the submissions to this inquiry support a rigorous legislative scheme and corresponding regulatory system although to varying degrees.

3.25. However, the Committee has concerns about gene flow from GE products, particularly from field trials that may be close to commercial and/or private plantings in the ACT.

3.26. While there is no large-scale agriculture in the ACT, according to Environment ACT, there are private plantings of pasture for livestock feed, a small number of market gardens, small commercial vineyards, a single commercial olive grove and those foods grown for private consumption. See Appendix 3 for a map of farming in the ACT.

3.27. The Committee understands that researchers are just as wary of gene flow into field trials as some members of the community are of gene flow out of field trials. It is in everyone's best interest that environmental contamination is prevented.

3.28. The Committee is supportive of GE research in contained environments.

3.29. With a GE-free status, the ACT could promote itself as a leading location for biotechnology business. Business ACT estimates that biotechnology could contribute $244 million to the ACT economy, based on a case study of Saskatoon, a Canadian town similar in size as Canberra.[51]

3.30. The Committee believes that a five-year moratorium on environmental release of GM product, as called for by the GeneEthics Network[52] to allow for informed, precautionary and science-based discussions on the future of GE in Australia, is appropriate given the lack of agreement on the issue as a whole.

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[50] Submission 11, p. 7
[51] ACT Bio-business Strategy, Business ACT, p. 9
[52] Submission 8, p. 2

Recommendation 3

3.31. The Committee recommends that the ACT, for the purposes of marketing itself as a centre for research excellence and for promoting bio-business, assert its right under section 21(b) of the bill to declare itself GE-free. This moratorium should be reviewed five years after the enactment of this bill.

3.32. The Committee recommends that this include a moratorium on dealings with transgenic organisms, such as that in place in Tasmania, on:

- **all new commercial environmental releases of transgenic crops;**
- **environmental releases of transgenic animals and transgenic animal feed;**
- **trials in the open environment of transgenic food crops; and**
- **trials in the open environment of transgenic non-food crops where no test is available to detect the presence of the transgenic material.**

International overview

3.33. The international agricultural community and governments are attempting to devise and/or amend regulation and/or management systems for handling GMOs. The debate over GMOs is resulting in extremes of regulation from complete ban (such as has been imposed by Zambia) to regulated but promoted cropping (as with the United States). Research shows that countries who have undertaken consideration of GMOs have initiated some form of regulation.

3.34. There are a number of international agreements or forums under which GM products fall, including the Codex Alimentarius (created by FAO/WHO in 1963), the Cartagena Protocol on Biosafety (created by the Convention on Biological Diversity in 2000), the International Organisation for Standardisation (commenced 1947) and the Organisation for Economic Co-operation and Development (initiated in 1961).[53]. Appendix D of the Productivity Commission report details the regulatory regimes for GMOs.[54]

3.35. While Australia and **New Zealand** share the food products regulating body, the Australia New Zealand Food Authority (ANZFA), New Zealand has a two-year moratorium in place on new commercial releases of GM products. Laboratory and field trials for research are permitted however.[55]

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[53] Stone et al, October 2002 p 34
[54] IBID., p.83
[55] Stone et al, October 2002 p 91

3.36. As recently as 17 October 2002, the **European Union's (EU)** new Deliberate Release Directive 2001/18 on genetically modified organisms took effect, setting new and transparent regulations on genetically modified food, and providing an effective system for authorisation of GMOs, and replacing its previous directive.

3.37. Although this new procedure does not achieve full centralisation of GMO regulation at this time, it is still the aim of most of the Member States. There is however, still concern over the levels of contamination acceptability in seed, which have been set at between 0.3% to 0.7% GMO before labelling is required.

3.38. The **United States of America (USA)** has a system of multiple regulators for separate aspects of GMOs. This system was reviewed in April 2000 by the National Academy of Sciences which concluded (among other things) that the "Regulatory agencies (USDA, FDA, and EPA) should more closely coordinate their regulatory and approval activities, and should make the process more open to the public." In August 2002, the Office of Science and Technology Policy proposed changes to the existing system.[56]

3.39. There are also two bills currently before the House of Representatives. Firstly, H.R. 4812 (referred to the Committee on Agriculture and subsequently to the subcommittee on Farm Commodities & Risk Management), the intent of which is:

> "to provide additional protections for farmers and ranchers that may be harmed economically by genetically engineered seeds, plants, or animals, to ensure fairness for farmers and ranchers in their dealings with biotech companies that sell genetically engineered seeds, plants, or animals, and for other purposes." [57]

3.40. Secondly, H.R. 4814 (referred to the Committee on Agriculture and the Committee on Energy and Commerce), the intent of which is:

> "To amend the Federal Food, Drug and Cosmetic Act, the Federal Meat Inspection Act, and the Poultry Products Inspection Act to require that food that contains a genetically engineered material, or that is produced with genetically engineered material, be labelled accordingly." [58]

3.41. **Canada**'s federal government established The Canadian Biotechnology Advisory Committee (CBAC) as an independent expert advisory committee on 27 September 1999. Its mandate is to provide advice to a Co-ordinating Committee of Federal Ministers on broad policy issues associated with the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology. In fulfilling its mandate, CBAC is to raise public awareness and engage Canadians in an open dialogue on these issues.[59]

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[56] http://www.colostate.edu/programs/lifesciences/TransgenicCrops/evaluation.html
[57] H.R. 4812, May 22, 2002.
[58] H.R. 4814, May 22, 2002.
[59] http://www.cbac-cccb.ca/english/principles.aro

3.42. The Government of Canada is currently reviewing and updating guidelines and regulatory directives that oversee novel foods, plants with novel traits and livestock feeds from plants with novel traits.[60]

3.43. **China** has changed its approval system on GM products requesting inclusion on an approved foods list before their products can be sold or brought into China. The change took effect on July 1, 2002.

3.44. Under the new health ministry rules, anyone wishing to produce or import GM foods into China must submit an application to include samples of packaging, labelling and technical documents evaluating edibility and nutrition quality. The application must also include a verification report on safety and nutrition from a ministry-accredited testing agency. This will have the effect of hindering GM trade into China.[61]

3.45. **Singapore** has established the Genetic Modification Advisory Committee (GMAC) which is the central regulatory body for the research, development, production, use and handling of GMOs[62]. They are also actively canvassing for biotech companies to base their research and development industries in Singapore.

3.46. **India** has established the Genetic Engineering Approval Committee which was established under the *Environment (Protection) Act 1986* to ensure that:

> "no person shall import, export, transport, manufacture, process, use or sell any hazardous micro-organisms of genetically engineered organisms/substances or cells except with the approval of the Genetic Engineering Approval Committee".[63]

3.47. **Taiwan** has regulations for identification and notification of GMOs in food under its *Food Sanitation and Management Law* and the *Health Food Management Law* (effective February 9, 2000 and August 3, 1999) providing increased protection of consumer rights by clearly defining the responsibilities of manufacturers. In particular, health foods must be examined, approved, and registered, as well as categorised and labelled, before entering the market.

3.48. An evaluation method for detecting genetically modified foods and ensuring their safety was drafted in 1998, and Taiwan's Department of Health has been working on developing a labelling and supervisory system for genetically engineered food products referring to international agreements on the management of genetically modified foods (such as the Catagena Protocol on Biosafety of the Convention on Biological Diversity) as a guideline for its policy.[64]

3.49. According to the government website, **Hong Kong** does not have any commercial production of GM crops or livestock to date. However, there are biotechnological research studies being conducted in some local universities. Under

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[60] http://www.inspection.gc.ca/english/plaveg/pbo/gatconsult/consultinte.shtml
[61] http://pewagbiotech.org/buzz/display.php3?StoryID=60
[62] http://www.gmac.gov.sg/subcommittee-agriculture-guidelines.html
[63] http://envfor.delhi.nic.in/legis/hsm/hsm3.html
[64] http://www.roc-taiwan.org.uk/taiwan/5-gp/yearbook/chpt15-8.htm

Part V of the Public Health and Municipal Services Ordinance, Chapter 132, food intended for sale in Hong Kong must be fit for human consumption. The Ordinance applies to all foods including those genetically modified. The government has commissioned a study into the economic, regulatory and trade impacts of labelling.[65]

3.50. In **Japan**, the government has extensive guidelines for dealings with GMOs at all stages from research to agricultural application[66], and has a Labelling Standard for Genetically Modified Foods (March, 2000, revised 2001 & 2002). Significant weight is also given to the importance of organic agriculture.[67]

3.51. According to the Tasmanian Food Industry Council report of June 2000, "In 1999 a leading Japanese economics newspaper reported on a Nihon Keisai Shimbun survey of 323 food producers in Japan that found that over two thirds of the producers had either stopped using GM ingredients or were intending to do so."[68]

3.52. In **Africa,** the Agence France Presse (AFP) has reported that Malawi, Lesotho, Mozambique and Zimbabwe have considered GMOs and have decided to accept GM product as part of international famine relief, as long as it has been milled and cannot be germinated in the event of spillage.

3.53. Zambia on the other hand, has chosen a total ban on GM food, branding it "poison"[69], and taking a controversial, strong stand against the dispersal of GE corn to its population on the grounds that there is insufficient information about the long-term effects of GE foods.

3.54. **South Africa** has in place the *Genetically Modified Organisms Act 1997* "To provide for measures to:

- promote the responsible development, production, use and application of genetically modified organisms;
- ensure that all activities involving the use of genetically modified organisms (including importation, production, release and distribution) shall be carried out in such a way as to limit possible harmful consequences to the environment;
- give attention to the prevention of accidents and the effective management of waste;
- establish common measures for the evaluation and reduction of the potential risks arising out of activities involving the use of genetically modified organisms;
- lay down the necessary requirements and criteria for risk assessments; to establish a council for genetically modified organisms; to ensure

[65] http://www.info.gov.hk/fehd/safefood/gmf/gen_info6.html
[66] http://www.s.affrc.go.jp/docs/sentan/eintro/intro.htm
[67] http://www.maff.go.jp/soshiki/syokuhin/hinshitu/organic/eng_yuki_top.htm
[68] Food Industry Council of Tasmania, June 2000: 17.
[69] http://pewagbiotech.org/newsroom/summaries/display.php3?NewsID=294

that genetically modified organisms are appropriate and do not present a hazard to the environment; and

- establish appropriate procedures for the notification of specific activities involving the use of genetically modified organisms; and to provide for matters connected therewith."[70]

3.55. It is clear that the many in the international community and governments are taking this issue very seriously and considering it within the scientific, social and economic context in which the GMO debate rightly sits.

Economic impact

3.56. The implications for Australian trade in the global market are a concern given the Asian market requirements as outlined above.

3.57. The ability of Australian scientists and manufacturers to remain at the top of their field has the potential to provide significant benefits to the Australian economy, if research organisations are given appropriate support and funding.

3.58. The Committee is extremely concerned about the potential impact on our trade position if widespread planting of GM crops is permitted. Since the introduction of genetically modified corn to the US market, US corn exports to the European Union have fallen from 2 778 162 metric tonnes (1995-96) to just 2 300 metric tonnes (2000-01).[71]

3.59. A similar response to Australian exports has the potential to have a devastating impact on our rural economy, and yet in considering license applications for environmental release of GMOs, the Gene Technology Regulator is not able to consider economic factors (such as the impact on organic or other farmers potentially contaminated by GM product).

3.60. The Committee considers this to be negligent and would like to see policy principles put in place to require the Regulator to consider the economic impact, not only for the applicant but also the wider community, of environmental release of GMOs when considering applications.

3.61. Considering the potential for GM-canola to contaminate non-GM wheat (for example) as noted at paragraph 2.56, the economic impacts could conceivably be widespread.

3.62. No work has been presented to the Committee regarding the economic impact on Australian trade. However, a recent Productivity Commission report found no clear evidence on the positive economic impact of using GM products[72], and again the Committee calls for caution before rushing into this new technology, given that benefits are unclear.

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[70] http://www.gov.za/acts/1997/act15.htm
[71] Market year data, US Commerce Department, Census Bureau Foreign Trade Statistics. Provided to the Committee by Mr Bob Phelps of the GeneEthics Network.
[72] Stone et al. 2002, p. 11

3.63. The Committee agrees with AusBiotech Ltd that "market forces will largely determine adoption of new genetically modified products, provided the Government establishes and maintains a regulatory system satisfactory for both producers and consumers".[73] However the Government must be confident that market pressure from consumers is based on reliable, consistent and balanced information and is not dominated by the interests of proponents on either side of the debate.

[73] Submission 2, p. 1

4. Regulatory Framework

4.1. The Gene Technology Bill 2002 (the bill) is modelled on the national *Gene Technology Act 2000* (the Commonwealth Act) and is consistent with legislation introduced or enacted in all States and the Northern Territory. Once this legislation has been enacted in all States and Territories, the application of the Commonwealth Act will be wound back.

4.2. The intention of the bill is set out in section 3 of the bill:

> "The object of this Act is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs"[74]

4.3. The bill provides for:

- the functions of the ministerial council;
- the gene technology regulator, where necessary and not referred by the Commonwealth Act;
- regulation of dealings with GMOs;
- the licensing system;
- the regulation of notifiable low risk dealings on the GMO register;
- the certification and accreditation of facilities and organisations;
- the establishment and functions of the gene technology technical advisory committee, gene technology community consultative committee and the gene technology ethics committee where not provided for in the Commonwealth Act.
- those administrative matters pertaining to the regulator relevant to the ACT; and
- enforcement of the law and powers of inspection.

4.4. The Committee acknowledges that the Australian regulatory system is considered to be one of the most stringent in the world, and generally supports the regulatory system as described in this bill, however with important qualifications. There are several issues outlined below that have been raised with the Committee and the Committee would like assurance from the Government that these will be addressed as a matter of priority.

[74] Gene Technology Bill 2002, Part 1, S3.

Role of the ACT Government

4.5. The ACT Government holds a place on the Gene Technology Ministerial Council, represented by the Minister for Health. The Ministerial Council is responsible for setting gene technology regulation policy and ensuring the effective operation of the national framework.

4.6. The Ministerial Council is supported by the Gene Technology Standing Committee and can also seek advice from the Gene Technology Technical Advisory Committee (GTTAC), the Gene Technology Community Consultative Committee (GTCCC) and the Gene Technology Ethics Committee (GTEC).

4.7. The Council has a range of responsibilities, including to "issue policy principles, policy guidelines and codes of practice to govern the activities of the Office of the Gene Technology Regulation [sic]"[75]. The Council can also propose changes to the Commonwealth Act.

4.8. Under section 21 of the bill, the ministerial council may issue policy principles in relation to ethical issues; recognising areas to be designated for GM or non-GM crops and matters relating to dealings with GMOs. Policy principles must be developed in consultation with the Regulator and Committees of the OGTR, and relevant industry, environmental and consumer groups.

4.9. The ministerial council may also issue policy guidelines in relation to matters relevant to the functions of the regulator (S23).

4.10. Some submitters[76] to the inquiry are concerned that the ACT Government maintain an active and leading role on the ministerial council. In the words of the Life Sciences Network:

> "representation and active participation by the ACT Government on the Gene Technology Ministerial Council is vital to ensure the interests of the public and those who have made an investment in responsible gene technology research and development are ensured".[77]

4.11. The Committee agrees with this statement and would strengthen it by including the interests of environmental health and safety.

4.12. The Committee would also urge the ACT Government to propose policies to the Ministerial Council to reflect those concerns as outlined below.

Office of the Gene Technology Regulator

4.13. The Office of the Gene Technology Regulator (OGTR) is currently situated within the Federal Department of Health and Ageing. There is an argument for the OGTR to be situated within the agriculture portfolio[78]. Several states have recognised

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[75] Submission 11, ACT Government, 12 August 2002, p. 15
[76] Submissions 3, 4, 7, 8 and 10
[77] Submission 10, Life Sciences Network, 9 July 2002, p. 3
[78] Public Hearing, 28 November 2002

this concern and placed the responsibility for gene technology within agriculture portfolios.

4.14. However, the Committee, acknowledging the cross-portfolio nature of gene technology involving areas such as agriculture, trade, health, environment and transport, believes that the portfolio responsibility should be placed in a central agency.

Recommendation 4

4.15. The Committee recommends that the Government make representations to the Ministerial Council to call on the Federal Government to move the responsibility for gene technology to the Prime Minister and Cabinet portfolio.

4.16. The Committee is heartened by the decision of the Gene Technology Regulator to postpone the decision regarding widespread planting of canola crops until the report on supply chain management for GM canola by the Gene Technology Grains Committee is released and would like to see that these consultation and research processes continue.

4.17. However, the Committee has several significant concerns about the processes of the OGTR.

4.18. Namely, in assessing applications, the Gene Technology Regulator (GTR) does not have to take into account the social and economic impacts of gene technology as outlined in chapter 3.

4.19. It is clear to the Committee that the social and economic impacts are going to be great, particularly on non-GM and organic farmers.

Recommendation 5

4.20. The Committee recommends the Government make representations to the Ministerial Council to require the OGTR to consider the economic and social impact of applications before granting licenses.

4.21. Some farmers are concerned that the Gene Technology Grains Committee, the advisory panel for farmers on gene technology, has 25% of its voting members from within the biotechnology companies and that this is a clear vested interest, which does not adequately represent farmers.[79]

4.22. This is the advisory panel that farmers turn to when considering the issues of gene technology and the impact at the local farm level. The Committee feels that this situation is not fully representative. This has the potential to seriously promote misinformation aimed at boosting the profile and profits of biotechnology companies as well as failing to consider the practical knowledge of farmers.

[79] Uncorrected proof transcript, 28 November 2002, p.4

Recommendation 6

4.23. The Committee recommends that the Government make representations to the Ministerial Council to call on the Federal Government to urgently review the makeup of the Gene Technology Grains Committee to ensure that it has more equitable representation of the community, including farmers.

4.24. This is an ideal opportunity for a broad debate surrounding agriculture. In recent times southern Australia has seen the effects of large loads of soil being lifted from farms by strong winds, and at the time of writing this report, Australia was in the grip of a severe drought.

4.25. Farmers are calling for a debate on agricultural practice and the community is calling for more information on gene technology and the Committee believes that the governments of Australia need to heed these calls and slow the push towards widespread release of genetically modified organisms.

Recommendation 7

4.26. The Committee recommends that the Government lobby the Federal Government for an independent inquiry into farming practice, including the use of GM products.

4.27. The Committee does not believe that publication on the Office of the Gene Technology Regulator (OGTR) website is sufficient to inform the community of the location of field trials, and believes that all residents within a reasonable radius of field trial sites should be informed in writing of these sites either by the Government or the proponent.

4.28. The 'reasonable radius' should be defined by the Regulator in consideration of the nature of each application.

Recommendation 8

4.29. The Committee recommends that the Government make representations to the Ministerial Council to ensure that all residents within a reasonable radius of field trial sites be informed in writing of the location and nature of the site and that the sites of field trials within the ACT be listed on the ACT Government website.

Risk assessment

4.30. The Gene Technology Regulator must prepare a risk assessment and risk management plan for applications. This assessment process includes calling on the organisation's institutional biosafety committee (IBC).

4.31. The risk assessment includes hazard identification, but only of a human or environmental nature. As the Committee states below, this is not acceptable and economic and social risks must also be taken into consideration.

4.32. A concern has been expressed to the Committee that "the OGTR frequently bases risk assessments and management plans on experimental data and opinion prepared years ago for approval in overseas jurisdictions"[80].

4.33. The Committee feels that this situation is inappropriate and believes that all risk assessments and management plans for environmental release of GMOs should be based on data obtained in Australian conditions.

4.34. Concerns have also been expressed that studies promoting the benefits of GE-crops are based on only three to four years of planting and there is doubt that these benefits will be achieved after a longer period of time.

Recommendation 9

4.35. The Committee recommends that the Government make representations to the Ministerial Council for the OGTR to establish a standard application that requires risk assessments and management plans to be based on long-term studies undertaken in Australian conditions.

4.36. Mr David Dall from Pestat Pty Ltd informed the Committee that Pestat undertakes a process called GENHAZ for preliminary risk assessments. GENHAZ was developed in 1991, based on the HAZOP process used in the chemical industry. This process in internationally recognised as an acceptable system to identify hazards, and to think imaginatively and carefully about unplanned events.

4.37. GENHAZ has the following attributes:

- "it is a review by a multi-disciplinary team of the behaviour of individual elements of a planned release in the context of the whole system in operation;
- it forces an exploration of the hazards that might arise, however improbably, if the processes were to operate in ways that were not intended;
- it is effective at an early stage as a planning tool, as well as in exposing potential hazards in the ultimate proposal for release."[81]

4.38. Pestat undertook this process over five days prior to placing an application for environmental release of a GMO and called on members from the scientific, farming and general communities to be involved, putting the question – what could go wrong?

4.39. This allowed them to assess the environmental, social, and economic risks involved in their proposal, and led them to alter some aspects of it.

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[80] Submission 8, p. 2

[81] Royal Commission on Environmental Pollution's Fourteenth Report (HMSO 1991) *'GENHAZ: A System for the Critical Appraisal of Proposals to Release Genetically Modified Organisms into the Environment'* as quoted by Ryan, Sarah.
www.geodata.soton.ac.uk/hypermail/envsci98/group4/topic4/0001.html

Recommendation 10

4.40. The Committee recommends that the Government make representations to the Ministerial Council that the GENHAZ process be a basic requirement for all license applicants to the OGTR.

4.41. Pestat requested the involvement of the OGTR in a recent GENHAZ process, but the OGTR declined to be involved for reasons not given, presumably the perception of a conflict of interest.

4.42. As this is facilitated by an outside facilitator, Pestat felt, and the Committee agrees, that it would be a valuable process for the OGTR to be involved in.

4.43. The OGTR should not avoid the scientific community because of the perception of a conflict of interest, as, in the long run, this will only damage its reputation and credibility.

Recommendation 11

4.44. The Committee recommends that the Government make representations to the Ministerial Council that the OGTR be involved in any future risk assessment processes it is invited to and that it puts in place processes to deal with any real or perceived conflicts of interest that may arise from this involvement.

4.45. Submitters raised the issue of amendments to applications stating that under the current system if amendments are to be made a new application must be lodged[82].

4.46. The Regulator has the discretion to make amendments to license applications if proposed variations are minor and do not pose additional or different risks to the health and safety of people and the environment.

4.47. However, if the variation is considered by the Regulator to be substantial or to pose different risks to human or environmental health and safety (including an expansion or change of location) than the Regulator can reject a variation application and request that a full application be submitted.[83]

4.48. For example, if approval has been granted for field trials in State A and an applicant wishes to extend the field trials to State B and C the Regulator will probably seek a new application due to the different environmental conditions in the new field trial locations. If the applicant wishes to add another field trial location within the same region of State A, the Regulator may choose to consider this as a variation to the existing license.[84]

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[82] Submission 2, p. 2; Submission 4, p. 2
[83] Office of the Gene Technology Regulator, 2000, p. 98-99
[84] IBID., p.99

4.49. The Committee is satisfied that this is an appropriate system and acknowledges the workload of applicants in preparing applications, but supports the right of the Regulator to request a new application process rather than variations to an existing application and would be reluctant to recommend more leniency in this process.

Recommendation 12

4.50. The Committee recommends that the Government make representations to the Ministerial Council that the Gene Technology Regulator ensures an open and transparent process if changes to applications are accepted as minor. The Committee further recommends that the Government, through the Ministerial Council investigate the potential for developing definitions of minor changes to applications.

Taxes and charges

4.51. Division 5.8, S72A deals with GMO licence – annual charge. It states:

> "(1) A person who is the holder of a GMO licence at any time during a financial year is liable to pay a charge for the licence for the year.
>
> (2) The amount of the charge for a financial year is the amount prescribed under the regulations.
>
> (3) The amount prescribed may be in the nature of a tax and not be related to the cost for providing any service.
>
> *Note* This section does not appear in the Commonwealth Act. Provision is included, however, in the *Gene Technology (Licence Charges) Act 2000* (Cwlth) for the imposition of an annual charge for a GMO licence.".[85]

4.52. The Committee is concerned about the legality of this legislation imposing a tax. This was raised by the Standing Committee on Legal Affairs, performing the duties of a Scrutiny of Bills and Subordinate Legislation Committee, in Scrutiny Report No. 4 2002.[86]

4.53. Section 55 of the *Constitution Act 1900* (the Constitution) states "Laws imposing taxation shall only deal with the imposition of taxation, and any provision therein dealing with any other matter shall be of no effect".

4.54. Given this, the Committee sees no reason why this provision should be covered in the ACT Bill. Indeed, it would appear that reference to a tax is not allowed under the Constitution.

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[85] Gene Technology Bill 2002, Division 5.8, S72A.
[86] The Standing Committee on Legal Affairs, performing the duties of a Scrutiny of Bills and Subordinate Legislation Committee, Scrutiny Report No. 4 2002, p. 2-4.

4.55. The Committee is satisfied that the *Gene Technology (Licence Charges) Act 2000* (Cwlth) which currently regulates the prescription of GMO licence charges does so adequately.

Recommendation 13

4.56. The Committee recommends that section 72A be withdrawn from the ACT bill and replaced with a reference to the *Gene Technology (Licence Charges) Act 2000* or appropriate legislation be introduced amending the Gene Technology Bill 2002 to resolve the issue of a tax in subordinate legislation.

4.57. Implementation and maintenance of regulatory activities in the ACT in 2002-2003 are currently being met within the existing resources of the ACT Department of Health and Community Care. Should Environment ACT or other agencies be asked to comment on applications, the cost to the ACT would increase.[87]

4.58. The Commonwealth has agreed to fully fund the OGTR until 30 June 2003. After that point the Regulator will be funded from the cost recovery from the States and Territories, which, for the ACT, currently stands at 1.4%, or $64,000.[88]

4.59. The Committee is concerned about a funding scheme for the OGTR based on self-funding through application charges, as are members of the research community.

4.60. Mr Tony Peacock, of the CRC for the Biological Control of Pest Animals expressed a concern that if application fees were introduced, they would be compelled to submit more general applications (i.e., one covering the whole of Australia rather than one for each State/Territory) which, in effect, would reduce the information released to the public. Presently the CRC, and its associated commercial company, Pestat Pty Ltd submit as many applications as possible to facilitate information being released to the public.[89]

4.61. Dr Mikael Hirsch, Co-ordinator of the CSIRO Biotechnology Strategy Group also expressed this concern to the Committee:

> "A lot of what we do is public good research. … If, all of a sudden, there is a significant cost to CSIRO to do that, or to any research organisation, it means that there might be hesitation in doing just an extra piece of research or it would change the nature by which research is being conducted into becoming far more cost-efficiency driven and not knowledge driven.
>
> We are concerned that the cost recovery proposed will change the nature of research. It would change it from being driven on discovery into being driven by commercial interests. Any organisation will try to pass on costs to a commercial partner, which means a lot of the current research may not be done. To us, that is one of the bigger risks that Australia will face by the OTGR coming into full cost recovery. … we are concerned about how it

[87] Undated correspondence from the Minister for Health to the Chair, Select Committee on Estimates 2002-2003.
[88] Transcript of evidence, 7 November 2002, p. 9
[89] Anecdotal evidence received 6 November 2002

would affect the whole research system in Australia should that be introduced."[90]

4.62. The Committee is concerned that costs to applicants of the regulation system will be a deterrent to public-good research being undertaken.

4.63. Given the uncertainty surrounding GM products, the Committee feels that the Territory and Federal Governments should make every effort to ensure that research, particularly public-good research, in this area is viable and ongoing, which includes continuing to fund the OGTR as per the current arrangement.

4.64. The Committee is concerned that the intent of the legislation will be ignored under corporate pressure to approve applications, particularly if the OGTR becomes self-funded.

4.65. While the field of gene technology is growing, the Committee does not envision it growing to such an extent that it can consistently fund the regulatory body. Given this, the Committee feels that there will be an inherent conflict of interest for the regulatory body, depending on a limited field for funding.

Recommendation 14

4.66. The Committee recommends that:

- **the ACT Government support the ongoing funding of the gene technology regulatory scheme through a cost-share arrangement between the Commonwealth, State and Territory Governments and at no stage should the OGTR be self-funding through application fees; and**

- **no moves should be made towards self-funding of the regulatory scheme until a public cost-benefit analysis of the implications of self-funding is undertaken.**

Confidential commercial information

4.67. Currently, in order for information to be treated as confidential commercial information, applicants must apply to the Regulator for such a declaration. This will continue under the proposed bill.

4.68. The Regulator can refuse confidential commercial information status "if satisfied that the public interest in disclosure outweighs the prejudice that the disclosure would cause to anyone"[91].

4.69. The Regulator must also refuse to declare confidential commercial information if the information relates to one or more locations where field trials are

[90] Transcript of evidence, 7 November 2002, p. 31-32
[91] Gene Technology Bill 2002, Division 12.3 S185(2)

occurring unless release of such information would pose risks to the health and safety of people and the environment.

4.70. The GT Bill allows for heavy penalties, including imprisonment for wilful destruction or interference with GMO research and/or facilities, in acknowledgement of the risks posed to researchers by the publication of field trial locations.

4.71. The Committee feels that this is an effective deterrent and would not like to see public health and safety compromised for the sake of commercial interests, and feels that at all times the public interest should be placed first and foremost.

Recommendation 15

4.72. The Committee recommends that, in order to increase transparency, that the Government make representations to the Ministerial Council requiring the Gene Technology Regulator to report on those licenses with confidentiality clauses in a similar manner to that required in the *Public Access to Government Contracts Act 2000*.

4.73. AusBiotech Ltd raised concerns that release of confidential commercial information to the Regulator could constitute a breach under the *Patents Act 1990* (Cwth) and that the regulatory system could inevitably lead to leaks of valuable information that would prevent institutions gaining patents for research[92].

4.74. Patent applications are published 18 months after their earliest priority date (the date on which an application disclosing the invention is first filed). Applications are in the form of a full application or a provisional application, followed within 12 months with a full application.

4.75. Advice from IP Australia states that "Most patent applicants, particularly in the field of biotechnology will first file a provisional application providing a general disclosure of the invention and will then file a more comprehensive complete application within the next 12 months."

4.76. The advice goes on to state:

> "provided the publication of the information by the Gene Technology Regulator is done after the priority date, then this should have no impact on whether or not the invention can be patented. This is because the patent application is assessed to see whether it is sufficiently new and inventive by comparing the invention against information that was published before the priority date."[93]

4.77. A patent application is likely to be submitted at the research stage, (i.e. when research is at an Exempt Dealing, Notifiable Low Risk Dealing, or Dealing Not Involving Release stage). It is unlikely that information will need to be released in the public interest if it is contained in a certified research facility and does not pose a risk to human and environmental safety. The Committee therefore does not believe

[92] Submission 2, AusBiotech Ltd, 16 June 2002, p. 2
[93] Correspondence to Committee Secretary, 7 November 2002

that concerns about patent applications outweigh information being released in the public interest.

4.78. However, the Committee does recognise concerns of applicants regarding the protection of valuable intellectual property and urges the Gene Technology Regulator to work closely with the scientific community to encourage timely patent and GMO license applications to ensure that neither the public nor intellectual property interests are compromised.

Recommendation 16

4.79. The Committee recommends that the Government make representations to the Ministerial Council for the Regulator to work closely with the scientific community to encourage timely patent and GMO license applicants to ensure that neither the public nor intellectual property interests are compromised.

4.80. Concerns were also raised with the Committee about the lack of a specified timeframe for consideration of confidential commercial information applications.[94] This serves as a discouragement of the use of this form of application process. The Committee feels that all applicants should be dealt with fairly in terms of the expected timeframes of application processes.

Recommendation 17

4.81. The Committee recommends that the Government make representations to the Ministerial Council to ensure that a clear policy is implemented regarding the timeframe for consideration and determination of all types of applications.

Appeal rights

4.82. Nowhere in the legislation do non-applicants have the right to lodge an appeal against the Regulator's findings.

4.83. The Committee believes that this is highly inequitable as it allows applications to be considered in isolation from the wider environment. For example, a farmer has no right to appeal the granting of a license to a neighbouring farm for planting of a GM-product, even if that decision has the potential to significantly impact on business. Nor does an individual concerned about the environmental safety of a region have a right of appeal.

4.84. It was claimed at a public hearing of this Committee that any individual could bring a complaint or issue about an application to one of the relevant OGTR committees[95]. The committees can then choose to pay heed to the issue, but has no obligation to do so.

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[94] Submission 4, Pestat Pty Ltd, p. 2
[95] Transcript of evidence, 7 November 2002, p. 9

4.85. The Committee does not believe that this is satisfactory.

Recommendation 18

4.86. The Committee recommends that a formal appeals process be established and legislated so that non-applicants may appeal decisions which have the potential to seriously impact on the broader public interest or their personal or environmental health and safety or economic well-being.

The precautionary principle

4.87. Submitters have raised concerns that the precautionary principle should be explicit in the legislation to require the Regulator to apply it to all licence applications in order to ensure protection of the environment.[96]

4.88. Although the precautionary principle is not specifically mentioned in the *Gene Technology Act 2000* (Cwth), Section 4 of the Act provides as follows:

> "The object of this Act is to be achieved through a regulatory framework which:
>
> (aa) provides that where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation; …"

4.89. Section 1 Part 4a of the Gene Technology Bill 2002 states verbatim the above (aa). As this is in the objectives of the Bill, as with the Federal legislation, and therefore applies directly to the manner in which the OGTR should operate. It is not included or referred to as a test in the licensing provisions.[97]

4.90. Neither the *Environment Protection and Biodiversity Conservation Act 1999*[98] (Cwth) nor the *Environment Protection Act 1997*[99](ACT) include 'cost-effective' in their definitions of the precautionary principle.

4.91. There has been legal concern raised as to the effectiveness of the OGTR in relation to the possibility of grounds for appeal. These concerns arise from the fact that the definition of the precautionary principle as it is applied to the objects of the Act does not include particular reference to human health and safety, and that it includes the constriction of cost-effectiveness in relation to prevention measures.

> The scope for appeal from decisions of the Regulator is therefore substantial. Licence applicants may perceive that an appeal is justified if, in relation to potential risks to the environment, the Regulator takes measures (such as refusing a licence or imposing onerous licence conditions) which in their view are not "cost-effective", or if the information on which the

[96] Submission 9, p. 1, Submission 8, p. 9
[97] Bristow, February 2001
[98] Environment Protection and Biodiversity Conservation Act 1999 Section 3A(b)
[99] Environment Protection Act 1997 No 92 Part 1 Section 3 (2) (a)

> Regulator based his or her decision displays in their view not only a "lack of full scientific certainty" (whatever that means) but a fundamental lack of scientific significance or relevance whatsoever. Licence applicants may also perceive that an appeal is justified if, in relation to potential risks to human health or safety, the Regulator applies (implicitly or explicitly) the precautionary principle or a precautionary approach which they see as going beyond that specifically required by the Act.[100]

4.92. The Committee feels that the current definition leaves too much room for interpretation as outlined above and feels that a stronger statement is needed; such as that used in the European Union whereby "the general principle and the case law of the Court [is] that the protection of health takes precedence over economic consideration"[101].

4.93. There is general, support for wise use of the precautionary principle, including from the scientific community involved in gene technology applications –

> "But the modern thinking on the precautionary principle, there is tension around that, with the pro-development people saying that if we adopt the precautionary principle we will never do anything and you have proponents of the precautionary principle saying that it should be adopted nevertheless and we should take a risk-weighted approach to the adoption of technology.
>
> I think that the modern synthesis would say that it is a reasonable thing to adopt and enshrine. The modern way of thinking about it just says that if you adopt it you take a very broad approach to the framing of your risk questions. What tends to happen, if you don't have the precautionary principle in the backs of people's minds, is that the risk thinking tends to be quite narrowly constrained right from the start.
>
> People are just thinking about the risks that they have already seen, that the hazards have already been identified in the past, and they are not tending to think more widely about the potential wider implications…"[102]

4.94. A fuller definition of the precautionary principle in the legislation may have wider legal implications that need to be considered, but the Committee believes that it is fundamental that it be included.

Recommendation 19

4.95. The Committee recommends that Section 1 Part 4(a) be withdrawn from the Gene Technology Bill and replaced with the definition of the precautionary principle as named in the Environment Protection Act 1997 (ACT), Section 3 (2)(a). This definition should explicitly name the precautionary principle and not include a reference to cost-effectiveness.

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[100] Bristow, February 2001
[101] Commission of the European Communities, 2000.
[102] Transcript of evidence, 7 November 2002, p. 34-35

Insurance issues

4.96. There currently seems to be some confusion regarding who is liable for holding insurance to protect from any unwanted consequences of environmental release of GMOs.

4.97. There is no requirement in the current Act, nor the proposed Bill, for licensees be insured against damage to human health, the environment and other producers.

4.98. Section 62(3) of the bill, dealing with conditions that may be prescribed or imposed states:

> 'Licence conditions may also include conditions requiring the licence holder to be adequately insured against any loss, damage or injury that may be caused to human health, property or the environment by the dealings authorised by the licence.'

4.99. However, there seems to be confusion as to who is responsible for holding insurance.

4.100. It was expressed to the Committee at a public hearing that it is the understanding of the Government that the onus of liability lies with the applicant (i.e. the producer/developer of the product) to obtain insurance to cover the GE product, including coverage to deal with accidental contamination of non-GE product.[103]

4.101. The Life Sciences Network believes that it would be up to the grower to take out insurance against claims of possible contamination by their product.[104]

Recommendation 20

4.102. The Committee recommends the Government make representations to the Ministerial Council to put in place a policy that the Gene Technology Regulator require all persons undertaking any dealings with GMOs to hold adequate insurance coverage.

4.103. The Commission of the European Communities' communication recognises that the issue of burden of proof must be addressed where action is taken over GMOs under the heading of the precautionary principle:

> "Measures based on the precautionary principle may assign responsibility for producing the scientific evidence necessary for a comprehensive evaluation"[105]

4.104. The Insurance Council of Australia is reported as saying that it is "loathe to insure farmers, biotechnology and food companies for claims involving GM foods"[106]. The Council is indeed heeding caution:

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[103] Transcript of evidence, 7 November 2002, p. 3
[104] Transcript of evidence, 7 November 2002, p. 22
[105] Commission of the European Communities, February 2000 6.4

> "At the moment insurers just do not have any bank of knowledge or information or experience drawn from past losses or past claims as to how to treat this particular risk. So inevitably it will mean caution and caution will mean very detailed and careful analysis of the risk, and … the likelihood [is] that any cost will be quite high."[107]

4.105. Indeed, the European Union Commission is currently debating a proposal that would hold the industries and firms dealing in GMOs liable for incidents that pollute water, air or soil or harm protected natural site or species.[108]

4.106. The Committee notes the contradictory evidence regarding liability and believes that it is in the public interest that all applicants hold adequate insurance and that the confusion regarding liability indicates serious underdevelopment of a basic aspect of the industry.

4.107. Liability is a serious issue and must be addressed before any environmental-release proceeds.

4.108. In a radio interview with ABC 7ZR in Tasmania 8 August 2002, Mr Robert Drummond of the Insurance Council of Australia stated that:

> "The insurance industry have no experience of [the science of GMOs], … no way really that it can measure the risk involved. And we really have no experience about how genetically modified crops can be contained in any one location or any one neighbourhood.." [109]

4.109. Mr Drummond went on to state that there would be a likelihood that premium costs would be "quite high" due to the lack of "knowledge or information or experience drawn from past losses or past claims"[110].

4.110. He states that information is emerging from overseas "that some genetically modified plants … don't adapt to local conditions. Some have led to a loss of biodiversity in many places. Occasional cultivation problems for example with genetically modified soya in the USA has crawled up to 40% reduction in yield." These problems would, according to his assertions of risk acceptance, cast doubt on the availability in Australia, of affordable insurance for GMOs[111].

Recommendation 21

4.111. The Committee recommends that the issue of liability and adequate insurance coverage be addressed as a matter of urgency and before any environmental release of GMOs occurs.

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[106] Champness, Boyd. November 2001.
[107] Robert Drummond, General Manager of Regulation, Insurance Council of Australia, 8 August 2002
[108] Pomeroy, R. EU firms fight 'blank cheque' eco-liability law in T*he Times of Malta*, Saturday, November 16, 2002. www.timesofmalta.com
[109] ABC 7ZR, August 2002. Transcript.
[110] IBID.
[111] IBID

Ethical issues

4.112. Essentially, after the scientific debate, the debate surrounding gene technology becomes one of ethics.

4.113. The ethical concerns of people related to the integrity of the food supply and the environment, as well as social and economic issues deserve the full attention of Governments, regulatory bodies and scientific organisations.

4.114. The Committee acknowledges that there are measures set in place to try to address the ethical concerns regarding gene technology.

4.115. The Gene Technology Ethics Committee (GTEC) was established under the *Gene Technology Act 2000* and its functions will continue under this bill. Its functions are to provide advice on:

> (a) "ethical issues about gene technology;
>
> (b) the need for, and content of, codes of practice about ethics for conducting dealings with GMOs;
>
> (c) the need for, and content of, policy principles about dealings with GMOs that should not be conducted for ethical reasons."[112]

4.116. The Committee has cross memberships with the Gene Technology Technical Advisory Committee (GTTAC) and the Gene Technology Community Consultative Committee (GTCCC) and the Australian Health Ethics Committee (AHEC) which is a principal committee of the National Health and Medical Research Council (NHMRC).[113]

4.117. The Committee is concerned that the Regulator is not able to consult with this committee on applications.

4.118. Although one of the priority work areas of this committee is 'the institutional and commercial context of consent in relation to GMOs and their possible impacts on the community'[114], the Committee is concerned that it does not balance the consideration of scientific and social ethics equally.

4.119. The Committee agrees that the ethical treatment of all living organisms in scientific research is essential.

4.120. However, the Committee is concerned that health in the context of this bill is being taken in a purely scientific way. The World Health Organisation defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."[115]

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[112] Gene Technology Bill 2002, Div 8.4 S112
[113] Submission 5, National Health and Medical Research Council, 18 June 2002, p. 1
[114] Gene Technology Ethics Committee meeting communique, 15-16 May 2002
[115] Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61

4.121. The Committee believes that the application of measures to protect health in regards to gene technology should take a holistic vision of health that incorporates the World Health Organisation definition which, in this context, needs to include environmental health as well as recognising that the community has the right to access a safe food supply.

Recommendation 22

4.122. The Committee recommends that the Government make representations to the Ministerial Council to put a policy in place that ensures that the application of measures to protect health incorporate the World Health Organisation definition of health, including environmental health.

4.123. Other ethical issues raised during consultation of the original bill are –

- Should life become a commercial property through patenting?
- Should we create transgenic organisms, particularly those containing human and animal DNA?
- Who advocates for nature?
- How do we ensure that our decision-making processes respect the diverse cultural, moral and religious beliefs within our multicultural society?[116]

4.124. The Committee further questions – what is the impact of creating a disease to eradicate a species in Australia on other ecosystems throughout the world?

4.125. The Committee is concerned with the ability of the GTEC to adequately represent the views of the community. While there can be no doubt that there is an extremely high level of expertise on the GTEC, there is only one member not representing an academic or scientific position. However, this member works for a commercial television station and the Committee is concerned that this could raise the perception of a conflict of interest.

4.126. The Committee notes that the GTCCC has several community representatives and would like to see more positions made available for community representation on the GTEC.

Recommendation 23

4.127. The Committee recommends that the Government make representations to the Ministerial Council to ensure that there is more community representation on the Gene Technology Ethics Committee.

States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948.

[116] First Australian Consensus Conference: gene technology in the food chain, Lay Panel Report, March 1999, Appendix 1, www.health.gov.au/ogtr/volsys/questions.htm#9

4.128. A recent survey undertaken by Market Attitude Research Services for Biotechnology Australia showed that 54% of people did not feel confident that GM foods were safe for human consumption. Those surveyed in the ACT had a slightly higher perception of the benefits versus the risks of GM foods. However, this survey was only undertaken on a small sample of people Australia-wide (ACT- 30, Australia-wide – 1000).[117]

Recommendation 24

4.129. The Committee recommends that the Government undertake a comprehensive survey of the perceptions about the safety and use of GMOs in the ACT and use these findings to undertake a comprehensive, unbiased education campaign to inform public debate during the proposed 5-year moratorium.

[117] Biotechnology Australia media backgrounder 02/187, and correspondence to Committee Office Research Officer dated 6 December 2002 from Mr Craig Cormick, Biotechnology Australia.

5. Conclusion

5.1. The issue of genetic engineering, or genetic modification is contentious, and one which should be taken seriously by governments. The long-term implications of genetically modified organisms in foods are not yet known and there is contention within the scientific community as to even the initial safety of genetically modified product.

5.2. Although the Committee has serious concerns about the regulatory system and has recommended several changes, it is recommending that the Assembly pass the Gene Technology Bill 2002 with the amendments recommended in this report.

5.3. It is appropriate that this scheme is a national regulatory scheme for the purpose of overseeing activities, however, the states and territories must maintain the right to define what happens within their borders.

5.4. Without relevant ACT legislation in place, the Office of the Gene Technology Regulator makes decisions based on the federal legislation, which does allow environmental release of genetically modified product.

5.5. At this time, the Committee believes this is inappropriate, which is why it has recommended a five-year moratorium on the release of genetically modified organisms into the ACT environment.

Recommendation 25

5.6. The Committee recommends that the Assembly pass the Gene Technology Bill 2002 with the proposed amendments recommended in this report.

Kerrie Tucker MLA
Chair
12 December 2002

Appendix 1 – Submissions and exhibits received

1 Ms Andina Farragher, CSIRO

2 Ms Lyndal Thorburn & AG Coulepis, AusBiotech Ltd

3 Ms Anna Cronin, National Farmers' Federation Limited

4 Mr David Dall, Pestat Pty Ltd

5 Professor Alan Pettigrew, National Health and Medical Research Council

6 Ms Kath Taplin, Environmental Defender's Office

7 Ms Paula Fitzgerald, Agrifood Awareness Australia

8 GeneEthics Network

9 Ms Catherine Moore

10 Dr William Rolleston, Life Sciences Network

11 ACT Government

Exhibits

1 Mr Scott Kinnear, Chairperson, Organic Federation of Australia Inc.

2 Sample of wheat and canola seeds, presented by Mr Graham Strong at public hearing, 28 November 2002

Appendix 2 – Witnesses at public hearings

On 7 November 2002

Dr Charles Guest, Deputy Chief Health Officer, ACT Government

Dr Julie Glover, Bureau of Rural Sciences, Agriculture, Fisheries and Forestry – Australia

Dr Wendy Craik, Life Sciences Network

Dr Mikael Hirsch, Coordinator, CSIRO Biotechnology Strategy Group

Dr Mark Lonsdale, Strategy Director, CSIRO Entomology

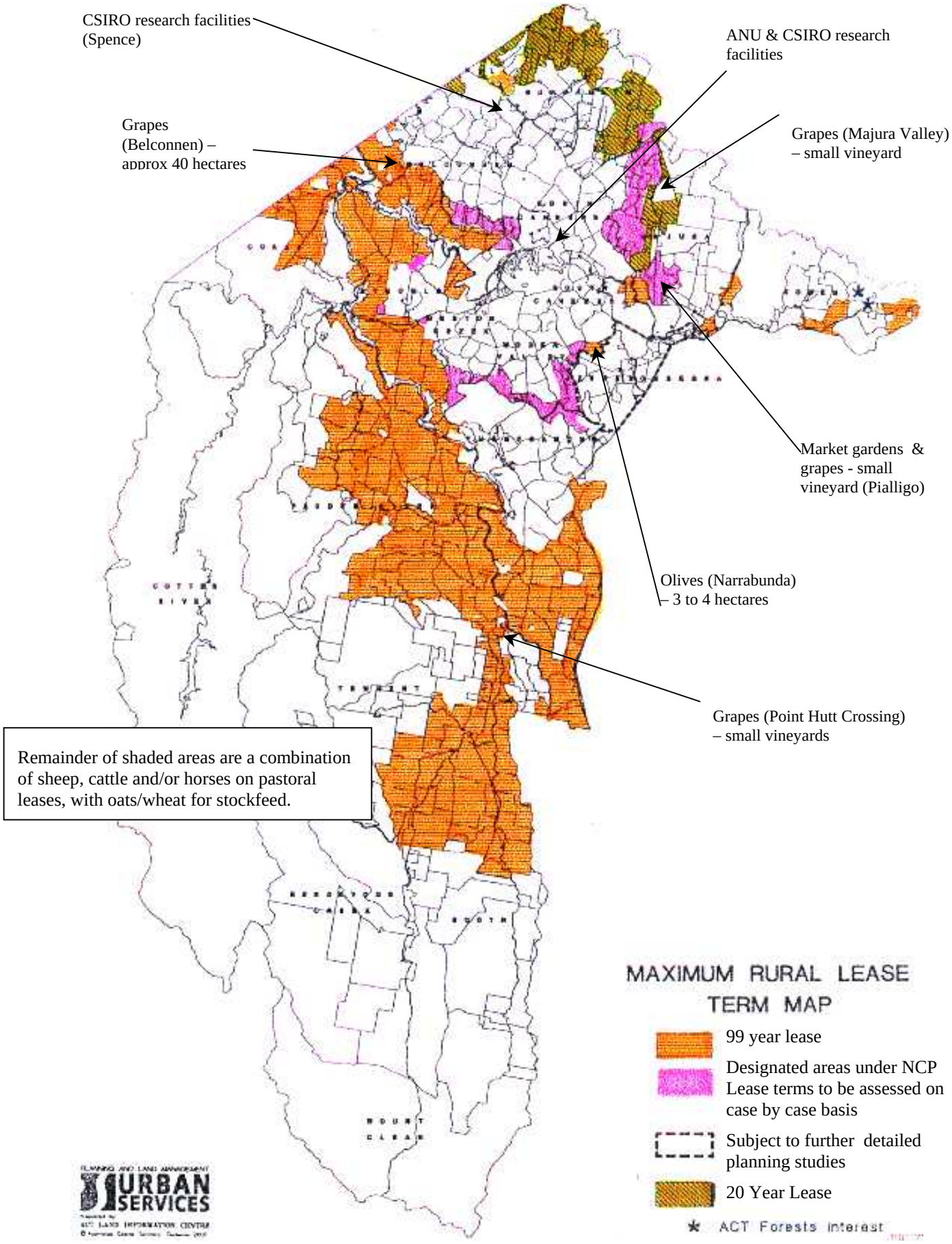
Dr Alan Richardson, Chair, CSIRO Plant Industry's Institutional Biosafety Committee

On 28 November 2002

Mr Graham Strong

Ms Rosemary Smith

Appendix 3 – Farming in the ACT



Appendix 4 - Acronyms

AHEC – Australian Health Ethics Committee

ANZFA – Australian and New Zealand Food Authority

CSIRO – Commonwealth Scientific and Industrial Research Organisation

FAO – Food and Agriculture Organisation of the United Nations

GE – genetically engineered/genetic engineering

GM – genetic modification

GMO – genetically modified organism

GT – gene technology

GTCCC – Gene Technology Community Consultative Committee

GTEC – Gene Technology Ethics Committee

GTGC – Gene Technology Grains Committee

GTTAC – Gene Technology Technical Advisory Committee

NHRMC – National Health and Medical Research Council

OGTR – Office to the Gene Technology Regulator

WHO – World Health Organisation

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