CHAPTER SIX

HUMAN HEALTH ISSUES

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A. Food and Pharmaceuticals

6.1 There are concerns that eating genetically altered plants or animals, or genetically altered food additives such as new flavouring agents or sweeteners, or taking into the body pharmaceuticals (vaccines or hormones) made using the new techniques may be dangerous for human health in some way. The unintended consequences of previous use of chemical pesticides and herbicides was cited as the kind of thing we must avoid.

6.2 Dr David Burch, et al., referred to three possible types of problems with food.[1] Firstly, naturally occurring toxins can be injurious to human health if ingested. The presence of solanine in potatoes is an example. Modifying food crops to produce greater quantities of those toxins in order to combat pests or disease may increase the risk. Secondly, introducing into food crops the ability to produce toxins previously only made by non-food plants could create new dangers. Thirdly, altering the level of anti-pest toxins produced by a food crop could change the nutrient profile of the food concerned making it less nutritious.

6.3 Clearly, there is a need to carry out tests on the effect on human health of adding new toxins to food sources or increasing the level of existing toxins in the desire to increase the crop's resistance to pests or disease. Such tests should include an examination of whether the toxins concerned are specific to the target or not. Evidence was presented that these matters are being taken into account. For example, the CSIRO is working on genetically modifying crops so that they produce an insect toxin normally produced by the bacterium *Bacillus thuringiensis*. Plants producing this 'BT toxin' should experience less insect damage. Dr Danny Llewellyn from CSIRO commented that BT toxin is registered as a safe biological insectide. "So there is already toxicological evidence that that is not toxic to humans. It is a highly specific toxin, only specific to insects and within the insects only to a very narrow range of species of insects."[2]

6.4 The ACF claimed there appeared to be unresolved problems to do with certain products - citing L-Tryptophan, artifical human insulin produced by GMOs, and milk containing bovine somatotropin (BST). Reference was also made to the clearance for human consumption of meat from the Adelaide transgenic pigs by the NH&MRC on the basis of an allegedly "small amount of data".[3]

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1 Burch, Dr D et al.: Submission 106 pp 31, 32

2 Llewellyn, Dr D, Division of Plant Industry, CSIRO: Transcript p 1077

3 Phelps, R, Australian Conservation Foundation: Submission 140 p 61

6.5 Some of the specific examples are examined in this chapter. The case of the Adelaide pigs is examined in detail in chapter 5 section F.2.(iii).

A.1 Food safety

6.6 It is axiomatic that consumers want safe, high quality products at reasonable prices. In the case of food, this is often translated to mean 'pure, natural and wholesome'. Consequently, the products of biotechnology are seen to be flawed because the technology is considered 'unnatural'.

6.7 Unfortunately, not all 'pure and natural' products are safe. There may be considerable risk to human health from naturally occurring compounds in the diet.[4] Products developed by traditional methods of breeding can also be hazardous.

> "The [potato] variety Lenape was being introduced commercially into the USA some two decades ago after having passed all of the then applicable screens and trials. It was belatedly realized that a fortuitous combination of day length and temperature variables resulted in an accumulation of the toxic alkaloids solanine and chaconine. ... a public health problem of major proportions was only narrowly averted."[5]

6.8 Nevertheless, "the consumer is naturally suspicious of claims that a new process is completely safe and can only benefit the world, and that there are no detriments associated with it."[6]

6.9 The situation is compounded regarding food safety because of claim and counter-claim.

> "The question of safety ... [depends] in a lot of cases on the last research result that came through and the people who were pushing it. If that research result is favourable to a point of view, it can get a lot of media hype, it can get a lot of pushing, and it may be five years down the track before someone comes along and says, 'Hey, there is a flaw in that. ..' .. But by the time you have got the information to show it, it is so imprinted in the public mind that it is very hard to turn around."[7]

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4 Graham, J: *Restoring consumer confidence in food,* in *Consumer Affairs Journal,* No 98, March/April 1989: Exhibit 79 p 3

5 Fenwick, G et al.: *Toxicity of disease-resistant plant strains,* in *Trends in Food & Technology,* July 1990 p 24 referring to: Curtis, R in *Proceedings of the XIII International Congress of Nutrition,* 1986 pp 822-826

6 Australian Federation of Consumer Organisations Inc: Submission 75.1 p 1

7 Peters, Dr F, Australian Federation of Consumer Organisations Inc: Transcript p 42

6.10 Consumer concerns were enumerated by the witness from the Australian Consumers' Association.

> "Will good manufacturing practice be rigorously enforced to insure against contamination of biotech substances? Is food poisoning more likely? Will a synthetic food be nutritionally comparable with the traditional equivalent? Will food imports containing biotech ingredients be adequately policed? Will a synthetic food have the same performance characteristics when cooked? Are there special handling instructions? How will one know if the food spoils? Will it smell, curdle or discolour like traditional products so that one knows it has gone off? ... Will biotech ingredients or additives cause adverse reactions with other foods or drugs? Are there any specific food allergy problems? Are there any other possible unintended effects?"[8]

6.11 Implicit in these concerns is a distrust of those whose function it is to ensure the safety and quality of foods and pharmaceuticals. As difficult as it might be in practice, it is important for consumers to be reassured that their concerns are being addressed.

A.2 Food sources modified to contain additional chemicals

6.12 There is substantial research into incorporating pest and disease resistance into crop plants. Two methods being attempted are the incorporation of BT toxin and capsid proteins to deter insect and virus attack respectively. It would be expected that products from these plants would contain varying amounts of these proteins. A possible concern is whether ingesting these chemicals could cause human health problems.

6.13 BT toxin has been available as a pesticide for some 30 years and, it is claimed, has "produced no detectable adverse effects on human health".[9] There have also been animal feeding studies to determine toxicity.

> "The feeding studies use doses much larger than those a human would encounter in sprayed produce or in genetically engineered plants ... The toxin spares animals ... because it does its job in the alkaline gut of certain insects, where it reacts with particular proteins they harbour."[10]

6.14 In addition, the processing of the food might further reduce risk because:

> "... heat-processing procedures render the BT protein inactive and benign to all organisms, ... [although] further experiments [are needed] to

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8 Isles, J, Australian Consumers' Association: Transcript pp 737, 738

9 Wickelgren, I: *Please Pass the Genes*, in *Science News*, Vol 136, 1989 p 121

10 ibid.

determine at what temperatures and how quickly the protein is denatured."[11]

6.15 The addition of genes for capsid proteins to protect against viral attack is similar to 'classical cross protection.' This involves inoculating plants "with a mild viral strain to prevent a more pathogenic strain from overwhelming a crop. For 50 years ... farmers have used cross protection in crops headed for the market, apparently without causing adverse health effects."[12]

6.16 Viruses often infect plants, and, using as an example tomatoes modified to contain capsid proteins, it has been calculated that "a person would have to eat 2,000 to 5,000 transgenic tomatoes to ingest the same amount of viral protein contained in one [naturally] infected tomato."[13]

A.3 Unintentional contamination of food or pharmaceutical products

A.3.(i) Hormone contamination of food

6.17 Several research projects are aimed at increasing the level of growth hormone (somatotropin) in animals. For example, genetically modified bovine somatotropin (BST) is injected into cows to enhance milk production and transgenic pigs with extra growth hormone genes are intended to produce low fat meat.

6.18 Consumers may be concerned that increased hormone levels will lead to product contamination or to indirect health effects.

6.19 Dr Kees Hulsman argued that cows injected with BST produce milk that has higher levels of insulin-like growth factor (IGF-I) and that this increases the metabolic rate of epithelial cells in the human gut. He argued that if this IGF-I survives digestion this will increase the likelihood of gut disorders. He also stated, however, that whether IGF-I survives digestion can be easily tested.[14]

6.20 If it can be easily tested then this should be done to remove or confirm the alleged problem.

6.21 Dr Hulsman referred to a report that the use of BST "has been banned in three Scandinavian countries and parts of Canada, while temporary bans have been enacted in two states of the USA and in the European Economic Community".[15]

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11 ibid.
12 ibid., p 122
13 ibid.
14 Burch, Dr D et al.: Submission 106.3 p 2
15 ibid., p 3

6.22 It is widely accepted that somatotropin or its breakdown products do not pose a health hazard.

> "BST is a protein, it occurs naturally in all cows and an infinitesimal quantity of BST is in all fresh milk. Because BST is a protein, it is digested if taken orally and broken down to inactive component amino acids. The amount that is in milk is not changed by supplementation of the cow herself, nor is any component of the milk significantly changed. Finally, somatotropins are species limited; [therefore] BST is not active in humans."[16]

6.23 This view that there "appears to be no evidence that genetically engineered BST milk constitutes any threat to human health" in the short term at least, is endorsed by a wide range of consumers' organisations.[17,18]

6.24 Similarly, evidence was presented that somatotropin is considered by European and US regulatory authorities "as a safe product for meat production in pigs and cattle."[19] Moreover:

> "Current research indicates that PST [porcine somatotropin] is species specific and would not have any deleterious effect on humans. It -
> . has a half life of 7 to 8 minutes and is then broken down into amino acids
> . does not accumulate in the tissues of treated animals
> . is destroyed by cooking
> . is not orally active and is broken down into amino acids in the digestive system"[20,21]

6.25 The objections to BST on animal health grounds may be stronger than those on human health grounds. There were reports that studies indicate high rates of mastitis, tissue loss, various stress related disorders and lowered fertility in cows injected with BST in the USA.[22]

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16 Straughan, R: *The genetic manipulation of plants, animals and microbes. The social and ethical issues for consumers: a discussion paper,* National Consumer Council U K, 1989: Submission 75.1, Attachment 2 p 20

17 ibid.

18 Peters, Dr F, Australian Federation of Consumer Organisations Inc: Transcript p 39

19 Taverner, Dr M: *Biotechnology for control of growth and product quality in meat production: implications and acceptability,* p 12. Notes compiled on an international Symposium organised by the American Society of Animal Science and the European Association of Animal Production, Washington DC, December 1990

20 Whan, B: *Growth Hormones PST and Pig Meat Production,* p 5, in *Porcine somatotropin - PST Implications and strategies for its use in the Australian pig industry.* Proceedings of the workshop 7-8 March 1991, Canberra

21 The 'half life' is the time it takes for the PST to be broken down to half its original quantity.

22 Phelps, R, Australian Conservation Foundation: Submission 140 pp 84, 85

A.3.(ii) Indirect health effects of hormone usage

6.26 It has been suggested that using BST to stimulate milk production can create indirect human health problems.

> "The trade-off with cows that have this ability to produce this extra milk - say, five to 25 per cent - is with their energy budgets because producing the extra milk usually means that the immune system becomes less effective and they are more prone to infectious diseases than other cows. Therefore, farmers use antibiotics, et cetera, on these beasts to control the infectious diseases. Low levels of these antibiotics then appear in the milk, and given that some consumers are sensitive to antibiotics, it can cause serious health problems to those people."[23]

6.27 This argument has been supported.

> "Giving a cow BST during the latter, declining phase of lactation mimics her physiology at the beginning of a cycle of lactation. At that time, a cow is normally two to three times more susceptible to infection. Mastitis, or infection of the mammary gland, was reported in three of nine published [milk production] trials with BST. In one trial, half the cows given a low dose of BST caught infections."[24]

6.28 However contrary arguments have been made by industry.

> "... although there is no vast supporting field or laboratory evidence, it would appear from a review of the literature ... that when used at levels anticipated to be used in food-producing animals, somatotropin treatment is not associated with detrimental effects on animal health - indeed there is research evidence of an immuno-enhancing effect of somatotropin."[25]

> "Numerous research studies have demonstrated no adverse effects of PST administration over the dose rate range 2 to 10 mg/pig/day on pig health. Although lameness and gastric ulceration have been reported in some studies these effects were observed at very high doses (15 to 20 mg/pig/d) and over extended administration periods."[26]

6.29 Nevertheless, using antibiotics to combat disease in animal husbandry is not a problem isolated to transgenic animals and so practices such as product withholding

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23 Hulsman, Dr K: Transcript p 1209

24 MacKenzie, D: *Science milked for all it's worth*, in *New Scientist*, 24 March 1988 pp 28-29

25 Taverner, M: op. cit., p 10

26 Campbell, R: *Exogenous Porcine Somatotropin (PST): Implications to the Australian Pig Industry and Current State of Development of the Technology*, p 7, in *Porcine somatotropin - PST Implications and strategies for its use in the Australian pig industry*. Proceedings of the workshop 7-8 March 1991, Canberra.

periods should apply. It would be expected that milk from BST treated cows would be monitored more closely by the authorities if the alleged problem of increased incidence of disease were likely. The issue therefore revolves around whether withholding periods are enforced.

6.30 If BST became widely used, the costs of any antibiotics et cetera, would be one economic factor determining whether this procedure was commercially viable.

> "... the objective of ... [using somatotropin] is to improve production efficiency by biological means, however, this will not transform a poor farmer into a good farmer - high if not higher standards of management will be required to elicit the maximum response from this technology."[27]

A.3.(iii) Contamination of pharmaceuticals

6.31 Another possible consumer concern is that modifying the micro-organisms used to produce pharmaceuticals could result in the production of toxic by-products. The issue is essentially one of product purity.

> "... when new biotechnology products came along, because of the scrutiny on them, levels of purity were applied that were way in excess of any other previous pharmaceuticals. The current commercial recombinant DNA insulin has seven parts per million impurities. For many decades people were treated with materials that had hundreds to thousands of parts per million of impurities. The degree of purity that is required of these products is way in excess of anything that previously occurred."[28]

6.32 However, there appears to have been a case where the product of a genetically modified bacterium created serious health problems including death in a significant number of consumers. The product in question was not the usual product of a GMO - namely, a protein "which at the end of the day get[s] broken down in the body to amino acids that are perfectly harmless."[29] In fact, the product was the amino acid, L-tryptophan.

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27 Taverner, M: op. cit., p 7

28 Gray, Prof P, Australian Biotechnology Association: Transcript p 703

29 ibid.

The L-tryptophan case

6.33 On 17 November 1989, following an epidemic of eosinophilia-myalgia syndrome (EMS), the USA Food and Drug Administration banned the sale of the amino acid, L-tryptophan. The chemical, which was classified as a nutrient,[30] had been available from health food shops and typically was being used to alleviate insomnia and premenstrual tension.[31] Since 1981 a few cases of EMS had arisen in L-tryptophan users, but from mid-1989 the incidence rapidly reached epidemic proportions - by July 1990, 1531 cases had been reported in the USA with 27 deaths.[32] Symptoms included skin rashes, muscle pain and raised levels of eosinophils (white blood cells).

> "The disease is often severe, disabling, and chronic. One third of the patients thus far reported on have been hospitalised. Even after the discontinuation of tryptophan, muscular symptoms often persist and sometimes worsen."[33]

6.34 L-tryptophan was produced by six manufacturers in Japan but the disease was sourced to the product of only one - Showa Denko.[34,35] The company, which was exporting some 70 tonnes of L-tryptophan to the USA annually, suspended production in November 1989.[36] In Australia, the product was withdrawn from the market in February 1990 following reports of cases in Europe and elsewhere and L-tryptophan therapy can now only be performed under medical supervision.[37]

6.35 In a study of the syndrome in the US State of Minnesota, it was found that:

> "The tryptophan manufactured by Showa Denko K.K. that was consumed by the 29 case patients was produced between October 1988 and June 1989 ... The company used a fermentation process involving *Bacillus amyloliquefaciens* to manufacture tryptophan. In December 1988, the company introduced a new strain ... (Strain V) [which] was used for the manufacture after December 25, 1988. ... In 1989, the amount of powdered carbon [used to purify the fermentation products] in most

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30 Garrett, L: *Drug's Genetic Engineering Probed*, in *Newsday*, 14 August 1990: Exhibit 82

31 Belongia, E et al.: *An investigation of the cause of the eosinophilia-myalgia syndrome associated with tryptophan use*, in *The New England Journal of Medicine*, Vol 323(6) 1990 p 359

32 Swygert, L et al.: *Eosinophilia-Myalgia Syndrome Results of National Surveillance*, in *Journal of the American Medical Association*, Vol 264(13) p 1701

33 Medsger, T: *Tryptophan-induced eosinophilia-myalgia syndrome*, in *New England Journal of Medicine*, Vol 322(13) 1990 pp 926, 927

34 Slutsker, L et al.: *Eosinophilia-Myalgia Syndrome Associated With Exposure to Tryptophan From a Single Manufacturer*, in *Journal of The American Medical Association*, Vol 264(2), 1990 pp 213-217

35 Belongia, E et al.: op. cit., p 359

36 *Showa Denko's L-tryptophan US suits*, in *SCRIP*, No 1541, 17 August 1990 p 19

37 Murray, R, Section Head Recalls Branch, NH&MRC, pers. comm.

> batches was [halved] ... From October 1988 to June 1989, a portion of some fermentation batches also bypassed a filtration step ..."[38]

6.36 It was later revealed that Strain V had been genetically modified.[39] The alteration:

> "... was carried out in several steps aimed at increasing the amount of L-tryptophan the bacterial strain can make. One step involved the enhancement, or duplication, of ... the cluster of genes that encode the amino acid and regulate its production. A further touch was the insertion of the gene for a rate-limiting enzyme from another bacterial strain."[40]

6.37 The Minnesota study identified a unique component of batches of L-tryptophan associated with EMS, 'Peak E' (sometimes called Peak 97), which was later determined by others to contain a double tryptophan molecule as well as "extremely biologically active compounds known as beta carbolines".[41]

6.38 Statistical analysis led the Minnesota researchers to conclude that the reduction in the amount of carbon used in purification was "significantly related to the eosinophilia-myalgia syndrome, and to the presence of Peak E". Furthermore, Strain V was "significantly associated" with the tryptophan that had been consumed by sufferers of the disease. It was suggested that "this strain may have produced larger quantities of the etiologic [disease causing] agent than earlier strains." However, the bypassing of the filtration step "was not a statistically significant risk factor in the analysis". Nevertheless, if it had contributed to the risk, "its significance was minor compared to the amount of carbon or the bacterial strain." Finally, the researchers were unable:

> "... to assess the independent contribution of the bacterial strain to the risk of the eosinophilia-myalgia syndrome. For this reason, it is possible that strain differences were unrelated to the production of the etiologic agent."[42]

6.39 Since late 1990 there has been little additional information concerning the affair. A contributing factor for the lack of a definitive statement from the US FDA may be that: "damages totalling more than $810 million have reportedly been requested in suits against Showa Denko from US patients alleging damage caused by L[-]tryptophan products."[43] "Showa Denko has reached out-of-court settlements in Japan ... The company has paid out about Yen 600 million ($4.6 million) in damages so far".[44]

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38 Belongia, E et al.: op. cit., p 360

39 Roberts, L: *L-Tryptophan Puzzle Takes New Twist*, in *Science*, Vol 249, 1990 p 988

40 Raphals, P: *Does Medical Mystery Threaten Biotech?* in *Science*, Vol 250, 1990 p 619

41 ibid.

42 Belongia, E et al.: op. cit., p 363

43 *S-Denko confirms contaminant*, in *SCRIP*, No 1560, 24 October 1990 p 24

44 *Showa Denko settles L-tryptophan suits in Japan*, in *SCRIP*, No 1595, 1 March 1991 p 10

6.40 It is interesting to note that in the US: "L-tryptophan, is classified as a nutrient, rather than a drug ... As such, its manufacture, purity and use weren't monitored by the FDA".[45]

6.41 Had the substance been classified as a drug, an assessment of safety would have been expected if a new method of manufacture was introduced. However, the L-tryptophan which caused EMS was "at least 99.6 per cent pure tryptophan, exceeding the standard specified by the United States Pharmacopeia (Revision XXI)."[46]

6.42 Moreover, since it was only after the epidemic that an animal susceptible to the disease was discovered,[47] it would not have been possible to identify unsafe batches of L-tryptophan other than by searching for Peak E (which was only identified because of the epidemic). Unfortunately, even after an animal susceptible to the disease was discovered, definitive proof of the cause of EMS has yet to be reported.

6.43 The fact that small numbers of people were contracting EMS before the introduction of the genetically modified bacteria was used, would suggest that the genetic modification per se was not responsible for EMS. The boosted activity and/or the changes in purification procedures might have led to greater levels of disease-causing impurity contaminating the final product.

6.44 Unfortunately, the key paper in the affair[48], by the Minnesota researchers, (in which Showa Denko, the use of a new strain of bacteria and the contaminant Peak E were identified), contained no reference to Strain V being a genetically modified organism. This is despite a detailed analysis of the manufacturing conditions and acknowledged assistance from Showa Denko. Consequently, when the nature of Strain V was revealed, a cover up was suspected.

> "Last week Michael Osterholm [leader of the Minnesota researchers] admitted publicly what teams of federal investigators have known for months: batches of the dietary supplement L-tryptophan that have been implicated in a mysterious disease were produced by a genetically engineered organism. ... his carefully crafted words, first published in an interview with *Newsday*, engendered a spate of newspaper headlines about genetic engineering gone awry and stirred up quite a ruckus at the Food and Drug Administration (FDA), where officials were apparently hoping to keep the recombinant link quiet until they could determine whether it in fact did play a role in the outbreak."[49]

6.45 The revelation stimulated those opposed to biotechnology, fuelling their arguments for "a risk assessment study by the FDA of the dangers of recombinant-

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45 Garrett, L: *Drug's Genetic Engineering Probed*, in *Newsday*, 14 August 1990: Exhibit 82
46 Belongia, E et al.: op. cit., p 363
47 Raphals, P: op. cit., p 619
48 Belongia, E et al.: op. cit., pp 357-365
49 Roberts, L: op. cit., p 988

DNA technology, full public disclosure of its findings so far in the inquiry ... and a re-evaluation of FDA's policy regarding the regulation of biotechnology products."[50]

6.46 No matter what the final outcome of this incident, it is clear that the interests of the biotechnology industry and the general public would be best served by openness.

B. Existing regulations addressing safety

B.1 The regulation of foods

6.47 The production and sale of processed food and beverages in Australia is subject to a complex web of State and Commonwealth legislation and regulation. A national Food Standards Code prescribes quality and labelling requirements. The contents of the Code are then given effect by the States.

6.48 The National Foods Standards Council (NFSC), which is composed of Commonwealth, State and Territory Ministers responsible for food standards, is ultimately responsible for changes to the Food Standards Code. The position to date has been that the NFSC has acted after receiving advice from the Public Health Committee of the NHMRC which in turn received advice from the Australian Food Standards Committee.

6.49 The membership of those committees contained representatives of bodies such as Commonwealth, State and Territory health authorities, the NHMRC, food manufacturers and importers, the Australian Federation of Consumer Organisations, the Commonwealth Departments of Primary Industries and Energy and Industry Technology and Commerce, the ACTU, the Confederation of Australian Industry, the Federal Bureau of Consumer Affairs as well technical and professional experts.[51]

6.50 The NHMRC's food regulatory committees, such as the Food Science and Technology sub-Committee and the Food Microbiology sub-Committee, have had responsibility for assessing the safety of food additives and processing applications for new food additives.[52]

6.51 In June 1991 royal assent was given to the *National Food Authority Act 1991.* This Act authorises the establishment of a new National Food Authority to consider changes to the Food Standards Code and to consider food safety and applications for new food additives. At the time of drafting this report the Authority is in the process of being established. It will largely replace the previous structure of committees, but will still report to the National Food Standards Council.

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50 Gershon, D: *Tryptophan under suspicion,* in *Nature,* Vol 346, 30 August 1990 p 787

51 Parliamentary Research Service, Department of the Parliamentary Library: *Bills Digest for National Food Authority Bill 1991,* 3 June 1991

52 Department of Community Services and Health & NH&MRC: Submission 117

6.52 The Authority will consist of

". a chairperson and two other members who must have expertise or experience in one or more of the following fields - public health; food science; human nutrition; food production or retailing; public administration; or consumer rights
. a member who is an officer of a State or Territory authority having responsibility for matters relating to public health (this person must have a good knowledge of food regulation systems in Australia)
. a member who has a background in consumer rights (and good knowledge of consumer affairs policy in Australia)
. such other members who may be appointed for a special purpose."[53]

6.53 All of the above will be appointed by the Minister after consultation with the National Food Standards Council. All, apart from the chairperson, are part-time members.[54]

6.54 The National Food Authority is required by the Act to establish a committee to provide advice on matters referred to it by the Authority, the Commonwealth, the States and the Territories. The National Food Advisory Committee will consist of the chairperson of the Authority; a member nominated by the Department of Community Services and Health; a member nominated by the Department of Primary Industries and Energy; a member nominated by each State, Territory and New Zealand; and such other members as the chairperson may appoint for specific purposes.[55]

6.55 One area of concern is that foods are not normally subject to assessment before they reach the market place.

"Substances which are traditionally eaten as foods, either processed or unprocessed, ... Are not normally subject to clearance through the food regulatory system. This means that a new strain or species of potato or wheat for example does not have to be assessed for safety before it may be sold."[56]

"However each State has an equivalent of paragraph five of the Model Food Act endorsed by the Health Ministers in May 1980. It states

5. A person who sells any food which -
. (a) is unfit for human consumption;
. (b) is adulterated; or
. (c) is damaged deteriorated or perished -
shall be guilty of an offence."[57]

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53 *National Food Authority Act No 118, 1991*, Section 40
54 ibid.
55 ibid., Section 42
56 Department of Community Services and Health, NH&MRC: Submission 117 p 5
57 ibid., p 1

6.56 Nevertheless, the Australian Food Standards Committee adopted a policy statement concerning biotechnology in the food industry.[58] The policy included the statement: "Foods, food additives and food processing aids produced by recombinant DNA technology shall, until such time as this issue is clarified, be assessed by the Food Science & Technology Subcommittee."[59]

6.57 In February 1991, the Food Science & Technology Subcommittee (FST) accepted a report from a working party reviewing biotechnology in the food industry. The working party recommended inter alia that: "all foods which have no or limited history of human consumption in Australia or which are produced from GMOs should be evaluated for safety and acceptability before they are considered acceptable for general human consumption."[60]

6.58 The working party had in fact noted "that classical breeding techniques had in a few instances resulted in unacceptable foods reaching the market place."[61]

Recommendation 26

6.59 The Committee recommends that new foods, new strains of existing foods, or new food additives which are developed using genetic manipulation techniques should be submitted to the Release Authority (see recommendations 40, 43 & 44) as a pre-condition before release.

6.60 Although it is outside the terms of reference of this inquiry, the Committee comments that there should be a similar requirement to ensure that novel foods or food strains which may be produced by other techniques are cleared as safe for human consumption before release.

B.2 The regulation of food additives

6.61 Food additives are subject to assessment before they reach the market place. The procedures were described by the Director of the Food Policy Section of the Commonwealth Department of Community Services and Health.

> "A person who now applies to use a new food additive, one that has not been used before, has to fulfil many tests and supply data on the

58 ibid., p 6

59 NH&MRC: *Draft Statement on Biotechnology in the Food Supply*, November 1987: Exhibit 43 p 2

60 NH&MRC Working Party to Review Biotechnology in the Food Industry: *Report to the eighty-first meeting of the food science and technology subcommittee*, February 1991, Recommendation 10

61 ibid., p 13

> toxicology of those products. Some of them take four, five or six years to obtain the data that one needs. That is animal data. Because one is not sure exactly how animal data relates to humans, one has to adopt a wide safety margin. We look at what we call the no-effect level on an animal of the most susceptible species, which may be a rat or a mouse or some small animal, and it is fed the product in large doses usually for a couple of years. If it is a rat, it is a two-year study. You are looking for the maximum dose you can feed to the animal that does not give an effect. We then cut that dose by 100. That is the level we give to human consumption."[62]

6.62 Details need to be supplied on the "specific type of food[s] for which the additive is requested" and the "proposed minimum and maximum levels of use".[63] For new additives, information is required on the method of manufacture, "the analytical controls used during the various stages of manufacturing, processing and packaging", and "a toxicological profile which includes studies on the biological activity and adverse effects". The information is required to be in sufficient detail to allow "independent scientific assessment" and "findings which may have an adverse effect on the process of safety evaluation shall not be omitted. Applicants will be required to attest that no significant information has been witheld."[64]

B.3 The Codex Alimentarius

6.63 Australia participates in the Codex Alimentarius Commission (which comes within the World Health Organisation). Problems could arise if Australia's assessment of foods and additives are inconsistent with those of the Commission.

> "The problem that we are going to have in Australia is that we have no direct control on how something is developed overseas. The only control we have in developing it overseas is through bodies such as the Codex Alimentarius Commission, which does set standards for foods and other commodities which work in international trade ... we are going to be faced with a situation that someone overseas like the Codex Alimentarius is going to say these products are safe, and therefore we could be in problems with GATT if we suddenly turn around and say we will not let them into Australia. Therefore we are in the situation of having to accept products which GMAC, for example, may have said are undesirable, or which some other committee that is set up in Australia may feel are undesirable."[65]

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62 Maynard, Dr G, Food Policy Section, Department of Community Services and Health: Transcript p 184

63 NH&MRC: *Draft Format for the Application to Review the Food Standards Code - Food Additive*: Exhibit 45 p 2

64 ibid., p 5

65 Peters, Dr F, Australian Federation of Consumer Organisations Inc: Transcript p 37

6.64 The Codex Alimentarius Commission has stated:

> "There is no evidence of unique hazards associated with the new technologies and potential risks that may occur are the same in kind as those associated with conventional methods. Safety evaluation should be based on accumulated experience and scientific knowledge based on the characteristics of the finished food substance."[66] [Emphasis added.]

Recommendation 27

6.65 **The Committee recommends that Australia seek harmonization between national standards for foods and food additives and the standards of international bodies such as WHO. However, Australia should reserve the right to set higher standards than international bodies in the public interest.**

B.4 The regulation of pharmaceuticals

6.66 Existing legislation dealing with therapeutic goods may have application to goods produced using genetic manipulation techniques. Genetic manipulation technology may effectively be controlled by such Acts where it is used for the 'manufacture for sale' of substances for the purposes of preventing, diagnosing, curing or alleviating disease in humans or animals, modifying a physiological process in humans or animals, testing susceptibility to disease or ailment or destroying or inhibiting micro-organisms that may be harmful. It is doubtful, however, whether the scope of these controls includes GMO research work where such work does not involve 'manufacture for sale'.

6.67 Legislation dealing with quality control of biological products in Australia is based on the type of product manufactured or its intended use and not on its method of manufacture.[67] The *Therapeutics Goods Act 1966* (Commonwealth), however, empowers the Commonwealth Director of Health to obtain information relating to the manufacture of a 'biological product'. This power might be used in respect of some organisms directly produced by means involving genetic manipulation.

6.68 A 'therapeutic good' is defined under the *Therapeutic Goods Act* as one that makes a therapeutic claim. Currently, it is possible to evade the scrutiny of the Act by not making any therapeutic claim on the label. Substances which may be reputed informally to have beneficial effects on human health could be sold as dietary supplements. For this reason it may be desirable to introduce safety requirements for dietary supplements, new foods and food additives which are no less stringent than those which apply to pharmaceutical products.

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66 Berkowitz, D and Maryanski, J: *Implications of biotechnology on International Food Standards and Codes of Practice*, Joint FAO/WHO Food Standards Program - Codex Alimentarius Commission, Eighteenth Session, Geneva, 3-12 July 1989: Exhibit 87 p 2

67 VLRC: Discussion Paper No 11, *Genetic manipulation*, March 1988 p 38

6.69 It should be noted that genetic manipulation is used to produce beneficial non-living substances such as pharmaceuticals which do not pose new hazards to society or the environment. To the extent that they may be chemically or otherwise hazardous, existing controls over their manufacture and their subsequent usage should prove adequate. There would appear to be little reason to treat them any differently from all other dangerous or hazardous substances or goods.

6.70 The marketing and clinical investigational use of pharmaceuticals are covered by the NDF 4 Guidelines produced by the Commonwealth Department of Health.[68] Recent appendices cover products of genetic modification.[69]

> "In toto, these documents require applicants to supply extensive data on the development, manufacturing and quality control aspects of new products (termed B1 data), data on pre clinical studies (B2 data) and data on clinical studies (B3 data). ... B1 data would need to include information on the origin and construction of the vector, the specific coding segments, the host organism, evidence of genetic stability, and full details of manufacturing, purification and testing. This data is evaluated by expert virologists, biochemists, molecular biologists and microbiologists."[70]

6.71 The method used to produce a product from a genetically modified organism is based on a 'seed lot system'. A single cell is used to prepare a 'master cell seed lot' and, from this pool of cells, "a large number of ampoules" are prepared. 'Production batches' would be "initiated from [an ampoule of] the master cell seed lot or ... [an intermediary] working cell seed lot". Care is taken to ensure the genetic stability of the ampoules of master cell seed lot by storing them, for example, in liquid nitrogen. If a new master cell seed lot is created "it must be fully characterized and the products derived from the new and original master cell seed lots compared."[71]

6.72 As part of an application:

> "Evidence is required to demonstrate the identity and purity of the recombinant DNA product by comparison with the equivalent naturally occurring substance where appropriate; alternatively an international or ...

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68 Department of Health: *NDF 4 Guidelines for Preparing Applications for the General Marketing or clinical Investigational Use of a Therapeutic Substance:* Exhibit 48

69 Australian Department of Health: *Appendix to NDF-4 Guidelines for Applications for Approval to Import or use Vaccines*: Exhibit 49; Therapeutic Goods Administration, Drug Evaluation Branch: *Guidelines for the preparation of applications for general marketing of substances produced by genetic manipulation for use in humans*: Exhibit 50; Department of Community Services and Health: *Guidelines for the preparation and presentation of applications for general marketing in monoclonal antibodies for use in humans*: Exhibit 51

70 Department of Community Services and Health; NH&MRC: Submission 117 pp 24, 25

71 Therapeutic Goods Administration, Drug Evaluation Branch: *Guidelines for the preparation of applications for general marketing of substances produced by general manipulation for use in humans*: Exhibit 50 p 8

approved in-house reference preparation may be used for comparative studies."[72]

6.73 One of the techniques which "may be used to obtain such evidence",[73] is 'high performance liquid chromatography.' It was this technique which was used to identify the contaminant implicated in the L-tryptophan induced disease.

6.74 Finally, after receiving approval, an applicant "must keep the TGA [Therapeutic Goods Administration] informed of developments or incidents related to the use of products and submit a post-marketing report on product usage for each of the three years after obtaining approval."[74]

6.75 In addition, the TGA "monitors the Australian community for adverse reactions attributable to the use of therapeutic products. ... TGA Laboratories (TGAL) [also] conducts selective testing on marketed therapeutic products."[75]

C. Occupational Health and Safety

6.76 It may be argued that those involved in research or commercial production activities with genetically modified organisms, or their products, are at greater immediate risk than the public at large.

6.77 The VLRC report says, however, that there were no confirmed reports of accidents particularly linked to recombinant DNA work up to 1986. The VLRC referred to an OECD study which reported in 1986 that the risks of even large scale recombinant DNA work are slight. The OECD apparently recommended that development of the technology should not be impeded and there should be international co-operation in developing standards.[76]

6.78 The ACF acknowledged that: "Microbiological work in laboratories appears to have been carried out quite safely to date. Most hazards have been met with adequate measures to ensure worker health and safety." They recommended, however, that: evidence concerning the risks to laboratory and other workers from coming into contact with DNA should be investigated; safety regulations and training for microbiology personnel should be reviewed to ensure uniformity throughout Australia;[77] and there should be periodic refresher courses.[78]

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72 ibid., p 11
73 ibid.
74 Department of Community Services and Health; NH&MRC: Submission 117 p 26
75 ibid., pp 26, 27
76 VLRC: Report No 26, *Genetic Manipulation*, June 1989 p 15
77 Phelps, R, Australian Conservation Foundation: Submission 140 p 44
78 ibid., p 79

6.79 The VLRC recommended special safety training for laboratory and other employees.[79]

Recommendation 28

> 6.80 **The Committee recommends that training in safety procedures for all laboratory personnel be a matter for periodic review by the relevant professional bodies and occupational health and safety authorities to ensure that they are in accordance with accepted international practice, and take into account the risks involved in GMO techniques.**

C.1 Existing legislation and guidelines

6.81 A number of existing occupational health and safety laws may currently enable control of risks associated with genetic manipulation work in a research or industrial workplace. Controls over goods and substances at both State/Territory and Commonwealth levels also may be applied to industrial and research processes utilising genetic manipulation techniques.

6.82 In 1984 the Department of Science and Technology and the Recombinant DNA Monitoring Committee commissioned a study of Australian law relevant to the regulation of recombinant DNA research and its applications. That study found that anomalies between the States/Territories in the laws relating to occupational health and safety depend on whether an 'old' or 'new' approach was adopted in the drafting of the legislation. Whether recombinant DNA work is affected, or might be affected, by such legislation depends on the approach of the particular States/Territories with respect to that legislation.[80]

6.83 Under the 'old' approach the occupational health and safety of all workers involved in genetic manipulation work cannot be comprehensively monitored or regulated. Generally, legislation which reflects the old approach is directed towards health and safety issues in factories which are defined in terms of their 'manufacturing' and 'commercial function'. Such Acts are not concerned with regulation of activities in public institutions which do not make goods or articles for trade, sale or gain.

6.84 It is therefore possible to draw the conclusion that the old type of legislation is likely to be of little relevance to much genetic manipulation research work which is carried out in a public institution as it will not be classifiable as a 'manufacturing

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79 VLRC: Report No 26 p vi, Recommendation 9

80 Barker, M: *The Recombinant DNA Technique and the Law: A Review of Australian Law which may be relevant to the Regulation of Recombinant DNA Research and Applications*, Report to RDMC and Commonwealth Dept. of Science and Technology, June 1984

process'. Large-scale work with GMOs carried out by industrial bodies for commercial purposes may, however, be the subject of regulation under the 'factory' definition.

6.85 Examples of legislation which reflect the old approach are to be found in the *Factories and Shops Act 1960* (Queensland) and the *Factories and Shops Act 1963* (Western Australia).

6.86 Under the 'new' approach to occupational health and safety issues, regulation is not restricted by narrow definitions of 'factory' and 'manufacturing process' which hinder the application of the old style Acts. Genetic manipulation work might be brought within the scope of the new style Act upon a declaration by the Governor that a research laboratory constitutes a 'place of work' or an activity such as the manipulation of DNA molecules constitutes a 'manufacturing process' for the purpose of the Act.[81]

6.87 For example, in the case of the *Industrial Safety, Health and Welfare Act 1972* (South Australia) which reflects the new approach, genetic manipulation work could be declared an 'industry' and places where such work is carried on could be declared 'industrial premises' for the purposes of the Act. In addition, a substantive duty is cast on employers of workers in an industry and occupiers of industrial premises to take all reasonable precautions to ensure the safety and health of workers employed therein. Specific regulation of genetic manipulation work, or places at which it is carried out, is therefore possible under the Act.[82]

6.88 Tasmania followed South Australia's adoption of the new approach with its *Industrial Safety, Health and Welfare Act 1977.* Unlike the South Australian Act, the Tasmanian Act might not be applied readily to genetic manipulation research work as a result of certain undefined terms. According to Barker, however, as persons involved in recombinant DNA work, even at a research level in public or private (non-profit) institutions, may be said to be 'employed or engaged' in 'work', there is no logical reason why all such work should not be considered within the scope of the Act.

6.89 In Victoria the safety of employees in all workplaces is protected by the *Occupational Health and Safety Act 1985.* Employers and occupiers are required by the Act to secure the health, safety and welfare of employees and other people in a workplace and also to protect the public. Laboratory and other workers who are injured during the course of their employment are entitled to compensation under the *Accident Compensation Act 1985.* The Act covers independent contractors and students at technical and further education colleges, as well as employees.[83]

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81 ibid., p 24
82 ibid., p 25
83 VLRC: Report No 26 p 13

6.90 Mrs Loane Skene from the VLRC stated that, although the *Occupational Health and Safety 1985* (Vic) applies to all work places in the State, given the limited resources of the Department of Labour, compulsory notification of all hazardous scientific work would alert the Department to the possible need to monitor particular work. Mrs Skene also stated that training programs based on safety hazards as they are identified would be better protection than a set of rules "enacted from on high".[84]

6.91 New South Wales enacted the *Occupational Health and Safety Act 1983* to complement its *Factories Shops and Industries Act 1962*. Work with GMOs in public institutions might be regulated under the former as it is capable of being classified as 'work' and employers are required to ensure the health and safety of persons engaged in work.

6.92 The *Occupational Health and Safety (Commonwealth Employment) Bill 1990* was assented to on 11 March 1991.[85] Its purpose is to provide for the protection of the health and safety of Commonwealth employees at work. It ensures a uniform approach to Commonwealth employees who hitherto have been subject to the differing legislation of the States and thereby to the anomalies illustrated above.

6.93 Research and laboratory workers in public institutions in some States/Territories may be excluded from the legislative framework which casts a duty upon employers to ensure the safety and health of workers. Nonetheless there has been evidence of a move towards the new style legislation across the States to provide protection for all workers.

6.94 The various guidelines produced by GMAC are designed to cover workers in both laboratories and in industrial situations. They are designed to ensure safe work practices. Experiments and production processes are assessed by the IBCs and by GMAC and an appropriate level of containment is determined. The RDMC apparently did not learn during its five year existence of any failure to observe its guidelines.[86]

6.95 The VLRC report said that, as more experience has been gained, risks have been reassessed and safety guidelines in both Australia and overseas have been relaxed for some categories of work. Consequently, "90% of [such work in the USA] ... is now exempt from the voluntary guidelines."[87]

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84 Skene, L, VLRC: Transcript pp 236, 237
85 House of Representatives Hansard p 1662
86 VLRC: Report No 26 p 15
87 ibid., p 14

Recommendation 29

6.96 The Committee recommends that occupational health and safety legislation in Australia enacted by Commonwealth and State Parliaments be revised to ensure that all employees are covered, not just those of the Commonwealth or those involved in the making of goods or articles for trade, sale or gain.

Recommendation 30

6.97 The Committee recommends that the Commonwealth Government negotiate with State Governments a uniform requirement to notify all potentially hazardous scientific work to the responsible State authority to assist in monitoring health and safety standards.

C.2 The risks associated with laboratory and industrial processes

6.98 Despite the determination of appropriate containment, it is conceivable that genetically modified organisms could accidentally escape into the laboratory or industrial shopfloor and contaminate workers. It has been argued, however, that the chances of this are remote.

> "Genetic manipulation has been in use now for some 15 years in thousands of laboratories around the world, quite literally millions of experiments using this technology have now been performed, and there really has been no evidence at all of any problem associated with the technology as far as health and safety are concerned. ... we have handled viruses of the most virulent sort and bacteria of great potency. We have done this at every level from test tubes up to hundreds of thousands of litres in tanks in the making of vaccines against botulism and tetanus and all sorts of horrible organisms. They have been safely contained because people understand how to do it and have designed equipment accordingly."[88]

6.99 Some of the possible hazards are outlined below.

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88 Millis, Prof N, Chairman, GMAC: Transcript pp 78, 79, 87

C.2.(i) The creation of a pathogen from a benign micro-organism

6.100 It is possible that genetic modification, because of imprecise insertion into the chromosome (or, more likely, an unexpected effect of the product encoded by the introduced gene on the properties of the host organism), could create a disease-causing organism. In this case the level of containment, which might be appropriate for the benign host, may be insufficient for the resulting pathogen. However, this scenario appears unlikely.

> "Because we can make organisms debilitated, their capacity to survive and compete successfully is something that we can manipulate.[89]... we now understand a lot more about pathogenicity than we did, say, 15 years ago. Because pathogenicity in most cases is multigenic [requiring several genes] ... the probability of converting a well-established laboratory strain of E.coli into a pathogen by the inadvertent introduction of the gene is now regarded as being practically zero. ... 15 years of work all over the world ... has failed to produce even the slightest angry organism."[90]

C.2.(ii) The ingestion of modified micro-organisms

6.101 A common 'worst case' scenario is one based on the establishment in the gut of workers of a colony of modified *E. coli* bacteria. The bacterium is often used in experiments and it might establish itself in the intestine or the additional genes it contained might be transferred to the *E. coli* population which normally lives in the human intestine.

6.102 A risk analysis was made at a US National Institute of Health workshop in Pasadena in 1980. It was asked what would happen if insulin-producing *E. coli* replaced all the *E. coli* in the intestine of a worker, but the capability was not transferred to other bacterial inhabitants. One per cent of the bacteria in the intestine are *E. coli* and so some two billion insulin-producing cells would be present. Assuming insulin production:

> "... at the rate of 1 million protein molecules in each bacterial cell in a generation of bacterial growth ... insulin would be produced at a daily rate of about 50 micrograms or 0.6 units. To put this in context, a normal human being produces about 25 units of insulin in the pancreas every day ... [this] would not make a great deal of difference."[91]

6.103 That this and similar fears have not been realised, is testament to the adequacies of the containment provisions employed in the industry. These include physical containment, the use of strains of bacteria, including *E. coli*, which are unable

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89 ibid., p 88

90 Pittard, Prof A, Chairman of Scientific Sub-Committee GMAC: Transcript p 88

91 Bartels, D: *Organisational hazards in biotechnology - towards a new risk assessment program*, in *Prometheus*, Vol 4(2), 1986 p 280

to survive outside highly specific conditions and the use of vectors which are unable to be transferred between bacteria.

6.104 Nevertheless, there may be problems if the bacteria are producing oncogenes (cancer causing genes) or oncogene proteins.

C.2.(iii) The hazards associated with oncogene research

6.105 There is considerable research into the role of oncogenes in cancer. Oncogenes and the proteins they produce:

> "... seem to occur in a normal state in normal cells, where they fulfil important cellular roles, most likely dealing with the regulation of cellular growth and development. But the normal oncogenes can become altered and activated, and then much larger quantities of oncogene proteins are produced, as well as modified forms of these proteins, and it is these altered conditions which bring about the cancerous state."[92]

6.106 In experiments using cells growing in culture, the human 'ras' oncogene can turn human lung cells cancerous. The oncogene was introduced by fusing the lung cells with bacteria containing the oncogene.[93] Furthermore, "tumours in chickens and mice have been induced by inoculating them with an oncogene from a chicken virus."[94]

6.107 Recently, the 'ras' oncogene was shown to cause tumours in mice when applied to their backs. The oncogene also became incorporated into the tumour cells which were then able to induce cancer if subsequently injected into other mice.[95] The leader of the researchers:

> "... said there was a need for more research to find out whether oncogenes can also trigger tumours when inhaled or swallowed, although he said scientists felt that either possibility was 'very unlikely'. The gut digests foreign DNA regularly and enzymes in the lining of the lung should break it down if it is inhaled."[96]

6.108 Nevertheless, if bacteria which produced oncogene protein became established in the gut of a researcher, digestive processes may not be sufficient to destroy all of the protein. "laboratory strains of *E. coli* can persist in the human gut for six days under normal conditions, and for up to 69 days in people receiving antibiotics."[97]

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92 Bartels, D: ibid., p 276, referring to: Weinberg, R: *A molecular basis for cancer,* in *Scientific American,* Vol 250, 1983 pp 102-116

93 Bartels, D: *Escape of the cancer genes?* in *New Scientist,* 30 July 1987 p 53

94 Brown, P: *Naked DNA raises cancer fears for researchers,* in *New Scientist,* 6 October 1990: Exhibit 92 p 5

95 ibid.

96 ibid.

97 Bartels, D: *Escape of the cancer genes?* in *New Scientist,* 30 July 1987 p 54

6.109 Using similar parameters as those in the insulin 'worst case' scenario already outlined, it can be calculated that about 25 micrograms of oncogene protein could be produced daily by modified bacteria gaining a foothold in the intestine. In contrast to the example of insulin, production of this amount of oncogene protein could have significant health implications.[98] Especially as it has been shown that ras oncogene protein injected into normal cells can turn them cancerous.[99] This effect would be expected to be temporary since the cells would revert to normal once the protein was removed. (The principal danger is from the gene becoming incorporated into the DNA of one or more human cells.)[100]

C.2.(iv) The cancer cases at the Pasteur Institute, Paris

6.110 In June 1986 it was reported that the Pasteur Institute initiated an inquiry into "three cases of bone cancer among workers in the same laboratory at the institute."[101] Over the next three years a total of seven laboratory researchers contracted cancer.[102] All the cancers were uncommon, including three cases of non-Hodgkin's lymphoma, a bone cancer "usually peculiar to children", and a muscle tumour. (Contrary to first reports there was only one primary bone cancer.)[103] The first researcher to die, Dr Françoise Kelly, had been working with oncogenes and, consequently, the suggestion was made that her cancer and those of the other researchers was linked to that work.[104]

6.111 The work in the laboratories, however, also included "testing industrial products ... for their ability to cause cancer"[105], and the second death involved a researcher who had only worked in an adjacent laboratory and for six months prior to the commencement of Dr Kelly's oncogene research.[106]

6.112 The cancer cases, if work related, may therefore have been caused by exposure to chemicals used in the laboratories. This is borne out by the fact that none of the cancers were intestinal or of the lung which might have been expected if bacteria producing oncogene protein had entered the researchers' bodies.

6.113 Preliminary results of the inquiry into the Pasteur Institute deaths were reported early in 1990[107,108] and in mid 1990 a letter was published in *The Lancet*.[109]

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98 Bartels, D: *Organisational hazards in biotechnology - towards a new risk assessment program*, in *Prometheus*, Vol 4(2) 1986 p 281

99 Bartels, D: *Escape of the cancer genes?* in *New Scientist*, 30 July 1987 p 53

100 Sleigh, Dr M, Division of Biomolecular Engineering, CSIRO: pers. comm.

101 Walgate, R: *Inquiry into lab's bone cancers*, in *Nature*, Vol 321, 1986 p 643

102 Coles, P: *Inquiry into Pasteur deaths*, in *Nature*, Vol 338, 1989 p 607

103 Roosa, N: *The Pasteur syndrome*, in *Omni*, October 1988 p 28

104 Bartels, D: *Escape of the cancer genes?* in *New Scientist*, 30 July 1987 p 54

105 Roosa, N: op. cit., p 28

106 Walgate, R: *Inquiry into lab's bone cancers*, in *Nature*, Vol 321, 1986 p 643

107 Coles, P: op. cit., p 583

The study found that, although the overall rate of cancer deaths was less than average (due possibly to the higher socioeconomic status of the group), some cancers, notably bone, brain and pancreatic, had a higher incidence. This could have resulted from increased exposure, especially of technicians, to carcinogens in biochemical laboratories. "The data fit earlier observations in Sweden and the US of increased incidence of pancreatic cancer among chemists."[110]

Conclusion

6.114 It appears that the cluster of cancers at the Pasteur Institute was not caused by contamination with oncogenes, their products or bacteria containing oncogenes. In response to news of the Pasteur incident, GMAC alerted researchers to the potential for risks in handling oncogenes.[111] The current guidelines contain procedures for the handling of virus vectors containing oncogenes or for work with hazardous fragments of DNA.[112]

C.3 The potential risks associated with changed agricultural practices

6.115 An argument for the incorporation of herbicide resistance into plants is that this will encourage a shift towards safer herbicides. Thus those spraying the herbicides onto resistant crops to control weeds should have reduced occupational hazard. This view was challenged by a witness to the inquiry.

> "The applications cover a whole range of different herbicides. Bromoxynol [sic] is the one that is being most debated at the moment because the corporations that produce that are also trying to produce a whole variety of crops that are tolerant to it. The view is that they should be phased out, not that a market should be further created for them."[113]

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108 MacKenzie, D: *French research centre admits cancer risk*, in *New Scientist*, 17 February 1990 p 4

109 Cordier, S: *Risk of cancer among laboratory workers*, in *The Lancet*, Vol 335, 1990 p 1097

110 MacKenzie, D: op. cit., p 4 quoting Cordier, S, French National Institute for Health and Medical Research

111 Millis, Prof N, Chairman, GMAC: pers. comm.

112 GMAC: *Guidelines for Small Scale Genetic Manipulation Work*, Appendices 5.6, 5.7, 1989 pp 33-38

113 Phelps, R, Australian Conservation Foundation: Transcript p 1166

6.116 Bromoxynil is "a herbicide that rapidly degrades in the environment. It has been shown to be less toxic to animals than many other herbicides commonly used."[114] Unfortunately,

> "Recently submitted data associate bromoxynil with birth defects in laboratory mammals ... Thus, the [US Environmental Protection] Agency, based on developmental studies of the effects of bromoxynil in laboratory animals, has concluded that farmers, farmworkers, and other users and handlers of bromoxynil may face similar risks of defects."[115]

6.117 To prevent the cancellation of registration of the chemical, warning statements had to be added to the label "restricting use to certified applicators, and requiring users to wear additional protective clothing". Similar restrictions have been imposed in Canada.[116]

6.118 Doubts have also been raised concerning the safety of 2,4-D to agricultural workers. (Resistance to 2,4-D is also being incorporatedinto plants.)

6.119 A study investigating the incidence of three types of cancers in agricultural workers exposed to herbicides and other pesticides found:

> "... a sixfold increase in NHL [non-Hodgkin's lymphoma] among farmers exposed to herbicides more than 20 days per year ... risk was elevated among persons exposed to phenoxyacetic acids, e.g. 2,4-D, not likely to be contaminated by dioxins."[117]

6.120 A link between the three cancers studied - NHL, Hodgkin's lymphoma and soft-tissue sarcoma, and phenoxyacetic acids had been reported in studies from Sweden, but in this case there was no association with the latter two types.[118]

6.121 There will always be risks to spray operators associated with herbicide use. In any assessment of the merits of changing herbicide use there has to be a comparison with the risks associated with using the old herbicides, as well as determining whether the actual amount of herbicide applied will alter (see Chapter 5 section D.4). This latter point, at least, is in dispute.

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114 Rissler, J and Mellon, M: *National Wildlife Federation comments to the USDA APHIS on two applications from Calgene, Inc. to field test cotton plants genetically engineered to tolerate the herbicide bromoxynil or resist insects and tolerate bromoxynil, 1991* p 6 quoting USDA, *APHIS*, 1990, p 29

115 ibid., p 7

116 ibid.

117 Hoar, S et al.: *Agricultural Herbicide Use and Risk of Lymphoma and Soft-Tissue Sarcoma*, in *Journal of the American Medical Association*, Vol 256, 1986 p 1145

118 ibid., pp 1141, 1146

D. BIOLOGICAL WARFARE

6.122 The ACF suggested that genetic modification allows "an almost infinite variety of lethal agents to be made by minor alterations to the surface coating of pathogens"[119] and recommended a prohibition of all genetic engineering work relevant to the production, stockpiling or use of biological warfare agents.[120] Other witnesses also were concerned about the potential for genetic manipulation techniques to be used for biological warfare.[121]

6.123 **The Committee supports the position taken in the VLRC report, namely that the possibility of the new technology being used to expand the capability of biological warfare "should not prevent or hinder its development for other purposes."**[122]

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119 Phelps, R, Australian Conservation Foundation: Submission 140 p 54

120 ibid., p 52

121 United Scientists for Environmental Responsibility and Protection: Transcript p 638

122 VLRC: Report No 26 p 9

CHAPTER SEVEN

LEGAL ISSUES

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LEGAL ISSUES

A. PROPERTY RIGHTS - THE PATENTING OF LIVING ORGANISMS

A.1 The nature of patents

7.1 There are two Acts which could be used to provide protection for genetically modified organisms: the *Plant Variety Rights Act 1989* and the *Patents Act 1990.* Both Acts provide protection in Australia and reciprocal protection for Australian applications overseas.[1]

7.2 The *Plant Variety Rights Act* provides protection for a single plant variety and is regarded as suitable for new varieties developed by traditional breeding rather than for protecting the products of genetic modification technology. Under the Act a fee is payable for each plant propagated vegetatively from the original plant; there is no restriction on the breeding of the plant by sexual means or on the use of the seeds.[2]

7.3 The advances of 'modern' biotechnology, which enables an accurate description of both the organism and the method used to create it, has enabled the new technology to fall within the purview of the patenting system.[3]

7.4 The purpose of intellectual property rights is to provide inventors with "an opportunity to gain, for a limited time and without competition, a return on their investment in genuine creative activity and a reward for their efforts".[4]

7.5 It is thus "a law conceived with the aim of promoting technology ... [and] can hardly be shaped in such a way as to act as an efficient safeguard against abuses or dangers of new technologies".[5]

7.6 Denying patents for a technology would not prevent research or the marketing of products since companies could adopt a 'trade secrets' posture until they were in a position to achieve a large market share immediately upon launching their product.[6] Such a course would therefore promote secrecy in the industry and could delay the release of products onto the market to the detriment of the general public.

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1 Santer, Dr V: *Intellectual Property Protection for Living Organisms:* Exhibit 90 p 1

2 Louden, B, Plant Variety Rights Section, Department of Primary Industries and Energy: pers. comm.

3 Skene, L, VLRC: *Legal Issues in Patenting Life-Forms*: Exhibit 118 p 9

4 Patent Trade Marks and Design Office: Submission 127 p 2

5 ibid., p 9

6 ibid., p 7; Singer, Prof P: Transcript p 265

A.2 Requirements of patents

7.7 For a patent to be granted it must satisfy several criteria: it must be new, an invention (i.e. not obvious), useful and be described in such a way as to allow others to recreate the invention.

7.8 In the UK, Genentech was denied a patent for its new method of producing tissue plasminogen activator because it failed on the second criterion - although a team of PhD scientists had been involved in its development, the source of the chemical (a particular human cell line) was known, and the methods used to develop the product were applications of known technology.[7]

7.9 The reproducibility criterion denies patent rights to organisms produced by traditional breeding techniques because it is not possible to repeat the steps involved to breed an identical organism.[8]

7.10 In Australia a patent may be refused on the grounds that its use would be contrary to law.

> "... if specific legislation were passed which prohibited activities on the basis of moral, ethical or other considerations, then inventions whose sole use related to those prohibited activities would be automatically excluded from the patent system. It is on the basis that it is not lawful to own or sell a human being that the Minister for Industry, Technology and Commerce, in the Parliament, and the Patent Office have stated that a patent for a human being would not be granted in Australia."[9]

7.11 Nevertheless, the Senate when considering the Patents Bill 1990, introduced an amendment. "Human beings, and the biological processes for their generation, are not patentable inventions."[10]

7.12 Thus genetically modified organisms are not excluded from patenting in Australia and, indeed, the Australian Patent Office in 1980 stated in a Practice Note: "no distinction is to be made solely on the basis that a claimed product or process is, or contains or uses, a living organism. Higher life forms will not be treated any differently from lower life forms such as micro-organisms".[11]

7.13 A patent lasts for 16 years although those covering pharmaceuticals for human use may be extended for a further 4 years if it can be shown that the patentee has not had sufficient opportunity for financial exploitation. This is because such products must undergo extensive testing before they are approved for use. It could be argued

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7 Skene, L, VLRC: *Legal Issues in Patenting Life-Forms*: Exhibit 118 p 11

8 ibid., p 9

9 Patent Trade Marks and Design Office: Submission 127 p 5

10 *Patents Act 1990*, Clause 18(2)

11 Australian Official Journal of Patents, 1980 p 1162

that a genetically modified organism, which was intended for release, might have to undergo extensive testing and, therefore, provision should be made for a similar patent extension.[12]

7.14 A similar recommendation was made by the Senate Select Committee on Agricultural and Veterinary Chemicals in Australia.

> "... the stringent regulatory requirements for clearance and registration and associated delays continue to erode the effective patent life of farm chemical products. ... The Committee recommends ... establishing a scheme, similar to that applying to human pharmaceuticals, to enable the patent term ... to be extended."[13]

Recommendation 31

7.15 **The Committee recommends that the patent period for genetically modified organisms, or products produced by genetically modified organisms, be extendable for a period beyond 16 years as is the case with pharmaceuticals for human use, if they have been subject to extensive testing requirements before clearance for sale. The length of the extension should be such as to allow a reasonable time to recover investment costs.**

A.3 The obligations of a patentee

7.16 In exchange for monopoly rights, a patent application must be accompanied by a description of the best way to recreate the invention. This description is published in the *Australian Official Journal of Patents* before the patent is granted. The purpose is to inform the public and interested parties in case they wish to oppose the granting of the patent. Opposition would need to be based on the criteria listed above. In addition, the description enables others to use the invention when the patent expires.[14]

7.17 In July 1987, Australia acceded to the Budapest Treaty on the *International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure*, the existing *Patents Act* having been amended in 1984. This enables a newly patented micro-organism to be deposited in a culture collection instead of providing a description of its method of manufacture. This obviously creates some practical difficulties in storing live organisms.

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12 Skene, L, VLRC: *Legal Issues in Patenting Life-Forms*: Exhibit 118 p 14

13 *Report of the Senate Select Committee on Agricultural and Veterinary Chemicals in Australia*, 1990, Sections 7.16, 7.17 p 93

14 Patent Trade Marks and Design Office: Submission 127 p 2

7.18 Material, if deposited, becomes unconditionally available to the public at the time the patent is granted with the proviso that those requesting a sample "give an undertaking not to make it available to anyone else and to use it only for experimental purposes".[15]

7.19 A sample would enable researchers to compare their own inventions to check that it was in fact different from an already patented organism.[16]

7.20 There is, however, no obligation on those applying for a patent to deposit a sample.[17] There may in fact be some reticence to deposit micro-organisms because not only are the details of the invention made available, but also the very micro-organism that manufactures it.[18]

7.21 It has been suggested that a new offence may be necessary to deter those who might be tempted to use such organisms for their own advantage.[19]

7.22 There are other conditions attached to the granting of a patent; it does not "permit the patented invention to be used for illegal purposes. There are also certain remedies available if an abuse of market power arises or the reasonable demands of the public for the invention are not met".[20]

7.23 Section 108 of the Act allows the granting of a compulsory licence to a competitor 3 years after the granting of a patent. The plaintiff must be able, however, to use the patent. Section 109 allows the compulsory licence to be revoked after 2 years if it has not been utilised. Nevertheless, no compulsory licences have been granted since Federation.[21]

A.4 The patenting of organisms overseas

7.24 Overseas, the patent system has been influenced by social and economic needs. Surgical and medical techniques for human therapy are regarded as unpatentable in many countries on public interest grounds. Some advanced countries, such as the UK, Germany, Switzerland and Japan, have at one time limited the patentability of chemical compounds to assist their indigenous chemical companies.[22]

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15 Skene, L, VLRC: *Legal Issues in Patenting Life-Forms*: Exhibit 118 p 10

16 McCay, Dr I, Assistant Secretary for Policy Planning and Coordination, Australian Patent Office: pers. comm.

17 ibid.

18 Skene, L, VLRC: *Legal Issues in Patenting Life-Forms*: Exhibit 118 p 10

19 ibid.

20 Patent Trade Marks and Design Office: Submission 127 p 3

21 McCay, Dr I, Assistant Secretary for Policy Planning and Coordination, Australian Patent Office: pers. comm.

22 The Institute of Patent Attorneys of Australia: Submission 44 p 4

7.25 Most OECD countries allow the patenting of micro-organisms and plants. Whereas in the USA, Japan and Australia transgenic animals are patentable, there has been confusion about the situation in Europe.

7.26 The European Patent Convention Article 53(b) states: "European patents shall not be granted in respect of plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof."

7.27 In 1984 the European Patent Office Technical Board of Appeals used a narrow interpretation of 'variety' and hence the European Patent Office (EPO) will grant patents for plants where a single gene has been inserted.[23]

7.28 Recently the Examining Division of the EPO interpreted animal variety broadly to exclude animals in general from patentability.[24] An application to patent a mouse which developed cancer, the 'oncomouse', was rejected on the grounds that

> "... the term 'animal variety' is not a criterion sufficient to delineate patentable from non-patentable subject matter, since there is no legal definition of animal varieties, and there is no uniform use of this term in scientific language. Other grounds for refusal were that the application ... went beyond the scope of disclosure, which adequately supported only claims directed to rodents."[25]

7.29 The Technical Board of Appeal subsequently held that the Examiner had incorrectly interpreted the exception provision.

> "Considering that any such exception must be narrowly construed, the Board of Appeal decided that the exception to patentability under Article 53(b) EPC applies to certain categories of animals but not to animals as such."[26]

7.30 Moreover, "the mere fact that a claim is broad is not in itself a ground for" claiming insufficient disclosure. Disclosure is proved "if at least one way is clearly indicated in which the skilled person could carry it out." Such a person would be "aware of other suitable mammals on which the invention can likewise be successfully performed."[27]

7.31 The application was referred back to the Examiner for consideration as to: whether the oncomouse was an 'animal variety'; whether the processes claimed were microbiological processes; and whether any ethical issues involved were a bar to the

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23 Patent Trade Marks and Design Office: Submission 127 p 6

24 ibid.

25 Santer, Dr V: *Intellectual Property Protection for Living Organisms*: Exhibit 90 p 6

26 Letter to the Secretariat from Teschemacher, T, Directorate Patent Law, European Patent Office, 4 June 1991

27 ibid.

granting of a patent.[28] (The European Patent Convention allows for the exclusion from patent protection of an invention which would be contrary to public order or morality.[29])

7.32 The European Patent Office apparently decided in October 1991 that the oncomouse could be patented. However, patent applications for other animals will have to be judged individually on their merits.[30]

A.5 Consideration of the arguments against patenting

A.5.(i) ' Genetically modified organisms do not qualify'

7.33 The patentability of organisms has been criticised on the grounds that the genetic information used is a discovery of nature and so is not an invention.

> "Firstly, we inherit the base organism whose genotype is going to be modified. Perhaps it is only going to be modified in a single base in a single gene somewhere in this complex genome. So although the person who is applying for a patent protection on doing this has, admittedly, made some intellectual or physical input to the process, he has inherited most of what he is then claiming to be protected by the patent. He is therefore deriving a benefit to which he is not properly entitled."[31]

7.34 However, it is not the discovery of a gene, or the act of modifying it that is patentable, but the actual use to which it is put which could be the inventive step, and hence able to be patented.[32]

7.35 A related argument is that organisms differ from machines in that they are much less uniform and predictable and are therefore not acceptable candidates for patenting. A group of modified organisms, although having an altered gene in common, are not identical genetically; their genes can move and their biological properties are not always stable.[33]

7.36 The Committee acknowledges that living organisms do differ from machines in many important respects. Undoubtedly one such area of difference is the fact that the genetic composition of living organisms can change from generation to generation. Also the genetic composition of some cells of an individual may change by mutation and some of those mutations may be inherited. The Committee is not convinced by

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28 ibid.

29 Santer, Dr V: *Intellectual Property Protection for Living Organisms*: Exhibit 90, pp 6,7

30 MacKenzie, D: *Europe rethinks patent on Harvard mouse*, in *New Scientist*, 19 October 1991 p 7

31 Murray, Dr D: Transcript p 815

32 Sleigh, Dr M, Division of Biomolecular Engineering, CSIRO: Transcript p 1090

33 Phelps, R, Australian Conservation Foundation: Submission 140 p 50

these arguments that the differences are sufficient in themselves to exclude GMOs from proper coverage by patent law.

A.5.(ii) 'Patents would degrade life'

7.37 Many argue against the patenting of genetically modified organisms on moral grounds.

7.38 The Australian Conservation Foundation argued that "patent ownership would reduce living things to mere chemistry ... [they] will be regarded as the equivalent of a pop up toaster or ball point pen, removing the distinctions between living and non-living things."[34]

7.39 Professor Singer argued that:

> "... in holding that an animal can be patented we are saying something about the status and nature of that form of life"[35]
> "... they are not mere things, ... they are not just objects of property worth a certain amount of money, but ... they are entitled to some respect in their own right ... [It] would be a barrier to the further progress and development of respect for non-human animals that I believe most people now support."[36]

7.40 There is a very lengthy history of legal recognition of ownership of live organisms. Nevertheless, it was suggested that patenting "is more fundamental than simply allowing ownership of ... animals ... because we are granting ownership rights in the genetic material of the animal".[37]

7.41 Monopolies for stud animals are readily available and this involves legal recognition of ownership of the genetic material of the animals. It was argued that "there is no commercial or ethical difference between the registering of stud animals or hybrid seed and the patenting of these organisms."[38]

7.42 The Committee does not consider that there is a major ethical difference between allowing the ownership of animals, including recognition of monopolies on breeding rights, and allowing patent rights in relation to animals. There is no logical contradiction between allowing the patenting of genetically modified animals and simultaneously recognising that they have a right to be treated with care for their

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34 ibid., p 49

35 Singer, Prof P: Transcript p 254

36 ibid., p 262

37 Holmes, P, Legal Research Project, Macquarie University: Submission 146 p 77

38 Patent Trade Marks and Design Office: Submission 127 p 8 - referring to Curry, J, *The Patentability of Genetically Engineered Plants and Animals in the US and Europe*, IPPL, London 1987

health and welfare. It does not follow that allowing the ownership or patenting of animals is the same as treating them merely as things or just objects of property. The argument that patents will degrade life, in the Committee's opinion, is not substantiated and therefore does not warrant banning patent rights in relation to live organisms.

A.5.(iii) 'Patents will reduce animal welfare'

7.43 The *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* sets out rules to protect animal welfare in research institutes. Animal Care and Ethics Committees overview research involving animals. It was argued, however, that "if the end result of a process involving a genetically modified animal is that the researcher wants to patent that idea then he is certainly going to be very cautious about giving out information to an ethics committee, or to his colleagues or anybody else".[39]

7.44 **The Committee considers that this argument misunderstands the nature of research. Researchers rarely operate in isolation and it would be difficult to prevent a concerned individual alerting an animal welfare committee to cases of possible animal suffering.**

7.45 Animal research is also controlled and monitored.

> "... research must be done either within an accredited research establishment or by a licensed animal researcher. Institutions or individuals will receive licences or accreditation only if they demonstrate that they are complying with the legislation, particularly the Australian Code of Practice."[40]
> "... On those site inspections there will not be simply scientists with expertise but there will also be representatives of animal welfare organisations, and there are also representatives of those interests on the animal care and ethics committees in institutions. So there is a fair degree of openness in terms of how that occurs."[41]

7.46 Witnesses did not express concern about breaches of confidentiality arising from research being overseen by ethics and institutional biosafety committees.

> "I have not heard or read of complaints from pharmaceutical companies that the extension of confidentiality to institutional ethics committees has been a particular problem in terms of the unwanted release of commercial information which they wish to remain secret."[42]

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39 Oogjes, G, Australian and New Zealand Federation of Animal Societies: Transcript p 368
40 Taylor, Dr R, Animal Research Review Panel: Transcript p 832
41 Rose, Dr M, Animal Research Review Panel: Transcript pp 832, 833
42 Andrews, K, St Vincents Bioethics Centre, St Vincents Hospital: Transcript p 493

7.47 Notwithstanding the role of animal welfare committees, The alternative to patenting - secrecy - "could easily lead to duplication of animal experiments by researchers who otherwise would be aware of each other's work because of disclosure in a patent or publication."[43] This may result in a greater number of animals suffering than under a system which allowed patenting.

7.48 **The Committee was not persuaded by the evidence presented that allowing the patenting of life forms would result in an increase in animal health and welfare problems.**

A.5.(iv) 'Where do you draw the line?'

7.49 The adding of human genes to organisms tends to produce fears of creating 'humanness' in organisms - starting on the slippery slope leading to the patenting of humans. This argument was expressed by the Australian Conservation Foundation.

> "There is nowhere to draw the line on patenting humans if any number of human genes can be put into other organisms, particularly primates. Many such transfers into a range of GMOs have already been made ... Only a prohibition on biological patents would suffice to prevent the moral ambiguities of patenting humans ... It is impossible to draw a line around what is acceptable and what is not and the only rational and morally defensible course is to ban all patents on living things."[44]

7.50 A major unstated premise of this argument is that putting 'human genes' into a non-human organism will result eventually in an organism which reasonably could be described as human. This is based on two assumptions which are seriously flawed.

7.51 The first assumption is that there is a clear distinction between human genes and genes of other organisms. In fact, human genes may differ from those of other organisms by only a few subunits. The products of animal genes can be used in treating human diseases. Pig insulin has been used to treat diabetes testifying to the similarity of insulin-producing genes in pigs and humans.

7.52 The second flawed assumption is that it is possible to change the genetic code for a non-human organism into the genetic code for a human being by adding ever-increasing numbers of human genes.

7.53 No evidence has been adduced to show that this is possible. It is far more likely that the organism would become malformed and cease being a viable, functioning organism long before it resulted in something which reasonably could be described as a human being. If the first assumption - that human genes are significantly different

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43 Santer, Dr V: *Intellectual Property Protection for Living Organisms*: Exhibit 90 p 8

44 Phelps, R, Australian Conservation Foundation: Submission 140 p 50

from those of other organisms - is correct, the addition of a significant number of functioning human genes would certainly severely disrupt the organism.

7.54 In any case there is a logical gap between the premises of the argument and the conclusion - that the only way to prevent the patenting of humans is to ban the patenting of all organisms. There are any number of modified organisms which the great majority of people would have no difficulty in describing as non-human, despite the inclusion in them of genes coding for the production of proteins normally made by the human body. To allow the patenting of such organisms does not in any way allow the patenting of human beings.

7.55 Another difficulty with the conclusion is that it would 'throw out the baby with the bath water'. There are substantial health benefits to be gained from, for example, modifying bacteria to produce human insulin. Such developments would be less likely to proceed without the protection of commercial interests which patent rights afford.

7.56 **The Committee considers that the philosophical problem of deciding if and when a progressively modified organism would become 'human' is a highly artificial one and of no practical consequence.**

A.5.(v) 'Traditional breeders will suffer'

7.57 It has been argued that patenting of animals will lead to the demise of traditional breeders.

> "At the moment, traditional breeders breed animals and sell them. They spend a lot of money, time and energy on breeding their animals ... It seems to me that the addition of one gene by a genetic engineer to an animal which may have been bred over the last centuries, that then makes it into a patentable commodity that some company can own is actually very unfair to traditional breeders."[45]

7.58 In their submission, however, the Australian Registered Cattle Breeders' Association (ARCBA) felt they still had a role in herd improvement.

> "Once a desired characteristic is expressed in a transgenic animal a farmer will need to buy genetic material such as semen or embryos from the producer of the transgenic animals and then follow a traditional selective breeding program to obtain maximum expression of the phenotype in subsequent generations. In this way the process is similar to the present methods of herd improvement."[46]

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45 Phelps, R, Australian Conservation Foundation: Transcript p 534

46 Australian Registered Cattle Breeders' Association: Submission 60.1 p 6

7.59 Most of the desirable features in cattle are influenced by many genes,[47] consequently transgenic animals would be adding to the gene pool used by animal breeders and be treated like other stud animals.

> "ARCBA would like to emphasise that a patent system would protect a developer of transgenic animals from others who may pirate the novel gene sequence. However, the marketing, sale and distribution of these new genes would occur in a manner similar to the way that it occurs with genes of animals which have been improved by selective breeding methods."[48]

7.60 **The Committee was not persuaded that allowing patents would disadvantage traditional breeders.**

A.5.(vi) 'Patents will advantage agribusiness'

7.61 It has been argued that allowing patents would favour large corporations.

> "Transnational agribusiness would gain unacceptable control over breeding, genetic resources and farming. Patents on living things would increasingly favour the interests of corporate patent holders over other users of biological material."[49]

7.62 There are ways of protecting discoveries other than by patents but it is possible that the existence of patent protection could favour those with the resources to carry out research. On the other hand, patents also may help protect small inventors from having their innovations usurped by others.

7.63 **It is likely that larger corporations are in a better position to secure and enforce patent protection for their discoveries. However, this prospect of gain is not a valid reason against the patenting of genetically modified organisms.**

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47 ibid.

48 ibid., p 12

49 Phelps, R, Australian Conservation Foundation: Submission 140 p 48

A.5.(vii) 'Patents will restrict competition and keep up costs'

7.64 The witness from the Australian Federation of Consumer Organisations raised the issue of patents being used to restrict competition and maintain high costs.

> "With the example that we quoted of insulin, the original patentee was bought out by Eli Lilly, the largest producer of insulin. That firm buried the patent in the sense it probably used the patent but would not let anyone else use the patent. The cost of insulin has not come down as a consequence. The cost of insulin should have come down. The original patentee was probably made an offer he could not refuse and he was probably in the situation where he could not go into production himself."[50]

7.65 After examining the supporting document[51], the Committee remains to be convinced of the accuracy of this interpretation of the events. It appears Genentech sold the patent rights because of

> "... lack of experience with the scaling up of production and the commercialization of final products ... It was obvious that Genentech would hardly be able to compete with established market leaders in fields where biotechnology products form a substitute for existing pharmaceuticals."[52]

7.66 The worldwide rights were sold "to Eli Lilly, the world's largest insulin producer, which had been among the early investors in Genentech." Subsequent costs may have contributed to the maintenance of the price of insulin. "Lilly eventually spent about US$ 100 million taking the bacterially produced insulin through clinical tests and production scale up."[53]

7.67 An important question in the sale of patent rights to larger companies is - if patents had been unavailable would the situation have been better? The inventor would have had the option of adopting a 'trade secrets' posture but if it was not possible to go into production the discovery still might have failed to reach the market. (This may well have been the case with Genentech which eventually lost its independence in 1990 when the Swiss multinational Hoffmann-La Roche acquired a controlling interest.[54])

7.68 Public interest groups are unable to mount an action under the compulsory licence section of the *Patents Act.* To be successful the plaintiff must be in a position

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50 Peters, Dr F, Australian Federation of Consumer Organisations: Transcript p 40

51 *Takeover of Genentech - Lessons for developing countries?* in *Biotechnology and Development Monitor,* No 3, June 1990 pp 3-5; joint publication of the Ministry of Foreign Affairs, The Hague, and the University of Amsterdam, The Netherlands

52 ibid., p 3

53 ibid.

54 ibid.

to produce the product and a consideration is made of the presence of existing products when courts assess a case.[55]

7.69 A similar argument to Dr Frank Peters' was made by Dr David Burch and others.

> "By patenting a process with broad applicability in the bioindustry, a firm can deny the process to competitors or receive a royalty for use of the process. ... With process patents breeders cannot use each other's technologies to improve new crop and animal varieties ... unless breeders can afford it."[56]

7.70 However, under the requirements of a patent application the details of how to replicate the invention must be lodged. Competitors are able to use the details provided for research. This can include the attempt to improve a product.[57] A 'significant difference' could arise as a result of this research which itself could be patentable.[58] The testing of this in the courts could involve considerable expense.

7.71 It is questionable whether a process patentee would wish to deny permission to use the process because of the probability of resulting litigation. Amongst other options, a compulsory licence could be sought. The charging of excessive royalties could also be construed as a denial of access to the patent.

7.72 A more likely scenario is that, following disclosure, a second party might develop a patentable product and there would be negotiations to enable both to benefit. This is made more probable because patents have a limited life and once a product is invented there is great incentive to circumvent any patent obstacles, for example, by discovering a different method of creating the discovery.

7.73 There may be an infringement of the process patent during research but, provided the product was not commercialized, there would be little value in the original patentee mounting an expensive infringement action.

7.74 It is arguable, therefore, that the disclosure provisions of the patents system could, after an initial delay whilst patent applications were being prepared, promote information dissemination and, consequently, competition.

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55 McCay, Dr I, Assistant Secretary for Policy Planning and Coordination, Australian Patent Office: pers. comm.

56 Burch, Dr D et al.: Submission 106.1 p 6

57 Holmes, P, Legal Research Project, Macquarie University: Submission 146 p 26 referring to Frearson v Loe (1879) 9 Ch.D. 48; Proctor v Bayley and Son (1889) 6 R.P.C. 538; Smith Kline and French v Micro Chemicals (1970) 60 C.P.R. 193

58 McCay, Dr I, Assistant Secretary for Policy Planning and Coordination, Australian Patent Office: pers. comm.

7.75 The witness from Biotech Australia, Dr David Harrison, stated that if patenting were not allowed in Australia: "Australia would be deprived of products that could be patented overseas but not in Australia. Generally that could affect all kinds of industries. It could affect our agriculture and medicine industries."[59]

7.76 The variety of available products could be reduced thereby restricting competition. This could, of course, be used to encourage this country's biotechnology industry; but the apparent reluctance of Australian companies to enter into joint ventures in this field suggests this strategy might not be successful. Such a stand also runs contrary to Australia's current attitude towards reducing trade barriers.

7.77 **The Committee concludes that any possible reduction in competition resulting from allowing the patents system to continue would be temporary and justified by the incentive it provides to investment and development of new products.**

A.5.(viii) 'Patenting will adversely affect farmers'

7.78 Increased costs to farmers and a possible change to farming practice has also been suggested as a consequence of patenting.

> "If it became impossible or illegal to reuse part of a genetically engineered crop for the succeeding year's sowing without permission from the patentee, then curtailment of the widespread practice of 'home breeding' could occur ... Many farmers might suffer adverse economic consequences from increased ... royalties."[60]

7.79 It would be difficult for a patent holder to prevent on-farm breeding whether by deliberate retention of seeds from a crop or the accidental interbreeding of livestock. There would be no guarantee, however, that the organisms produced by such unauthorised means would retain the desired characteristics.

7.80 A patent, if granted, would enable a vendor to enter into common law contracts with buyers to allow 'home breeding'. In any case it might be difficult to obtain a patent which contradicts common usage.

7.81 If patents were allowed and there was a system of royalty payments, either visible or added on to the purchase price, this would become part of the equation determining whether products of the new technology were competitive. If the royalty payments required from farmers were excessive the genetically modified product would be uncompetitive in the market. There is therefore an incentive for the patent holder not to charge excessive royalties.

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59 Harrison, Dr D, Biotech Austalia: Transcript p 784

60 Burch, Dr D et al.: Submission 106 p 42

7.82 The Committee does not consider that the patenting of genetically modified animals or crops will cause hardship to farmers. Any increase in cost which may result from royalty payments would have to be at least matched by an increase in return to farmers from using the genetically modified product or it would not be an economic proposition and would not be competitive against the more traditional source of animal or crops stocks.

A.5.(ix) 'Patenting will adversely affect biodiversity'

7.83 It is argued that genetic modification will reduce biodiversity and this will be enhanced by the commercial interest guaranteed through patenting.[61]

7.84 A contrary argument has been put that patenting:

> "... promotes the value of naturally occurring organisms which are used as the starting material for genetic manipulation. This means that the likelihood of naturally occurring strains being preserved in a depository institution is greatly enhanced. This could provide a reservoir of the strain in the event that its natural source was destroyed."[62]

7.85 However, it has become clear that seed banks and other repositories are inadequate as the sole or major means of preserving a wide variety of strains.

> "... not all seeds survive in the cold, and ... some varieties die faster than others ... '75 per cent of the [varieties of the] world's major food crops are gone'. ... Several factors are contributing to the decline. One is the success of the seed-breeding industry."[63]

7.86 Consequently, there is a move to pay third world countries to conserve their crop diversity. Permitting patent protection may provide greater incentive for the "private foundations, seed companies and the UN" who are funding this initiative.[64]

7.87 It has been argued that the effect of patenting on Australia's genetic resources needs to be researched in the light of the current desire for ecological sustainable development and that: "this would necessitate further review of the Patents Bill 1990 to incorporate the findings of the ESD process."[65]

7.88 One submission proposed that there be created:

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61 Holmes, P, Legal Research Project, Macquarie University: Submission 146 p 39; referring to "*An Information of ...*", Rainbow Group, European Parliament (GRAEL) Hannes Lorenzen ARD 319, 97-113 rue Belliard, B-1040 Brussels, Belgium.

62 Santer, Dr V: *Intellectual Property Protection for Living Organisms:* Exhibit 90 p 8

63 MacKenzie, D: *The West pays up for Third World seeds*, in *New Scientist*, 11 May 1991 p 14

64 ibid., p 15

65 Burch, Dr D et al.: Submission 106.1 p 4

> "... an interactive institutional structure comprising the Patents Office and an Office of RDNA Patent Review and Evaluation. The latter office ... would initially examine a r-DNA patent application in terms of community risk - that is, social and ecological risk. ... The patent application in passing this review and evaluation stage satisfactorily could then proceed to the Patents Office".[66]

7.89 Under the proposed system, the additional costs involved in applying for a patent, both in time and money, and the uncertainty of outcome, could be construed as a de facto ban on patents for this type of research and innovation. At the time of a patent application the product may well not have reached the commercialization stage. Therefore it probably would not have been evaluated for release.

7.90 **The Committee considers that it would be excessively restrictive to require a full 'social and ecological risk' assessment at the initial patent application stage. The Committee further considers that protection of the diversity of species, or the range of genetic information existing within species, are not goals that require, and would not be particularly well served by, a ban on the patenting of genetically modified organisms.**

A.5.(x) 'Patenting will affect research priorities'

7.91 It has been suggested that allowing patents will affect research priorities.

> "... financial incentives, as well as government specifications (for example the 30% industry funding required in CSIRO projects), will cause researchers to focus on area[s] with commercial applications, rather than crucial basic research, to the detriment of the pursuit of scientific knowledge."[67]

7.92 In evidence from witnesses from the Department of Arts, Sport, the Environment, Tourism and Territories it was suggested that research priorities are misdirected already.

> "Biotechnology is still a high risk investment for a lot of companies, and while they can see the immediate sales of something like a blue rose, they cannot see immediate sales for something that might be in the national interest - removing organochlorins from ground water, or something like that."[68]

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66 ibid., p 3

67 Holmes, P, Legal Research Project, Macquarie University: Submission 146 p 28

68 Ireland, R, Science 2, Department of Arts, Sport, Environment, Tourism & Territories: Transcript p 1113

> "Quite a lot of money is invested by the Government in science and R and D one way or another anyway, so another way is to seek to have expenditure - say, by the CSIRO - on this kind of thing given a higher priority than perhaps it has been in the past."[69]

7.93 **The Committee notes, however, that CSIRO does carry out a great deal of research in the national interest, for example, into controlling the rabbit via a genetically modified infertility agent.**

7.94 **In the commercial area the focus is on producing a product. Patents are a device for obtaining reward for effort. The committee believes that denying the right to patent will not necessarily change the direction of research. It could, however, prevent publicly funded research from receiving the rewards of patent protection.**

7.95 In addition, in the current financial climate, if funds were unavailable from commercial sources the amount of research undertaken in Australia could decrease.

> "... many research projects can only be supported if they have some prospect of commercial application. In these situations, support from commercial companies is available only if the research is kept secret, or has been made the subject of a patent application. Academics are generally unwilling to forgo publication of their research, and so the availability of patent protection in order to protect their work is essential."[70]

7.96 **The Committee does not believe there will be any distortion of research priorities due to the patenting of genetically modified organisms.**

A.5.(xi) ' Patents should only be allowed for a DNA sequence'

7.97 It was suggested by the Australian Registered Cattle Breeders Association that there may be a way to overcome the objections of those opposed to the patenting of organisms.

> "ARCBA recommends that patents only be granted for the new gene sequence and not for the organism or phenotype or the complete animal. In this way, an organism that has been genetically engineered will have a unique and proprietary gene sequence as part of its genome, which can be identified separately (by DNA sequencing) from organisms that have been produced from non-recombinant methods but have a similar phenotype. This also overcomes the concerns of some groups that it is unethical to patent a whole organism or life form."[71]

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69 Quinn, N, Environment Protection Division, Department of Arts, Sport, Environment, Tourism & Territories: Transcript p 1114

70 Santer, Dr V: *Intellectual Property Protection for Living Organisms:* Exhibit 90 p 3

71 Australian Registered Cattle Breeders' Association: Submission 60.1 p 12

7.98 It is unlikely, however, that such patents would pass the test of 'non-obviousness'.

> "To some extent a DNA sequence is obvious because you can make any DNA sequence that you like in a machine. The question is what it does and what you might use that piece of DNA for. That is why the focus in patenting is on the actual product that you make, whether it is an animal with particular characteristics or a protein."[72]

7.99 **The Committee does not consider that allowing patent rights for gene sequences, rather than for the complete organism, would achieve the objective of placating groups opposed to the patenting of live organisms. The patent system is not the appropriate vehicle for regulating the use of particular technologies on ethical grounds.**

A.6 Is patenting a commercially sensible option?

7.100 If the present situation of allowing patenting were maintained, it is by no means certain that an increase in the development of genetically modified organisms would be accompanied by a corresponding increase in patent applications. Despite the landmark decision in 1980 in which Dr Ananda Chakrabarty was granted the first patent for a micro-organism by the US Supreme Court, the researcher subsequently did not consider it worthwhile seeking further patents for other organisms.[73]

7.101 The initial patent claimed in a new area of genetic modification tends to be broad in scope. Thus the Harvard oncomouse patent in the US purported to cover any recombinant animal modified to contain an activated oncogene.[74]

> "Establishing the true ambit of these patents would involve much litigation, costing both parties substantial sums of money. Therefore establishing the scope of protection and proving infringement could well be a very drawn out process".[75]

7.102 This would be especially so if inventions were able to be improved and the improvements, if 'significant', patented.

7.103 In fact the most defensible patents are those that are narrow in scope.

> "From a practical point of view, by far the best patent is a patent on the product where you clearly have an invention for a new product, because you can defend that. It is possible to get patents for a process by which

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72 Sleigh, Dr M, Division of Biomolecular Engineering, CSIRO: Transcript p 1090
73 Jones, the Hon B: pers. comm.
74 Holmes, P, Legal Research Project, Macquarie University: Submission 146 p 18
75 ibid.

> that product is produced. They can be very useful sometimes - they can be useful as an overall patent portfolio - but they are not as useful as a product patent; they are always weaker and harder to defend."[76]

7.104 The trend towards narrow, defensible patentable organisms may, in fact, be counter-productive.

> "The biological variability which is the wellspring of the evolutionary process and of traditional animal-breeding procedures will come to be seen as an annoyance by people wanting to ... defend their patents. We foresee a tendency to make new strains of animal genetically more and more uniform so that patent claims can be more easily defended. This will undercut the resilience of populations of farm animals when confronted with disease, climate change, etc."[77]

7.105 Consequently such animals if produced would not constitute an advance over current livestock and thus would fail in the marketplace.

7.106 Nevertheless, it was suggested that:

> "... as the number of patents granted and the amount of research done grows it would become increasingly more difficult to deny an assertion of obviousness. This is especially relevant since the Patents Act 1990 extends the realm of inquiry from that which was known or used in Australia on or before the priority date of the claim to that which was known worldwide."[78]

7.107 There are

> "... high compliance costs of patent protection, and these costs are multiplied if overseas protection is sought, a requirement vital to most worthwhile inventions ... Even when patents have been obtained the patentee remains uncertain of there [sic] validity until litigation tests this in the relevant jurisdiction."[79]

7.108 These high costs must be balanced against the potential gain from the resulting monopoly. For small companies, and in an area of rapid developments, patenting may not be economically justified and a trade secrets posture may be more fruitful.

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76 Harrison, Dr D: Transcript p 776

77 Newman, S: *The Difficulties of Patenting Transgenic Animals*, in *ASM News*, Vol 56, No 5, 1990: Exhibit 122 p 252

78 Holmes, P, Legal Research Project, Macquarie University: Submission 146 p 13

79 Australian Federation for the Welfare of Animals: Submission 147 p 59

A.7 Summary

7.109 Disallowing the patenting of genetically modified organisms would deter the development of the industry in Australia, deny rewards for products developed in Australia, deny the public access to products, many of which are pharmaceuticals, developed overseas.

7.110 Australia would have to depart from the current situation which permits patents for genetically modified organisms and move contrary to the practice in many countries of allowing patents, at least for micro-organisms.

7.111 Products could still be developed in Australia but a trade secrets attitude would appear in the development of products by companies which would affect the release of information.

> "... private firms may withhold proprietary information under trade secrecy, information pertaining to genetic material and processes that may be vital for solutions to national or local environmental disasters."[80]

7.112 **Denying the right to patent, allowed in many other countries, would probably adversely affect the biotechnology industry in Australia. The decision whether to seek a patent should be a commercial one to be made by the companies themselves.**

7.113 **The Committee considers that there is no justification for denying the biotechnology industry the opportunity to use the Patents Act to seek a reward for effort. The Patent Act is not the appropriate vehicle for hindering, or preventing, the development of technologies to which society may have an objection. If that is the aim more direct means such as legislation should be used.**

B. Regulation of Product or Process

7.114 Existing regulatory procedures already, to some extent, provide for the process of manufacture of a product to be taken into account when considering whether the sale of the product should be authorised.

7.115 The Committee noted in Part B.1 of Chapter 6 of this report that a National Food Authority is being established. The Authority will have responsibility for considering changes to the Food Standards Code, which sets down food quality requirements, and will consider applications for new food additives. The Committee noted that the Food Science and Technology Sub-Committee of the NH&MRC, which is to be superseded by the National Food Authority, had accepted that "all foods which have no or limited history of human consumption in Australia or which are

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80 Burch, Dr D et al.: Submission 106.1 p 6

produced from GMOs should be evaluated for safety and acceptability before they are considered acceptable for general human consumption".[81]

7.116 The Committee considers that it is a sound policy to require new food or food additive products, whether derived from genetic manipulation technology or otherwise to be tested for safety before release on the market. The emphasis, however, is on the fact that the food or food additive is novel rather than on the particular technology used in its development.

7.117 The Committee also noted in section B.4 of Chapter 6 that the Department of Health *Guidelines for preparing applications for the general marketing or clinical investigational use of a therapeutic substance* now specifically cover products of genetic manipulation.

7.118 In section C.1.(iii) of this chapter (Chapter 7), it is mentioned that the definition of chemicals under the *Agricultural and Veterinary Chemicals Act 1988* includes biological agents, whether naturally occurring or genetically modified. Applications for clearance must include, among other things, detailed information about the process of manufacture. So the existing procedures already allow the manufacturing process to be taken into account as one of the factors which may be relevant when considering the safety of a product.

7.119 The Department of Community Services and Health stated that, unless additional risks unique to GMOs can be identified, the *Quarantine Act 1908* provides adequate legislative framework for the storage, use, release and disposal of GMOs including human pathogens.[82]

7.120 The VLRC recommended that products made by genetic manipulation techniques should not be specially regulated for quality control. Products produced by GMOs should be regulated on the basis of their intended use in the same way as other biological products. The VLRC argued that there are already adequate laws, regulations and codes of practice concerning quality control of products.[83] "As new products are developed, appropriate government agencies should review this legislation to ensure that the quality control provisions apply and, if necessary, should amend their legislation."[84]

7.121 It was argued to the Committee that the VLRC recommendation did not take account of possible dispersal of a product to adjacent habitats where it was not intended for use.[85]

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81 NH&MRC Working Party to Review Biotechnology in the Food Industry: *Report to the Eighty-first meeting of the Food Science and Technology Subcommittee*, February 1991, Recommendation 10

82 Department of Community Services and Health: Submission 25 pp 1, 2

83 VLRC, Report No 26: *Genetic manipulation*, June 1989 p vii

84 ibid., pp 37, 38

85 Burch, Dr D et al.: Submission 106 p 50

7.122 What needs to be established with respect to products made by genetic manipulation techniques is whether the danger of their escaping 'to adjacent habitats' is any greater than the danger of other biological products and whether the consequences of their escaping are any more hazardous. Is there anything about the production processes themselves which makes the product inherently more dangerous?

7.123 The danger of products made by GMOs escaping to adjacent habitats would obviously vary widely depending on whether the product is itself a live organism or not; and if it is, what sort of organism is involved. Similarly, the consequences of such an escape to an unintended habitat would vary widely for the same reasons.

7.124 Another argument against focussing on the process of manufacture in legislation and regulations is the likelihood that genetic manipulation techniques will change. As Dr Sleigh from CSIRO commented:

> "... if you set up a system which is there only to monitor process it is quite likely that this system will become obsolete quite quickly, either because people's perceptions change and they are no longer concerned about the process or because the technology changes which it certainly is doing very rapidly and some new approach comes in which falls totally outside the definition which you have set up."[86]

7.125 **The Committee considers that it would be an over-simplification to treat all products produced by genetic manipulation techniques as being equally hazardous. The process of manufacture by itself is not a good indication of the dangers which may be inherent in the product. The process of manufacture should, however, be considered when examining the safety of products for which approval is sought before sale.**

Recommendation 32

7.126 The Committee recommends that those seeking approval for registration or clearance for sale of new products should indicate to the approving authorities the method of manufacture, as well as the nature of any organism involved, so that this can be taken into account in consideration of the safety or efficacy of the product.

86 Sleigh, Dr M, Division of Biomolecular Engineering, CSIRO: Transcript pp 1063, 1064

C. PRODUCT LABELLING

7.127 The use of genetically modified organisms in the production of commercial products, or as products themselves, raises the issue of whether special product labelling requirements should be introduced.

7.128 The Australian Consumers' Association called for "a labelling system for biotechnology produced products which identifies the production process in a standardised format which can be clearly recognised by consumers".[87]

7.129 The issue is one of 'the right of choice'.

> "Citizens must have the right, whether there is a safety issue involved or not, to avoid those products on moral grounds, given that we are talking about a morally contentious technology."[88]

> "The same applies with country of origin. Some people have particular objections to food originating from particular countries ... provision exists, as I understand, for the country of origin to be labelled."[89]

7.130 The provision of freedom of choice is supported by a resolution approved by the European Parliament in July 1988 which "called for all products from livestock intended for human consumption to indicate clearly all treatments used in their production with a view to safeguarding consumers and giving them a choice".[90]

7.131 A second argument in favour of the identification of the production process in product labels is to enable those with particular medical problems to avoid certain foods. It has been argued that cows given bovine growth hormone to enhance milk production suffer more infectious diseases.

> "Therefore, farmers use antibiotics, et cetera, on these beasts to control the infectious diseases. Low levels of these antibiotics then appear in the milk, and given that some consumers are sensitive to antibiotics, it can cause serious health problems to those people."[91]

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87 Australian Consumers' Association: Submission 132 p 13

88 Isles, J, Australian Consumers' Association: Transcript p 742

89 Chapman, Dr S, Consultant, Australian Consumers' Association: Transcript p 743

90 Australian Federation of Consumer Organisations Inc: Submission 75.1; Attachment 2, Straughan, R: *The genetic manipulation of plants, animals and microbes. The social and ethical issues for consumers: a discussion paper,* National Consumer Council U.K. 1989

91 Hulsman, Dr K: Transcript p 1209

C.1 Current product labelling regulations

C.1.(i) Regulations concerning food

7.132 The labelling of food is covered by the Food Standards Code of the NH&MRC,[92] which depends for its force on State legislation. Products are labelled according to their content and not the process by which they are made. The Code sets out precisely what should be on the label and specifies the composition of the product.[93]

7.133 The Code requires the country of manufacture to be indicated. Thus, 'Product of Australia' only denotes where the final article was produced and need not indicate the origin of ingredients.[94] There are, however, two major exceptions; information concerning origin is required in the case of fruit juices and where 'Packed in Australia' provisions apply.[95]

C.1.(ii) Regulations concerning pharmaceuticals

7.134 The *Therapeutic Goods Act 1989*, Therapeutic Goods Order No. 32 contains the general requirements for the labelling of therapeutic goods. A therapeutic good is defined as one which makes a therapeutic claim. Under the order, the label must contain the details of manufacture. If a drug was made by genetic modification it should be possible to ascertain this from the label.

C.1.(iii) Regulations concerning agricultural and veterinary chemicals

7.135 The Australian Agricultural and Veterinary Chemicals Council (AAVCC) was established under the provisions of the *Agricultural and Veterinary Chemicals Act 1988* to co-ordinate the pre-registration assessment and clearance process for agricultural and veterinary chemicals. Such chemicals can include biological agents, either naturally occurring or genetically modified.

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92 NH&MRC, Department of Community Services and Health: *Food Standards Code*, 1991; NH&MRC, Department of Community Services and Health: *Supplement to the Food Standards Code*, 1991. (This covers food additives.)

93 With meat, for example pork, Section C1-(1) (d) states: "Meat shall be derived only from appropriate animals that are in good health and condition at the time of killing. Where the meat bears a name description of its kind, composition or origin it shall correspond thereto." It might be argued that meat from pigs containing a human gene does not derive solely from a pig (see Chapter 5).

94 NH&MRC, Department of Community Services and Health: *Food Standards Code*, 1991, Section A-1 (4) (a)

95 Commonwealth Of Australia Gazette No P 16, 21 June 1991 pp 12, 13; NH&MRC, Department of Community Services and Health: *Food Standards Code, 1991, Section A-1 (4) (b)*

7.136 The AAVCC has Commonwealth and State members including representatives from the National Health and Medical Research Council (NH&MRC), the Australian and New Zealand Environment Council (ANZEC), the Council of Nature Conservation Ministers (CONCOM) and the National Occupational Health and Safety Council (NOHSC). The secretariat is provided by the Commonwealth Dept of Primary Industries and Energy.[96]

7.137 The pre-registration clearance process involves consideration of public health matters by the NH&MRC; occupational safety and health issues by NOHSC; environmental hazards by ANZEC, CONCOM and the Australian Fisheries Council; and hazards from genetic manipulation work by GMAC. State Departments of Agriculture evaluate the efficacy of products and the safety of their use on target species.[97]

7.138 Registration of agricultural and veterinary chemicals, following clearance, is the responsibility of the States and Territories. State and Territory legislation concerning such matters as public health, pesticides, agricultural chemicals and stock medicines requires registration of both the products and the product labels before sale.[98]

7.139 In 1989 the AAVCC produced codes of practice for labelling agricultural and veterinary chemical products. The clearance process has involved discussion concerning the information to be included on the labels with reference to these codes.[99] There is no requirement in the codes for the method of manufacture to be indicated. Consequently, the label for 'NoGall' has no mention of genetic manipulation.[100]

7.140 The July 1990 *Report of the Senate Select Committee on Agricultural and Veterinary Chemicals in Australia* referred to evidence that the *Agricultural and Veterinary Chemicals Act* had significantly improved uniformity in clearance and registration requirements between the States. "Under the Act, agreement would be reached on a final draft of a product label prior to the issuing of the clearance certificate".[101]

7.141 On 2 August 1991 the Minister for Primary Industries and Energy announced that agreement had been reached on a national registration scheme for agricultural

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96 Australian Agricultural and Veterinary Chemicals Council: Submission 81 p 2

97 ibid., pp 3, 4

98 ibid., p 2; *Report of the Senate Select Committee on Agricultural and Veterinary Chemicals in Australia*, July 1990 pp 6-9

99 Australian Agricultural and Veterinary Chemicals Council: *Code of practice for labelling agricultural chemical products 1989;* Australian Agricultural and Veterinary Chemicals Council: *Code of practice for labelling veterinary chemical products* 1989

100 The label lists as the active ingredient "1000 million Agrobacterium radiobacter var. radiobacter K1026/g peat".

101 *Report of the Senate Select Committee on Agricultural and Veterinary Chemicals in Australia*, July 1990 p 10

and veterinary chemicals. "The Commonwealth has accepted responsibility for the registration of chemicals and the States and Territories will remain responsible for control of use activities."[102] This should greatly assist in establishing a national system concerning labelling requirements.

C.2 Practical difficulties

7.142 If the manufacturing process is to be identified on a label, records would have to be kept so that the source of the raw materials could be traced. This would be essential if the origin cannot be determined from the characteristics of the material. This could be achieved if the production process is simple, for example, in the case of 'dolphin friendly' tinned tuna. However, difficulties may arise if the product is made from a variety of ingredients. If such records have to be kept this would result in increased prices to the consumer.

C.2.(i) The problem of identity

7.143 Problems will arise if the product of genetic manipulation is identical to one coming from a non-modified organism . "How on earth could you ever tell whether a product was produced from a recombinant organism or not? The product is the same, whatever the source. It is absolutely identical and non-distinguishable."[103]

7.144 The issue is complicated if the genetically modified organism is used as a food source for farm animals or, in the case of altered rumen bacteria, to enhance feed conversion.

> "... there is no way you can differentiate an animal that had recombinant bacteria in its rumen from one that did not have. We would not expect it to have any effect on body composition - on any characteristic of the meat, which is the muscle of the animal - so in terms of policing that, I would say it would be impossible. It would certainly not be economically possible, particularly if the organisms transferred between animals within the herd. If it did not, then presumably it would be given to each individual animal and it is not inconceivable that you could mark the animal in a certain way, and a declaration could be made by the producer when he put it into the abattoir - as is done now with hormonal growth promotants, for instance."[104]

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102 Minister for Primary Industries and Energy: Media Release DPIE91/204C 2 August 1991

103 Harrison, Dr D, Biotech Australia: Transcript p 785

104 Johnsson, Dr I, Australian Meat and Livestock Research and Development Corporation: Transcript pp 802, 803

C.2.(ii) The problem of ingredients and blends

7.145 Even if the products of genetic manipulation were identified and could be tracked through the production chain, problems would arise if the raw materials were available from both genetically modified and traditional sources.

7.146 The manufacturer's choice of which source to use should depend, in the absence of other constraints, on the relative prices of the alternatives. If the product was a food with many ingredients or a blend like wool or cotton yarn, manufacturers would have to produce different labels to indicate whether the product contained genetically modified raw material or only traditional ingredients or a mixture of both. This would complicate production processes and could result in the production of two **identical** products, with different labels.

7.147 It is possible that manufacturers may forgo cheaper raw materials in order to maintain a simple production process. The consumer, therefore, may have a more expensive product and possibly a reduced choice. Alternatively, secrecy and deception may occur and products containing genetically manipulated material may be sold with incorrect labels. There would need to be enforcement; and proving an infringement, especially with identical ingredients, would be extremely difficult. These additional costs would have to be met and could increase prices.

C.2.(iii) Singling out the genetic manipulation industry

7.148 It was argued that a requirement for genetically modified products to be identified via a label, would single out the industry unfairly and would act as a disincentive to its development.

> "If it were necessary to have labelling on the bread, and on other consumer items for all categories of manipulated organisms, you would basically reduce, if not eliminate, this area of innovation with food ingredients. Because it would be considered to be such a strong marketing negative, it would be in no-one's interest to pursue it and I think that would be to the detriment of the consumer, ultimately."[105]

7.149 The inequity would be particularly acute if the products were identical to traditional products and/or had been assessed as safe.

7.150 An alternative is to require all manufacturing methods to be identified on labels. This might stimulate the production of labels containing a plethora of information, much of it unnecessary and confusing to consumers. Again, the problems identified above, concerning products made from various ingredients would apply. Although the

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105 Friend, Dr J, Technical and Research, Food and Fermentation Division, Burns Philp & Co: Transcript p 1208

informed consumer might be able to sift out the useful information, everyone might be faced with more expensive products.

C.2.(iv) The problem of consistency

7.151 If Australia adopted a policy on labelling which was inconsistent with overseas practices, problems could arise if imports which didn't comply with the labelling standards were embargoed.[106] Australia could be accused of erecting barriers to trade.

7.152 Additional problems would arise with the policing of labels if a genetically modified import was identical to the traditional one. "If it was produced in Australia, you could police it, yes; but, if it was coming in from overseas, you would have no way of telling and you could not police it."[107]

7.153 Australia participates in the Codex Alimentarius which, unfortunately, gives no clear direction concerning whether the manufacturing process should be identified on labels.

> "The Codex may consider that those products of biotechnology that are deemed to be safe and that are identical to traditional foods, food ingredients, or additives shall be designated on the labels by the common name of the food, food ingredient, or additive.
>
> From the points of view of quality and identity, however, Codex may also have to give some consideration, in specific cases, as to whether genetically altered fruits, vegetables or animal products essentially retain the quality factors and composition of the original product, or whether this food represents a new product or a sub-species of the original food and would therefore warrant the use of a new common name."[108]

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106 Peters, Dr F, Australian Federation of Consumer Organisations: Transcript p 37

107 Harrison, Dr D, Biotech Australia: Transcript p 785

108 Berkowitz, D, and Maryanski, J: *Implications of Biotechnology on International Food Standards and Codes of Practice*, Joint FAO/WHO Food Standards Program - Codes Alimentarius Commission Eighteenth Session, Geneva, 3-12 July 1989: Exhibit 87 p 5

C.3 The UK Food Advisory Committee

7.154 In October 1990 the Food Advisory Committee (FAC) of the UK Ministry of Agriculture, Fisheries and Food produced *Guidelines for the Labelling of Foods Produced Using Genetic Modification.* Four categories of food were identified but, nevertheless, the guidelines were:

> "... developed to assist the Committee with its own work. Therefore it should not be assumed that the labelling advice for each of the four categories would automatically apply in every case. The Committee wishes to consider the labelling requirements for such foods on a case-by-case basis".[109]

7.155 The four categories of food are:

> "i) Nature Identical Food Products of Genetically Modified Organisms (GMOs): This category includes GMO-derived foodstuffs which do not contain the cells or DNA of the GMO and which are identical [to] conventional products traditionally consumed in Western Europe. The Committee considers special labelling would not be required for most foods in this category as they would not be materially different from conventional products.
>
> ii) Food from Intra-Species GMOs: The Committee recommended that most foodstuffs from a GMO which has been derived only from organisms within its own species would not require special labelling as such modification is effectively an accelerated form of traditional breeding methods.
>
> iii) Novel Food Products of GMOs: These are GMO-derived foodstuffs which do not contain the cells or DNA of the GMO and which differ from conventional products traditionally consumed in Western Europe. The Committee has stated that as a general principle these foods should be labelled.
>
> iv) Foods from Trans-species GMOs: The Committee recommended that labelling would be required for foodstuffs derived from an organism which had been modified to contain a gene or genes from sources outside its own species."[110]

7.156 The third category raises the question of how long a 'novel food' would need to be on the market before it was no longer to be considered novel. It is not known whether this has been considered.

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109 UK Ministry of Agriculture, Fisheries & Food news release: *New Guidelines Introduced for the Labelling of Foods Produced Using Genetic Modification*, 17 January 1991: Exhibit 107 p 4

110 ibid., p 2

7.157 In March 1990 a genetically modified yeast was cleared for use in the UK. The yeast "had genes from a sister strain inserted to speed the production of certain enzymes responsible for dough fermentation."[111] It is not known what, if any, labelling requirements were imposed but, since the organism falls into Category (ii), specific labelling presumably was not required.

7.158 A second product was cleared in January 1991. The product was the enzyme chymosin, which traditionally comes from calf rennet and is used to clot milk.

> "The organism involved is a yeast modified by the addition of genetic material from calf cells. This allows the yeast to produce calf chymosin when it is grown under controlled conditions. The enzyme is then purified, and the preparation to be used in cheese-making contains none of the yeast cells."[112]

7.159 The FAC, when it considered the labelling of cheese made with this product, "concluded that since the enzyme is identical to the one found in calf rennet, special labelling is unnecessary".[113]

C.4 Conclusion

7.160 Labels should provide information which is both useful and meaningful. Product labelling lies at one of the points where biotechnology meets the public. Public acceptance is vital if the industry is to flourish.

7.161 The labelling issue revolves around the moral right of the consumer to know, balanced against the practicability and value of providing the information which is sought. The debate is all the more sensitivebecause genetically modified food may be seen as a marketing negative.

7.162 If labelling was required for products produced by genetic modification, the industry would be singled out. It could suffer a financial penalty in trying to overcome possible consumer resistance and could be vulnerable to any emotional argument from those vehemently opposed to the technology.

7.163 If there were no labelling, it could be argued that public concerns about the technology and the right of the consumer to make a choice in a fundamental area were being ignored. There might also be a spate of 'GMO free' labels similar to those proclaiming 'cholesterol free' on products which have never contained cholesterol. Such an outcome is not desirable.

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111 Department of Health (UK), Ministry of Agriculture, Fisheries and Food, Advisory Committee on Novel Foods and Processes: *Annual report 1990*, Annex I

112 ibid., Annex III p 1

113 ibid., Annex III p 2

7.164 The Committee considers that there should be labelling of some products which contain GMOs or are produced by GMOs. However, this should be decided on a case-by-case basis. The guidelines of the Food Advisory Committee of the UK Ministry of Agriculture, Fisheries and Food are a useful basis for deciding which products should be labelled.

D. Compensation for Personal Injury or Property Damage Outside the Workplace

7.165 The VLRC recommended that there be no special remedy for people injured or suffering property damage as a result of recombinant organisms other than the usual common law remedies.[114] The VLRC report stated, however, that there might be doubt about the "applicability of the existing common law remedies to injuries caused by [GMOs]" and difficulties in establishing a causal relationship or reasonable foreseeability of the harm caused.[115]

7.166 Actions for trespass or nuisance could conceivably be taken to obtain an injunction against people accidentally or deliberately releasing GMOs which were causing or threatened to cause damage. In addition actions for trespass, nuisance, negligence, or a breach of the duty of care established by the case of *Rylands v. Fletcher*, could be taken in order to obtain financial compensation for the loss or damage suffered.[116]

7.167 Trespass involves "unauthorised entry or interference to land". A defence to this action may be made on the basis that the interference was involuntary or was authorised by statute.[117]

7.168 Private nuisance actions for damages to land, or to the things upon it, are limited to instances where the loss is suffered by the owner or lawful occupier of the land affected.

7.169 Public nuisance relates to unlawful actions which endanger "the lives, safety, health, property or comfort of the public, or obstructs them in the exercise of their rights". Damages may be awarded to a person who suffers 'particular' or 'special' damage as a result of a public nuisance, although there may be difficulty in establishing that 'particular' damage has been suffered by an individual when similar damage has been suffered by a number of others.[118]

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114 VLRC: Report No 26 p vi

115 ibid., p 22

116 Barker, M: *The Recombinant DNA Technique and the Law: A Review of Australian Law which may be relevant to the Regulation of Recombinant DNA Research and Applications*, Report to RDMC and Commonwealth Depart. of Science and Technology, June 1984 p 87

117 ibid., p 89

118 ibid., pp 88, 89

7.170 As Mr Michael Barker, of the Faculty of Law at the Australian National University, observed in his 1984 study of Australian law relevant to recombinant DNA work, a successful action for negligence must establish: a duty of care owed by the defendant to the plaintiff; a breach of that duty of care which was reasonably foreseeable; and loss resulting from the breach. A breach of the GMAC or RDMC guidelines may or may not be interpreted by the court as indicating a breach of the duty of care.[119]

7.171 The case of *Rylands v. Fletcher* established a more stringent duty of care. The ruling was that "a person who for his own purposes brings on his land and collects and keeps there anything likely to do mischief if it escapes must keep it in at his peril, and, if he does not do so, is *prima facie* answerable for all the damage which is the natural consequence of its escape".[120] The UK Royal Commission on Environmental Pollution commented that the doctrine seems to relate to accidental release and may not relate to deliberate release. Also "plaintiffs may have difficulty in proving a causal link between their loss and a release of GEOs".[121]

7.172 Mr Barker noted that a qualification to the *Rylands v. Fletcher* rule is that "the use of the land from which the thing escapes must be 'non-natural'". Mr Barker also pointed out that the rule does not apply " unless the escape occurs from the defendant's land; where a person suffers loss on the defendant's premises; or where the activity [is] carried on with statutory authority".[122]

7.173 As noted above, many of these common law actions for damages can be successfully defended if the action which causes the damage was authorised by statute. The *Biological Control Act (1984)*, which covers the release of live organisms as pest control agents, specifically removes the right to sue for damages if the correct procedures under the Act have been followed.

7.174 A number of submissions called for a legislative solution to the problem of uncertainty concerning legal liability for damage or loss as a result of GMOs released to the environment.[123]

7.175 Various remedies were suggested. Mr Kevin Andrews MP of St Vincent's Bioethics Centre recommended that a breach of the rules concerning the environmental use of GMOs should provide a basis for action if damages occur. The ACF and Dr David Burch et al. favoured compulsory insurance for those undertaking

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119 ibid., p 88

120 1868 Law Reports 3 House of Lords - as quoted in Royal Commission on Environmental Pollution, Thirteenth Report: *The release of genetically engineered organisms to the environment*, July 1989 p 55

121 ibid., p 55

122 Barker, M: op. cit., p 89

123 For example - Australian Consumers' Association: Submission 132 p 13; University of Adelaide: Submission 49 p 2; United Scientists for Environmental Responsibility and Protection: Submission 34 p 2; Queensland Department of Environment and Heritage: Submission 73 p 4

experimental releases or production of GMOs as products.[124] The ACF also favoured allowing class actions to spread the cost of litigation.[125] Dr Burch et al. recommended either strict liability on the producer or the releaser, or that the producer or releaser carry the onus of proof that the organisms (or product) are safe.[126]

7.176 The Committee considers that those who release GMOs, without following the correct procedures, should not benefit from the difficulty experienced by plaintiffs in a common law action for negligence of establishing a duty of care; nor should they benefit from the anomalies which appear to exist in other common law remedies.

Recommendation 33

7.177 The Committee recommends, in terms similar to those of the UK Royal Commission on Environmental Pollution, that legislation should provide that any person, or the directors of any company or other organisation responsible for carrying out the release of a genetically modified organism without the necessary approval, will be subject to strict liability for any damage arising.[127]

7.178 The Committee also considers that, if those who are responsible for a release which results in loss or damage, obtained the required approval prior to release and fully complied with the conditions and procedures attached to the approval, this should mitigate their legal liability.

7.179 The UK Royal Commission also recommended that "neither the licensing and registration authorities, nor members of the Committee on whose advice they ... acted in granting the licence or registration, should be liable in respect of the consequences of the release."[128]

7.180 The Committee considers that the liability of the authorities approving a release from which damage or loss results, and the liability of those on whose advice the authorities relied, should depend on the diligence with which they carried out their duties. However, if an approval were to be granted on the basis of the best scientific knowledge available at the time, then there should be legal protection for this class of people against liability for loss or damages which may result.

7.181 The degree of danger inherent in a particular product is a matter which should be taken into account in the process of approval for release of the product onto the market in the first place and in the standards applicable for manufacture, storage,

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124 Burch, Dr D et al.: Submission 106 p 50

125 Phelps, R, Australian Conservation Foundation: Submission 140 p 80

126 Burch, Dr D et al.: Submission 106 p 2

127 UK Royal Commission on Environmental Pollution: op. cit., para. 12.24 p 94

128 ibid., p 95

distribution or use. Legal liability for damage or loss suffered by consumers can then be treated in a way which is consistent for manufacturers of any product without discrimination.

7.182 To create separate degrees of strictness of product liability, dependent on the perception of risk connected with a product, would lead to unacceptable complexity in the law. Such a practice would also be flawed in that the perception of risk may change over time as knowledge changes. Given that the degree of risk would also vary considerably between GMO products, it would be unreasonable to group all such products together as 'ultra-hazardous'.

7.183 Once having met the required standards, manufacturers should be able to rely on protection under the law concerning the extent of their liability. A standard of 'absolute certainty' concerning safety is probably one which is logically impossible to meet - any assessment of safety is necessarily limited by the current state of scientific knowledge.

7.184 **The Committee considers that there should be the same product liability obligations attaching to products made by genetically modified organisms, or including such organisms, as there is in relation to other products.**

7.185 The Committee notes that the Government has announced that it intends to introduce certain reforms to product liability law.[129] Existing rights of action under the law of negligence would not be affected by the new law.

7.186 The Government proposes to implement the provisions of a 1985 European Communities Directive on product liability with some changes. The Minister for Justice and Consumer Affairs has commented that while there is already in Australia: "an array of legal rights where people are injured by products ...these existing rights depend more on whether or not the claimant bought the product than on the real issues - whether the product was defective and whether or not the product was misused."[130]

7.187 According to the Minister, the EC Directive defines a product as defective only if it "fails to provide the degree of safety which persons are generally entitled to expect". Factors which are relevant in assessing the degree of safety which can be expected include: "the presentation of the product (including any instructions and warnings), the use to which it could reasonably be expected that the product would be put, and the time at which the product ... left the manufacturer's control".[131]

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129 Tate, Sen the Hon M, Minister for Justice and Consumer Affairs: *Media Release*, 13 May 1991 and *Media Release*, 11 November 1991

130 Tate, Sen the Hon M, Minister for Justice and Consumer Affairs: *Keynote Address at AIC Product Liability Conference*, Sydney 11 November 1991 pp 5 & 6

131 ibid. p 7

7.188 Among the defences provided for under the EC Directive are: that the defect did not exist when the product left the manufacturer's control; the defect existed only because of compliance with a mandatory standard; in the light of scientific knowledge at the time of manufacture, the defect could not have been known; and in the case of a product component manufacturer, the defect resulted from the design of the product into which the component was fitted or from the instructions given by the product manufacturer.[132]

7.189 The Government has decided to accept responsibility for compensation in the case of damage caused by a defect which could not have been known at the time of manufacture, owing to the current state of scientific knowledge.[133] The Government has also decided to extend the 'Statute of Repose' on personal injury claims from 10 to 20 years "in cases of toxic harm and products with possible long term carcinogenic effects".[134]

7.190 Concerning the onus of proof, the proposed legislation will provide that "the plaintiff will bear the substantial onus of showing injury or damage, causation and the existence of a defect." The plaintiff's initial burden to establish a prima facie case will be considered as being met:

> "... where the circumstances of the case allow a reasonable inference to be drawn that the injury was caused by a defect in the product. ... But at the end of the case, the question for the court will continue to be: has this claimant shown, on the balance of probabilities, that a defect in the product caused the injury or damage".[135]

7.191 **The Committee supports the broad thrust of the Government's proposed changes concerning product liability and their application to products involving the use of genetic modification techniques. The Committee notes, however, that recovery of loss arising from damage to property would be limited to property of a kind ordinarily acquired for personal, domestic or household use. The exclusion of property acquired for commercial use is not justifiable.**

Recommendation 34

7.192 The Committee recommends that product liability laws apply to all products, irrespective of their method of manufacture, and regardless of whether purchased for personal, domestic, household or commercial use.

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132 ibid. p 8
133 ibid. p 11
134 ibid. p 12
135 ibid. p 17