CHAPTER FOUR

PHILOSOPHICAL/ETHICAL/SOCIAL ISSUES

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A. PHILOSOPHICAL/ETHICAL CONCERNS

A.1 'Playing God'

4.1 One major objection to genetic manipulation is that its capacity to intermingle the characteristics of separate species usurps the role of Creator, or is, in the common phrase, 'playing God'. "It is the simple act of creating new forms of life that changes the world, that puts us forever in the deity business. We will never again be a created being; instead we will be creators."[1]

4.2 The Judeo-Christian tradition which has shaped Western civilisation advanced two different teachings about man's relationship with nature, each receiving about equal space in the Bible:

(a) Man sharing with God transcendence over nature and transforming it; but also

(b) Man as the good steward and trustee of nature, with a duty to tend the garden for all succeeding generations.

4.3 The first view contributed to the 19th century doctrine of material progress in which all transformation was deemed useful and nature was regarded as indestructible. The second view is relied on by conservationists who urge that human society should live with nature instead of transforming it.

4.4 The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioural Research (1982), quoted in the Victorian Law Reform Commission (VLRC) report, stated

> "... in the biblical tradition of major Western religions, human beings are, in a sense, 'co-creators' with the Supreme Creator. They took the view that, in using the powers of intelligence and freedom given to them by God, people must accept responsibility for their actions and for the development of human nature."[2]

4.5 **The Committee has no brief to determine questions based on moral and religious belief, but they are - and will continue to be - legitimate subjects of community debate. However, the Committee does not interpret community opinion as demanding the outlawing of genetic manipulation, although there is concern that researchers must operate within ethical guidelines adopted after full debate.**

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1 McKibben, W: *The End of Nature*, Random House, New York 1989 p 165 as quoted in Holmes, P: Submission 146 p 67

2 VLRC: Report No 26, *Genetic Manipulation*, June 1989 p 2

A.2 The Human/Nature relationship

4.6 The differences set out in paragraph 4.2 result in deep disagreement about the relationship of humanity and nature, and were reflected in submissions to the Committee.

4.7 The Social Responsibilities Commission of the Anglican Diocese of Melbourne expressed concern over the "mechanistic world view" which it saw as part of the scientific perspective underlying biotechnology. The Commission was concerned about potential threats to the "integrity of creation"[3] as was the Australian Council of Churches.[4]

4.8 Reverend Dr Greg Moses and Neil Ormerod of St Paul's National Seminary asserted:

> "One ethical consideration which hangs over the whole genetic engineering project is how it will affect both our self-understanding and our understanding of our relationship to nature. The very term genetic 'engineering' reveals a tendency to view nature in mechanistic terms. A machine is simply the sum of its parts, each part interacting with the others in a totally predictable way. Living organisms are not like this. They are more than the sum of their parts, interacting in complex and unpredictable ways. We run the danger of turning our image of life itself into that of a consumer commodity. This downgrading of our self-understanding could have unpredictable effects [on] the human psyche."[5]

4.9 All cultures, and in particular Western cultures, use a wide range of resources for human benefit. Advances in scientific knowledge have increased the use of resources, extended the average life span and allowed a significant increase in population.

4.10 Some writers argue that resources should not be regarded as being available only for human consumption in the short term; that in the long term the health of ecological systems, maintenance of species diversity and human welfare are inextricably linked.

4.11 Environmentalists argue that the increase in human population and the range of material goods demanded have increased considerably the pressures on the earth's natural systems. They further argue that, in addition to the sheer weight of human numbers, the way in which agricultural, manufacturing and mining activities have been carried out has resulted in a number of problems. These include soil erosion, air and water pollution, the erosion of the ozone layer, an increase in 'greenhouse gases' and an increase in the rate of extinction of plant and animal species. This line of

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3 Social Responsibilities Commission, Anglican Diocese of Melbourne: Submission 135 p 1

4 Church and Society Commission, Australian Council of Churches: Submission 97

5 Moses, Rev Dr G and Ormerod, N, St Paul's National Seminary: Submission 123

argument is further developed by those who favour the use of 'alternative technologies' and this is examined in more detail in section B.6 below.

4.12 Genetic manipulation of organisms is seen by some opponents of the technology as exploitation.[6]

> "... all living things are becoming the new industrial materials, as the earth's non-renewable resources are exploited to exhaustion. In this process, the status of all biological resources is being changed from the common heritage of humanity to the private property of corporations".[7]

4.13 The VLRC considered that "the non-theological, ethical objection to manipulation is based on an assumption that one should not try to interfere with the natural evolutionary development of life."[8] The Commmission found, however, that genetic manipulation is not wrong on ethical grounds. The Committee agrees with the VLRC.

A.2.(i) 'We are not doing anything new'

4.14 The VLRC presented a number of counter-arguments to concerns that are raised:

. one argument is that selective breeding has long been used and species have been crossed before. "Recombinant DNA techniques represent a more refined and controlled means of carrying out genetic manipulation."[9] Therefore we are not really doing anything new.

. another argument is that we are not really crossing species: "... the transfer of a single gene, or even many genes, will not alter the nature of an organism. The organism ... is still a member of the same species."[10]

. another argument is that: "Individuals within a species (already) may have different DNA and that may change as organisms evolve. Also, organisms may exchange genetic material in nature."[11]

. "... the degree of interference with evolution caused by recombinant DNA technology is insignificant when compared with that resulting from the effect of human activity on the environment, including the extinction of species of plants and animals and the alteration of the temperature of the earth."[12]

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6 Thirkell, K: Submission 3 p 1; Jones, C: Submission 5

7 Rifkin, J: *Is nature just a form of private property?* as quoted in Holmes, P: Submission 146 p 68

8 VLRC: Report No 26 pp 2, 3

9 ibid., p 2

10 ibid.

11 ibid.

12 ibid., p 3

4.15 Dr Richard Cotton made the point that the organisms produced by genetic manipulation may be phenotypically the same as those produced by more traditional techniques but genotypically they are not.[13] He stated that those who claim genetic manipulation techniques are no different from traditional techniques of selective breeding but merely involve a speeding up of the process, are not being "entirely honest".[14]

4.16 Professor Bruce Holloway, from the Department of Genetics and Developmental Biology at Monash University, agreed that the products of selective breeding by traditional means and by genetic manipulation techniques are not identical. He argued that the genetic manipulation process is more precise, changing only the targeted genes and not fairly randomly shuffling the genetic make-up of the organism: "you are merely increasing the frequency of getting the desired result."[15]

4.17 **There will be some continuing debate within the scientific and general community as to whether organisms, plants or animals created by genetic manipulation should be characterised as being genetically 'different' or 'new' in contrast to traditional breeding techniques. It is beyond dispute that genetic manipulation produces some results which cannot be achieved by traditional techniques. The Committee believes the ethical question of whether the results are ones which should be pursued can only be determined by the appropriate regulatory body on a case by case basis.**

A.2.(ii) 'Crossing the species barrier'

4.18 Another argument was that species are not really being crossed: "the transfer of a single gene, or even many genes, will not alter the nature of an organism. The organism ... is still a member of the same species."[16]

4.19 Despite this disclaimer, it is clear that the new techniques do allow the crossing of species barriers in a way not previously possible. For example prokaryotic cells, such as bacteria, can be made to express genes from higher forms of life which they could not previously do, through the intervention of recombinant DNA techniques.[17]

4.20 The new techniques have enormous potential for change, the limits of which are uncertain. Crossing has previously been possible only between closely related species and frequently resulted in infertile offspring. Nevertheless, it must be remembered that in the late 18th and 19th centuries reforming farmers such as Robert Bakewell and Thomas Coke of Holkham achieved massive increases in the size and body weight of cattle through selective breeding. (For an example, see the painting on the front cover.)

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13 Cotton, Dr R: Submission 4
14 Cotton, Dr R: Transcript pp 298, 299, 311, 312
15 Holloway, Prof B: Transcript p 343
16 VLRC: Report No 26 p 2
17 Burch, Dr D et al.: Submission 106 p 21

4.21 A related argument was that: "Individuals within a species [already] may have different DNA and that may change as organisms evolve. Also, organisms may exchange genetic material in nature."[18] Therefore, there should not be any strong phobia about crossing genes from species to species by genetic manipulation.

4.22 On the other hand, it was pointed out that random mutations usually produce non-functional genes whereas genetic engineering techniques involve the placement of fully functional genes into the genome.[19] It must be noted, however, that the production and insertion of non-functional genes may sometimes also be the goal of genetic manipulation - for example, this was the case with the ice-minus bacteria.

4.23 The exchange of genetic information between species is generally thought to be a rare event in life forms other than micro-organisms. What is becoming possible is a speeding up of the rate of occurrences of this phenomenon. The question whether deliberately making changes in DNA is a 'safe' or 'wise' thing to do then must still be addressed. Also, the fact that organisms may exchange genetic information in nature could equally be used as an argument for not putting new genetic information into organisms because that information may then be transferred to organisms other than the targeted ones.

4.24 **Changes in genetic composition undoubtedly occur from generation to generation as a result of random mutation and natural selection. It is clearly a different thing to attempt to add direction to this process of change. It must be acknowledged that human intervention could result in changes that would not occur without human intervention. The Committee, however, does not see this as implying that such directed change should be banned. It is simply that the fact must be acknowledged and responsibility for it accepted.**

A.2.(iii) 'There has already been great interference'

4.25 Another argument was that:

> "... the degree of interference with evolution caused by recombinant DNA technology is insignificant when compared with that resulting from the effect of human activity on the environment, including the extinction of species of plants and animals and the alteration of the temperature of the earth."[20]

4.26 Even if the proposition in paragraph 4.25 is correct, this should not be taken as a blanket endorsement of all future techniques in genetic manipulation which may have potential to cause significant environmental damage.

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18 VLRC: Report No 26 p 2
19 Burch, Dr D et al.: Submission 106 p 21
20 VLRC: Report No 26 p 3

A.2.(iv) 'There is no pre-ordained plan for life on earth'

4.27 This argument states that "there is no such thing as a pre-ordained 'plan' for life on earth" which would be disrupted by genetic manipulation. Genetic variation in the past has proceeded randomly and by selective breeding. Those variations which have been successful in terms of reproducing themselves survive, those which have not been successful have not survived. "In biological terms, species have no particular purpose other than to survive and reproduce."[21]

4.28 The Committee believes that regardless of the argument in paragraph 4.27, there is a global ecological system in dynamic equilibrium, with species which are interdependent. The disruption of any particular species will affect to a greater or lesser extent the survival of all species including humans.

4.29 The assertion that 'there is no pre-ordained plan for life on earth' fails to advance the discussion about genetic manipulation in any useful way. It is disputed by those of religious persuasion, and denies the ecological role of species in assisting the survival of other species.

A.2.(v) Conclusions

4.30 The Committee does not believe that these scientific arguments are very useful counter-arguments against ethical objections to genetic manipulation. Some of them miss the point and others exhibit a certain logical imprecision. They are probably irrelevant. The ethical objections which have been raised are fundamentally value judgements and do not stand or fall on questions of fact.

4.31 The philosophical argument about the appropriate way of viewing the relationship between the human species and the rest of nature is an important one. Its implications are much broader than whether the technology of genetic manipulation should proceed.

4.32 It is impossible to live on the planet without having an impact upon it. Correct predictions about the extent of those impacts clearly depend on an understanding of the interconnections between the different systems in nature. Equally clearly the health and survival of the human species depends on how those natural systems continue to function. This does not necessarily preclude the use of any particular technology, but it does require that the effects of its use be appreciated.

4.33 Basic philosophical concerns about these perceived attitudes: that human beings are separate from and superior to nature; that all forms of life can be explained in purely 'mechanistic' terms; and that it is ethically justifiable to manipulate life at the most fundamental level underlie many of the other concerns which are discussed in the following chapters of this report.

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21 ibid.

A.3 Reading the human blueprint

4.34 Background information relevant to this topic is contained in section C.1 of chapter 3.

A.3.(i) Germ cell gene therapy

4.35 Perhaps the most fundamental ethical concern expressed about the application of genetic modification techniques to human beings was that the techniques could be used to create new 'breeds' of people - in an attempt to create a master race or a race of 'drones'.[22] People with these concerns therefore distrust human gene therapy, and in particular germ cell gene therapy.[23]

4.36 Some scientists have commented that any such public concerns are largely unnecessary since germ cell gene therapy for humans is a long way off. It has been argued that most characteristics which might be said to be desirable in humans are the result of many genes and their interactions, as well as other, non-genetic factors.[24]

4.37 In any case, germ cell gene therapy would probably involve in-vitro fertilisation and then detection of an egg which was defective. In which case it would be simpler to use another non-defective fertilised egg rather than to treat the defective egg.[25]

4.38 The NH&MRC said in 1987 that human gene therapy to make heritable changes is ethically unacceptable because there is insufficient knowledge about the possible effects on future generations. The NH&MRC adopted a recommendation of the Medical Research Ethics Committee that it invite:

> "... all institutions undertaking research on humans in Australia to agree that they will not for the time being, and not without reference to the Secretary of the [NH&MRC], approve of any research involving the insertion of pieces of DNA into human germ cells or fertilised ova."[26]

4.39 On the other hand, the Victorian Law Reform Commission stated in the report of its inquiry:

> "... germ cell gene therapy to make inheritable changes may be permissible in some circumstances ... If it should become possible to correct safely a genetic defect in an embryo before birth, to avoid passing

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22 VLRC: Discussion Paper No 11, *Genetic Manipulation*, March 1988 p 12

23 The difference between germline cell therapy and somatic cell therapy was referred to in chapter 3 section C.1.

24 VLRC: Discussion Paper No 11 p 13

25 ibid., pp 12, 13

26 ibid., pp 13, 14

> a serious disease on to that child and later generations, the Commission does not believe that it should be prevented by legislation. ... If it were to be undertaken, it should be subject to the same controls ... as somatic cell gene therapy."[27]

4.40 The Committee believes that the matter of germ cell gene therapy on human beings may involve ethical questions which are different to those which must be taken into account in considering the application of genetic manipulation techniques to other forms of life.

Recommendation 1

4.41 The terms of reference of the inquiry relate to the "development, use and release of plants, animals and micro-organisms". Consequently, the Committee has not inquired into the use of germ cell gene therapy techniques on human beings. The Committee therefore does not make any recommendations concerning whether such therapy on human beings should be permitted or banned. The issues raised by the possibility of applying these techniques to human beings, however, will clearly need to be considered. The Committee recommends that the possible application of germ cell gene therapy techniques to human beings should be dealt with in a separate Parliamentary inquiry.

A.3.(ii) Somatic cell gene therapy

4.42 NH&MRC guidelines on human somatic cell gene therapy state that it should only be used if there is no effective treatment for the disease and it causes a severe burden or suffering.[28] The guidelines require institutions undertaking medical research to have an institutional ethics committee including non-scientists.

4.43 The NH&MRC's Medical Research Ethics Committee guidelines require ethical committees to be satisfied that:

> "... the technique of insertion has been shown by experiments in animals:
> (i) to confine the inserted DNA to the intended somatic cells, without entry into germ cells;
> (ii) to achieve adequate function of the relevant gene in a high proportion of attempts; and
> (iii) rarely to cause undesirable side effects."[29]

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27 VLRC: Report No 26 p 8
28 ibid., p 6
29 Community Services and Health; NH&MRC: Submission 117 p 13

4.44 The comment was made in a submission from the CSIRO that should somatic cell gene therapy become widely practised, especially in less severe cases, it is likely that ethics committees would insist that the transferred genes were inserted at precise locations. This would be contingent on an advance in the current technology.[30]

4.45 The VLRC found that there was concern that:

- experiments may proceed outside the guidelines (the guidelines are not legislative and carry no statutory penalties)
- the system of surveillance is not satisfactory because members of the ethics committee are appointed by the institution
- "there is no opportunity for broad public scrutiny and participation in developing policies"
- "there is limited public accountability"
- "members may have limited scientific knowledge"
- "ethics committees evaluate the proposals independently of one another; their meetings are closed and not reported; they do not give reasons for their decisions; and there is no central register of decisions taken and projects considered".[31]

4.46 Despite these concerns the VLRC found that "ethics committees ... can effectively oversee human gene therapy."[32] The Commission concluded that:

> "The problem of evaluating the risks of gene therapy for the patient is not different in kind from that of assessing the possible hazards of any new drug or transplant therapy. Procedures for assessing such hazards are already well established in hospitals."[33]

Recommendation 2

4.47 **The Committee supports the recommendation of the Victorian Law Reform Commission concerning somatic cell gene therapy, namely**

> **. gene therapy on human patients should continue to be regulated by the National Health and Medical Research Council guidelines and monitored by institutional ethics committees co-ordinated by the NH&MRC.**

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30 Stocker, Dr J, Chief Executive, CSIRO: Submission 109 p 6
31 VLRC: Report No 26 p 7
32 ibid., p 8
33 ibid., p 5

A.4 Animal suffering

4.48 Animal health and welfare arguments against genetic manipulation rely on a moral judgement that it is wrong to intentionally cause pain or suffering to creatures which are capable of experiencing physical or psychological distress.

4.49 This is to state the argument in its simplest form. It becomes more complex when consideration is given to:

. the amount of pain or suffering involved as a result of any particular procedure
. the availability of alternative procedures which do not involve the use of animals
. the number of animals affected
. whether the pain or suffering is caused by experiments of a limited duration or whether it is continuous and ongoing, for example as part of a meat production process; and
. the possible benefits which may be gained for animals or humans as a result.

4.50 It becomes even more complicated if it is accepted that there are differences between animals in the complexity of their nervous systems and in their capacity to experience pain or suffering. For example, most people would have stronger objections to vivisection experiments on chimpanzees than they would to similar experiments on tape worms. There might be less agreement concerning whether a distinction between rats and dogs is justifiable.

4.51 What needs to be established is whether there is anything inherent in genetic manipulation of animals which makes it particularly likely to cause pain or suffering, or likely to cause more pain or suffering than the use of traditional selective breeding techniques. A number of different possibilities were raised.

A.4.(i) Specific concerns

Abnormal physical characteristics

4.52 The Australian and New Zealand Federation of Animal Societies (ANZFAS) expressed concern about animals being produced with abnormal physical characteristics either for experimental work or for increased farm production.[34] ANZFAS pointed out that traditional breeding techniques have been used to modify the characteristics of a number of animal species and that some of these modifications have resulted in animals which have physical deformities or which are more susceptible to certain diseases. ANZFAS claimed that these problems are also likely

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34 Australian and New Zealand Federation of Animal Societies Inc (ANZFAS): Submission 103 pp 3, 18

to arise from genetic manipulation of animals and that as the number of animals subject to genetic manipulation increases the "probability of disorders increases".[35]

4.53 ANZFAS stated that the imperfection of genetic manipulation techniques results in a number of errors which cause such disorders.

> "Spliced genes often finish up in the wrong organs of the body and do not always get into the right cells to be passed on to transgenic offspring. Some may develop abnormally and die in utero and be aborted or resorbed, or be born with a variety of developmental defects, or be infertile."[36]

4.54 The way this claim is phrased may reveal a misunderstanding of the normal process of embryonic development or of the manner in which organs function.

4.55 In an organism produced by 'normal' breeding methods each cell contains the same genetic information as every other cell in the organism. Therefore each organ contains the same genetic information as every other organ. However, because of the specialisation of function of organs, normally genes do not express themselves except in the appropriate organ. Therefore, there should not be any concern about genetic manipulation simply on the basis of genetic information finishing up "in the wrong organs". If the information was in the 'wrong' organ then it should not be expressed and should not cause abnormalities. If there was inappropriate expression of an inserted gene then this would indicate some other problem - such as: inserting the gene in the incorrect place on the chromosome; inadvertently inserting multiple copies of the gene; or ineffective control of the operation of the inserted gene.

4.56 It was acknowledged by Dr Merilyn Sleigh from the CSIRO that problems may arise if a gene is inserted in the wrong place in the chromosome or if the rate of production of the protein, for which the inserted gene is the code, is not appropriate.

> "At the moment the predominant technology allows only for random insertion, so there is always a risk that the gene will go in and disturb some other function of the animal. ... there is still a lot to be learnt in terms of how to control the genes that we are introducing. The main issue is trying to limit the usage of those genes to the organs where you actually want them to be used. ... So until there is the scientific ability to carry out both of those processes predictably and effectively - and I predict that there will be; certainly within the next five years, perhaps less - there will certainly be a very strong requirement for animal welfare monitoring of all animal genetic engineering.
> Certainly within CSIRO and I believe elsewhere, this monitoring does occur through animal ethics committees which look at protocols for experiments both before they are done and during the carrying out of the

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35 ibid., p 4
36 ibid.

> experiments. The committees are kept very much informed as to the results."[37]

4.57 Dr Philip Greenwood, Secretary, Standing Committee on National Affairs of the Australian Veterinary Association commented:

> "... we do have the animal welfare legislation, and veterinarians sit on most if not all animal care and ethics committees. Any expected side effects will be weighed up against the benefits, and the unexpected side effects will be considered as they arise and appropriate action taken immediately. In other words, if with transgenic animals you have these severe malformations occurring, as soon as they are recognised then the animal care and ethics committee should make a decision to terminate that experiment immediately on the basis of animal welfare. That is within the legislation of this State, and of Victoria and South Australia as well, and we heartily endorse those regulations."[38]

4.58 Dr Greenwood was asked whether it would be part of the research program to breed several generations of the genetically modified animal in order to determine whether there was any hidden defect. He replied:

> "For sure. Such a program makes sound commercial sense if one wants to cover one's [bets] in the program. The majority of these projects for developing transgenic animals have an ultimate commercial aim. Some may be for purely basic research, but the majority have an applied aim in mind. So, yes, ultimately all the animal welfare concerns should have been well and truly satisfied before any release of these animals to the environment - to open sale."[39]

4.59 It was argued that there are strong financial disincentives to using sick animals in commercial production.[40] However, it was also pointed out that there are examples of animals, such as meat chickens, bred for fast growth using traditional breeding methods, which suffer health problems such as lung and liver disease or crippled legs. The commercial benefits of their use outweigh the financial disincentives from stock loses.[41]

> "... the trade-off which you are talking about between the productivity versus the welfare impact is often made at a point which is beyond the welfare level that we would consider acceptable."[42]

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37 Sleigh, Dr M, Division of Biomolecular Engineering, CSIRO: Transcript pp 1077, 1078

38 Greenwood, Dr P, Secretary, Standing Committee on National Affairs, Australian Veterinary Association Ltd: Transcript p 887

39 ibid., p 888

40 Campbell, Dr R, Director, Pig Research and Development Corporation: Transcript p 62

41 ANZFAS: Submission 103 pp 3, 7

42 Sullivan, R, Executive Member, ANZFAS: Transcript p 380

> "... they might be able to lose 5 per cent a year and still make a profit. That is what happens in the egg industry and the chicken industry - they can take a certain loss before it starts to affect the economic bottom line. That is a huge welfare problem. You are talking about billions of meat chickens worldwide. If you then take 2 or 3 per cent of those that many animals are dying every seven weeks. It is quite horrendous and yet it is profitable."[43]

4.60 The occurrence of animals with physical defects as a result of genetic manipulation appears to result from the new gene being inserted in the wrong place in the chromosome, or from multiple copies of the gene inadvertently being inserted, or from a lack of control over the expression of the gene. These problems reflect the present state of the technology and are expected to be rectified.

4.61 The Committee considers that in case the financial disincentives from using animals with health or welfare problems are not sufficient, there is clearly a need for animal health and welfare authorities to be alert to this possibility - both in relation to animals produced by traditional breeding methods and ones produced by genetic manipulation techniques.

Growth stimulation

4.62 Animal health or welfare problems, as a result of animals being 'designed' to have faster rates of growth, may arise from the rate of growth itself rather than from some error. The example of fast growing chickens bred by traditional means having difficulty in standing was referred to above. The argument was that genetic manipulation may increase the incidence of this kind of result.[44]

4.63 A number of submissions referred to problems experienced in experiments with growth hormone usage in pigs - either in injected form or by genetic modification. Professor Peter Outteridge referred to the "often deleterious effects of the transgenic technique on the health of the animal." He mentioned that:

> "... transgenic pigs with added growth-hormone genes have been found to be lethargic, lame, uncoordinated, with bulging eyes and thickened skin. There are inflammatory disease problems which are also associated with failure to reproduce."[45]

4.64 In contrast, Metrotec Pty Ltd, which has carried out extensive work in the development of pigs with added growth hormone genes, stated that arthritis was the only health problem it had experienced in its animals and that this was not in

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43 Oogjes, G, Director, ANZFAS: Transcript p 381

44 ibid., p 365

45 Outteridge, Prof P, Head, Department of Farm Animal Production Queensland University: Submission 8 p 1

numbers beyond what would be expected in any pig herd. Dr Barry Lloyd, the Managing Director of Metrotec, attributed the adverse publicity concerning the insertion of growth hormone genes in pigs to work that had been carried out in the United States of America. He claimed that the use of bovine and human growth hormone gene constructs instead of porcine ones, and the failure to use systems to control the rate of expression of the growth hormone genes were the probable cause of the difficulties which had become extensively publicised.[46]

4.65 Dr Judith Blackshaw, however, referred to evidence of the deleterious effects on animal health of porcine somatotropin (PST), a growth stimulation hormone for pigs.

> "High doses of PST have caused deaths in sows, respiratory distress and marked pathological changes in organs of pigs. Long-term administration of PST has been associated with impairment of mobility of swine and increased incidence of osteochondrosis lesions. Impaired ovarian development in prepubertal gilts and lowered incidence of oestrus has been associated with PST administration. Similar conditions are seen in transgenic pigs."[47]

4.66 Dr Judith Blackshaw's evidence leaves open the possibility that these problems with porcine somatotropin could have been the result of large doses of the hormone being used or a lack of control of the inserted gene in the transgenic pigs.

4.67 It should not be assumed that increasing growth rates in animals whether by selective breeding, injection of growth hormones or genetic manipulation must inevitably lead to animals which suffer skeletal or other deformities. Dr Alan Blackshaw, Council Member of the Australian Federation for the Welfare of Animals, commented:

> "... you have got to remember that with regard to growth hormone in the pig, in particular, we are not interested in growing great big pigs because we cannot sell them. All we are really interested in is getting a pig that has a lower level of fat so that there is a higher lean fat ratio. You only want that switched on in the last phase of fattening. You can just switch it on for three weeks or so."[48]

4.68 The Committee accepts that animal health or welfare problems may arise from producing fast growth animals. Heat stress among animals with high rates of protein turnover is one possible area of difficulty.[49] These problems with fast growth animals should be addressed by State and local government authorities with responsibility for

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46 Lloyd, Dr B, Metrotec Pty Ltd: Transcript pp 592, 593

47 Blackshaw, Dr J, Senior Lecturer in Animal Behaviour, Department of Farm Animal Medicine & Production Queensland University: Submission 10 p 3

48 Blackshaw, Dr A, Council Member, Australian Federation for the Welfare of Animals: Transcript p 1042

49 Campbell, Dr R, Director, Pig Research and Development Corporation: Transcript p 65

animal welfare. They are not, however, specific to animals which have been genetically modified.

Increased animal experimentation

4.69 ANZFAS also expressed concern that genetic manipulation techniques enable an increased use of animals in experiments to find cures for human diseases and that as a result animal pain or suffering increases.[50] It was also claimed that, more generally, experiments with genetic manipulation techniques probably will result in an increased number of experiments on animals.[51]

4.70 Genetic manipulation has increased the ability to create animals which suffer from diseases to which human beings are prone. The ethical justification for such work must depend on the extent of pain or suffering likely to result in each case and the likely benefits. Changes in experimental techniques have raised issues about whether the need for animal experimentation will be increased or decreased. Research organisations internationally are adopting more rigorous standards in determining the appropriateness of using experimental animals. Experiments need to be examined critically on a case by case basis. An increased use of animals as 'models' in the study of human diseases presumably will reflect an increased possibility of decreasing human pain or suffering by developing treatments for human diseases. More generally, an increased use of animals in experiments may be morally justifiable - each experiment needs to be looked at separately in order to make that assessment.

Intensive animal husbandry/increased production demands

4.71 ANZFAS expressed concern about enhanced disease resistance as a result of genetic manipulation leading to more intensive husbandry which may cause animals stress.[52] ANZFAS also argued that farm animals genetically modified to be more productive would necessarily suffer more bodily stress because of the increased production demands on their bodies. These animals therefore might be more susceptible to disease. This could further increase the use of intensive animal husbandry practices in order to allow the kind of close attention which such animals might require.

4.72 The Committee considers that enhanced disease resistance in animals is desirable. This might lead to an increase in the practice of intensive animal husbandry or to an increase in the intensity of such practices. The animal welfare aspect of intensive husbandry practices is a separate issue to the development of disease resistance in animals and consideration of the two matters should not be confused.

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50 ANZFAS: Submission 103 p 4

51 *Oogjes, G, Director, ANZFAS: Transcript p 365*

52 ANZFAS: Submission 103 p 6

4.73 It was acknowledged in evidence that modifying animals to increase production may place these animals under increased stress. Dr Robert Gee, President of the Australian Registered Cattle Breeders' Association commented:

> "... the normal modern dairy cow is almost an abnormal animal really. She produces far more milk than a calf could possibly utilise, so she is a high production animal which has been developed for very special conditions, and there is always a risk of metabolic disorders and breakdowns with very high producing animals. They have a finely balanced nutritional requirement and they have to be very, very carefully looked after. ... there is a risk, from the animal welfare point of view, in developing these sorts of high producing animals. That is a risk that will have to be taken care of and assessed, and the animal welfare conditions will have to be monitored very carefully. Every research institution has an animal welfare ethics [committee] in it, at least in Australia. These committees contain scientists but also community representatives; in other words, they are not in-house things. Their objective and their responsibility is to determine that animals are not submitted to procedures that will be inimical to their welfare."[53]

4.74 **The Committee believes that the effect on animal welfare of genetically modifying animals for increased production is a matter which should be considered by State and local government authorities with responsibility for animal welfare on a case by case basis.**

Inheritance of harmful effects

4.75 Professor Peter Singer argued that genetic manipulation may result in harmful changes and because these changes would be heritable particular consideration needs to be given to the animal welfare effects of such work.

> "... when you genetically modify an animal, you may modify it in a way that means it has a built-in health problem and that its progeny will have a built-in health or welfare problem. That perhaps is something that needs more careful consideration because it is not simply the suffering inflicted once off in an experiment, or even once off in terms of one animal lifetime. It might be a whole series of generations of suffering. We have seen this with the development in the United States of a mouse that is genetically engineered to develop cancer. We have seen it certainly in the United States Department of Agriculture experiments with altering the growth hormones of pigs, where they appear to have genetically built-in problems of arthritis and other animal welfare aspects."[54]

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53 Gee, Dr R, Australian Registered Cattle Breeders Association: Transcript p 720

54 Singer, Prof P: Transcript pp 256, 257

4.76 The possibility of causing heritable, harmful changes in laboratory or farm animals is a matter of legitimate concern but it is not unique to genetic manipulation work. Traditional selective breeding can and has been used with similar results. The example of dwarfism in breeding cattle in the USA in the 1940s and 1950s was mentioned in section D 'Increased Efficiency in Breeding Animals' in chapter 3. In addition, a distinction should be drawn between the two examples quoted by Professor Singer.

4.77 The moral justification, or lack of justification, of intentionally developing an animal susceptible to an illness for medical experiments is surely the same regardless of the method used to achieve this result.

4.78 The passing on to subsequent generations of an unintended defect should not be a problem in practice if the existence of the defect is detected in the experimental or developmental stages. The solution would be to breed several generations of the animal under controlled conditions to see whether any unintended effects emerge, before going on to large scale production.

4.79 The important question is whether genetic manipulation techniques are more, or less, likely to produce unintended, harmful, heritable changes than are traditional selective breeding techniques. Traditional selective breeding, which involves a fairly random shuffling of genetic information, has the disadvantage that it is difficult to control what characteristics, other than the one being sought, may be passed on to the progeny. A concentration of harmful recessive genes has occurred in many attempts at traditional selective breeding.

4.80 **The Committee concludes that genetic manipulation holds out the promise of enabling a precise alteration of a carefully selected and limited part of the genome. As genetic manipulation techniques are further developed they may reduce the chances of unintentionally causing harmful changes to farm animals which are able to be passed on to subsequent generations. However, the Committee believes that the animal welfare authorities should be obliged to enforce the existing rules and regulations.**

Beneficial consequences

4.81 It is worth noting that people who expressed concern about the animal welfare implications of genetic manipulation mentioned that some applications of this technology could have beneficial consequences for animal welfare. For example, ANZFAS approved of the work being done to modify viruses so that they could be used to reduce the fertility of rabbits.[55] Experiments to develop sheep resistant to footrot were also approved of by ANZFAS provided that the experiments were carried out humanely. Approval was, however, very guarded:

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55 Oogjes, G, Director, ANZFAS: Transcript p 367

> "While we believe that the possibilities are there for improvement in animal welfare through genetic engineering, given the current controls that are in place, we do not believe that is in practice what will happen in laboratories, unless there is an increasing amount of resource dedicated to monitoring those animals under that type of experimentation."[56]

4.82 It is therefore important to consider what measures presently exist to regulate animal welfare, both at the experimental and production stages, and whether these are adequate to deal with any problems arising from genetic manipulation work.

A.4.(ii) Regulation of animal welfare

Commonwealth

4.83 At a national level there is an *Australian code of practice for the care and use of animals for scientific purposes.* The latest revision of the Code, in 1990, was sponsored by the National Health and Medical Research Council (NH&MRC), the Commonwealth Scientific and Industrial Research Organisation (CSIRO), and the Australian Agricultural Council (AAC). Representatives of the New South Wales, South Australian and Victorian governments participated in the revision.

> "The Code encompasses all aspects of the care and use of animals for scientific purposes in medicine, biology, agriculture, veterinary and other animal sciences, industry and teaching. It includes their use in research, teaching, field trials, product testing, diagnosis, and the production of biological products."[57]

4.84 The Code requires that proposals involving the use of live non-human vertebrate animals in genetic manipulation research work must be submitted to the institution's Animal Experimentation Ethics Committee (AEEC) for approval before experiments begin. The work must be carried out in accordance with the guidelines of GMAC, the relevant biohazards committee of the institution and the AEEC. Researchers are required to inform the AEEC of the "known potential adverse effects on the well-being of the animals" and to monitor for, and report, "unusual or unexpected adverse effects."[58] "Investigators have direct and ultimate responsibility for all matters relating to the welfare of the animals they use in experiments. Techniques which replace or complement animal experiments must be used wherever possible."[59]

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56 ibid., p 374

57 NH&MRC/CSIRO/AAC: *Australian code of practice for the care and use of animals for scientific purposes*, July 1990: Exhibit 47 p 1

58 ibid., p 29

59 ibid., p 6

4.85 All institutions using animals for scientific purposes are required under the Code to "establish one or more AEECs or their equivalents directly responsible to the governing body of the institution".[60] The role of an AEEC is to, inter alia:

> "... examine and approve ... proposals relevant to the use of animals in experiments ... [approving] only those for which animals are essential ... taking into consideration ethical and welfare aspects as well as scientific or educational value".[61]

4.86 The membership of an AEEC under the Code consists of at least four people, including one from each of the following categories:

> ". A person with qualifications in veterinary science ... or a person with qualifications and experience to provide comparable expertise;
> . A person with substantial recent experience in animal experimentation;
> . A person with demonstrable commitment to, and established experience in, furthering the welfare of animals, who is not employed by or otherwise associated with the institution, and who is not involved in the care and use of animals for scientific purposes. The person should where possible be selected on the basis of membership of an animal welfare organisation; and
> . An independent person who does not currently and has not previously conducted experiments using animals, and who is preferably not an employee of the institution."[62].

4.87 The institutions carrying out animal experiments are required to "review periodically the operation of each AEEC ... [and] upon the advice of the AEEC, discipline investigators who contravene the Code or decisions of the AEEC".[63]

4.88 The Code also specifies that inspections of animal housing and laboratories must be carried out and that adequate records must be kept by the AEEC. The AEEC has the responsibility to stop any experiments which breach the Code.[64]

4.89 A number of submissions commented on the lack of legislative backing for the Code in some States. The Code is given legislative backing in New South Wales, Victoria and South Australia but not yet in other States; although evidence was received that Queensland and the Australian Capital Territory 'soon' may provide such backing.[65] Mention was made that Tasmania too was considering new legislation.[66]

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60 ibid., p 9
61 ibid., p 10
62 ibid., p 11
63 ibid., p 9
64 ibid., p 15
65 ANZFAS: Submission 103 p 25
66 Rose, Dr M, Chairman, Animal Research Review Panel (NSW): Transcript p 833

4.90 The Commonwealth Department of Primary Industries and Energy also noted that "once a genetically manipulated strain of animal was in production it would not be covered in terms of animal welfare concerns" by the current *Australian code of practice*.[67] The Department commented that it would be desirable to extend the code to cover the development as well as research phase.

Recommendation 3

4.91 The Committee recommends that the Commonwealth Government pursue with State and Territory governments the need to give legislative force throughout Australia to the *Australian code of practice for the care and use of animals for scientific purposes*. The Committee recommends that AEECs be required to submit annual reports (as in NSW).

Recommendation 4

4.92 The Committee recommends that the *Australian code of practice* be amended to require observations of genetically modified animals by the researchers for a sufficient number of generations of those animals to ensure the detection of any latent effects on health and welfare and to require reports on the findings to the institution's Animal Experimentation Ethics Committee.

4.93 There are a number of national codes concerning the transport, handling and husbandry of farm animals.[68] The Committee has not investigated the contents or enforceability of these codes, although the role played by the Sub-Committee on Animal Welfare of the Australian Agricultural Council in developing such codes presumably assists in attaining broad State and Territory agreement on their contents.

4.94 In 1989 the Commonwealth Government established the National Consultative Committee on Animal Welfare (NCCAW). It consists of nominees of Commonwealth and State governments and of the following organisations: the Australian and New Zealand Federation of Animal Societies, the National Farmers Federation, the Australian Veterinary Association, the Australian National Parks and Wildlife Service, and the National Health and Medical Research Council.

4.95 The Minister for Primary Industries and Energy approves the nominations for membership of the NCCAW and appoints the chairman. Among the intended activities of the NCCAW, as mentioned in the 1989-90 annual report of the Department of Primary Industries and Energy, is to undertake reviews of genetic

67 Commonwealth Department of Primary Industries and Energy: Submission 143 p 32

68 NH&MRC/CSIRO/AAC: *Australian code of practice*: Exhibit 47 p 3

manipulation and animal experimentation.[69] The Committee is not aware of these reviews having been carried out so far.

The States

4.96 Legislative control over animal welfare matters rests principally with the State and Territory governments. "In each State and Territory there is legislation for the prevention of cruelty to animals."[70] In addition, in New South Wales there is separate legislation, the *Animal Research Act 1985*, "to control the use of animals for research and teaching".[71]

4.97 The relevant legislation in each of the other States, as at 1989, was as follows[72]:

Animals Protection Act 1925- 1977 Queensland
Prevention of Cruelty to Animals Act 1986 Victoria
Cruelty to Animals Prevention Act 1925 Tasmania
Prevention of Cruelty to Animals Act 1985 South Australia
Prevention of Cruelty to Animals Act 1920-1976 Western Australia
Prevention of Cruelty to Animals Act 1980 Northern Territory
Prevention of Cruelty to Animals Act Ordinance 1959 Australian Capital Territory

4.98 Descriptions of the above Acts and comments on them may be found in chapters 13 and 14 of the 1989 report of the Senate Select Committee on Animal Welfare - *Animal Experimentation*. The Senate Select Committee noted that "there are significant differences of approach among the States" on animal welfare issues[73], although New South Wales, Victoria and South Australia have similarities. Each of those States have established animal welfare advisory committees with broad representation and are members of the Commonwealth/State Joint Animal Welfare Council.[74]

4.99 The 1990 regulations under the NSW *Animal Research Act* require compliance with the *Australian code of practice*. The regulations, which are administered by the NSW Department of Local Government, require "the licensing of researchers, accreditation of establishments and supply units" and in addition:

> "The premises will be subject to inspection by the [NSW] Animal Research Review Panel to ensure compliance with the Act and the research will be supervised by Animal Care and Ethics Committees.

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69 Department of Primary Industries and Energy: *Annual Report 1989-90* p 211
70 Senate Select Committee on Animal Welfare: *Animal Experimentation*, AGPS, Canberra, 1989 p 202
71 ibid.
72 NH&MRC/CSIRO/AAC: *Australian code of practice:* Exhibit 47 p 2
73 Senate Select Committee on Animal Welfare: op. cit., p 204
74 ibid., p 203

> Penalties for non-compliance are cancellation of accreditation or licence and fines up to $10,000."[75]

4.100 The NSW legislation specifies that the Animal Care and Ethics Committees include animal welfare and community members and that decisions are reached by consensus. The Animal Research Review Panel inspection teams also investigate complaints. The Panel publishes an annual report. All accredited research establishments and licence holders are required to submit an annual return on animal use. Animal Care and Ethics Committees "must also provide details of their activities each year, including the number of meetings held, proposals assessed, approved, rejected or terminated".[76]

4.101 As described in the report of the Senate Select Committee on Animal Welfare, the requirements of the Victorian and South Australian legislation resemble that of New South Wales. The Western Australian and Queensland legislation and the ACT Ordinance have similarities, although regulations had not been made under the Queensland legislation and the situation in the ACT was complicated by the process of moving to self-government.

4.102 The Senate Select Committee commented that the "authorisation provision" in the Northern Territory legislation for animal experimentation "is, to all appearances, not being used at all". Concerning Tasmania the Senate Select Committee stated that the Act "is permissive rather than regulatory" which led them to conclude: "In Tasmania, therefore, there is no legislative framework for the regulation of animal experimentation".[77] Presumably in practice many of the research institutes in the Northern Territory and in Tasmania do adhere to the kind of procedures set out in the *Australian code of practice* despite the apparent lack of legal requirement. Clearly the situation would be preferable if the procedures were given legal force.

4.103 ANZFAS commented that most State animal welfare legislation "specifically exclude[s] farm animals where a code of 'accepted' husbandry practice is relevant, and such codes make no mention of transgenic animals, or genetically engineered treatments that may be ... applied first to farm animals".[78]

Recommendation 5

4.104 **The Committee recommends, as suggested by the Animal Research Review Panel of NSW, that existing agricultural codes of practice should be updated to cover the welfare and care of genetically manipulated livestock.**

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75 NSW Department of Agriculture and Fisheries: Submission 116 Appendix 1 p 1

76 Animal Research Review Panel: Submission 62 Appendix C

77 Senate Select Committee on Animal Welfare: op. cit., pp 215-226

78 ANZFAS: Submission 103 p 26

4.105 ANZFAS also criticised the lack of resources for monitoring adherence to existing animal welfare requirements.

> "I would say that in Victoria, where we have the most experience ... there is only one person in the Department of Agriculture, which is the department responsible for the prevention of cruelty to animals Act here, looking after over 100 institutions. Even if he was to go to two every week, that is only once a year that they are visited, and so the monitoring leaves a lot to be desired."[79]

4.106 There are also Animal Experimentation Ethics Committees involved in monitoring adherence to the legal requirements, but ANZFAS expressed doubts about the expertise of the members of these committees.[80]

Recommendation 6

4.107 The Committee recommends that GMAC consider issuing guidelines to assist Animal Experimentation Ethics Committees in examining proposals involving genetic modification of animals. These should include suggested questions to ask which would help expose possible animal health and welfare consequences of proposals.

B. Political and Social Impacts

4.108 The political and social criticisms of genetic manipulation are, in large part, based on a perception that technological change serves to enhance the power of large commercial enterprises while decreasing the power of the individual and families. Linked with this is the perception that commercial interests have inordinate influence in the setting of scientific research priorities and in making decisions about whether new technology should be implemented. The dominance of commercial interests is often seen to be in conflict with the interests of society as a whole and environmental protection in particular.

4.109 Suggestions to redress this imbalance include: increasing the rights of the public to have access to knowledge about individual proposals before they are approved; increasing the rights of the public to have an input into the decision making processes; and promoting alternative technologies which are claimed to be either under greater individual control or safer for the environment. The environmental issues are dealt with in greater detail in the next chapter.

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79 Oogjes, G, Director, ANZFAS: Transcript pp 377, 378

80 ibid., p 377

B.1 Social change in rural areas

4.110 Reference was made to the allegedly adverse social impacts of the release of productivity-improving GMOs in the rural sector

> " - the economic marginalisation of certain sections of family-farm agriculture
> - increasing pressure on family members to take off-farm work (which may in many regions be impossible to find and so lead, as a consequence, to rural depopulation)
> - the growth of corporate farm ownership and the further industrialisation of agriculture
> - the increasing dependence of farmers on the agribusiness input sector."[81]

4.111 Although the effect of "this trend towards a 'high tech' agriculture" might be productivity gains in the short term, it was argued that in the long term it is likely to:

> " - remove a large number of farmers and threaten the economic viability of Australia's smaller inland country towns
> - increase profits for the (often foreign-owned) companies which have portents [sic] over new forms of life
> - lead to the production and sale of inputs which tie the farmer to the proprietary products of an agribusiness corporation (a situation which might result in a significant proportion of Australia's food and fibre being controlled by a smaller number of companies)".[82]

4.112 The argument presented by Mr Geoffrey Lawrence, Senior Lecturer in Sociology and Director of the Centre for Rural Welfare Research, Charles Sturt University, was that:

> "The restructuring of agriculture is not occurring in an haphazard or accidental manner. Corporations are employing new biotechnologies in specific ways, and the state is assisting with particular measures, designed to develop the forces of production in agriculture."[83]

4.113 The process of restructuring was said to occur through 'appropriationism' and 'substitutionism'. 'Appropriationism' was described as "the process by which industrial capital attempts to remove the barriers which the biological nature of agriculture production places in the way of corporate control of farming". It allegedly does this by selecting "particular aspects of agricultural production and (converting)

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81 Lawrence G, Director, Centre for Rural Welfare Research: Submission 6

82 ibid.

83 Lawrence, G: *Structural Change in Australian Agriculture - The Impact of Agri-Genetics.* Paper presented at the annual conference of the Sociological Association of Australia and New Zealand Nov/Dec 1988: Exhibit 2 p 22

these into industrially-produced inputs". Examples given of such inputs were fertilizers, insecticides and farm machinery.[84]

4.114 'Substitutionism' was described as the process by which "corporate capital involved in food processing has sought to reduce reliance upon farming". It was said to do this "by attempting to produce food through industrial rather than agricultural processes".[85] "Biotechnology represents the most recent and profound means by which capital has consciously and systematically attempted to restructure agriculture".[86]

4.115 The fear was raised that biotechnologies would lead to a concentration of ownership among the manufacturers of agricultural inputs, allowing the possibility of inflated prices for those inputs;[87] or that vertical integration would occur leading to large corporate monoplies.[88]

4.116 Mr Lawrence described the assistance provided by the Government to "the development of a corporate-sector biotechnology industry" as:

. tax incentives for investment
. shifting the research focus of the CSIRO
. providing protection for monopoly control under plant variety rights and patent legislation
. allowing scientific monitoring to be regulated by voluntary guidelines and self-appraisal
. promoting corporate agribusiness as the preferred system in the rural sector.[89]

4.117 There has undeniably been a long-term trend in Australian agriculture towards the use of technology to improve productivity and maintain competitiveness in world markets. Biotechnology, including the use of genetic manipulation techniques, will in all probability be very important to ensure future productivity improvements. As with previous technological changes in agriculture,[90] this may result in an increase in average farm size and a decrease in the number of farm operators.

4.118 The social change which technology may bring is understandably often a cause of concern, particularly to those most immediately affected. It is simplistic, however, to depict the process of technological and social change as the result of a conspiracy of transnational corporations and national governments.

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84 ibid., p 9
85 ibid.
86 ibid., p 11
87 Australian Council for Overseas Aid: Submission 84 point 3 (b)
88 Galloway Cattle Society of Australia Inc.: Submission 152
89 Lawrence, G: *Structural Change in Australian Agriculture - The Impact of Agri-Genetics*. Exhibit 2 pp 24-30
90 ibid., p 3

4.119 The driving force of change has been the need to remain competitive. As a general rule, the agricultural sector has been squeezed between rising costs and increasing price competition. Productivity improvements as a result of technological progress have been the means by which agricultural producers have managed to stay in business.

4.120 It is erroneous to argue that the rural sector can be preserved from social change by hindering the adoption of new technology. To refuse to adopt the latest technological methods would result in Australian agriculture quickly becoming uncompetitive in world markets. The consequent social change in rural areas would be even more severe than that which is being experienced.

4.121 Where the introduction of new technology results in a significant reduction of labour, the Committee supports the principle of government adjustment assistance such as retraining for other occupations. The Committee notes that the Trade Practices Commission may act to prevent the emergence of monopoly control.

B.2 Invasion of privacy

4.122 The Social Responsibilities Commission of the Anglican Diocese of Melbourne commented that technology is not neutral or value free. "There is a real danger that it may become an instrument in the hands of the powerful. It may become trapped in vast networks of power which are complex, systemic, often multinational, and which exist primarily to maximise profit."[91]

4.123 From time to time the possibility of using information about the genetic make-up of people in deciding whether to issue life and health insurance, or whether to employ someone, are raised as examples of the shifts in power which may flow from the technology.[92]

4.124 Evidence was received by the Committee that the European Parliament considered these issues in March 1989. The resolution adopted included the following details:

> "14. ... a statutory ban on the selection of workers on the basis of genetic criteria
> 15. ... a ban on the general use of genetic analysis for mass examinations of employees
> 16. ... genetic examinations of workers ... [to be] carried out only with their consent ... by a doctor of their choice ... The results of such examinations

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91 Social Responsibilities Commission, Anglican Diocese of Melbourne: Submission 135 p 3

92 Brown, B and Concar, D: *Where does the genome project go from here?* in *New Scientist*, 17 August 1991 pp 11, 12; also Suzuki, D and Knudtson, P: *Genethics - the ethics of engineering life*, Allan and Unwin, Sydney, 1988 pp 160-180

> may only be made available to the individual concerned and may be passed on only by that individual ...
> 19. Considers that insurance companies have no right to demand that genetic testing be carried out before or after the conclusion of an insurance contract nor to demand to be informed of the results of any such test which have already been carried out".[93]

4.125 **The application of new technologies can and will have serious implications for privacy and these implications need serious and sustained examination by Parliament.**

Recommendation 7

4.126 **The Committee recommends that a Parliamentary Standing Committee be given responsibility for examining and monitoring complex issues involving the overlap between technology, law and the protection of individual rights.**

B.3 The setting of research priorities

4.127 The Conservation Council of South Australia commented that links with commercial companies are increasingly being seen by research institutions as a means of obtaining funds. The Council considered that scientists "coming from a rather more altruistic, naive background" might not be equipped to "understand the true motives of the companies they are associating with".

> "... the introduction of the paramount principle of commercial profit, and the need to protect a competitive position, will inevitably introduce demands for secrecy previously unfamiliar to many scientific researchers ... The usual 'commercial confidentiality' will seriously curtail public access to much information about genetically modified organisms that is currently available.
> A third concern is the likelihood of new criteria for which research is undertaken coming to the fore. Research which is likely to have direct commercial application will be favoured because of the stronger likelihood of commercial funding being available."[94]

4.128 The Commonwealth Department of the Arts, Sport, the Environment, Tourism and Territories (DASETT) expressed concern that commercial development of the technology might neglect applications which are in the national interest but have little commercial appeal. The solutions DASETT proposed included using government grant programs to promote projects in the national interest and raising the priority

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93 EEC: *European Parliament report on the ethical and legal problems of genetic engineering,* in *Europe Environment Fortnightly,* No 317 21 March 1989 p 4: Exhibit 125

94 Conservation Council of South Australia: Submission 65 pp 3, 4

given to such projects by government funded research and development bodies like the CSIRO.[95]

4.129 Mr Bob Phelps from the ACF stated:

> "The setting of research priorities is a very fundamental issue. It is no good, it seems to us, to start evaluating projects when they are at the stage of readiness for release to the environment. The public has to know what is being proposed in the way of research. We need to start right at the proposal stage."[96]

4.130 It was argued that the high costs involved in bringing a product almost to the stage of commercial release would give it a certain momentum. The public interest could be disadvantaged because it would be difficult to prevent approval for release being granted once a large amount of money had been spent on a product's development.[97]

4.131 **The Committee considers that full inquiries are not necessarily warranted in the early stages of research and development for projects which could conceivably lead to a commercial product or environmental release. Many projects are abandoned long before reaching the stage of commercial release and the expense and delay involved in assessing the possible impacts of those projects would be an unnecessary waste of funds. The possibility of ultimately not being given approval for release is a risk that commercial developers must assess when deciding to invest in a particular line of research.**

4.132 There is a history in Australian science of strength in research and lamentable weakness in development. One approach in attempting to overcome this problem is to more closely involve corporations in supporting research by universities and other scientific institutions. This carries with it the danger that the focus of research will be shifted too far away from projects without obvious commercial potential. In the past 'curiosity-led' research has often opened up quite unexpected commercial possibilities.

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95 Quinn, N; Ireland, R, DASETT: Transcript pp 1113, 1114

96 Phelps, R, Australian Conservation Foundation: Transcript p 517

97 ibid.,

Recommendation 8

4.133 The Committee recommends that the Government support, through research grants and through funding for the CSIRO, projects in genetic manipulation which have the potential for public benefit but no obvious commercial appeal. It is noted that current CSIRO research does include a number of such projects, for example, those to find solutions to the problem of introduced species such as the rabbit and the fox.

B.4 Choosing applications of the new technology

4.134 It was stated that the Genetic Manipulation Advisory Committee (GMAC) has focussed on scientific questions but has not addressed the broader questions.[98] The idea of leaving it to the market place to decide which applications are beneficial to society was criticised as "naive".[99]

> "It is said the present system relies on a science based approach, yet when the regulators are challenged with addressing the other issues, they generally say that if someone is prepared to put research money into something and is then prepared to go to the expense of marketing a product, then, of course, there must be benefits; because somebody must want to buy it. It seems to me that this rather naive economic account of how the other activities of genetic engineering are going to be taken into account and assessed is wrong and should be absolutely rejected. GMAC is not fitted to make those kinds of judgments and we have to find somebody else to do it."[100]

4.135 The Committee accepts that the market place has its imperfections as a place for deciding the public interest. The establishment of environmental impact assessment procedures has been one response to perceived inadequacies in the market mechanism. The Committee considers, however, that the market place performs a vital role in allowing individuals to decide which products they wish to purchase.

4.136 The kind of pre-release assessment being proposed by some went beyond an analysis of possible environmental effects to include 'social risk analysis on a case-by-case basis'.[101]

4.137 The term 'social risk' is extremely broad. There would seem little point in attempting an abstract definition of what kind, or what level, of social risk should be

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98 ibid., p 513
99 ibid., p 515
100 ibid.
101 Burch, Dr D et al.: Submission 106 p 1

sufficient to warrant banning projects from proceeding or products from being released. Obviously, however, there may be strong public feeling that the social consequences of some particular application of genetic manipulation technology are such that it should not proceed. An avenue needs to be provided for these issues to be raised in the pre-release approval process.

Recommendation 9

4.138 The Committee recommends that concerns that are raised about the social impacts of particular releases of genetically modified organisms, or products originating from genetically modified organisms, should be considered by the body which may be charged with responsibility for granting approval for those releases. (In Chapter 8 the Committee recommends the creation of a GMO Release Authority: recommendations 40 - 48).

B.5 The public's right to know

4.139 This concerns the extent of the public's right to be informed prior to experiments being conducted or organisms being released to the environment. There is, at present, no requirement under the GMAC guidelines that the public be informed of any proposal for release of, or actual release of, GMOs to the environment.

4.140 The Australian Consumers' Association referred to the absence of clear duties of disclosure in pollution control laws, commenting that while the NSW legislation had been amended to allow a discretion to release such information this was not sufficient.[102] The ACF and others made similar comments.[103]

4.141 The ACF representative, Mr Bob Phelps, stated that a list of the names of the principal researchers, the institutions, and other details concerning all GMO projects registered with GMAC had been requested. The information was refused apparently on the grounds of commercial confidentiality.[104] Mr Phelps commented that after GMAC has assessed "a proposal as able to proceed, it will, if you ask, distribute a one-page, A4 sheet which gives a very general description of what is entailed in the work. It contains no information about what institution or researcher submitted the proposal."[105]

4.142 GMAC responded that the legal advice it had was that the proposers, who had provided the information, would have to be contacted before the information could be

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102 Australian Consumers' Association: Submission 132 p 10
103 Australian Conservation Foundation: Submission 140 p 17, 65
104 Phelps, R, Australian Conservation Foundation: Transcript pp 516, 517
105 ibid., p 521

made public. Since there were some 2000 current proposals, GMAC felt it did not have the resources to get these clearances.[106]

4.143 Similar comments were made by the ACF about the unwillingness of the Australian Agricultural and Veterinary Chemicals Council (AAVCC) to provide information about products of genetic manipulation it was assessing for release. The AAVCC "will not even say which products are being assessed. It will give no details of where the assessment process is up to and so on".[107]

4.144 A number of suggestions were made to increase the capacity of the public to know what was happening in genetic manipulation work. These included:

. public availability of all applications for the use of GMOs and of all impact assessments

- a variation on this was for summaries to be made available with commercially sensitive information deleted

. public availability of the documents recording the deliberations of decision-making bodies

. public education/information campaigns

- one suggestion was for frequent and regular briefings by government departments

. full disclosure about the manufacturing process and the ingredients on all product labels

. public representation on bodies which review proposals for genetic manipulation projects and which monitor those projects.

Recommendation 10

4.145 The Committee endorses the CSIRO's travelling exhibition on genetic manipulation and its consideration of other means of informing the public about this new technology and its applications.[108] The Committee recommends that the Government ensure that there is a specific appropriation for the CSIRO to undertake such public information campaigns.

Recommendation 11

4.146 The Committee further recommends that GMAC and the Release Authority (see recommendation 40) be given funding for public information activities about the nature of their work and about proposals they are considering.

4.147 The issues concerning compulsory identification on labels of products originating from, or containing, genetically modified organism are dealt with in detail in section C

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106 GMAC: Submission 88.2

107 Phelps, R, Australian Conservation Foundation: Transcript p 517

108 Sleigh, Dr M, Division of Biomolecular Engineering, CSIRO: Transcript p 1079

of Chapter 7. The Committee's recommendations concerning the regulatory structure and the composition of decision-making bodies are in Chapter 8.

4.148 There are two general objections which could be raised to the rest of the suggestions mentioned above. These are that the requirement to keep the public informed "might unduly hinder and delay scientific progress" or that it could "impinge on the confidentiality of new procedures and products that must be protected for commercial reasons."[109]

4.149 **The Committee considers that as a general principle the public's right to know should need no justification in a democratic society, although it is rarely made explicit in legislation or regulation. The right to know is particularly important when public funds are involved through grants and other research and development incentives in promoting a technology. Openness is clearly desirable in order to assure the public that correct procedures are being followed. Nevertheless, provision needs to be made to protect commercial confidentiality. These two competing principles need to be carefully balanced.**

B.5.(i) Commercial confidentiality

4.150 There was some disagreement about the importance of commercial confidentiality. The ACF called for "the contents of all applications for the use of GMOs ... to be freely available from the registering authority" and all impact assessments to be public documents. Commercial confidentiality should have to be argued for and justified. Members of the public should be able to have access to commercial-in-confidence documents by agreeing to certain restrictions as provided for in section 10 of the North Carolina legislation.[110]

4.151 The Committee has received as evidence a copy of a Bill to be entitled *An Act to Regulate the Release and Commercial Use of Genetically Engineered Organisms* dated 26 May 1989 which it believes was intended for consideration by the General Assembly of North Carolina. The restrictions under the Bill to which the ACF referred are that people seeking access:

> . should have to sign an affidavit stating they are not involved in a business in competition with the applicant or which could use the information for commercial gain, and do not represent anyone who is in such a business; and
> . should not use confidential information, to which they are granted access, for commercial gain.[111]

4.152 The North Carolina legislation focussed on release or commercial use and not on contained experimental work.

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109 VLRC: Report No 26 p 34

110 Australian Conservation Foundation: Submission 140 p 18

111 Australian Conservation Foundation: Submission 140 Appendix 1; and Advisory Committee on Biotechnology in Agriculture - North Carolina Biotechnology Centre: Proposed Legislation 26 May 1989: Exhibit 33

4.153 Representatives of companies expressed some concern about having to provide confidential information. Dr David Harrison, Managing Director of Biotech Australia Pty Ltd stated:

> "Obviously, as a company, we do have some sensitivity in terms of commercial confidentiality in that before something gets patented one likes to keep it confidential, because otherwise you do not get a patent position on it.
> All our projects are listed in GMAC and are published. We have no problem with this. Most people find out the areas we are working in and what we are doing. Clearly, that is where there has to be a feedback from the community. As you say, if it was felt that GMAC was not doing its job or not doing it right, that should become apparent to the community. To me, that openness will be the safeguard."[112]

4.154 Dr Robert Evans, Strain Development Manager, Food and Fermentation Division, Burns Philp and Co Ltd stated:

> "I think we would have some concerns about spelling out precisely what we intended to do before the project started. That would be solely because this type of work may take two to three years to complete. By making that information available to the public domain, you are inevitably tipping off competitors exactly what your commercial plans are. Even if this information was to be supplied commercially in confidence, I think it would still make people feel rather uneasy if it had been deposited so far ahead of any possible commercialisation."[113]

4.155 Mr Kevin Andrews, Acting Director of the Bioethics Centre at St Vincent's Hospital, Melbourne (now MP for the federal seat of Menzies) commented that, in the field of human research with which he was familiar, members of institutional ethics committees have access to confidential information and treat the information accordingly.

> "... and 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. That is at that initial level of research. When the research is being done in the laboratory, one might say it is appropriate that the disclosure be limited at that stage to the institutional ethics committee and to GMAC. But when one gets to the level of taking that research out of the laboratory and

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112 Harrison, Dr D, Biotech Australia Pty Ltd: Transcript p 783

113 Evans, Dr R, Strain Development Manager, Food and Fermentation Division, Burns Philp and Co Ltd: Transcript p 909

> putting it into some sort of open air type of trial or study, at that stage I believe that the public has a right to know generally."[114]

4.156 The Victorian Law Reform Commission report was silent about the public's right of access to information about proposals at the stage of contained development. However, recommendation 13 of the report stated that the supervising agency should be required to "advertise state-wide any proposed experimental release of recombinant organisms and to ensure that interested individuals are able to obtain information and to participate in the decision-making process before the proposal is approved."[115] (emphasis added)

4.157 The UK Royal Commission inquired into measures to control the release of GMOs and did not comment on the right of the public to access to information at the contained experimental stage.

4.158 The Royal Commission stated that the public should have a right of "access to information at several stages of development" since field trials may be a matter of concern as well as product releases. The Royal Commission recommended that there be a register of applications for release licences and of licences granted.

> "This should contain the names and addresses of the persons or organisations making applications, particulars of the organisms, the purposes of the releases and descriptions of the release sites ... the register should be maintained nationally. Relevant sections of it should be kept in the localities of releases.Other information about releases, concerning foreseeable effects and arrangements for monitoring and dealing with emergencies, should be made available by the DOE or the HSE on request. The national register should contain, in addition, details of applications and licences granted for the sale or supply of GEOs as or in products ... The register of authorised releases ... should also be made public.
>
> Persons or organisations applying for licences to carry out trial releases of GEOs should be required to place advertisements, in the local press serving the areas of intended releases, announcing their proposals ....
>
> The legislation should empower the licensing authorities to allow public access to information on the basis of which the Release Committee has made its recommendation. It should also enable them ... to invite the applicant to comment on the request for information and to take account of the applicant's views on commercial confidentiality."[116]

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114 Andrews, K, Acting Director, Bioethics Centre at St Vincent's Hospital, Melbourne: Transcript p 493

115 VLRC: Report No 26 p vi

116 UK Royal Commission, Thirteenth Report: *The release of genetically engineered organisms to the environment*, July 1989 pp 62 & 63

4.159 Evidence was presented by Dr Merilyn Sleigh from the CSIRO that the National Institutes of Health (NIH) in the USA carry out their deliberations in meetings which are usually open to the public and publish their deliberations. Most contained work in the USA is approved by IBCs, apart from work involving toxins and human gene therapy which is referred to the NIH. A pre-submission to the Recombinant DNA Committee of the NIH is treated as confidential. The submission which follows this stage contains only information which is publicly available.

> "Certainly, public opinion should be a major input into the decision making process. The question we have to ask is: how should this public opinion be collected and how should its input occur? ...
> Whether there should be public input on individual projects, I think, is a difficult one. Having such input would certainly help public perception that the regulatory regime was operating responsibly. But working out a method whereby this can occur effectively is, of course, quite difficult. One way that this has been handled in America is that the National Institutes of Health committee, which regulates mainly contained work, has always carried out all of its deliberations in public. It actually publishes its deliberations in a journal which is available freely in Australia and all over the world. So all of the considerations of that group are really carried out in public. That gives very wide access to anyone who is interested, both to come to the meetings to have an input if they need to, and to certainly be aware of what is going on."[117]

4.160 The Council of the European Communities issued two Directives in April 1990, one concerning the contained use of GMOs and the other concerning the deliberate release of GMOs (and the marketing of a product).[118] These Directives were expected to be implemented by Member States no later than 23 October 1991. Both contain a general provision concerning possible public consultation in relation to proposals.

4.161 The Directive on contained work includes an Article relating to planning for emergencies before an operation commences. This refers to the need to make the public aware of the safety measures.

> . **Article 14**: "The competent authorities shall ensure that, where appropriate, before an operation commences:
>
> (a) an emergency plan is drawn up ... and the emergency services are aware of the hazards and informed in writing;
>
> (b) information on safety measures and on the correct behaviour to adopt in the case of an accident is supplied ... to persons liable to be affected by the accident. The information shall be repeated and updated at appropriate intervals. <u>It shall also be made publicly available.</u> ..." (emphasis added.)

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117 Sleigh, M, CSIRO: Transcript pp 1066 & 1067

118 European Communities Council Directives Nos. L 117/1 and L 117/15 both of 23 April 1990

4.162 Both Directives contain similar Articles specifically concerning commercial-in-confidence information. The Article in the 'contained use Directive' states:

> . Article 19: "1. The Commission and the competent authorities shall not divulge to third parties any confidential information notified or otherwise provided under this Directive and shall protect intellectual property rights relating to the data received.
> 2. The notifier may indicate the information in the notifications submitted under this Directive, the disclosure of which might harm his competitive position, that should be treated as confidential. Verifiable justification must be given in such cases.
> 3. The competent authority shall decide, after consultation with the notifier, which information will be kept confidential and shall inform the notifier of its decision.
> 4. In no case may the following information, when submitted according to Articles 8, 9, or 10, [which refer to GMO work] be kept confidential:
> - description of the genetically modified micro-organisms, name and address of the notifier, purpose of the contained use, and location of use;
> - methods and plans for monitoring of the genetically modified micro-organisms and for emergency response;
> - the evaluation of foreseeable effects, in particular any pathogenic and/or ecologically disruptive effects.
> 5. If, for whatever reasons, the notifier withdraws the notification, the competent authority must respect the confidentiality of the information supplied." (emphasis added.)

Recommendation 12

4.163 The Committee recommends, concerning the research phase of genetic manipulation work, that:

- . information concerning genetic manipulation research projects for which approval has been sought, and the deliberations of the approving authority, should be publicly available from the approving authority, except that
  - those who seek approval to carry-out such research should be able to designate part of the information they provide to the approving authority as confidential on commercial grounds
- . there should be a procedure by which members of the public can challenge the commercial-in-confidence designation and seek access to the information
  - the decision of the approving authority on a request for access to commercial-in-confidence information should be referred, before action is taken, to the provider of the information who should have a right of appeal to the responsible Minister
  - access should be granted only where the public interest to be served by releasing the information outweighs the commercial interest of the provider of the information.

Recommendation 13

4.164 The Committee recommends, concerning the release of genetically modified organisms, that the provisions of section 10 of the North Carolina legislation be used as a model with some modifications as included below. These would provide that:

. an applicant for a permit under the Act may request that part of the application be treated as confidential on commercial grounds
  - substantial reasons should be required before such a request was granted
  - the nature and extent of such claimed confidential information should be indicated in general terms in a document publicly available from the approving authority without defeating the purpose of the grant of confidentiality

. members of the public may request access to such undisclosed confidential information stating the reasons why they need access

. persons seeking access shall be required to make a commitment that they are not, and do not represent anyone who is, in a business which is in competition with the applicant, and that they will not breach the confidentiality or use the information for commercial gain

. the applicant shall be notified of the request for access and shall have an opportunity to respond

. the response of the applicant may
  - include an offer to produce the information subject to a written agreement between the applicant and the person requesting the information
  - explain why the person requesting the information does not need it, or why the stated reasons are not valid
  - offer other information which is not confidential but which meets the reasons stated in the request

. the approving authority may delay consideration of the request for access by the mutual written agreement of the applicant and the person requesting access

. the approving authority shall make a decision concerning whether access should be granted to some, all or none of the information requested and notify the applicant and the person requesting the information

. the applicant shall provide the information which the approving authority has decided should be made available, or appeal against the decision to the responsible Minister, or withdraw the application

. the confidential information shall not be disclosed pending hearing of the appeal, or if the application is withdrawn

Recommendation 13 continued on next page.

Recommendation 13 continued.

. persons receiving such confidential information by the above procedures who use it for their own gain or release it for any other purpose shall be guilty of a criminal offence and subject to substantial penalties
. none of the above procedures shall authorise the withholding from the public of information concerning adverse effects of a proposed release
. time-limits shall be imposed on responses from applicants and on those making requests for information
. the process of adjudication of such claims shall proceed within a specified timeframe.

B.6 Alternative technologies

4.165 Opposition to genetic modification technology often leads to a call for the government to support research into alternative technologies.[119] The expressed justification for this may be that traditional agricultural techniques have proven efficacy whereas the promise of the new techniques is still largely speculative.[120] There is also a concern that looking to GMOs to solve problems diverts attention away from the need to change human behaviour which has caused many of the problems.[121]

> "I want people to ask, 'Why? Why do we need to take these risks? Do we actually need this new technology?' ... the present commitment to genetic engineering has successfully prevented any serious discussion of research into more appropriate and less risky alternatives to solve our problems at their roots."[122]

> "Genetic engineering is the glamour science at the moment but it is not the only technology, not the only science. There are many other things around that are tried and proven, like traditional breeding which has been much talked about here, and I think should not lightly be overthrown or put on the back burner. At the moment ... priorities in terms of research funding reflect the fact that microbiology is seen as the glamour science and that certain other very useful lines of research are being ignored or underfunded."[123]

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119 Australian Conservation Foundation: Submission 140 p 2;
Burch, Dr D et al.: Submission 106 p 32

120 Australian Conservation Foundation: Submission 140 p 21

121 ibid., p 41

122 Gardener, G: Transcript p 500

123 Phelps, R, Australian Conservation Foundation: Transcript p 514

4.166 The ACF advocated a change from the practice of monoculture agriculture which leads to the demand for crops to be genetically manipulated to be able to tolerate herbicides.[124] Dr Burch et al. also raised the argument that many of the problems it is hoped biotechnology might solve, arise from earlier innovations in agricultural methods. They argued that biotechnology is simply another technological fix which distracts attention away from the need to develop sustainable agricultural methods.[125]

4.167 The Committee is aware of the environmental problems which are said to flow from monoculture agriculture. Those problems do need to be identified and quantified so that their true costs may be taken into account. However, given the production efficiencies which monocultures allow, it seems unrealistic to imagine that this form of agriculture could be abandoned without a considerable decrease in world food output. The more practical alternative is to pursue techniques for preventing these problems where possible, or limiting their impact.

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124 Australian Conservation Foundation: Submission 140 pp 82, 83

125 Burch, Dr D et al.: Submission 106 p 25

CHAPTER FIVE

ENVIRONMENTAL ISSUES

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ENVIRONMENTAL ISSUES

A. WHAT ARE THE FEARS?

A.1 Fear of 'Frankenstein's monster'

5.1 There are fears that some unspecified genetically altered form will be released for short-term gain, or that something will escape, which will have harmful consequences which have not been anticipated, and which can neither be controlled nor undone.[1] Fears of this kind include concerns about damage to the environment as well as directly to human health. The human health issues are examined in the next chapter.

5.2 One submission identified the following as potential adverse ecological effects:

> "- adversely affecting ecosystem processes such as nutrient cycling (for example, nitrogen cycle);
> - disrupting biotic communities;
> - adversely affecting non-target organisms;
> - creating new pests;
> - enhancing the adverse effects of existing pests;
> - incompletely degrading a hazardous chemical and producing by-products which are more toxic than the parent chemical; and
> - squandering valuable biological resources, for example, accelerating evolution of pest resistance to pesticides".[2]

5.3 Professor Phillip Nagley from the Department of Biochemistry at Monash University argued that the risks from GMO work must be seen in perspective and that there are many other activities which involve greater risk.[3]

> "I feel it was unfortunate that at the beginning of the recombinant DNA debate certain people, and this is going back 15 years now, wished to show how responsible they were by drawing attention to all these conjectural risks. That actually has coloured a lot of people's thinking in the field because of the emotive content."[4]

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1 Wells, B: Submission 1; Cotton, Dr R: Submission 4; Phelps, R, Australian Conservation Foundation: Submission 140 p 1; Bailey, Dr A, Mather, Dr P, Queensland University of Technology: Submission 13

2 Burch, Dr D et al.: Submission 106 pp 17, 18

3 Nagley, Prof P, Department of Biochemistry, Monash University: Transcript p 328

4 ibid.

5.4 Many of the submissions which expressed fear about the technology did so in very general terms. A meaningful assessment of the risks involved in genetic manipulation work can only take place, however, at more specific levels.

B. Risk Assessment

5.5 "Risk" may be defined as an "exposure to the chance of injury or loss".[5] What constitutes an "injury" or a "loss" in a particular circumstance may need definition as well. "Risk assessment" can be described as "the process of determining and evaluating, in any given circumstances, the potential risks, their magnitude and the probability of their occurrence".[6] Quantitative or qualitative measures, or both, may be involved in this process.

5.6 It is important to distinguish "risk assessment" from "risk management", which may be described as "the process of defining and implementing control regimes on an optimal basis having regard to the relevant risks, the probability of them having effect and the relative benefits and costs of alternative measures".[7] Many would argue that the control regimes should also include a means of monitoring for the occurrence of damage or loss and a mechanism of responding to those occurrences through 'clean-up' or damage limitation.

5.7 The purpose of carrying out a risk assessment is to help in deciding whether the level of risk attached to an activity is acceptable. Whether the risk is acceptable must also depend on some assessment of the potential benefits and the probability of those benefits actually being achieved. In our economy, when a project is being undertaken for commercial gain, assessments concerning potential benefit are for the most part left to those who are responsible for the investment. The investors must decide whether the products they are developing will have sufficient market appeal to make the investment worthwhile.

5.8 **Those who are responsible for deciding to grant approval for a project may have to rely to a large extent on the proponents for information about potential benefits. Under these circumstances, the Committee considers that it would appear sensible to require those who stand to gain directly from marketing a product to bear the costs of the risks involved. This should, as far as possible, include the costs of any damage or the costs of insuring against damage.**

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5 *The Macquarie Dictionary*, revised edition 1985

6 Australian Quarantine and Inspection Service (AQIS), Discussion Paper: *The Application of Risk Management in Agricultural Quarantine Import Assessment*, Canberra 1991 p 3

7 ibid.

B.1 Asking the right questions

5.9 It is clear that there may be risks involved in genetic manipulation work and that some assessment of these risks must be made when considering whether approval should be given for a particular line of research or for a release of modified organisms. The risks will vary depending on, among other things:

. the nature of the organisms being modified (including reproduction rates and dispersal mechanisms in the environment)
. the nature of the genetic change being made (including the stability of the change)
. the kind of physical containment (if the organisms are not intended for release)
. whether it is intended to release live organisms or inanimate chemical products
. the number of organisms involved in a release and the frequency with which releases of those organisms may occur
. the environment into which the organisms may be released, either accidentally or intentionally, and
. the possibility of retrieving the released organisms and/or their progeny, or of destroying them if necessary after release.

5.10 It is important to consider whether the modified organisms could spread outside the environment into which they may be released, and how they might interact with other organisms in that environment. It is also important to consider whether the modified organisms could transfer their genetic material to other organisms in the environment.

5.11 In assessing risk it is not simply a matter of considering the probability of any one of the risk factors occurring but also the seriousness of the consequences if they do occur. Consideration of 'worst possible case scenarios' is an essential part of risk assessment. In relation to worst case scenarios, Professor Nancy Millis from GMAC said:

> "... if the proponent does not put it up, we certainly ask them. In fact, our molecular committee, scientific sub-committee and our release committee spend most of their time trying to think what could be the worst thing that could happen if such and such were to occur. ... is this event likely to occur in one in 100 organisms, or one in one million organisms? ... So you can multiply up the probability with which your safe release could conceivably become something that is hazardous."[8]

5.12 There have been many cases where the proponents of change have never addressed the possible adverse side effects, for example the environmental devastation caused by the introduction of rabbits, carp, cane toads, prickly pear and mimosa into Australia. Nobody seems to have asked the proponents: 'could these species grow to uncontrollable numbers? Will this cause long term damage?' Similarly, the impact of

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8 Millis, Prof N, Chairman, GMAC: Transcript p 89

fallout after nuclear testing was theoretically understood, but none of the proponents of testing felt responsible or accountable for downstream effects. When thalidomide was prescribed as a sedative during pregancy there was no serious consideration of the side effects on the foetus. Risk was recognised but regarded as too remote to be taken seriously. In the case of the contraceptive pill, some research recognised the possibility of thrombosis as a side effect for women, but warnings were not provided for users. The Committee believes that proponents of all research ought to be required to address 'worst case scenarios' in their applications for research funding and/or approvals for release and to seek advice from experts in related disciplines so that proper risk evaluation can be undertaken.

5.13 GMAC listed some of the questions which it considers when assessing possible hazards and the level of physical containment required:

> ". whether the host and donor organisms are known to exchange DNA under natural conditions;
> . whether the host and donor organisms belong to the same species;
> . whether the host organism is a pathogen or pest species and whether it is debilitated;
> . whether the inserted DNA is derived from a pathogen or pest, and whether the inserted DNA is fully characterised;
> . whether the inserted DNA produces a toxin, or other pharmacologically powerful agent;
> . whether the vector used to transfer the DNA into the host is a virus with potentially harmful properties, or is capable of being converted into an infectious particle after entering the host organism;
> . whether as a result of the manipulation, resistance to a drug or pesticide will be conferred on an organism not known to acquire that resistance naturally".[9]

5.14 The above is by no means a complete list of the questions GMAC asks when considering proposals concerning contained work or for releases of GMOs to the environment.

5.15 Additional questions which it might be useful to ask, depending on the particular circumstances, are:

> . how likely it is that the released organism will survive and proliferate
> . whether the modified genes confer some survival advantage or disadvantage[10]
> . whether genes from other organisms can be transferred to GMOs more readily than to naturally occurring organisms[11]
> . the population structure and dynamics of the species found in environments to which released GMOs may spread

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9 GMAC: Submission 88 pp 4, 5

10 Cossins, A: Submission 151 p 12

11 Department of Arts, Sport, the Environment, Tourism and Territories: Submission 138 p 9

. whether any species which may come into contact with released GMOs have particular toxicological sensitivities and
. how nutrients are processed and cycled through those eco-systems to which GMOs may spread.[12]

5.16 One limitation in risk assessment is clearly that scientists can only ask the questions of which they are aware. However, the above questions would be a useful start to a comprehensive risk assessment process.

Recommendation 14

5.17 The Committee recommends that researchers applying for grants from the National Health and Medical Research Council (NH&MRC), the Australian Research Council or other publicly funded bodies and applications to GMAC and the GMO Release Authority be required, as part of the application, to set out a 'worst case scenario' to help ensure adequate consideration of possible adverse side effects.

B.2 Is there sufficient knowledge?

5.18 Some submissions challenged whether risk assessment was possible or very reliable. Clearly there may be difficulties in quantifying with a high degree of precision the risk involved in some genetic modifications. This depends not only on the extent of knowledge about each of the factors contributing to the risk but on the number of factors which must be taken into account.

5.19 A lack of data about the Australian environment was mentioned as one factor making it very difficult to assess risk in any useful way.

5.20 There were calls for federal government funding of environmental research to generate the data needed to allow adequate assessment of the likely impact of releases in Australia, claiming that the data from overseas may not be relevant to Australian conditions. It was argued that public interest group representatives be included in bodies allocating research funds.[13]

5.21 Dr Merilyn Sleigh from the CSIRO considered that there is sufficient knowledge and experience within agencies looking at biological control and within GMAC, and adequate methods to assess the risks involved in releases. Dr Sleigh recommended building up knowledge by practical experience on a case-by-case basis. The dangers would be explored by graduating from contained work to field trials before authorising full-scale release as has been done with biological control agents.

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12 ibid., p 10

13 Phelps, R, Australian Conservation Foundation: Submission 140 p 20; United Scientists for Environmental Responsibility and Protection, Sth Aust: Transcript p 637

> "Obviously, the issues will be different for each new organism which has been considered which really calls for case by case assessment, at least in the first instance, but I think experience in other areas of regulation says that you can fairly quickly build up categories or guidelines on the organisms you are assessing."[14]

5.22 Dr David Burch et al. commented that field trials to test the safety of organisms prior to release themselves entail risks. It was also stated that laboratory experiments and even field trials may not give good information about the possible environmental reactions. Adverse impacts may not be apparent except in the long term. Therefore, it was stated, statements about the level of risk can only be conjecture.[15] "Nature cannot be simulated in the laboratory and biotechnologists cannot predict with any certainty how altered organisms will 'behave' once released, due to limited scientific knowledge concerning genetics, ecological processes and ecosystems".[16]

5.23 It is clear, however, that if risk is to be measured that may involve the necessity for experiment, using the best possible safety controls.

Recommendation 15

5.24 **The Committee recommends that, considering the likely increase in requests to release genetically modified organisms into the Australian environment, the Commonwealth and State Governments should review the level of funding of environmental research.**

B.3 Is it simply a question of knowledge?

5.25 It was pointed out that any weighing of risk of harm to the environment would entail a value judgement about what constitutes "harm". Accordingly risk assessment is not simply a scientific process.

> "... it is necessary to distinguish between harm and a mere change in the environment. If the criterion is ecological then any irreversible change in the biological status quo will be harmful, whereas ... if the criterion is economic then change will only be harmful [if] it threatens the safety, health, or welfare of human beings."[17]

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14 Sleigh, Dr M, Division of Biomolecular Engineering, CSIRO: Transcript pp 1064, 1065

15 Burch, Dr D et al.: Submission 106 p 24

16 ibid. p 17

17 Cossins, A: Submission 151 p 4

5.26 The kind of questions which GMAC presently asks in relation to genetic manipulation proposals, which were outlined earlier in this section, are clearly questions about matters of fact. The answers to them are theoretically obtainable by scientific investigation although in practice it may not always be easy to do so with certainty. This does not mean that these are the only questions which could or should be asked. Whether other questions about social or economic impact should be asked, and what those questions should be, may involve value judgements.

5.27 **The Committee considers that as far as possible the regulation process should attempt to keep decisions about matters of fact separate from value judgements in order to avoid confusion.**

B.4 Probability of damage/level of certainty about risk

5.28 In relation to the probability of damage, Dr Burch et al. pointed out that:

> "... [although] the probability of ecological damage resulting from an environmental release [may be] extremely low, the frequency of its occurrence will increase with the number of and frequency with which GEOs are released into the environment".[18]

5.29 It was argued that the experience gained from the introduction of exotic species could be relevant in considering the probability of damage from GMOs. Reference was made to one study that found that over 12% of introduced species resulted in the extinction of some indigenous species. It was argued that even 1% could be unacceptable given the possibility of large numbers of releases.[19]

5.30 Many were inclined towards requiring a very high level of certainty before giving approval to genetic manipulation projects or releases. Some went even further, requiring not just a high level of certainty and no environmental impact, but the presence of social or environmental gains.[20] The ACF stated that the onus of proof concerning the absence of risk should be placed on the proponents.[21] Rather than arguing that GMO proposals should not adversely affect ecological sustainability the ACF argued that these proposals must actually enhance sustainability.

5.31 It is clear that the risks of some activities can be more reliably assessed than the risks of others. In almost any activity there will remain some residual uncertainty even after the most stringent tests have been undertaken. There are safeguards which can be used to reduce, if not eliminate, risk. The necessity will remain, however, for value judgements to be made about the level of risk and the type of damage that may be an acceptable for particular benefits in particular cases.

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18 Burch, Dr D et al.: Submission 106 p 19

19 ibid. p 23

20 Cotton, Dr R: Transcript pp 298, 303, 305, 306

21 Phelps, R, Australian Conservation Foundation: Submission 140 p 31

B.5 Risk assessment procedures

5.32 There are a number of examples of risk assessment procedures already in use in Australia which are relevant. The procedures used by GMAC were described in detail in Chapter 2 of this report. As well, the Australian Quarantine and Inspection Service (AQIS) has had a great deal of experience in evaluating the risks involved in the import of exotic organisms into Australia.

B.5.(i) Risk assessment of imported organisms

5.33 AQIS produced a discussion paper on risk assessment and management in March 1991 which described the processes it believed were desirable. The prime concern of AQIS in risk assessment is with the biological factors. Economic and social consequences are considered by AQIS only if they flow "directly ... from the biological considerations". If the biological risks are assessed as being "sufficiently low, if measures can be put in place to ensure that they remain low and/or it is obvious that adverse economic and other consequences are negligible in terms of the nation, the task is complete at this point".[22]

5.34 AQIS stated that only if the biological risks or consequences are considered "significant", "simple control measures cannot be put in place" and preliminary assessments of the economic and other consequences indicate they also may be "significant", would further evaluation be required and deeper consideration would need to be given to "other relevant national interest criteria". These other criteria would include human health and environmental effects.[23]

5.35 The assistance of Commonwealth Departments and agencies such as Health and Community Services; Arts, Sport, Environment, Tourism and Territories; and the Australian Bureau of Agricultural and Resource Economics would be called on at this stage. "The extent to which these assessments are taken in each case is ... impossible to define. Essentially it remains the judgement of the quarantine decision-maker ... in consultation with those other experts providing advice...".[24]

5.36 AQIS suggested that the Government be responsible for consideration of the broader and less direct social and economic issues.[25]

5.37 AQIS acknowledged that "while a professional, scientific and objective approach is essential ... ultimate judgements ... will usually be at least partly subjective."[26] Even the analysis of biological risks may be subject to disagreement. For these and other reasons, AQIS considered that a broad and ongoing consultation process was

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22 ibid., p 10
23 ibid.
24 ibid., p 11
25 AQIS Discussion Paper: *The Application of Risk Management Assessment*, p 6
26 ibid., p 7

desirable. One of the outcomes AQIS hoped would flow from a more structured and transparent quarantine risk assessment process would be better communication with the public. However, it was stated that there are "limits of practicality" to consultation. "The level of consultation, its frequency and the methods employed will vary from case to case."[27]

5.38 Some of the key steps in the proposed process for considering applications to import exotic organisms would be:

. lodging of the application, which would be required to contain "sufficient information to enable a general assessment to be made"

. a general assessment of the biological and other consequences including health and environmental effects

- separate guidelines concerning biological control agents, plants, and animals or genetic material are included in the discussion paper, indicating the sort of information needed to perform the general assessment

. a determination whether the organism falls within a particular category, based on precedents in quarantine management

- different categories would require different degrees of risk assessment

. ongoing consultation with interested groups or individuals and notification through the *AQIS Bulletin* of the various stages of the clearance process[28]

- periods would be specified in which comments should be received

. separate in-depth biological and other assessments if required

- included in the minimum requirements of this level of analysis are possible quarantine strategies if the risk disease or pest becomes established in Australia; possible environmental impact; and a recording of the assumptions made in the assessment

. determination of the best strategy

. publication of the conclusions

. further consultation

. decision and announcement.[29]

5.39 A possible criticism of the AQIS approach would be that, although it emphasises that ongoing public consultation would be an important feature of the suggested procedure, it refers to the "limits of practicality" on consultation and does not propose the establishment of formal mechanisms to ensure that it takes place.

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27 ibid., p 12

28 The comment is made at p 25 of the discussion paper that this detailed consultation would "not be practical for other than the relatively small number of applications which are subject of an in-depth risk assessment."

29 ibid., pp 17-31 & appendices 1-4

B.5.(ii) The GENHAZ proposal

5.40 The Committee found great merit in a formally structured approach which was recommended by the UK Royal Commission on Environmental Pollution in its Fourteenth Report, *GENHAZ: a system for the critical appraisal of proposals to release genetically modified organisms into the environment* in June 1991.[30] The 'GENHAZ' risk assessment process has been adapted from the 'HAZOP' procedure developed for the UK chemical industry.

> "[GENHAZ] is a technique for identifying hazards and not a procedure for quantifying the risk that may be consequent on a given hazard. It may be desirable to evaluate quantitatively, as a separate exercise, some of the consequences [of a given hazard]".[31]

5.41 The recommended process would commence with a questionnaire designed to cover the seven stages involved in the construction and release of a genetically modified organism. The answers are regarded as "statements of intent".

> "The seven stages are:
>
> i. MAKE or SELECT - the selection of the recipient, the preparation of the construct and its incorporation in the recipient to form the product.
>
> ii. RELEASE - the process of introducing the product into the release environment.
>
> iii. ESTABLISH - the events during the period following release during which the product either settles in and establishes itself in the release environment, or fails to do so. ...
>
> iv. POPULATION - the pattern of growth, spread and reproduction that follows the initial period of establishment; the interaction of the product and the release environment.
>
> v. GENETIC TRANSFER - the unintended transfer of DNA from any component into other DNA, at any stage of the release.
>
> vi. MONITOR - the monitoring of the progress and outcome of the release.

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30 UK Royal Commission on Environmental Pollution, Fourteenth Report: *GENHAZ: a system for the critical appraisal of proposals to release genetically modified organisms into the environment* June 1991

31 ibid. p 33

vii. TERMINATE AND CLEAN UP - what is planned either for when the trial has been completed or in the event of an early termination proving necessary."[32]

5.42 The GENHAZ team would then consider the answers in the questionnaire.

"... guide words are applied one by one to answers to the questionnaire to suggest ways in which outcomes may depart from the plan. More than one deviation could be generated by one guide word and the same deviation might arise from more than one combination of guide word and statement of intent."[33]

"The application of guide words encourages lateral thinking and forces attention onto possibilities that might not have been considered, or might have been rejected out of hand without adequate consideration."[34]

5.43 The guide words and their meanings are:

"NO or NOT a complete negation of the intention (eg a gene fails to insert into a vector)

MORE a quantitative increase (eg the level of expression of a gene is greater than had been expected); could also be applied to time in terms of duration or frequency

LESS a quantitative decrease (eg the deflowering of plants to prevent spread of pollen is incomplete); could also be applied to time in terms of duration or frequency

AS WELL AS a qualitative increase - something additional to the design intention happens (eg insects other than those targeted by a gene product are killed)

PART OF a qualitative decrease - something less than the design intention happens (eg one of the genes inserted into the recipient fails to express)

OTHER THAN something quite different from the design intention happens (eg the wrong construct is inserted)

WHERE ELSE an intended event takes place in a location other than that planned (eg genetic material or the product of its expression occurs elsewhere than was planned)

WHEN ELSE some effect appears at a time different from that

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32 ibid. p 16
33 ibid.
34 ibid. p 12

> expected (eg a modified plant flowers earlier or later than its unmodified form even though this was not the purpose of modification)."[35]

5.44 The possible deviations from the intent of the release would be examined by the GENHAZ team to identify possible short and long term consequences. These consequences would then be assessed to decide whether they are acceptable. If not, it would be determined whether existing safety measures in the proposal were sufficient to prevent them. Action would be required if the safety measures were inadequate. The procedure enables the team to recommend additional safety measures or request further information from those proposing the release. Additional information or modified proposals would be subject to further GENHAZ assessment.[36]

5.45 The GENHAZ procedure has a number of features which recommend it. Firstly there is the very comprehensive nature of the more than 50 questions which are included in the questionnaire. These have been carefully framed so as to minimise the danger of assumptions about the hazards or lack of them precluding consideration of all the possibilities. Of course the questions themselves could be further developed in the light of experience. Secondly the process of applying the guide words to the answers on the questionnaire could help expose matters which had not been properly considered. Thirdly the keeping of formal records containing details of the evaluation deliberations would be very useful in ensuring that the procedures had been followed and would enhance the credibility of the assessment. Fourthly the evaluation process itself would indicate any action which needed to be taken to ensure safety.

5.46 The Royal Commission suggested that:

> "The GENHAZ study team should include scientists from all relevant disciplines so that, among others, genetics, ecology, and safety are represented ... The team should be drawn mainly from those who have planned and from those who will carry out the release, since it is on them that the responsibility for safety and efficacy rests. ... Some people who are not directly involved in the release should also join the team."[37]

Recommendation 16

5.47 The Committee recommends that the GENHAZ procedure be used by institutional biosafety committees and the results of their findings be forwarded to the Release Authority (see recommendation 40) as part of the risk assessment process.

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35 ibid. p 17
36 ibid. pp 32, 33
37 ibid. p 28

B.5.(iii) Some other proposals received in evidence

5.48 During evidence Dr Richard Cotton suggested a point scoring scheme for risk assessment.[38] Under this scheme an organism being considered for release would be assessed in terms of possible hazards to other organisms, its dispersal and potential benefits, both human and economic. The organism would receive a score in each category and the total score would determine release or otherwise.

5.49 One criticism of this kind of approach is that it is invalid to add scores which are essentially on different scales. "Not only are they incommensurate [unable to be compared], but scores on different scales are also neither strictly multiplicative ... nor strictly additive".[39]

5.50 The scheme is an attempt to impose a simple category-based system onto the interaction of a released GMO with the ecology of an area which is likely to be complex. Allowing a total score to determine release would cause problems associated with cut-off points. Furthermore, such a simple system of assessment would increase the relative influence of the value judgements of the assessors.

> "Each ... [biological discipline] has its own values, and that influences how the scientists interpret a given set of data. So you can have a group of scientists come in who have the same set of data, and depending on whether they are [an] ecologist, a microbiologist, a geneticist or whatever, they will come up with different interpretations of that particular data. That is simply the effect of the value judgement."[40]

5.51 To address the complexity of the interaction of a released GMO and the environment, Professor Arthur Brownlea proposed the use of an 'Environment-Organism Index'. Four categories of release conditions were suggested based on the nature of the organism (either known or novel) and the proposed release environment (either complex or simple). The interaction of the index with the level of uncertainty (defined as high, moderate or low) would be used as a guide to determine the type of regulation required.[41]

5.52 Under this proposed scheme the release of a "novel organism" into a "simple" environment for which there was a "high" level of uncertainty would be subject to a "total ban".[42] This scheme can be criticised on the basis that the four categories in the index could not adequately cover the full range of organism-environment interactions. The terms themselves are open to interpretation which could cause lengthy and perhaps unnecessary debate.

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38 Cotton, Dr R: Transcript p 1176; Submission 4.1

39 Tiedje, J et al.: *The planned introduction of genetically engineered organisms: ecological considerations and recommendations,* in *Ecology* 70(2) 1989 pp 298-315: Exhibit 112

40 Hulsman, Dr K: Transcript p 740

41 Brownlea, Prof A: Transcript p 936, 945

42 ibid. p 945

5.53 A procedure for determining uncertainty has been suggested by Tiedje et al.[43] Their summary table "was inspired by a similar table prepared by the Recombinant DNA Monitoring Committee 1987."[44] The release proposal would be considered in terms of the:

. attributes of the genetic alteration
. attributes of the parent (wild type) organism
. phenotypic attributes of the GMO in comparison with the parent organism
. attributes of the environment.

5.54 Eight or nine separate items of information would be required for each area and each response would be placed on a sliding scale indicating the "level of possible scientific consideration" that would be needed, the extremes being "less" and "more". The authors point out that: "Position on [the] scale is only qualitative or semi-quantitative [i.e. cannot be ascribed a number]. The importance of position on one scale may be contingent on another scale. The importance of particular scales will vary with different cases."[45]

5.55 The authors urge, however,

> "... that any case that falls at the ... ['more'] end of *one or more* scales ... should receive appropriate regulatory scrutiny in regards to the attributes in question. Ecological safety, as well as public confidence in a fledgling industry, will be fostered by this approach."[46]

5.56 The Committee considers that the use of quantitative scales involving the addition of scores received in different categories may not be valid. However, the use of non-quantitative scales in relation to risk factors may be a useful part of the risk assessment process. The development and refinement of such scales should receive continued attention by GMAC and should be a matter raised with interested community groups for comment.

C. Risk in contained development work

5.57 By definition, with contained development work there is no intention of immediate release of live organisms to the outside environment. Such work may be carried out on a small or large scale. It may be carried out in a laboratory or in an industrial plant. The GMAC guidelines specify the levels of physical containment required depending on the nature of the organisms, the nature of the genetic modification involved, and the scale of the work. Chapter 2 of this report describes the kinds of physical containment which GMAC may indicate as desirable.

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43 Tiedje, J et al.: *The planned introduction of genetically engineered organisms*: Exhibit 112 pp 308-310

44 ibid., p 307 referring to RDMC: *Procedures for the Assessment of the Planned Release of Recombinant DNA Organisms* 1987, Section 7

45 ibid., p 310

46 ibid., p 307

C.1 Escapes

5.58 The main environmental concern about contained work is the possibility of escape of the organism to the outside environment. There are different degrees of risk of escape depending on the level of physical containment and different chances of recapturing the organism after escape, depending on the nature of the organism.

5.59 The Department of Arts, Sport, the Environment, Tourism and Territories (DASETT) stated that the distinction between contained work and releases was not absolute. The Department claimed that "US officials have commented that more GMOs may have been released to the environment incidentally than have been deliberately released".[47]

5.60 DASETT argued that a definition of how many organisms constitutes a release, whether intentional or not, for the purposes of regulation is a critical issue. The Department indicated that the number at which a release (or escape) becomes significant is "when sufficient organisms are released to become established". This number depends on a great many factors concerning the "characteristics of the organism and the receiving environment".[48]

5.61 Professor Nancy Millis from GMAC argued that there was a great deal of experience in handling dangerous organisms in contained environments and that this experience was directly applicable to safely containing GMOs.

> "I think we need to recognise that 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."[49]

5.62 The GMAC submission argued that:

> "With respect to contained work with [GMOs], and the products made by these organisms, ... [the GMAC] guidelines and the existing regulations are adequate to ensure the safety and rights of individual workers and the general public, and the safety of the environment."[50]

5.63 Biotech International Limited, however, stated: "In general, one must assume that the probability of an organism reaching the natural environment is 1, whether the

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47 DASETT: Submission 138 p 29, referring to: OECD: *Draft International Survey on Biotechnology Use and Regulations*, May 1990 p 37

48 DASETT: Submission 138 p 29

49 Millis, Prof N, Chairman, GMAC: Transcript p 87

50 GMAC: Submission 88 p 2

organism is intended for release or not. ... Any activity involving man is subject to the unpredicability of human error".[51]

5.64 The ACF recommended that it be compulsory to notify the IBC, and the responsible State environment protection authority of any inadvertent releases of GMOs from contained facilities.[52] They further recommended that:

> "Routine monitoring of effluents from contained laboratory and factory work with GMOs should be required and the results ... reported periodically to the State EPA ...[and that] The release of living GMOs in effluents from factories should be absolutely prohibited".

5.65 In order to ensure that no living GMOs are released in effluent the ACF recommended complete sterilisation of all effluents.[53]

5.66 There is disagreement concerning whether any level of unintentional release of any kind of GMO is acceptable. As noted above, DASETT commented that the number of organisms released is important.

> "... at the C1 (lowest) containment level, a number of micro-organisms can be expected to be released with every routine operation. This is not considered to be a problem because the number of organisms released is considered to be insufficient to establish a viable population."[54]

5.67 Dr Sue Meek from the Australian Biotechnology Association made similar commented:

> "Whether one organism gets out may not be relevant because if that organism cannot compete in the environment it is not a problem; it is going to die anyway. What you need to know is whether escaped organisms are capable of establishing self-sustaining populations."[55]

5.68 The Committee considers that the complete sterilisation of all effluent from laboratory and factory premises is not necessary if the GMOs which could escape to the environment do not pose a threat. Such a requirement should be left to the discretion of the agency which authorises the work to impose as part of the containment conditions.

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51 Biotech International Limited: Submission 90, Appendix 3, p 6

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

53 ibid. p 46

54 DASETT: Submission 138.2 p 2

55 Meek, Dr S, Australian Biotechnology Association: Transcript p 706

Recommendation 17

5.69 The Committee recommends that State governments ensure that there is regular monitoring of the effluent from contained laboratories and factories which are required to ensure that no, or no more than specified quantities of, live genetically modified organisms are released and that the results be reported to the State pollution control authorities. The most practical monitoring mechanism might be to require the factory or laboratory to carry out the monitoring and to make their records available to the State authorities on request.

Recommendation 18

5.70 The Committee recommends that there be a requirement on those carrying out contained development or commercial work with genetically modified organisms to report immediately all unintended releases of those organisms in excess of the limits which may have been specified by the regulatory authorities.

5.71 The ability of GMOs, which have unintentionally been released, to survive in the environment is obviously very important. Also important are: the ability to track the movement of the organism or of the introduced gene in the environment so that remedial measures may be taken if possible; the ability of the introduced gene to express itself; and whether the released organism is pathogenic.

C.2 Ability to survive

5.72 Dr Richard Cotton, the Deputy Director of the Murdoch Institute, commented that, while it could not be said with certainty that the organisms they used in laboratories could not escape, those organisms had growth requirements that could not be met in the outside environment.[56]

5.73 A requirement for nutrients which are unlikely to be readily available in nature may be able to be inserted in GMOs.[57] This is an example of biological, as opposed to physical, containment.

5.74 Organisms which are released into the environment are immediately subject to competitive pressures from other organisms.[58] Whether they survive will depend on

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56 Cotton, Dr R: Transcript p 296

57 GMAC: Submission 88 p 8

58 Meek, Dr S, Australian Biotechnology Association: Transcript p 707; Greenwood, Dr P, Australian Veterinary Association: Transcript p 891

a number of factors including whether a threshold population level has been reached[59] and the type of environment. The comment was made that under more extreme environmental conditions the population of other organisms may be lower and therefore there may be less competition.[60] Many environments in Australia may be at higher risk because they are extreme. However, the risk would be higher only if the released organism had some special advantage in that extreme environment compared with the bulk of other organisms that were unable to survive there.

5.75 A further claim is sometimes made that genetically modified organisms may be at a survival disadvantage, either because they are modifications of domesticated species which are less robust than wild types, or because the modification process may weaken them.[61] For example, it was claimed that modified crop plants are unlikely to escape and become super-weeds because domesticated plants usually depend on human cultivation to survive, that is, they are at a disadvantage in the wild.[62]

5.76 While it is accepted that some modified organisms might have growth requirements which could not be met in the outside environment it is by no means clear that this would be true of all released organisms. Again, while it could be true that some organisms might be debilitated as a result of being genetically modified it is not certain that this would be universally true. Some modifications might in fact convey a selective advantage, depending on the nature of the changes made.[63] It is also relevant to ask, even with debilitated organisms, how long it would take for them to die out and how much damage they may cause before they do.[64]

5.77 Clearly no definitive statement can be made about this matter - it would require a case-by-case assessment.

5.78 A possible safeguard related to the ability of escaped organisms to survive and proliferate would be the use of so-called suicide genes. These are genes which could be implanted in a GMO to give it either a limited lifespan or to make it self-destruct if it came into contact with an environment which it would not be desirable to allow it to enter.[65]

5.79 Alternatively, genes could be added to released organisms which would make them vulnerable to a particular chemical spray. This would facilitate their eradication if so desired. Also a lethal gene, repressed by genes elsewhere in the bacterium, could

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59 Biotech International Limited: Submission 90, Appendix 3 p 7

60 Meek, Dr S, Australian Biotechnology Association: Transcript p 706

61 Davies, Dr J, Department of Microbiology, Monash University: Transcript p 331; Nayudu, Dr M, Department of Botany, Australian National University: Transcript p 167

62 Murray, Dr D: Submission 11 p 5

63 Biotech International Limited: Submission 90, Appendix 3, pp 6, 7

64 Burch, Dr D et al.: Submission 106 p 20

65 Rolfe, Prof B, Transcript p 205

be added to genetically modified plasmids. Should the plasmid be transferred, its lethal component would kill any recipient wild-type bacterium.[66]

Recommendation 19

5.80 The Committee recommends that the GMO Release Authority be invested with the power to decide whether a requirement - such as 'suicide genes' or dependence on an artificial, controllable substance for survival, growth or performance - be imposed as part of the conditions for approval of releases of GMOs into the environment. (This might be appropriate for the release of a micro-organism.)

C.3 Monitoring movement

5.81 The use of marker genes, linked with the use of the polymerase chain reaction process if necessary,[67] could substantially aid in identification and post-release monitoring of GMOs, particularly micro-organisms, and of inserted genes. Marker genes could be attached to the 'active' gene but would have no function other than to provide a means by which the presence of the active gene could be readily established.

5.82 Monsanto Australia Ltd indicated that they are working with the CSIRO on developing marker genes. Their representative stated that "it would be essential to support any application for release of a genetically modified organism".[68] Often the marker gene is used to get information on the behaviour of the organism to be modified - how long it persists in the soil, how it spreads from the site, et cetera. This information is needed to answer questions associated with the proposed release of a GMO.

5.83 Often the introduced gene itself could be detected by polymerase chain reaction or simple hybridisation. In which case, the use of marker genes would be an unnecessary burden.

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66 Connor, S: *Genes on the loose*, in *New Scientist*, 26 May 1988 p 68

67 The polymerase chain reaction process enables genetic sequences to be multiplied in the test tube. It can be used to enable measurement of quantities which may otherwise be undetectable.

68 Sheers, M, Regulatory and Environmental Affairs, Monsanto Australia Ltd: Transcript pp 447, 448

C.4 Controlling gene expression

5.84 Another possible control mechanism is to include with the gene a promoter sequence, the activity of which can be regulated externally. The activation of the promoter would be required before the inserted gene became active. The promoter could be one which required the presence of a particular nutrient not normally found in the environment into which the organism could escape.[69] A promoter of this kind is being used in the experiment in Adelaide with growth hormone genes in pigs. The development of such mechanisms is clearly worth exploring.

Recommendation 20

5.85 The Committee recommends that GMAC be invested with the power to decide whether the use of 'gene promoters', the activity of which can be regulated in response to specific stimuli, be required as one of the conditions of approval for genetic modification experiments or for work which is meant to take place in a contained environment.

C.5 Escape of pathogenic organisms

5.86 The use of pathogenic organisms, or of genes from pathogenic organisms, in genetic modification experiments obviously necessitates the taking of special precautions against escape. The possibility of inadvertently increasing the pathogenicity of an organism by adding a gene also has to be borne in mind.[70]

5.87 Professor Jim Pittard, Chairman of the Scientific Sub-Committee of GMAC, referring to the risk of accidentally creating a pathogenic organism, stated that it appears that pathogenicity is a characteristic "requiring the cooperative interaction of a number of different gene products and unlikely to be conferred on laboratory strains."[71]

5.88 Professor Pittard identified the use of animal or plant viruses "as vectors to introduce new genes into animals and plants" as a practice which would need "to be kept under close consideration". He referred, however, to several instances where these have been 'disarmed' to allow them to be safely used.[72]

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69 Beresford, M, Conservation Council of South Australia: Transcript p 654

70 Pittard, Prof A J, Professor of Microbiology, University of Melbourne; Chairman of Scientific Sub-Committee GMAC: Submission 2 pp 6, 7

71 ibid., p 6

72 ibid., p 7

C.6 'Kitchen sink' experiments

5.89 The spectre was raised of people being able to carry out genetic manipulation work in their kitchens.[73] The comments of Professor David Danks and Professor Allen Kerr help put this concern in perspective.

5.90 Professor Danks commented:

> "The main characteristic of genetic engineering is that it involves a large series of steps, each one of which is really quite simple. Somebody with sufficient persistence could do quite a lot of moving of a gene into another organism or out of one bacterium into another bacterium, or out of some human tissues into a bacterium. The much more sophisticated part comes if you are trying to put this into human cells or into a human body, or into plant cells or into a whole plant, or a mouse egg into a transgenic mouse. That requires much more sophisticated skills and equipment."[74]

5.91 Professor Kerr was asked whether there was any possibility of children conducting GMO experiments in the kitchen. He replied:

> "I do not think that is a realistic comment. You would certainly have to have a pressure cooker to sterilise your media; you would have to have sterile facilities before it would work properly. I agree that it is a simple technology but I cannot agree that it could be carried out in the home without a great deal of trouble. You could set up your own lab at home, but you could not do it in the kitchen."
>
> " ... The mind boggles. It is quite a complicated process to get DNA out, to cut it and to stitch it back again and put it back into another organism. It is really not on."[75]

5.92 It was stated by Mr Bob Phelps, ACF, that the UK Royal Commission on Environmental Pollution, in its report *The Release of Genetically Engineered Organisms to the Environment*, expressed "a very real concern" about the possibility of such home experiments carried out by school children.[76] The only relevant reference in the Royal Commission's report that the Committee could find is paragraph 10.21 (and summarised in para 12.65).

> "Knowledge of genetics and ecology should be included in the curriculum in schools. We were encouraged to see some of the teaching material on the techniques of biotechnology ... but it is important that students should

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73 Phelps, R, Australian Conservation Foundation: Transcript p 541

74 Danks, Prof D, Gene Therapy Expert Committee, Human Genetics Society of Australasia: Transcript p 556

75 Kerr, Prof A, Department of Plant Pathology, Waite Agricultural Research Institute, University of Adelaide: Transcript p 567

76 Phelps, R, Australian Conservation Foundation: Transcript p 541

also be aware of the factors involved in judging the impact on the environment of a proposed release."[77]

5.93 **The quotation above hardly supports the claim that the Royal Commission was strongly concerned about possible home experiments. The Committee considers that this particular danger is highly exaggerated.**

C.7 The 'New Zealand fungus'

5.94 There were a number of references to an experiment in New Zealand involving a nitrogen fixing fungus which allegedly went dangerously wrong and which resulted in apparent pathogenic effects on radiata pine trees. The circumstances of this alleged 'incident' are set out below.

5.95 The experiments were carried out by scientists from the Plant Physiology Division, D.S.I.R., Palmerston North and were reported in *Plant and Soil* in 1977.[78] The research aimed to incorporate nitrogen fixing ability into a mycorrhizal fungus of *Pinus radiata* roots; if successful the tree roots may have been able to absorb some of the fixed nitrogen. Mycorrhizal fungi live in close association with their host plant and are thought to aid in nutrient uptake. Many orchids, for example, are unable to live without their mycorrhizal fungal partners.

5.96 The fungus, *Rhizopogon sp*, which is normally found associated with *Pinus radiata* roots, was modified by inducing fungal cells to absorb whole cells of the nitrogen fixing bacterium *Azotobacter vinelandii*. Five strains of the thus modified fungus were used and were each grown with 10 *Pinus radiata* seedlings. The plants were all grown in a greenhouse under controlled temperatures.

5.97 All 10 plants grown with Strain 1 of the modified fungus appeared to be killed by the fungus which grew throughout their tissues. There was tree/fungal association in 26 of the remaining 40 seedlings but the relationship was unnatural because fungal tissue was found inside the cells of the tree roots (normally it would grow between the cells of the roots). The penetrated cells of the seedlings were dead, but it was not clear whether the fungus had killed them or had entered after death.

5.98 Because of the pathogenicity revealed by the experiment: "Strain 1 of the fungus and the trees inoculated with it were autoclaved and sterilely destroyed."[79]

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77 UK Royal Commission on Environmental Pollution, Thirteenth Report: *The release of genetically engineered organisms to the environment*, July 1989 p 78

78 Giles, K and Whitehead, H: *Reassociation of a modified mycorrhiza with the host plant roots (pinus radiata) and the transfer of acetylene reduction activity*, in *Plant and Soil*, Vol 48 1977 pp 143-152

79 ibid., p 151

5.99 Because of the apparent sub-pathogenic behaviour of the other strains which could adversely affect other species of pine trees "all strains are being grown only under restricted sterile conditions and under no circumstances being released for field trials."[80]

5.100 The authors acknowledged that "much more work is necessary to ensure such systems are both biologically safe and effective before anything can be said of their potential agronomic role."[81]

5.101 The following comments can be made about this particular case study:
. the techniques involved whole cells and were relatively unsophisticated by today's standards
. there was no release to the environment and none was contemplated
. the scientists acted responsibly and destroyed the pathogenic strain of modified fungus and intended to proceed with caution with the other strains
. there was no cover up; the experiment was reported in a reputable scientific journal
. the research was carried out in 1977 and no reports of subsequent incidents concerning the experiment have surfaced in the submissions to, or hearings of, this inquiry.

D. Releases of GMOs

5.102 A range of concerns were expressed about releasing genetically modified organisms to the environment. A particular concern was that the organisms may behave in ways after release which were not predicted in pre-release trials - or which may not be able to be predicted in such trials. They might outcompete other 'natural' organisms, leading to the decline or extinction of those other organisms. They might attack or cause disease in other organisms, or in some other unanticipated way upset the balance of ecological systems. The diversity of life forms, ecosystems, or genetic information within species might be reduced.

5.103 Another concern was that the genetic information inserted within the released GMOs might be transferred in unexpected ways to other organisms, or even to other species. The consequences of this might be impossible to predict but might be undesirable or dangerous to the environment.

5.104 As with the concerns about the 'escape' of GMOs, the actual risks involved in releasing GMOs would vary considerably depending on the nature of the particular modified organisms, the nature of the change which had been made to them and the environment into which they were released - including what other organisms were already present in those environments. Underlining all these concerns is a distrust of the ability of scientific studies to predict with confidence the possible effects.

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80 ibid., p 152
81 ibid.

D.1 Unanticipated behaviour by released GMOs

5.105 One of the claimed benefits of the new genetic modification techniques over more traditional selective breeding is that usually only one gene is being changed rather than a fairly random 'shuffling' of genes taking place. It can be known very precisely what the inserted genetic information codes for before it is inserted. Whether the gene has been inserted in the correct location may not be known until after the organism develops.[82] One of the concerns expressed, however, was that the characteristic added by the insertion of the gene may result in unexpected behavioural changes in the organism.

5.106 Some who support the development of genetic manipulation techniques argued that exotic biological control agents, being totally new to an environment, would often be more of a danger than a released GMO which involved only slight changes to an otherwise very familiar organism.[83]

5.107 A cautious outlook was displayed by one witness from the Australian National Parks and Wildlife Service.

> "One of the real problems ... is the enormous capacity of nature to take advantage of an opportunity in a way that is not necessarily the way we humans thought about it. ... Organisms just do not obey our rules and there is a real danger that the genes as they occur or by normal processes of evolutionary mutation, will become susceptible to use by that or other organisms to their advantage so they can spread or do other things. I guess we have a greater respect for nature's capacity to take advantages of opportunity than the molecular biologists, who are laboratory based, would have."[84]

5.108 It was claimed that releasing micro-organisms is particularly dangerous because of their high reproductive potential and the fact that their relationship with other organisms in the environment is poorly understood.[85] One estimate was that 80 to 90% of soil microbes are unnamed and have not yet been cultured in the laboratory.[86]

5.109 Other claimed difficulties were that genetic engineering of microbes can increase mutational frequency;[87] special techniques are needed to monitor their

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82 Gray, Prof P, Vice-President, Australian Biotechnology Association: Transcript p 706

83 Sleigh, Dr M, Division of Biomolecular Engineering, CSIRO: Transcript p 1065; Millis, Prof N, Chairman, GMAC: Transcript p 98

84 Richardson, Dr B, Australian National Parks and Wildlife Service: Transcript pp 154, 155

85 Hallen P: *Genetic Engineering - Miracle or Destroyer?* in *Habitat Australia*, February 1990 pp 9-12

86 ibid., quoting US Environment Protection Authority

87 ibid., p 10

survival and dispersal; they can grow rapidly; and some species can exchange genetic material leading to less predicability.[88]

5.110 Professor Bruce Holloway from Monash University advocated that before the release of GMOs, tests should be carried out on: "(i) genetic interactions of any of the released micro-organisms with the present biological environment; and (ii) persistence of the released micro-organisms in the environment."[89]

5.111 On the other hand, Professor Barry Rolfe from the Australian National University, while acknowledging that the soil is a very complex environment about which very little is known, commented that it is also a very big buffer. In effect he contended that, although it might not be possible to assess risk very precisely, the risk may not be so great, at least in respect to the release of micro-organisms.

> "... over the last three billion years the bacteria basically have played an awful lot of games and have probably done most of the things that we can do to them, even to having captured human genes as they chew up bodies in the soil and so forth. So my suspicion is that we will probably in the bacteria be able to do very little that has not at some point in time been tried by the bacteria themselves."[90]

5.112 Similar comments were made by Dr John Davies of the Microbiology Department at Monash University.[91]

5.113 Professor Jim Pittard advised extreme caution "about releasing genetically modified insects unless the genetic modification was designed to decrease or ... eliminate survival of the released organisms and to ensure that they did not multiply and produce progeny."[92]

5.114 Professor Pittard commented that the possibility of released plants becoming weeds was probably not great. He argued that the capacity to become a weed was one which was likely to involve several genes and would not be likely to result from altering a single gene. "The major risks ... would ... only arise if such plants had significantly increased ability to survive and propagate or to mate with other plants which may acquire those characteristics."[93]

5.115 The existing procedures before approval for release is given already have certain safeguards built into them. The testing of GMOs under controlled conditions

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88 Burch, Dr D et al.: Submission 106 p 22; Murray, Dr D: Submission 11 p 1

89 Holloway, Prof B: Submission 45 p 1

90 Rolfe, Prof B: Transcript p 221

91 Davies, Dr J, Department of Microbiology, Monash University: Transcript p 327

92 Pittard, Prof A J, Professor of Microbiology, University of Melbourne; Chairman of Scientific Sub-Committee GMAC: Submission 2 p 10

93 ibid.

can, and should be, very thorough. Professor Nancy Millis from GMAC described the process of proceeding to a release of a modified plant:

> "... we go through the steps of, first of all, the laboratory, the greenhouse where the plant's performance is looked at, and then we would do things like pot trials where again we can retrieve the situation if something goes amiss. Ultimately, we do a small field trial, again so that if anything untoward were to occur, we could use a bromide or soil sterilant on the site. We have a number of steps on the way where each time we are getting a broader area that is affected, but we try to be very sure before we allow a large release that the steps on the way have given us the impression, or the information, that our organism is not going to produce a hazard."[94]

5.116 Dr Merilyn Sleigh of the CSIRO referred to the possible engineering of the myxoma virus to cause rabbits to become sterile. The sort of safeguards which are being envisaged involve testing and screening populations of other organisms, including humans, to see whether they are capable of being infected by the virus; and having only proteins which are specific to the rabbit built into the virus.[95]

5.117 The Australian Meat and Live-stock Research and Development Corporation (AMLRDC) argued that "informed persons will be able to make predications about the likely behaviour of a particular modified organism in the environment, and the correctness, or otherwise, of their conclusions may be tested in a controlled, contained situation."[96]

5.118 The AMLRDC referred to the example of developing a rumen microbe which digests cellulose more efficiently. Predictions might be made that the new microbe would be no better at establishing a niche in the rumen or surviving outside the rumen than its predecessor (both the new and the old varieties would be killed by exposure to oxygen). It might also be predicted that the new microbe, like the previous microbe, could be transmitted between animals in close contact - such as parent and offspring - but not between animals of different species who would not be in such close contact. If these predictions were true then the environment would not be endangered by the inoculation of live-stock with the new microbe.

5.119 The Corporation argued that these predictions can be tested in contained experiments. They stated that if it were not possible

> "... to plan and execute a set of sensible experiments which are designed to assess the effect of the organism on the environment ... then the organism should not be released. If the contained tests showed that the organism did not behave as thought, then the release of the organism

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94 Millis, Prof N, Chairman, GMAC: Transcript p 90

95 Sleigh, Dr M, Division of Biomolecular Engineering, CSIRO: Transcript pp 1075, 1076

96 Australian Meat and Livestock Research and Development Corporation: Submission 14 p 3

should be withheld until the unexplained behaviour is not only modified, but understood in detail."[97]

5.120 The ACF argued that the modification of the microbes in the gut of ruminants to aid in the digestion of food "is an invitation for ... these animals to extend their forage range and to feed on a wider selection of plants in fragile environments".[98] This is probably as much an example of a possible livestock management change as it is of an environmental impact from the changed behaviour of the livestock.

5.121 Several submissions mentioned a concern about transgenic fish.[99] The submission of the ACF referred to the possible dangers of adding growth hormone genes to fish - the roles of predator and prey could be altered; there could be increased demand for food; and the genetic structure of native fish populations could be changed.[100] Similar comments were made by Professor Peter Outteridge from Queensland University.[101] It was suggested in one submission that only sterile fish be used for release experiments or for production purposes and that there should be research to improve the efficiency of sterilization techniques.[102]

5.122 The suggestion concerning infertility was extended to all genetically modified animals "which may be released, accidentally or otherwise, into the wild."[103] The modification of animal or fish species intended for consumption might, however, be less attractive from a commercial point of view if they could not breed.

5.123 Obviously there may be dangers in releasing genetically modified organisms. It is also clear that these dangers vary widely depending on the nature of the modified organism, the nature of the modification and the environment into which the release takes place. The risks can only be assessed on a case-by-case basis. The solution is to proceed with caution using very thorough testing procedures before approval for release is granted.

5.124 In addition there are safeguards which can be built into released organisms, such as controllable promoters and monitoring aids, such as marker genes, which can and should be used where possible. These have been outlined earlier in this chapter when examining the possibility of minimising the risks involved in 'escapes' of contained organisms.

5.125 **Risk assessment procedures have been discussed earlier in this chapter. The Committee considers that if those procedures are thoroughly applied then the chance of a totally unanticipated occurrence of a dangerous nature will be minimised.**

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97 ibid.
98 Phelps, R, Australian Conservation Foundation: Submission 140 p 2
99 Blackshaw, Dr A: Submission 19; Outteridge, Prof P: Submission 8
100 Phelps, R E, Australian Conservation Foundation: Submission 140 p 22
101 Outteridge, Prof P: Submission 8 p 2
102 Blackshaw, Dr A: Submission 19 p 6
103 Bailey, Dr A, Mather, Dr P, Queensland University of Technology: Submission 13 p 2

D.2 The spread of altered characteristics to non-target organisms

5.126 One concern expressed was that characteristics implanted in a released organism may be transferred inadvertently to some other organism or species by natural means after release thereby causing unintended consequences. The potential damage from the transference of genes in micro-organisms, plants and animals is examined below.

D.2.(i) The transfer of genes between micro-organisms

5.127 A number of witnesses and submissions expressed particular concern about the lack of knowledge of soil micro-organisms and the extent of transfer of genetic information between micro-organisms in the soils and in aquatic environments.

5.128 Dr David Burch et al. referred to the important ecological role of bacteria, which mediate ecosystem processes and "which, if disrupted, [would] adversely affect biotic communities and populations".[104] They argued that "the frequency and extent of genetic transfer in nature requires further investigation before widespread environmental release of GEOs [should] occur."[105]

5.129 An example of the impact of the transfer of genetic material between bacteria has been the

> "... spread of genes for resistance to antibiotics. Scientists have [also] observed a wide range of genetic transfers between micro-organisms living in a variety of habitats, such as soils, fresh water, sewage and the gastrointestinal tract of humans and animals".[106]

5.130 In genetic modification experiments, genetic material is usually added to bacteria as plasmids. Bacteria usually contain plasmids and these may be present as multiple copies. The ability for plasmids to be transferred varies; some plasmids do not appear to be transferred at all.[107]

5.131 Professor Jim Pittard stated:

> "If the [micro-organism] to be released contains novel genetic information, one must also consider the future of this information apart from its host. ... if this ... information is carried on a plasmid it is almost certain that this will be transferred to other micro-organisms in the ... environment particularly if very large numbers are involved. If such a transfer could create another novel genotype which has a strong selective

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104 Burch, Dr D et al.: Submission 106 p 21
105 ibid., p 22
106 Connor, S: op. cit., p 68
107 UK Royal Commission on Environmental Pollution, Thirteenth Report p 31

> advantage this may be sufficient reason not to approve a release. If ... the novel genes offer no selective advantage ... the consequences of their transfer could be of no great significance. One way around this problem is to integrate any genes into the bacterial chromosome rather than introducing them as plasmids. In this way the survival of these genes is much more closely tied to the survival of the host itself."[108]

5.132 Dr John Pemberton from Queensland University also expressed caution about gene transfer in micro-organisms:

> "Our own research shows that some of the so-called vectors which were originally put up for biological containment can replicate and be maintained in other organisms. The question is whether they are actually transmitted, and whether the frequencies are sufficient. ... A biologist really cannot rule that out completely, I am afraid. ... but the majority of the vectors that are used only have the so-called narrow host range debilitation: that is, they are based on a plasmid which presumably can only replicate in E. coli. ... [however] the host range of a number of these vectors is not limited to E. coli alone. They will be stably maintained in other organisms. I can say that with absolute certainty, and for organisms that are not related to E. coli."[109]

5.133 Transduction is another method by which genetic material may be transferred between species in nature. Transduction is the transfer of genetic information from one bacterium to another through the agency of bacteriophage (a virus). Bacterial genes may become incorporated in the bacteriophage particles which, after release from the dead host cell, act as vectors in transporting this genetic material into other bacterial cells.

5.134 Recent research suggests that this process may be significant even in aquatic environments where it had been thought that "bacteria are too far apart for the viruses to make the journey from one host to another." It has been shown that "bacteriophages are major effectors of transduction even at these low bacterial concentrations. ... This must be taken into account when evaluating the potential risks associated with the release of genetically engineered micro-organisms".[110]

5.135 The UK Royal Commission into Environmental Pollution felt that:

> "... the potential hazards may be less than might appear. ... organisms containing cellulase genes will break down cellulose, a major component

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108 Pittard, Prof A J, Professor of Microbiology, University of Melbourne; Chairman of Scientific Sub-Committee GMAC: Submission 2 p 9

109 Pemberton, Dr J, Institutional Biosafety Committee, University of Queensland: Transcript p 974

110 Coghlan, A: *Watery microbes fuel fresh fears over genetic release*, in *New Scientist*, 29 June 1991 p 17 referring to Kokjohn, T et al.: *Attachment and replication of Pseudomonas aeruginosa bacteriophages under conditions simulating aquatic environments*, in *Journal of General Microbiology*, Vol 137 p 661

> of wood. It might therefore seem undesirable to release novel micro-organisms containing cellulase genes. In fact these genes are already widespread in the environment, in organisms responsible for one part of the carbon cycle, but living trees are not decomposed."[111]

5.136 Even high concentrations of genes may not result in transfer.

> "The bacterium *Bacillus thuringiensis* (Bt) contains a gene, which can be on a highly mobile plasmid, producing a substance toxic to many insects. ... populations of *B. thuringiensis* become very large in insects that they kill ... So far as is known, the toxin gene is not widespread in other bacterial species."[112]

5.137 The UK Royal Commission, however, still advocated caution: "Nevertheless, with any newly engineered organism it will be prudent to begin with the assumption that an introduced gene is capable of spreading widely and then to challenge that assumption."[113]

5.138 Professor Jim Pittard suggested that proposals may come forward to release organisms designed to survive in the environment, albeit only in the presence of particular pollutants, or "in the case of viruses" only where there is a particular target species. In such cases there will be a need to

> "... ensure that the metabolic activity of these bacteria does not extend beyond the target substrates [the polluting substances], that genes which are good for the ecology in these organisms cannot escape to others where they could create a damaging phenotype [ie. another organism], that viruses do not have a wider host range than was first imagined and that they cannot mutate to create less desirable phenotypes."[114]

5.139 Professor Peter Outteridge advocated that a register of virus strains which are released be maintained and that stored samples also be kept for later reference: "This could be accommodated at the Australian Animal Health Laboratory at Geelong Victoria and be accompanied by a genetic map of the recombinant virus."[115]

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111 UK Royal Commission on Environmental Pollution, Thirteenth Report p 32

112 ibid.

113 ibid.

114 Pittard, Prof A J, Professor of Microbiology, University of Melbourne; Chairman of Scientific Sub-Committee GMAC: Submission 2 p 9

115 Outteridge, Prof P: Submission 8 p 2

Recommendation 21

5.140 The Committee recommends that the approving authorities pay particular attention to genetically modified micro-organisms which are intended for release and the possible consequences of the genetic information they contain being transferred to other organisms. Given the present state of knowledge in this area, the approving authorities should make the initial assumption that the inserted genetic information will be spread to other micro-organisms in assessing risk. The use of marker genes and the keeping of a register of released micro-organisms would assist in monitoring their dispersal and any spread of the genetic information inserted in them. The approving authorities should consider the imposition of a requirement to use marker genes as a condition of approval for release and should consider maintaining a register of released micro-organisms.

D.2.(ii) The transfer of genes between plants

5.141 Plants reproduce sexually through the production of pollen which is transported, in outbreeding species, to the stigma of flowers on other plants. Thus introduced genes could escape from modified plants via pollen transfer. Alternatively, modified plants could be pollinated by wild relatives and the seeds produced could be dispersed into the environment.

5.142 Dr David Murray stated that there is:

> "... no guarantee that genes conferring herbicide resistance will remain confined to the crop species in which they are placed. This will depend on the identity of the crop plant, and its degree of relatedness to attendant weeds. Almost every field crop has at least one related weed form (Harlan, 1969). In some instances, interbreeding between crop plants and closely related weeds happens routinely."[116]

5.143 Resistance for the herbicide atrazine could be transmitted via pollen even though the gene resides in the chloroplast because, although "many plants inherit chloroplasts only from their female parent, inheritance through pollen is not unknown."[117]

5.144 Transferred genes "that confer a new ability, such as insect or disease resistance, or salt or drought tolerance, could also change the physiological tolerances

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116 Murray, Dr D: Submission 11 p 2 referring to Harlan, J: *Evolutionary Dynamics of Plant Domestication*, in *Proc. XII Int. Congress in Genetics, Japanese J. of Genetics*, Vol 44, Suppl.1 1969 pp 337-343

117 Young, S: *Wayward genes play the field*, in *New Scientist*, 9 September 1989 p 26

or geographic distribution of wild plants, causing them to become economically important weeds or altering their roles in natural communities."[118]

5.145 However, leakage of genes from crop plants is not a new phenomenon.

> "Sorghum fields are often plagued by weeds which arise through hybridisation between the cultivated plant and its wild relatives. ... Researchers believe that genetic leakage must occur in a wide range of crops, such as oilseed rape, other brassicas, apples and sugar beet ...[however] the Royal Commission on Environmental Pollution (in its Thirteenth Report) ... found no evidence that traits such as resistance to insect pests had spread from traditional crops into wild relatives."[119]

5.146 A simple precaution might be to release the genetically modified plant in areas free from weedy relatives.

> "... soybeans, wheat and maize, were [probably] introduced into the US, North American and Canadian environments from other environments. There are no real close cousins ... that could pick up pollen from these potentially genetically engineered organisms."[120]

5.147 An alternative could be "altering the timing of flowering so that it no longer coincides with ... nearby wild relatives, or growing strains that cannot produce viable pollen."[121]

5.148 The use of sterile plants grown for their vegetative features such as timber would enable "not only prevention of unwanted crossbreeding, but also productivity gains through saving of the energy normally directed ... into the reproductive process."[122]

5.149 **As with micro-organisms, attention must be paid in conducting risk assessments on proposed releases of genetically modified plants to the possibility of gene transference, particularly if there are wild relatives nearby. There are safeguards such as the use of sterile plants, and alterations in the time of flowering which should be used where possible.**

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118 Tiedje, J et al.: *The planned introduction of genetically engineered organisms*: Exhibit 112 p 304, referring to, inter alia, Ellistrand, N in Hodgson, J and Sugden, A. (Ed.): *Planned release of genetically engineered organisms. Trends in Biotechnology/Trends in Ecology and Evolution Special Publication*, Elsevier, Cambridge UK 1988 pp S30-32

119 Young, S: op. cit., p 23 referring to UK Royal Commission on Environmental Pollution, Thirteenth Report p 32

120 Rolfe, Prof B: Transcript p 206

121 Young, S: op. cit., p 25

122 Stocker, Dr J, Chief Executive, CSIRO: Submission 109 p 21

D.2.(iii) The transfer of genes between animals

5.150 Professor Jim Pittard saw the main risk of this kind being from animals such as:

> "... fish, rodents, rabbits, and other animals that are widespread and clearly able to survive in the environment. Introduction of new genes into a particular species if it resulted in improving its competitiveness could result in major alterations in the ecology. There is less danger with domesticated animals that have for centuries been bred for characteristics unsuited for competitive survival."[123]

5.151 Professor Pittard argued that:

> "Since much genetic work in the immediate future will be directed towards the goal of improving the marketability of ... major livestock species and should involve for the most part changes that are little different from changes already achieved by selective breeding, we need a system that will allow a reasonably rapid assessment and subsequent release of new improved species that are regarded as ecologically benign."[124]

5.152 A commonly mentioned concern was in relation to animals which have been genetically modified to contain genes to produce extra growth hormone. The risk of transference of such genes will vary from case to case. For example, the CSIRO regards the risk of cross breeding with feral populations as being "low for a merino sheep, [but] higher for a goat".[125] However, the risk with animals bred for commercial production which have wild relatives nearby could be reduced by physical containment.

5.153 Another possible safeguard is the use of a controllable promoter in association with the growth hormone gene, so that dietary supplements are required for the growth hormone gene to be activated. An escaped animal living in the wild would be less likely to receive the particular dietary supplement in the quantity needed to trigger hormone release or to receive the amount of feed necessary to allow additional growth should extra hormone be produced.[126] Genes which are not expressed, could not confer an advantage and so are less likely to be selected for in an already well-adapted feral population.

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123 Pittard, Prof A J, Professor of Microbiology, University of Melbourne; Chairman of Scientific Sub-Committee GMAC: Submission 2 p 11

124 ibid., pp 11, 12

125 Stocker, Dr J, Chief Executive, CSIRO: Submission 109 p 21

126 Campbell, Dr R and Taverner, Dr M, Pig Research and Development Corporation: Transcript pp 60, 61

Recommendation 22

5.154 The Committee recommends that research should be encouraged into limiting the potential for the transfer of altered genes to non-target organisms. It does not consider, however, that the risks of such transfers warrant a moratorium on the release of genetically modified organisms. The possibility of the transfer of altered genes to non-target organisms should be considered as part of normal case-by-case risk assessment.

D.3 Effect on biodiversity

5.155 Biodiversity can refer to diversity of genetic information within a species, diversity of species within ecosystems and a diversity of ecosystems in the world as a whole. Quite apart from the aesthetic argument that the diversity of life in the world adds to its beauty, there is the argument that this diversity is essential for the continuation of life itself.

5.156 Diversity of genetic information allows for adaptation to changing conditions in the environment. The evolution of species results from the interaction of changing environmental conditions and the existence of genetic diversity. One fundamental argument put forward against genetic manipulation was that the main thrust of evolution has been to "establish a diversity of gene pools .... without allowing them to coalesce again" and that genetic engineering reverses this trend.[127] The implication is that this trend towards less diversity could disrupt the evolution of life as the response to changed conditions and therefore be dangerous for the long-term survival of life itself.

5.157 One form of the argument is that, through the release of 'favoured' plants and animals or cloning, genetic diversity in the total gene pool will be decreased[128] and the more simplified an environmental system becomes the more inherently unstable it becomes. Agricultural areas are already highly simplified environments, often involving the use of monocultures. Monocultures can be particularly vulnerable to pests and diseases.[129]

5.158 The International Union of Conservation and Nature (IUCN) was quoted to the effect that 5-15% of the world's species are likely to become extinct between 1990 and 2020. The argument is that genetic manipulation may contribute to that process.[130]

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127 Phelps, R, Australian Conservation Foundation: Submission 140 p 13

128 Killmier, G: Submission 9; Burch, Dr D et al.: Submission 106 p 34

129 Hulsman, Dr K: Transcript p 968

130 Burch, Dr D et al.: Submission 106 p 37

5.159 The concern was expressed that released GMOs might out-compete unmodified organisms. It was argued that the fact that the modification was only a minor one could mean that the released organism might therefore be able to occupy the same niche in the environment as the unmodified one making it an even more direct competitor.[131]

5.160 An increase in the intensity of competition of different life forms for the same niche does not necessarily mean that there will be a decrease in genetic diversity. Competition between organisms and between species is a natural condition of life. The diversity of niches helps ensure that no one species is able to dominate all of them. The addition of genetically modified organisms, if they have a survival advantage, may result in a decrease in the numbers of some non-modified competitor. It is by no means certain that a genetically modified organism will have a survival advantage in the wild.

5.161 The ACF stated that natural means of preserving biodiversity - such as the maintenance of wilderness - should have priority over technical means such as gene banks.[132] The difficulty with gene banks as a means of preserving genetic diversity is that the preserved organisms and their genes are still being removed from evolutionary selection and, in any case the particular environmental habitat on which they depend for survival may have been destroyed by the time it is decided to return them to it.[133]

5.162 **The existence of biodiversity is clearly a matter of importance in the healthy functioning of the world's ecosystems. The effect of the whole range of human activities on the survival of other species, on the diversity of genetic types within species, and on the diversity of ecosystems in the world is a matter which requires serious consideration by governments. This is not, however, a matter which is unique to genetic manipulation. Nor is it established that genetic manipulation will have a major adverse impact on genetic diversity.**

D.4 Herbicides - increased usage

5.163 There is a concern that the development of herbicide resistant crops through genetic manipulation will result in an increased use of the herbicides to which the crops are resistant and that this will result in increased environmental damage.

5.164 Increased use of a herbicide might occur if, previously, use of that herbicide was kept below optimal levels, or not used at all, because it damaged the crops themselves. The fear is that farmers might be tempted to overuse a herbicide if they

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131 Phelps, R, Australian Conservation Foundation: Submission 140 p 38

132 ibid., p 37

133 Hennessy, K, Australian Conservation Foundation: Transcript p 868

know that their crops will not be adversely affected, in order to ensure that the weeds are destroyed.[134]

5.165 Genetically modifying plants to make them resistant to herbicides implies an acceptance of the need for herbicide use in agriculture. The point has been made in chapter 4 that monoculture in agriculture may have the disadvantage that it requires the use of herbicides but, because of the production efficiencies which it allows, it is not likely to be abandoned. Soil cultivation is an alternative method of weed control but cultivation encourages soil erosion and soil erosion is seen as possibly Australia's major environmental problem. The trend has therefore been to minimise the use of cultivation in Australia for weed control purposes.

5.166 The argument in favour of genetically modifying crops to be resistant to herbicides is that, by producing crops which are resistant to environmentally less harmful herbicides, use of those herbicides may be encouraged in preference to more environmentally damaging ones.

5.167 When a herbicide is applied to destroy weeds before a crop is planted, there is always the risk that it will persist in the soil and cause subsequent damage to the crop. Moreover, if a herbicide is applied from the air, spray drift damage may also affect adjacent crops. Thus the selection of a herbicide is influenced by its persistence and its toxicity to crops, as well as its effect on human health and its cost.

5.168 An example given was the herbicide, 2,4-D, which is rapidly broken down in the soil by micro-organisms. This lack of persistence is an environmental advantage. It also has the advantage for farmers of being cheap, effective and "safe to use (in spite of its undeserved association with the dioxin-contaminated 2,4,5-T (agent orange))."[135]

5.169 2,4-D is often used to control weeds in wheat fields. However, it is extremely toxic to cotton. When sprayed on wheat it has been known to be carried many kilometres by wind and cause damage in cotton fields. Where wheat is planted near cotton other herbicides are used which are more persistent in the soil. The CSIRO is therefore developing cotton plants which are resistant to 2,4-D.

> "... engineered plants with a resistance to herbicides will obviously make farmers use more herbicides of that particular kind. But our rationale is that we are trying to shift the usage away from herbicides which persist in the environment for many months afterwards towards more environmentally safe herbicides which persist only for a few weeks in the environment. We are looking at a shift in the usage pattern."[136]

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134 Murray, Dr D: Submission 11 p 2

135 Stocker, Dr J, Chief Executive, CSIRO: Submission 109 p 46

136 Llewellyn, Dr D, Division of Plant Industry, CSIRO: Transcript p 1076

5.170 There is also research aimed at incorporating resistance to glyphosate ('Roundup'). "Glyphosate is a foliar applied herbicide which does not last long in the soil but breaks down to natural components."[137]

5.171 Other arguments were presented in favour of this form of genetic modification. The argument that crop production costs may be reduced substantially through the use of herbicide resistant crops is mentioned in chapter 2. The Committee was also told that the use of plants tolerant to herbicides may delay the appearance of resistant weeds by increasing the range of herbicides that can be used.

> "At the moment, the range of chemicals you could use to control weeds in a crop is limited to those which are safe to the crop. To avoid weed resistance developing you should use as many different products as possible, go through a rotation of different product use. It could be that having a [herbicide] resistant crop would allow a wider range of products to be used in rotation".[138]

5.172 Moreover, it was argued that herbicide resistant plants "would provide greater flexibility in the choice of crops for rotation or double crop plantings".[139]

5.173 The allegation that herbicide resistant plants will be an invitation for excessive herbicide use was disputed by the National Farmers' Federation. "The only reason they would use more chemical as a result of some development such as weedicide resistance is if that improved the performance of their farm. ... They will not use more chemicals unless it is economically appropriate to do so."[140]

5.174 Some in the chemical industry argued that it was their experience that farmers in fact have a natural tendency to use lesser quantities of herbicides than they should, rather than more than necessary, in order to cut costs.[141]

5.175 The claim was made that the development of new herbicide tolerant crops is being extended to herbicides which are not environmentally benign. For example, it was claimed that Ciby-Geigy is engineering soy-beans to be resistant to Atrazin, which breaks down only slowly in the environment.[142] It was argued that the creation of crops resistant to persistent herbicides could limit crop rotation, leading to greater pest problems.[143]

5.176 The development of crops resistant to herbicides which are persistent in the soil has a certain logic. It would presumably allow the planting of a resistant crop in a

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137 Sheers, M, Regulatory and Environmental Affairs, Monsanto Australia Ltd: Transcript p 451
138 ibid., p 452
139 Queensland Department of Primary Industries: Exhibit 113 p 5
140 Mackenzie, J, National Farmers Federation: Transcript pp 127, 128
141 Sheers, M, Regulatory and Environmental Affairs, Monsanto Australia Ltd: Transcript p 451
142 *The Genetic Engineering Debate,* in *Search,* Vol 20, No 3 May/June 1989 pp 77-80
143 Burch, Dr D et al.: Submission 106 p 27

field where a persistent herbicide had been previously sprayed. It could remove some of the concern in crop rotation. However, the desire of farmers to rotate their crops - which could still involve some which are not resistant to the herbicide - may in fact act to discourage the use of persistent herbicides or limit the quantity of the herbicide used.

5.177 It was also argued that the CSIRO's work on the development of tolerance to the herbicide 2,4-D should be a matter of concern. The claim was made that the herbicide does have human health and environmental effects and, moreover, its use makes crops more susceptible to insect infestation and disease, increasing the need for higher doses of insecticides and fungicides.[144]

5.178 The Committee considers that there is the possibility of risk in the release of plants which have been made resistant to particular herbicides.

> "Whether ... this is a good idea depends on which herbicides are involved and how they will be used. If ... the herbicide ... has a very short half life in the ground and if the plants' resistance means that spraying can occur early in plant life resulting in less rather than more use of herbicide, the strategy seems highly desirable. If ... the resistance is to a herbicide which has a long half life and if the strategy results in much more herbicide being used, the strategy is clearly undesirable."[145]

5.179 **The Committee concludes that there may be positive effects from genetically modifying crops to be resistant to herbicides. It clearly depends on which herbicides are involved and how usage of them may change as a result of the introduction of resistant plants. It is not possible to make a blanket judgement on the issue. There is certainly not a case for a complete ban on such work given the benefits which may be possible. The regulatory authorities should be allowed to decide each case on its individual merits.**

D.5 Pest resistance in plants

5.180 Dr David Murray argued that the release of crop plants with increased resistance to pests should not pose a serious problem for the environment since wild plants usually already possess greater natural pest resistance than the cultivated forms.[146]

5.181 The question has been asked: in what way might insects or bacteria evolve if crop plants are engineered to be resistant to them?[147] The argument is that

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144 ibid., p 26

145 Pittard, Prof A J, Professor of Microbiology, University of Melbourne; Chairman of Scientific Sub-Committee GMAC: Submission 2 pp 10, 11

146 Murray, Dr D: Submission 11 p 5

147 Smith, R: Submission 12 p 3

engineering into plants the ability to produce insecticides might result in greater selection pressure for immunity in insects than occasional spraying would. This creates the need to continually find other toxin genes - creating another tread mill. It was claimed that there is evidence that resistance to the BT toxin, from the bacteria *Bacillus thuringiensis*, which is the main biotoxin being developed, has already occurred.[148]

5.182 An additional danger could arise if a decline in the numbers of one kind of insect, as a result of increased plant resistance to that pest, caused an increase, because of less competitive pressure, in the numbers of another pest. These second pests conceivably could be more of a problem than the original ones.

5.183 Also insects which may be a pest as larvae could be important as pollinators in the adult stage of their life cycle.[149]

5.184 Plants which have better survival chances, as a result of genetic manipulation, and which have their pollen or seeds distributed widely, through wind or any other mechanism, could cause environmental disturbances.[150]

Recommendation 23

5.185 **The Committee recommends that, as part of the release approval process for plants genetically modified for pest resistance, consideration be given to possible secondary ecological effects. Examples of such effects might be: influencing the evolution of insect pests; and possible unintended damage to economically or ecologically useful insects.**

E. Adequacy of Existing Laws

5.186 The submission from DASETT stated that, although there was no "specific legislation requiring the assessment of biotechnology or genetic manipulation projects"[151], such projects might fall within the jurisdiction of existing legislation.

5.187 For example, the *Industrial Chemicals (Notification and Assessment) Act 1989*:

> "... requires the assessment of all new industrial chemicals. It applies to all commercial chemicals not covered by other legislation and includes 'biological material other than a whole plant or animal'. It therefore includes genetically modified micro-organisms produced by or used in an industrial process. This Act, however, excludes quantities below 50 kg per

148 Burch, Dr D et al.: Submission 106 p 28
149 ibid., p 29
150 ibid., pp 29, 30
151 Department of the Arts, Sport, the Environment, Tourism and Territories: Submission 138 p 14

year. This, and the exclusion of whole plants and animals, leaves significant gaps in the coverage of GMOs."[152]

5.188 The United States *National Environmental Policy Act 1969* can be used to compare the adequacy of Australian environmental protection legislation in covering the release of genetically modified organisms.

> "[The US Act] 'requires agencies to fully consider and disclose to the public environmental impacts and uncertainties, to speculate on all but highly remote consequences, and to divulge competing scientific views.' Indeed an EIS [Environmental Impact Statement] in some cases may have to comply with the 'worst case' rule, that is, an analysis of the environmental effects of a low probability/high risk action associated with the project and of the probability of the action."[153]

5.189 The advantages of Environmental Impact Assessment (EIA) procedures are that they:

. facilitate public and expert input;
. have time limits on the assessment process; and
. provide for recommendations on conditions to be applied to approved projects.[154]

5.190 EIA procedures generally involve the following steps:

> ". initial information is provided to the environment department;
> . the information is assessed and a decision is made on whether an environmental impact statement (EIS) or similar document is required;
> . if so, guidelines are prepared on matters to be examined ...;
> . the EIS is made available for public review;
> . an inquiry may be held;
> . there is consultation with expert bodies [eg. GMAC]...;
> . assessment is undertaken, leading to recommendations as to whether the proposal should be approved and, if so, under what conditions."[155]

5.191 Concern exists that even if

> "... a proposal to release [GMOs] ... comes to the notice of a Government agency or the GMAC, there is no requirement that any environmental impact assessment should be conducted before the release is approved.

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152 ibid., pp 14, 15

153 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 p 61

154 Australian Environment Council: *Environmental Protection and Biotechnology - A Discussion Paper on the Implications and Regulation of the Release of Genetically Manipulated Organisms to the Environment of Australia*, November 1987 p 12

155 ibid., p 13

> The ... [GMAC] guidelines recommended that the potential environmental consequences of proposed releases should always be considered. But those guidelines are not contained in legislation and cannot be enforced".[156]

5.192 Given the competitive nature of the industry there may be pressures to "cut corners and take risks".[157]

5.193 Nevertheless, in some cases only an abbreviated assessment may be necessary. Prof Nancy Millis (Chair of GMAC) commented: "I believe there are examples where one would feel that a very full environmental impact statement may not be necessary ... I feel that should be a matter of discretion for the committee."[158]

5.194 In Australia, existing "EIA legislation and procedures ... generally apply to environmentally significant proposals which involve government actions, decisions or funding."[159] Private activities need only be assessed when subject to Government approval, or if specifically defined in State legislation.

> "Deliberate release of genetically engineered organisms may therefore be subject to EIA because:
> . the effects of such releases may be environmentally significant;
> . government decisions may be involved in the proposals through government funding of research, activities undertaken directly by government authorities, or because government approvals are required (eg. under legislation relating to health, drugs, pollution, pest control or quarantine); and
> . the EIA legislation may apply to proposals for establishing and operating private biotechnology laboratories (the schedules listing 'designated developments' or 'scheduled premises' in State legislation or regulations could specifically include such proposals)."[160]

5.195 However, the results of an

> "... environmental assessment are generally recommendations, with no enforceable provision for monitoring or control under the enabling legislation. The application of EIA to biotechnology proposals would therefore need to be clearly linked with appropriate control mechanisms."[161]

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156 VLRC: Report No 26, *Genetic Manipulation*, June 1989 p 32
157 Burch, Dr D et al.: Submission 106 p 46
158 Millis, Prof N, Chairman, GMAC: Transcript p 82
159 Australian Environment Council: op. cit., p 12
160 ibid.
161 ibid., p 13

E.1 Commonwealth legislation

5.196 Compared with the Unites States *National Environmental Policy Act 1969*, there has been no such legal or administrative development of EIS law under any Commonwealth Act. The *Environment Protection (Impact of Proposals) Act 1974*, which applies principally to Federal Government decision making:

> "... provides for the formulation and approval of 'Administrative Procedures' in respect of the preparation and use by government decision-makers of environmental impact statements ... [The Act, however,] does not impose an enforceable obligation on Commonwealth decision-makers to have regard to environmental factors".[162]

5.197 Nonetheless, the spirit of the Act

> "... is to subject to environmental assessment all government decision-making having the potential to affect the environment. ... It is open to argue, especially under Procedure 4.1(h),[163] that a rigorous analysis of the potential impact of deliberate release, its cumulative effect, and indeed a 'worst case' analysis [are required]."[164]

5.198 Consequently, the thorough US approach could be justified in the Australian context under the 'Administrative Procedures'.[165]

5.199 There is, however, uncertainty concerning the 'Administrative Procedures':

> "Neither the initiation nor the operation of the procedures are prescribed in the Act or the regulations made pursuant to it. In addition, the power of Australian Courts to enforce 'Administrative Procedures' is uncertain. ... It is arguable that a Minister has not breached his duty ... if procedures entrusted to others have not been fulfilled."[166]

5.200 There is a considerable element of discretion in the power of Ministers to decide whether a proposal requires an impact assessment, particularly at the Commonwealth level under the *Environment Protection (Impact of Proposals) Act* and it could be very difficult for members of the public to challenge that in the Courts.[167]

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162 Barker, M: op.cit., p 58

163 Procedure 4.1(h) states that an EIS shall: "assess the potential impact on the environment of the proposed action and of any feasible and prudent alternative to the proposed action, including, in particular, the primary, secondary, short-term, long-term, adverse and beneficial effects on the environment of the proposed action and of any feasible and prudent alternative to the proposed action". Quoted from Barker, M: op. cit., p 61

164 Barker, M: op. cit., pp 60, 62

165 ibid., p 61

166 Andrews, K: *The regulation of genetic engineering in Australia*, Master of Law Thesis, Monash University: Exhibit 41 p 144

167 VLRC: Report No 26 pp 32, 33

5.201 There is the question as to who has standing under the Act:

> "... proceedings under the [Act] may only be initiated by a member of the public with a 'special interest' in the subject matter ... An intellectual or emotional interest is not sufficient"[168]

5.202 Another avenue for public involvement is via Section 10

> "... which requires the Minister to respond to a request from any person for information concerning what action, if any, has been taken, or is proposed, for ensuring consideration of the environmental aspects of a matter. However, the Act makes no provision for public objection [if] the Minister decides no action is necessary or if an individual is dissatisfied with the action taken."[169]

5.203 In assessing the adequacy of the *Environment Protection (Impact of Proposals) Act* one has to balance the need to accommodate those with genuine and legitimate concerns against the discouragement of those who would wish to obstruct and delay technological advances at all costs.

5.204 The *Wildlife Protection (Regulation of Exports and Imports) Act 1982* regulates the import and export of wildlife and wildlife products. One aim is to "prevent establishment of further pests that could damage the Australian environment."[170] Control is effected by a 'reverse listing' feature - Schedules 5 and 6 of the Act list animals and plants which can be imported or exported; any unlisted organism is prohibited.

> "[The] Act is restricted to regulation of trade in specimens (live or dead) from the Animal and Plant (including Fungi) Kingdoms and does not embrace micro-organisms such as viruses, bacteria, Rickettsia and leptospiras."[171]

5.205 The Australian National Parks and Wildlife Service (ANPWS) understands that these micro-organisms would be covered by the *Quarantine Act 1908*. This Act, however, "in its current form does not take into account environmental concerns; its principal concerns are with disease risks."[172]

5.206 The *Wildlife Protection Act* "may opportunistically and indirectly control the release of micro-organisms through regulations on the import of the vector or reservoir organism."[173]

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168 Dekker, B: *Regulation of the release of genetically manipulated organisms in New South Wales*, Research Assignment, University of Technology, Sydney: Exhibit 52 p 6

169 ibid.

170 Australian National Parks and Wildlife Service: Submission 87.1 p 4

171 ibid., p 5

172 ibid.

173 ibid.

5.207 The ANPWS states that the *Wildlife Protection Act* should not be amended so that it covers micro-organisms.[174]

5.208 The Act also "does not address the release into the environment of genetically modified organisms derived from native plants and animals. Only their export would be regulated".[175]

5.209 Moreover, with regard to the schedules listing permitted imports:

> "There is no standard nomenclature to deal with transgenics ... [which] may confuse the interpretation of the Schedules ... Whether a transgenic is a species as listed under the Schedules or whether it is considered a new species is fundamental to the application of the provisions".[176]

5.210 It is possible that organisms could be genetically modified in order to become biological control agents. The *Biological Control Act 1984* could thus be invoked to facilitate their release into the environment.

5.211 The Act was introduced, with complementary legislation in the States, to overcome an injunction in 1980 which prevented the release of a biological control agent to combat Paterson's Curse.[177]

5.212 The legislation enabled the Commonwealth Biological Control Authority

> "... to establish programmes for the eradication of pest organisms. Section 36(1) prevents any court proceeding to prevent the release of agent organisms ... or to recover damages suffered in a State or Territory by reason of the release ... Accordingly, a member of the public would be prevented from obtaining an injunction against the Biological Control Authority."[178]

5.213 When an application to the Authority proposes that "an organism be targeted or made a control agent, the proposal must be publicly advertised and public comment on the proposal considered by the Authority."[179]

5.214 There has to be consideration as to whether there will be significant harm to the environment or people. Nevertheless, under s30 of the Act, approval procedures may be circumvented in emergencies.[180]

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174 ibid.

175 ibid.

176 ibid., pp 5, 6

177 Barker, M: op cit., p 80; Dekker, B: *Regulation of release of genetically manipulated organisms*: Exhibit 52 pp 7, 8

178 Andrews, K: *Australian Controls on the Environmental Application of Biotechnology*, in *Environmental and Planning Law Journal*, Vol 5 1988 p 203

179 Barker, M: op cit., p 81

180 ibid.

5.215 Mr Michael Barker has argued that EIA procedures under the *Environmental Protection (Impact of Proposals) Act* would not be applicable to the *Biological Control Act.*

5.216 The *Biological Control Act* is not meant to be a substitute for any other law and this might suggest that the EIA obligations of the *Environmental Protection (Impact of Proposals) Act* could be added to its publicity provisions. However, "the EIA obligations under the Impact of Proposals Act only exist to the extent that they are consistent with any other law ... [and so may be] inconsistent with the broadly similar functions of the [Biological Control] Authority".[181]

E.2 Legislation enacted in the States

5.217 Environmental assessment legislation and procedures vary from State to State. For example: "New South Wales assessment procedures are applicable to all 'designated developments', those in Tasmania to 'scheduled premises' and those in South Australia to any 'development of major social, economic or environmental importance'."[182]

5.218 In Victoria the *Environment Effects Act 1978*

> "... provides that an 'Environmental Effects Statement' and a 'Preliminary Environmental Report' may be required when 'public works' are undertaken which could 'reasonably be considered to have or be capable of having a significant effect upon the environment'. ... 'Works' might include a project involving the release of recombinant organisms."[183]

5.219 The final decision is made by the Minister for Conservation who also determines whether the public are to become involved in the environment impact assessment process.[184]

5.220 The *Environmental Protection Act 1970* (Victoria) "is framed in sufficiently wide terms to regulate aspects of genetic engineering, both in the laboratory and in any environmental use. The environment is defined to include the 'biological factors of animals and plants'."[185]

5.221 Waste products of genetic manipulation would be covered by the general Industrial Waste Provisions of the Act.[186]

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181 ibid., p 82

182 Australian Environment Council: op. cit., p 12

183 VLRC: Discussion Paper No 11, *Genetic Manipulation*, March 1988 p 23

184 Andrews, K: *Australian Controls on the Environmental Application of Biotechnology*, in *Environmental and Planning Law Journal*, Vol 5 1988 pp 203, 204

185 ibid., p 202

186 The Victorian Government: Submission 154 p 2

5.222 The scope of the *Environmental Planning and Assessment Act 1979* (New South Wales) is limited. Arguably,

> "... the deliberate release of genetically-engineered micro-organisms is a 'physical activity' within the definition of the legislation. A court accepting a broad definition of 'activity' has power to require an EIS to be prepared in accordance with prescribed regulations before allowing a government department to approve or carry out an activity."[187]

5.223 The Act could, therefore, be used to require an environmental impact assessment to be prepared prior to the release of a genetically modified organism.[188] Nevertheless, a major restriction is that the Act "will only apply to activities either carried out by or subject to the approval or funding of a government agency. Thus, a large percentage of the commercial biotechnology industry would not be covered".[189]

5.224 In New South Wales, however, the *Environmental Offences and Penalties Act 1989* "supplements other legislation concerning environmental protection by creating additional offences regarding the illegal disposal of waste and the spillage of environmentally hazardous material."[190]

5.225 In South Australia the

> "*Planning Act* (1982) allows the Minister to require the preparation of an EIS where a person proposes to undertake 'a developmental project ... of major social, economic or environmental importance'. One commentator has argued that s.49(1) of the *Planning Act* may allow the Minister to require an environment impact assessment of a proposed deliberate release project".[191]

5.226 The *State Development and Public Works Organisation Act 1971-1978* (Queensland) "only applies to government departments, authorities and local government bodies."[192] Administrative procedures enable the Department of the Environment to require the preparation of an EIS but this requirement does not seem to attract any legal sanctions.[193]

5.227 In Western Australia the *Environmental Protection Act*

> "... provides a statutory responsibility for reviewing proposals within Western Australia involving genetically modified organisms and the

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187 Andrews, K: *Australian Controls on the Environmental Application of Biotechnology*, in *Environmental and Planning Law Journal*, Vol 5 1988 p 203

188 The Cabinet Office, New South Wales: Submission 116, Appendix 1 p 3

189 Dekker, B: *Regulation of release of genetically manipulated organisms*: Exhibit 52 p 7

190 The Cabinet Office, New South Wales: Submission 116, Appendix 1 p 3

191 Andrews, K: *Australian Controls on the Environmental Application of Biotechnology*, in *Environmental and Planning Law Journal*, Vol 5 1988 p 203

192 ibid.

193 Barker, M: op cit., p 61

> [Environmental Protection] Authority has established procedures for undertaking the necessary environmental assessment or proposals. All groups which are likely to be involved in the development and release of genetically modified organisms have already been advised by the Authority that there is a responsibility on the agency, organisation or individual which or who intends to release the genetically altered material or make it available for release, to refer that proposal to the Environment Protection Authority well in advanced [sic] of such intentions being implemented. A proposal would be considered to include experimental trials as well as commercial release."[194]

5.228 The Australian Environment Council suggested that "if the actions [of GMAC] ... were subject to the Commonwealth EIA legislation ... all environmentally significant proposals [involving genetic manipulation] ... could be referred to the Commonwealth environment department for assessment."[195]

5.229 There are other options for fuller environmental assessment before genetically modified organisms are released into the environment:

> ". the existing environment assessment laws could be extended to private works. This would bring recombinant DNA work within the ambit of work which may be subject to environment impact assessment but would not make it mandatory;
> . special administrative directions could be issued under existing environmental impact assessment laws requiring notification and assessment of all deliberate release programs. Since the various Acts are limited to public works the requirement for mandatory assessment would still not apply to private works;
> . special legislation could be enacted requiring all proposals for the release of recombinant organisms to be notified and to be environmentally assessed. This would not only make environmental assessment mandatory but also extend the requirement to private as well as public works."[196]

5.230 Support for mandatory environmental impact assessments for releases of novel organisms in this country stems from past experience of damage caused to the environment when exotic species were introduced without careful scientific deliberation and with no consideration of the consequences, for example, blackberries, foxes and rabbits.[197]

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194 Premier, Western Australia: Submission 145, Letter from Minister for the Environment

195 Australian Environment Council: op. cit., p 12

196 VLRC: Discussion Paper No 11, p 37, 38

197 Pittard, Prof A, Professor of Microbiology, University of Melbourne; Chairman of Scientific Sub-Committee GMAC: Submission 2 p 12

E.3 Other possibly relevant environmental legislation of GMOs

5.231 In all States there is legislation controlling the discharge of pollutants into the water and air, or onto the land.

5.232 For example, the *Environment Protection Act 1970* (Victoria) contains "clean water and clean air provisions (which) are sufficiently wide to prevent the release of a genetically-engineered organism if such an organism was likely to change the physical, chemical or biological conditions of the air or water."[198]

5.233 Moreover, definitions of 'waste' within legislation addressing waste disposal enable recombinant DNA materials to be classified as the by-product of laboratory research which is covered by the legislation.[199]

5.234 The Victorian Act, as well as the *Environment Protection Act 1973* (Tasmania) makes it an offence to cause soil pollution. Generally speaking, the pollution of soil from an accidental release of recombinant material would constitute an offence under these Acts.[200]

5.235 In New South Wales the management of waste disposal to the soil is effected through the *Waste Disposal Act 1970.* The Act has been criticised because it "does not affect the treatment, storage [or] disposal of wastes on the site of the place where they were brought into being. Nor does it create a specific pollution offence."[201]

5.236 The *South Australian Waste Management Commission Act 1979,* the *Health Act 1911* (Western Australia), and the *Health Act 1937-81* (Queensland) have been criticised because they too do not create specific soil pollution offences.[202]

5.237 Discharges to water likely to affect marine and aquatic life are affected by water pollution controls. In all States/ Territories a sanction is created for water pollution, either under specific waters Acts such as the *Clean Waters Act 1970* (New South Wales), the *Clean Waters Act 1971* (Queensland) and the *Water Resources Act 1976* (South Australia) or under comprehensive Acts such as the *Environment Protection Act 1970* (Victoria) and *Environment Protection Act 1973* (Tasmania).[203]

5.238 Besides laws designed to maintain water quality, there are often 'nuisance' offences under public health, local government or water management legislation. The

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198 Andrews, K: *Australian Controls on the Environmental Application of Biotechnology,* in *Environmental and Planning Law Journal,* Vol 5 1988 p 202

199 ibid.

200 Barker, M: op cit., pp 48, 49

201 Dekker, B: *Release of genetically modified organisms*: Exhibit 52 p 13

202 Barker, M: op cit., p 48

203 ibid., pp 49, 50

State and Territory sewerage legislation are also sufficiently broad to cover the discharge of recombinant materials.[204]

5.239 In most States, air pollution legislation controls the discharge of material into the air. However sanctions may be absent, for example, the *Clean Air Act 1963-1978* (Queensland) "does not specifically make it an offence to pollute air. Instead, a number of its provisions are designed to control pollution."[205]

5.240 The *Clean Air Act 1961* in New South Wales also has no specific air pollution offence. "Instead, the level of air pollution is controlled through a system of licences and notices. The occupier of scheduled premises must be licensed."[206] "The requirements of this Act could control the release of aerosols or spore clouds from premises and could be used to prevent the escape of micro-organism GMOs in this way."[207] Nevertheless, the level of penalties have been criticised for not reflecting the potential seriousness of a release of genetically modified organisms.[208]

5.241 In South Australia and Northern Territory there is no specific air pollution offence under the relevant legislation. Nonetheless, the *Health Act 1935-75* (South Australia) and the *Public Health Act* (Northern Territory) respectively enable air pollution to be controlled by regulation and thus offences may be created by regulation.[209]

5.242 The ability of such pollution legislation to effectively regulate biotechnology may be questioned. For example, the *Environment Protection Act 1970* (Victoria):

> "... allows the Authority to issue an abatement notice in the case of air pollution, or seek the imposition of a penalty in the case of water or soil pollution or upon the discharge of solid waste. The air pollution abatement notice does not take effect for thirty days. These sanctions are used primarily to halt further pollution of the environment, even though the legislation does have an educative and preventative function."[210]

5.243 Such legislation, by definition, must act after the event. Genetically modified organisms which escape accidentally may be capable of replication and, if they are micro-organisms, could be extremely difficult to eradicate.

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204 ibid., p 51

205 ibid., p 52

206 Dekker, B: *Release of genetically modified organisms*: Exhibit 52 p 9

207 The Cabinet Office, New South Wales: Submission 116, Appendix 1 p 2

208 Dekker, B: *Release of genetically modified organisms*: Exhibit 52 p 2; "The maximum penalty for not complying with these provisions is, in the case of a corporation, $40,000 (with a maximum daily penalty of $20,000 for continuing offences)".

209 Barker, M: op cit., pp 52, 53

210 Andrews, K: *Australian Controls on the Environmental Application of Biotechnology*, in *Environmental and Planning Law Journal*, Vol 5 1988 p 202

5.244 If recombinant DNA materials are accidentally released and harm flora and fauna, various criminal laws, prevention of cruelty to animals legislation, and wildlife protection Acts may be infringed.[211]

5.245 During evidence, however, the Queensland Department of Environment and Heritage complained that the State's "National Parks and Wildlife Service are faced with (the problem) of having no legislative control over colour morphs of wild type budgerigars. ... (These) have been released into the wild and can interbreed with the wild stock ... (which) could lead to the contamination of the genetic pool."[212]

5.246 In Western Australia the *Wildlife Conservation Act 1950* requires a licence to cover "importation to, or release in, WA of any animal out of its natural range". Major amendments are currently being drafted which will require a licence for, inter alia:

> "... the importation or release of ... [any] lifeform or genetic material capable of being reproduced or replicated in the wild which could in the opinion of the Minister for CALM [Conservation and Land Management] become or threaten to become injurious to naturally occurring native organisms."[213]

5.247 In addition, all States and Territories have legislation which enable the control of animals and plants which are declared to be 'pests'. Typically the legislation requires

> "... land occupiers and, ultimately, a government body or official to take measures to 'suppress', 'destroy', or eradicate pests. It is unusual, however, for these Acts to particularise appropriate control measures, although regulations made under the Acts often do. ... The Acts do not, even where regulations may sanction the use of a particular measure, put beyond doubt the legal immunity of official action. Even where some legal immunity is granted by statute, it will only be in respect of the 'reasonable exercise' of the statutory powers."[214]

5.248 It was to overcome this problem in respect to biological control measures that the *Biological Control Act 1984* and its mirror legislation was introduced.[215]

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211 Barker, M: op cit., p 54

212 Queensland Department of Environment and Heritage: Submission 73 pp 2, 3

213 Western Australian Government: Submission 145, Correspondence from the Minister for the Environment p 3

214 Barker, M: op cit., pp 79, 80

215 ibid., p 80

E.4 Common law remedies

5.249 In addition, "traditional common law remedies (trespass and nuisance in particular) may have some utility in the case of accidental discharge of recombinant DNA materials into the environment."[216]

5.250 "Trespass occurs whenever a person intentionally permits or causes interference with anothers property." Damages can only be recovered by the owner or occupier and no offence is committed if the interference was "involuntary or authorised by statute."[217]

5.251 Nuisance occurs when the use and enjoyment of land is infringed. There are two categories: private and public, and for the latter, the action has to be brought by someone "who has a 'special interest' in order to be granted standing". Again an adequate defence is the demonstration that the interference was involuntary or authorised by statute.[218]

5.252 A third avenue of redress is via the charge of negligence:

> "... the plaintiff must show that he was owed a duty of care, the duty was breached, that damage occurred as a result of the breach, that a causal nexus exists between the breach and the damage and that the damage was reasonably foreseeable. A defendants non-compliance with GMAC's Guidelines ... may suggest a breach of the relevant duty of care, however this is not certain."[219]

5.253 The rule has been qualified due to the *Rylands v Fletcher* case[220], since "... the use of the land from which the thing escapes must be 'non-natural'. (Is recombinant work non-natural?) Also, the rule will only apply if the escape occurs from the defendant's land (rendering it inoperative in most deliberate release programs). The rule does not apply where a person suffers loss on the defendants land as it cannot be said to have escaped."[221]

5.254 Nevertheless, "because recombinant DNA activities [are diverse] ... and an escape might not only be deliberate but accidental, it is not with any certainty that one could predict the outcome of the rule in *Rylands v. Fletcher* in this area."[222]

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216 ibid., p 54
217 Dekker, B: *Release of genetically modified organisms*: Exhibit 52 p 14
218 ibid., p 15
219 ibid.
220 *Rylands v Fletcher* (1868) LR 3HL 330
221 Dekker, B: *Release of genetically modified organisms*: Exhibit 52 p 15
222 Barker, M: op cit., p 90

5.255 If a plaintiff is seeking redress under common law there may be "difficulty in obtaining information about what occurred in the laboratory and the nature of the organism that escaped."[223] This may lead to use of the "old lawyer's adage about whom you sue being everybody"[224] so besides the institution, internal committees could be targeted. "That could lead to the situation that we sometimes hear about of ethics committees holding up research and projects for what are seen as pettifogging legal niceties."[225]

5.256 To overcome the difficulties of common law it has been suggested that:

> "To protect the people, their property and the environment adequately, legislation should be enacted to either impose strict liability on the GEO's producer (or agent) or reverse the onus of proof. ... If proponents ... oppose strict liability, it means that from the strict liability perspective GEOs pose an unacceptable risk to those who bear the liability. **In other words, it may indicate that they are not confident of the safety of GEOs in this context.**"[226]

5.257 Dr Philip Davies suggested that "whoever stands to gain the most from the release should bear the greatest burden of liability. It could possibly be a shared liability but you may consider that the population at large would bear some of it if it was going to benefit the population at large."[227]

5.258 Reversal of the onus of proof may be unrealistic: "it will be very difficult, in many instances, to conduct assessments which can unequivocally and conclusively demonstrate that the product is safe. There will have to be a balancing of risks and benefits in any assessment process that is developed".[228]

5.259 It may be that concern about insurance for possible environmental damage is unwarranted.

> "[Biotechnology research] is already covered ... we are liable for environmental damage, for third party liability and everything else, in the way every other company is and we have insurance.
> **Question:** How do we know all your competitors have that? I suppose they take the risk if they do not.

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223 VLRC: Report No 26 p 22

224 Andrews, K, Acting Director, St Vincent's Bioethics Centre, St Vincent's Hospital: Transcript p 497

225 ibid., pp 497, 498

226 Burch, Dr D et el.: Submission 106 p 49

227 Davies, Dr P, United Scientists for Environmental Responsibility and Protection: Transcript p 651

228 Fowler, R, University of Adelaide Biohazards Committee: Transcript p 584

Answer: Yes. The onus on directors these days is pretty horrendous. Personal onus, they would not sleep well - if they did not have it."[229]

E.5 Conclusion

5.260 Mr Kevin Andrews concluded:

> "The discussion about Australian environmental law suggests an inadequate system for the regulation of genetic engineering. The coverage of existing laws is limited and legislation varies from State to State. As micro-organisms know no boundaries, it is necessary to enact a more effective means to monitor advances."[230]

5.261 Mr Michael Barker, on the other hand, considered that for accidental releases of recombinant substances: "existing laws are adequate, or can be made so, to protect properly workers, the public and the environment".[231]

5.262 There is agreement concerning environment impact assessment laws that:

> "... existing environmental impact assessment laws do not have automatic application to such programs, and that most environmental quality laws are not designed to deal with such discharges. While some animal and plant legislation may enable limited control over production, they are not designed to ensure a full assessment of all the risks involved with a deliberate release program before it proceeds."[232]

5.263 Barker suggested three possibilities for improvement:

> "... to tighten existing environmental impact assessment laws so that all activities likely to significantly affect the environment are properly assessed.
> ... to issue special administrative directions under existing administrative style environmental impact assessment laws, requiring assessment of all deliberate release programs.
> ... to enact special legislation requiring all proposals for the release of recombinant organisms to be environmentally assessed."[233]

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229 Harrison, Dr D, Managing Director, Biotech Australia: Transcript pp 789, 790

230 Andrews, K: *Australian Controls on the Environmental Application of Biotechnology*, in *Environmental and Planning Law Journal*, vol 5, 1988 p 203

231 Barker, M: op cit., p 96

232 ibid.

233 ibid., pp 96, 97

5.264 The Victorian Law Reform Commission stated that:

> "The existing regulatory machinery will only be effective ... if every proposed experimental release of genetically altered organisms:
> . falls within the review responsibility of a regulatory agency ...;
> . must be notified in advance to that agency;
> . must be preceded by environmental impact assessment where appropriate;
> . may, in the case of experimental releases, be subjected to public scrutiny and participation;
> . may be stopped if correct procedures are not observed, or if something goes wrong."[234]

5.265 Mr Andrews expressed concern about the ability of common law to redress damage due to the escape of micro-organisms: "Reliance on common law remedies in this area may be misplaced because of difficulties in establishing a duty of care and a causal relationship of a genetically engineered micro-organism and damage".[235]

5.266 Notwithstanding the difficulties regarding common law, Mr Barker commented:

> "... recent history shows that the availability of common law actions to prevent the use of novel processes (for example the biological control of pests) may roughly be compared with the insertion of a large spanner in what are generally considered socially useful works."[236]

5.267 The Victorian Law Reform Commission added:

> "... the Commission is not convinced that recombinant DNA work presents unique risks that require the creation of a special right to compensation for injuries or property damage. Common law remedies are available and although their applicability ... is not entirely clear, that applies also to some remedies for other injuries. There is no justification for imposing statutory liability without proof of fault on the part of the institution. Nor is it necessary to require that institutions ... should take out special insurance."[237]

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234 VLRC: Report No 26 p 29; it is emphasised that this recommendation does not apply to modified organisms once they have reached the commercial stage.

235 Andrews, K: *Australian Controls on the Environmental Application of Biotechnology,* in *Environmental and Planning Law Journal,* vol 5, 1988 p 203

236 Barker, M: op cit., p 96

237 VLRC: Report No 26 pp 22, 23

F. ADEQUACY OF SUPERVISION AND ADHERENCE TO GUIDELINES

F.1 Adequacy of supervision: IBCs

5.268 The ACF expressed scepticism about the extent to which IBCs exercised daily control in practice, especially in large institutions with many projects. However, they believed IBCs could perform a worthwhile supervisory function with some safeguards.

5.269 The ACF recommended that:

. the appointment of IBCs should be made compulsory in all institutions carrying out GMO work

. IBCs should be registered with the Commonwealth Environment Protection Authority

. IBCs should be required to exercise genuine regular supervision and control

- unannounced visits to facilities should be encouraged

. they should have to report regularly on their activities including minutes of meetings, attendance records and records of on-the-spot inspections

. there should be legal protection for IBC members who advise the authorities of unacceptable practices

. IBCs should be required to conform with GMAC guidelines concerning membership

- there should be an ecologist and at least one genuinely independent member of the general public as members.[238]

5.270 Dr David Burch et al. also recommended that membership on IBCs of one or more ecologists should be compulsory. They further suggested that IBCs of different institutions have joint membership, or cross-membership to help overcome the problem of internal bias, or that there be an advisory IBC to review any other IBCs release proposals.[239]

5.271 Dr Burch et al. expressed concern about the lack of legal incentive for IBCs to detect all biohazards involved with a planned release. They suggested the establishment of a centralised data base "to which it is mandatory that IBCs provide data and check for data prior to a clearance".[240]

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238 Australian Conservation Foundation: Submission 140 p 29

239 Burch, Dr D et al.: Submission 106 p 51

240 ibid., p 52

5.272 GMAC guidelines require that the IBC should include in its membership: "at least one informed or interested external member from the wider community who need not have a technical background"[241]

5.273 The IBC Information Form produced by GMAC requires the organisation setting up an IBC to list the members of the IBC and "indicate how the composition of the IBC complies with clause 3.3.18 of the Small Scale Guidelines".[242]

5.274 Evidence was received that some organisations do not adhere to the GMAC guidelines concerning the composition of IBCs. Dr Philip Lehrbach of Arthur Webster Pty Ltd stated: "On the IBC we do not have an outside component at this stage, but we have a non-technical representative."[243]

5.275 Dr John Pemberton from the University of Queensland was asked whether the University's IBC had someone from outside the institution as a member. Dr Pemberton replied: "It does not appear to, from the list that I have here. ... There is a person from geology and minerology. I guess that they are probably as close as you can get to a lay person."[244]

Recommendation 24

5.276 **The Committee recommends that procedures be established to ensure that organisations conducting genetic manipulation work are made aware of their obligation to adhere to the GMAC guidelines concerning the composition of their IBCs. The form in which the composition of IBCs is conveyed to GMAC should enable GMAC to check that the guidelines have been followed. There should be a requirement for organisations conducting genetic manipulation work to convey to GMAC any changes in the composition of their IBCs and GMAC should have the responsibility of checking that such changes do not result in the guidelines being breached.**

241 GMAC: *Guidelines for Small Scale Genetic Manipulation Work*, December 1989 p 14

242 Section 8 of the Form

243 Lehrbach, Dr P, Genetic Research, Arthur Webster Pty Ltd: Transcript p 875

244 Pemberton, Dr J, Institutional BioSafety Committee, University of Queensland: Transcript p 974

Recommendation 25

5.277 The Committee further recommends that:
. the appointment of IBCs should be made compulsory in all institutions carrying out genetic manipulation work
. IBCs should be registered with GMAC
. IBCs should be legally required to exercise genuine regular supervision and control
. IBCs should be required to conduct unannounced inspections of facilities
. IBCs should have to report regularly on their activities including minutes of meetings, attendance records and records of on-the-spot inspections
. there should be legal protection for IBC members who advise the authorities of unacceptable practices
. there should also be indemnity insurance provided by the institutions for IBC members who act reasonably, in good faith and exercise due diligence in giving advice.
(The Committee draws attention to the complexity of these issues which will require close attention in the drafting of legislation and regulations.)

F.2 Adherence to guidelines

5.278 Dr David Murray, of the School of Biological Sciences at Sydney University, stated in his submission that:

> "... the containment procedures that should apply in laboratories handling recombinant DNA in Australian institutions are not being uniformly observed. Some firm procedures for licensing individuals and laboratories need to be set up and actually implemented."[245]

5.279 The institution to which Dr Murray was referring, Wollongong University,denied the allegations.

5.280 Dr Richard Cotton commented that people can become lax about stringent requirements, perhaps because they do not perceive a risk as existing. He also acknowledged that it was possible that people who worked in an organisation could act to protect the organisation if anything went wrong.[246]

5.281 Mrs Loane Skene from the VLRC commented when asked whether she was aware of breaches of the GMAC or animal welfare guidelines:

> "I took a tour of the Walter and Eliza Hall Institute and during the time that I was there I saw two breaches of the guidelines. ... this shows that

245 Murray, Dr D: Submission 11 p 1
246 Cotton, Dr R: Transcript pp 296, 297

> whatever guidelines you have, people are not always going to follow them. One of them involved work in a small laboratory that was enclosed, had reverse air conditioning so that everything was sucked back into the laboratory, white coats, gloves, having to put your hands into a container to work; so it was a high security laboratory. Two researchers were in there in their white coats doing all this and they had forgotten something that was to be brought in. There is a walkie-talkie system and they asked for whatever it was to be brought in, so somebody went in from outside in ordinary clothes. Another one involved somebody dropping a test tube with something in it and it was just wiped up and put into the ordinary garbage disposal.
>
> Whatever laws you have, people are not going to obey them just because they are there. These people all know what the safety guidelines require. So I think that a better way to deal with these sorts of problems - I am not saying that either of these posed any safety hazard; this is just something that I observed in this one laboratory - is to instruct them in procedures."[247]

5.282 **The Committee considers that there is a need for regular retraining of laboratory staff to ensure that they are aware of, and follow, the GMAC guidelines and proper laboratory practices. IBCs should made legally responsible for regular supervision of facilities to ensure that staff are following the GMAC guidelines concerning their work.**

5.283 There were repeated references made in evidence to certain alleged examples of guidelines not being adhered to, or circumvented, in Australia and overseas. Some of these are examined as case studies below.

F.2.(i) The case of NoGall[248]

Overview

5.284 The NoGall strain K1026 was registered by the NSW Department of Agriculture on 9 December 1988 for use as a pesticide, and sales commenced in January 1989. The product is a genetically modified bacterium used to combat crown gall disease in stone fruit trees and roses.

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247 Skene, L, VLRC: Transcript p 238

248 In April 1990 the inaugural Australia Prize for achievement in a selected area of science and technology promoting human welfare was presented to Prof Allen Kerr, Prof Jeff Schell and Prof Eugene Nester for work on the crown gall bacterium *Agrobacterium tumefaciens*. It was this work which led to the production of the product, NoGall.

5.285 NoGall is applied in the form of a suspension in water into which is dipped seeds, cuttings or the roots of young plants. The bacterium has been patented and production and distribution rights are held by Bio-Care Technology, NSW.

5.286 It has been stated that:

> "[The release] went ahead without any field trials in that State, without an EIA [environmental impact assessment] and without the Department seeking any toxicological or safety data. ... Comprehensive data on the behaviour of NoGall in soil, and with other soil-dwelling organisms and plants, is needed for a full assessment of its release to the environment."[249]

5.287 Dr David Burch et al. added: "There is reason to suggest that either the NSW Department of Agriculture did not read the GMAC assessment, or that GMAC provided their assessment retrospectively."[250]

5.288 The NoGall strain K1026 was derived from a naturally occurring bacterium: *Agrobacterium radiobacter* var. *radiobacter* strain K84, originally isolated from an Adelaide Hills plant nursery. The original bacterium had been used world wide to control the disease-causing bacterium *Agrobacterium radiobacter* var. *tumefaciens*. Control was effected through the production of an antibiotic which only affected the disease organism.

5.289 Unfortunately,

> "... it was found that this ability to produce the antibiotic was being transferred from the control organism to the pathogen; as a result the pathogen started to produce the antibiotic and was also immune to the antibiotic. ... we found the mechanism of (the) spread of the gene controlling antibiotic production and we cut out the genes concerned with the spread."[251]

5.290 The unmodified parent strain, K84, had been registered in 1976 as a pesticide and has been in use since then. This strain had received exemption from the poison scheduling provisions of the Drugs and Poison Schedule Committee of the NH&MRC (DPSC), as well as exemption from the maximum residue limit provisions of the Pesticides and Agricultural Chemicals Committee of the NH&MRC (PACC).[252]

5.291 The application for federal clearance of strain K1026 experienced substantial delays.

> "Registration by the Federal Government was applied for in September 1988 but has not yet been granted. It is hoped that future applications will

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249 Phelps, R, Australian Conservation Foundation: Submission 140 p 70

250 Dr Burch et al.: Submission 106 p 14

251 Kerr, Prof A: Transcript p 563

252 Bio-Care Technology Pty Ltd: Correspondence to the Secretariat, 11 September 1991 p 2

be expedited. Otherwise, the prospect for the commercialization of genetically engineered organisms in Australia is poor."[253]

5.292 Five criticisms have thus been made concerning the NoGall case:
1) the release proceeded without field trials in NSW;
2) the release proceeded without an environmental impact assessment, EIA;
3) the NSW Department failed to seek toxicological or safety data;
4) the NSW Department did not read GMAC's assessment or GMAC's assessment was provided after the event;
5) there were inordinate delays in obtaining Federal clearance.

The application for NoGall registration in NSW

5.293 In the development of strain K1026, the University of Adelaide researchers designed an experiment to determine the effectiveness of the new strain when applied to almond seedlings growing in large pots. They felt that the work fell into the exempt category under the RDMC guidelines. However, they were informed by RDMC that no exemptions would apply to release experiments.[254] Accordingly, the pot trials were conducted following advice from RDMC, and a report was submitted to GMAC on 18 March 1988.

5.294 The trials, which were conducted at the Waite Agricultural Institute SA, demonstrated that the new strain controlled crown gall as effectively as the existing NoGall agent.[255] There were, however, no field trials of K1026 in NSW prior to its registration in December 1988.

5.295 When the application was made on 1 June 1988 to the NSW Department of Agriculture for registration of the modified strain K1026, it was made on the basis that K1026 was a pesticide. "I understand the definition of an agricultural and veterinary chemical includes an organism if it has an effect on a plant pest. That is why it was covered".[256]

5.296 Bio-Care Technology, the company marketing NoGall, had also stated that it wished "to substitute the strain K1026 of the same bacterium in the same proportion in the same peat carrier [as the already registered K84 strain]."[257]

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253 Waite Agricultural Research Institute, University of Adelaide: Submission 26 p 4

254 Correspondence supplied to the Secretariat by Kerr, Prof A, University of Adelaide, 4 September 1991

255 GMAC: Correspondence to the Secretariat, 12 September 1991

256 Ireland, R, Department of the Arts, Sport, the Environment, Tourism and Territories: Transcript p 1112

257 Letter from Bullard, G, Managing Director, Bio-Care Technology to Baker, H, Registrar of Pesticides, NSW Department of Agriculture, dated 1 June 1988

5.297 Consequently, an environmental evaluation was not conducted because: "It is usual practice not to require environmental data on pesticides which are the same as, or very similar to, products which are already registered."[258]

5.298 The company had discussed the application "several months" previously with the NSW Registrar of Pesticides who had "indicated that it would be possible to substitute this new variation of the active ingredient." It was not clear, however, from the covering letter that strain K1026 was a genetically modified organism. It was referred to as "a mutant strain", "the more modern K1026 strain", and having been "isolated by Professor Alan [sic] Kerr".[259]

5.299 Nevertheless, the covering letter also referred to two papers describing Professor Kerr's work which accompanied the application. From the titles of these papers it is clear that strain K1026 was a genetically modified organism.[260]

5.300 The prior registration of strain K84 could have confused the registration for the new K1026 strain, since a simple strain substitution would not have required reassessment. The use of a new genetically modified organism, however, should have prompted the registration authorities to undertake a full re-evaluation.

5.301 On 9 December 1988 the new NoGall strain K1026 was registered in NSW "On the basis of advice from the manufacturer that it was only a minor strain variation".[261] It was described as "an image of an existing product".[262] Neither toxicological nor safety data was sought, presumably because the unmodified K84 strain had received exemption from the NH&MRC poison scheduling and maximum residue limits.[263]

5.302 Neither the NSW Department of Agriculture nor Bio-Care Technology applied to RDMC or its successor, GMAC, for advice. At that time RDMC was in the process of being replaced by GMAC (members were appointed in August 1988[264]), but there should still have been an assessment process.

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258 Byrnes, C, Technical and Policy Division, NSW Department of Agriculture and Fisheries: Correspondence to the Secretariat, 18 September 1991

259 Letter from Bullard, G, Managing Director, Bio-Care Technology to Baker, H, Registrar of Pesticides, NSW Department of Agriculture, dated 1 June 1988

260 The titles were: Jones, D and Kerr, A: *The efficacy of Agrobacterium radiobacter strain K1026, a genetically-engineered derivative of strain K84, in the biological control of crown gall*; and Jones, D A et al.: *Construction of a Tra⁻ deletion mutant of pAgK84 to safeguard the biological control of crown gall.*

261 Toffolon, R, Registrar of Pesticides, NSW Department of Agriculture and Fisheries: Correspondence to the Secretariat, 12 September 1991

262 Hooper, G, Director, Agriculture and Veterinary Chemicals Unit, DPIE: Correspondence to the Secretariat, 11 September 1991, describing the basis upon which approval for strain K1026 was granted by NSW Department of Agriculture and Fisheries.

263 Bio-Care Technology Pty Ltd: Correspondence to the Secretariat, 11 September 1991

264 GMAC: *Report for the period 22 August 1988 to 30 June 1989*, p 3

Application for federal clearance

5.303 In 1988 federal clearance had to be sought from the Technical Committee on Agricultural Chemicals (TCAC) of the Department of Primary Industries and Energy. Application to the Drugs and Poison Schedule Committee (DPSC) and the Pesticides and Agricultural Chemicals Committee (PACC) - both part of the NH&MRC - was needed concerning poison scheduling and maximum residue limits.

5.304 On 1 July 1989 the *Commonwealth Agricultural and Veterinary Chemicals Act* changed the clearance procedure making the Commonwealth Government responsible for approving new pesticides both federally and in any State. Under the procedures laid down by the Act, an application is pre-screened by the secretariats of both the Australian Agricultural & Veterinary Chemicals Council (AAVCC) and the NH&MRC, and officers from the Agriculture and Veterinary Chemicals Section of the Commonwealth Department of Primary Industries and Energy. Pesticide applications are sent to the AAVCC's technical advisory committee, the Agricultural Chemicals Advisory Committee (ACAC), which co-ordinates the subsequent evaluation process.[265]

5.305 On 15 September 1988 Bio-Care Technology sought federal clearance of NoGall strain K1026 from the TCAC and requested exemption from poison scheduling and maximum residue limit requirements from the DPSC and the PACC. The submission was subsequently circulated to TCAC members on 30 September 1988.

5.306 As part of the assessment procedure, GMAC assessed NoGall strain K1026 because it was a modified organism. GMAC received information from TCAC on 17 April 1989 and, after assessment by the Scientific and the Planned Release Subcommittees, advised the TCAC that "the strain ... (was) no hazard to the user, the community, or to the environment" on 13 June 1989.[266]

5.307 As of 1 August 1989 the ACAC (now co-ordinating the assessment of the application) was still awaiting replies from the DPSC, the PACC and the Australian Environmental Council who are amongst its members. Eventually exemption from maximum residue limits requirements was granted on 11 September 1989 and from poison scheduling on 13 March 1990.[267] "Agreement to Clearance from all members of ACAC was achieved in August 1990 and a final draft clearance was circulated ... on 9 January 1991. Subsequently the final Clearance was prepared and circulated ... [to AAVCC] on 21 August 1991."[268]

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265 Australian Agricultural & Veterinary Chemicals Council: *Annual Report 1989-90* p 6

266 GMAC: Correspondence to the Secretariat, 12 August 1991 p 7, and 12 September 1991 p 2

267 Bio-Care Technology: Correspondence to the Secretariat, 11 September 1991

268 Hooper, G, Director, Agriculture and Veterinary Chemicals Unit: Correspondence to the Secretariat, 11 September 1991

5.308 Meanwhile, based on the Agreement to Clearance and the final draft clearance, NoGall strain K1026 had been registered in Western Australia, South Australia, Tasmania and Victoria between 12 December 1990 and 9 September 1991.[269]

5.309 Finally, almost three years to the day, formal federal clearance was granted on 13 September 1991, enabling Bio-Care to begin processes to export NoGall. The company pointed out that several countries had requested the Australian Clearance Document before product trials could be permitted.[270]

Conclusions

5.310 All the scientific evidence indicates that NoGall strain K1026 is safe. The naturally occurring parent strain had been in use for over 10 years without adverse effects. The modification involved the deletion of a gene and GMAC only took two months to provide advice that the release of NoGall K1026 was safe. There is no evidence of duplicity concerning GMAC's advice as implied in paragraph 5.287.

5.311 There appears to be an anomaly regarding clearance for biological control agents. Some may be assessed as pesticides employing procedures and criteria used for chemicals which may be inappropriate for living organisms.

5.312 The NSW Department of Agriculture should have been aware of the need to refer a clearance application for a genetically modified organism to RDMC or its successor GMAC. Bio-Care Technology could have been more explicit about the fact that strain K1026 was genetically modified. The company should have been aware of the GMAC Guidelines for release of genetically modified organisms following Professor Kerr's experience with the pot trials conducted during the development phase.

5.313 The GMAC guidelines are voluntary for company operations, so there was no legal obligation for Bio-Care Technology to state the nature of strain K1026 in its application or contact RDMC. However, the incident calls into question the value of voluntary guidelines when they are faced with 'the commercial imperative'.

5.314 The three years it took to achieve the granting of federal clearance is grossly excessive. The unmodified strain of NoGall was exempt from maximum residue limit and poison scheduling provisions yet it took almost a year and over seventeen months respectively to obtain similar exemptions for the modified strain. Once there was Agreement to Clearance from all members of the ACAC a further year elapsed before the final clearance document was produced.

5.315 The current system for clearance of pesticides is 'a one-stop-shop' system which, it has been suggested, is desirable to achieve efficiency. In the history of

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269 ibid.

270 Bio-Care Technology: Correspondence to the Secretariat, 13 September 1991

NoGall, however, this has been far from the case. The bureaucratic delays experienced by Bio-Care Technology, if typical, are not conducive to the development of the genetic modification technology in Australia.

F.2.(ii) Rabies vaccine in Argentina - when regulations are absent

5.316 In 1986 an agreement was reached between the Wistar Institute (Philadelphia, USA) and the Pan American Health Organization (PAHO) to conduct an experiment designed to test a genetically modified rabies vaccine in cattle at an experimental farm operated by the Pan American Zoonoses Centre (CEPANZO) in Argentina. In September 1986 Argentina's sanitary authorities closed the experiment down and destroyed and disposed of the animals which were involved. The allegation has been made that the experiment was undertaken without the permission or knowledge of the Argentine authorities or scientific community.

5.317 A paper was presented at an international conference on the release of genetically-engineered micro-organisms in Wales in April 1988 which contained a number of allegations about the experiment.[271] The paper was presented on behalf of Sr. Jose L La Torre of Serrano, Argentina's Animal Virology Centre. The allegations made may be summarised as follows:

> . Argentina's import laws were circumvented as well as laws against the introduction of exotic micro-organisms:
>
> > "The Custom Office's franchises and the diplomatic status enjoyed by PAHO staff, under the UN-Argentina agreement on technical cooperation was apparently used for the introduction into the country of the recombinant virus"[272]
>
> . Argentinians were not involved in the planning of the experiment, and workers were not informed about the risks or possible consequences of the experiment
> . the caretakers of the animals involved were not vaccinated against smallpox immediately before the experiment (it was assumed they had already been vaccinated because they had scars consistent with vaccination)
> . the caretakers were not under medical supervision during the experiment
> . the unpasteurised milk from the vaccinated cattle was allowed to be consumed by the caretakers and their families with the excess being sent to the local market for sale after pasteurisation
> . one of the four caretakers involved developed antibodies to rabies
> . there were no warning signs placed near the experimental area, indicating an ignorance of the risks or, possibly, an intent to maintain secrecy

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271 Unless indicated otherwise, the information is taken from La Torre, J in *The Release of Genetically-engineered Micro-organisms, Proceedings of the First International Conference on the Release of Genetically Engineered Microorganisms, Cardiff, UK, 1988*, Ed. Sussman, M et al., Academic Press pp 253-263

272 ibid. p 257

. there were no satisfactory animal models available for assessing the virulence of recombinant vaccinia viruses or their efficacy as a vaccine
. it was uncertain whether genetically modifying the vaccinia virus would alter the range of organisms in which it could survive and reproduce, or its effect on tissues.
. little was known of the ecology of that group of viruses and whether they could become established in nature or undergo recombination with related viruses.

5.318 A spokesperson for the Pan American Health Organisation, Mr David Epstein, has been quoted as saying: "The experiment presented no risks to the people in Argentina. ... It was just part of an ongoing project."[273] A biologist at the United States National Science Foundation has also been quoted as saying that "he believes Argentina asked the PAHO to test the vaccine, and that the PAHO's agreement with Argentina does not require permission for each experiment."[274]

5.319 The scientific veracity of the tests, which claimed to show the presence of antibodies in cows in contact with the inoculated animals and in one of the caretakers, was questioned by researchers from the Wistar Institute.

> "'According to the data we know, 30 days after the test was begun, the [inoculated] animals developed antibodies ... but the controls and handlers did not,' says veterinarian Charles Ruprecht of Wistar. ... Secondary transmission ... remains 'very difficult to achieve' even among animals kept in close contact in the lab, he says. Such inconsistencies 'cast doubt on the veracity of the Argentine allegations,' another Wistar official notes."[275]

Conclusions

5.320 An experiment of the kind described would not be permitted in Australia without a thorough prior risk analysis and stringent monitoring of both the environment and workers involved. If the allegations about a deliberate circumventing of the Argentine customs laws and laws about the introduction of exotic micro-organisms are correct then the incident is a matter of serious concern. The Committee is not aware of any investigation of the allegations by the Argentine or United States authorities. In the absence of such an investigation then it remains a matter of the credibility of the protagonists.

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273 Joyce, C: *US exports genetic experiments*, in *New Scientist*, 20 November 1986 p 15
274 ibid.
275 Fox, J: *A controversial test case*, in *Bio/technology*, Vol 6 July 1988 p 762

F.2.(iii) The Adelaide pigs

5.321 The case of the genetically modified pigs which were sent to the abattoir in Adelaide has received considerable publicity. The pigs were the product of a research program into transgenesis and growth factors involving researchers from Adelaide University, Metrotec Pty Ltd and Bresatec Pty Ltd. Metrotec is partly owned by Bresatec which is a manufacturing company connected to the Biochemistry Department in Adelaide University. The South Australian Department of Agriculture partly collaborated in the program.

5.322 Press reports first appeared in late April/early May 1990 alleging an unauthorised release of genetically modified pigs. As a result GMAC conducted an inquiry into the matter.

5.323 The GMAC report found that the guidelines were breached by the principal investigators when they failed to inform the Adelaide University Biohazards Committee (AUBC) of their intention to move the genetically modified pigs from a contained to an uncontained site. GMAC found, however, that the pigs were securely transported to the abattoirs in accordance with the RDMC principles.

5.324 The report found that the AUBC's monitoring of the project had been inadequate and that communication between the AUBC, the researchers and the commercial interests was poor. GMAC considered, however, that those responsible had acted in good faith, believing that all the necessary government clearances had been obtained. The report stated:

> "The pigs were cleared for human consumption by the National Health and Medical Research Council's Food Science and Technology subcommittee, and were only slaughtered and sold after this clearance had been obtained. Advice was sought from the SA Health Commission and State Minister for Health by Metrotec."[276]

5.325 Among other things, GMAC recommended that the University of Adelaide review the operations of its biosafety committee and that consideration be given to establishing an additional biosafety committee to supervise the work of Metrotec and the South Australian Department of Agriculture.

5.326 The Minister for Administrative Services received GMAC's report and commented in the Senate on 15 October 1990:

> "In view of GMAC's findings, I have considered the report and have decided not to seek withdrawal of Commonwealth funding for this particular project. I also assure Senator Crowley and others who are interested in this area that all steps have been taken to ensure that the parties involved fully understand their responsibilities to undertake

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276 GMAC: *Transgenic Pigs GMAC Inquiry Report*, attachment to Exhibit 111 pp 1 & 2

> procedures under the guidelines and all have given written undertakings to abide by the guidelines in the future."[277]

5.327 The GMAC report indicated that the unauthorised transport of the pigs to the abattoir was not the only breach of the guidelines which occurred in the history of the program. Advice was sought from the RDMC in January 1986 concerning the proposal. Press reports in 1985, however, indicated that the project had already commenced. "This was subsequently confirmed by the AUBC, who reminded the researchers of their obligations under the Guidelines".[278]

5.328 The researchers proceeded to larger scale work and to transporting some pigs to the abattoir without consulting GMAC. The GMAC secretariat became aware of plans to build a larger scale piggery and asked in September 1989 for a proposal for large scale contained work or a proposal for planned release.

> "A copy of this correspondence was sent to the AUBC. No response was received from Metrotec.
> In late February 1990, the GMAC Secretariat learnt from a telephone call from the AUBC Secretary that Dr Barry Lloyd, a Director of Metrotec, had stated at the last AUBC meeting that transgenic pigs had been killed at an abattoir. The GMAC Secretariat informed the GMAC Chairman and briefed the Minister. The Chairman wrote to the AUBC requesting that the AUBC investigate the matter, instruct the firm to cease transporting the transgenic pigs, and submit a planned release proposal. As far as GMAC was aware, no action on those matters was taken by the AUBC until the time of the GMAC inquiry [May 1990]."[279]

5.329 The comments in the GMAC report concerning the supervisory behaviour of the AUBC are quite serious. "Metrotec's obvious contemplation [before 1990] of sale of the pig meat did not elicit any communication from the AUBC to GMAC."[280]

5.330 Communication difficulties seemed to have been caused by a number of factors and persisted because of failings in a number of parties.

> "In spite of the fact that specific recommendations were made [by the RDMC] to improve communications, both formal and informal, between researchers and the AUBC as far back as 1986, communications have clearly not improved. This inquiry identifies these factors as contributing to the situation:
>
> . the lack of genuine monitoring which involves being pro-active and asking questions;

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277 Bolkus, Sen N, Minister for Administrative Services: Senate Hansard 15 October 1990 p 3007
278 GMAC: *Transgenic Pigs GMAC Inquiry Report*, attachment to Exhibit 111 p 5
279 ibid. p 6
280 ibid. p 7

> . concern by the commercial partner that the project's confidential nature might not be respected;
> . a failure on the part of the project leaders to keep the AUBC fully informed of progress with the project and their future plans."[281]

5.331 Transport of transgenic pigs for slaughter took place on more than one occasion. The South Australian Department of Agriculture was involved in some of these removals and its biosafety and ethics committees apparently was consulted. The Department seemed to be unaware of any need to contact the AUBC or GMAC. The two principal researchers, Dr Robert Seamark and Dr Julian Wells from Adelaide University

> "... were aware of their responsibilities with respect to the GMAC Guidelines, as these had been pointed out to them on a previous occasion. [However] Dr Seamark was unaware of the fact that the Agriculture Department's biosafety committee is not registered with GMAC."[282]

5.332 The report by GMAC stated that Metrotec had obtained clearance from the NH&MRC Food Science and Technology Sub-Committee (FST) and the South Australian Health Commission for the sale of the pigs for human consumption.[283] The approval by the South Australian Health Commission was on the basis of the clearance provided by the FST. The FST gave in principle approval for human consumption of meat from genetically modified pigs subject to several conditions, one of which was that "the added genetic material was derived entirely from pig tissue". "In the event that any of the ... criteria are not able to be met, the issue will require further consideration by FST."[284]

5.333 Dr Wells stated in evidence: "The control sequence which we used to control the activity of that gene [the growth hormone gene]... originally came from the human chromosomal material."[285]

5.334 The Department of Community Services and Health commented that:

> "... FST set the criteria for acceptance of the meat and the onus was on the producer to comply. There is no reference in the minutes of FST that the promoter was derived from human genetic material. It was made quite clear by FST that the pigs should be derived entirely from pigs. No record of a representation by Metrotec to use the promoter mentioned is available. If it had been it would certainly have been discussed by FST."[286]

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281 ibid.
282 ibid. p 8
283 ibid. p 2
284 ibid. p 9
285 Wells, Dr J, Bresatec/Metrotec: Transcript p 595
286 Department of Community Services and Health: Submission 117.1 p 2

5.335 Dr Wells argued that the origin of the genetic switch is irrelevant "because it never forms a product, there is nothing that will go into the meat that is of human origin in that sense"[287] and that if one wanted to be ultra-pedantic all the genetic material used was in fact produced by bacteria as part of normal genetic manipulation procedures.

5.336 The question is whether genetic material, isolated from a human cell culture, multiplied initially by bacteria and subsequently by pig cells during cell division as the animal develops from an embryo, is 'non-porcine material'. The issue may not have great significance, given that the promoter sequence does not produce any substance found in the meat or the growth hormone and the genetic material involved is made up of chemical components present in all organisms.

Conclusion

5.337 The Adelaide pig release demonstrates the importance of proper supervision of projects by IBCs, the need for more effort in making researchers and Government Departments at both State and Federal level aware of the guidelines, and for the means to ensure compliance with those guidelines.

5.338 The proper procedures were not followed on a number of occasions. Work apparently commenced in 1985 without approval under the guidelines; the experiment was increased in scale, and transport to the abattoirs occurred, without prior reference to GMAC; and consultation with the NH&MRC Food Science and Technology Sub-Committee was not as complete as it should have been.

5.339 **The Committee considers that the use of a promoter sequence derived from human chromosomal material should have been brought to the attention of the FST by Metrotec.This example reinforces the need for legislation to ensure proper behaviour or to allocate responsibility.**

287 Wells, Dr J, Bresatec/Metrotec: Transcript p 596