Genetic manipulation : the threat or the glory? report / of the House of Representatives Standing Committee on Industry, Science and Technology.

The Parliament of the Commonwealth
of Australia

GENETIC MANIPULATION:

THE THREAT OR THE GLORY?

Report by the House of Representatives
Standing Committee on Industry,
Science and Technology

February 1992

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PREFACE

The House of Representatives Standing Committee on Industry, Science and Technology is one of eight general purpose standing committees established pursuant to sessional orders of the House on 8 May 1990. Each of the general purpose standing committees corresponds in its areas of interest with a Federal Government department or group of departments. In the case of the Industry, Science and Technology Committee those departments are: Industry, Technology and Commerce; Primary Industries and Energy; and Industrial Relations.

The resolution of appointment of the Committee empowers it to inquire into and report on any matters referred to it by either the House or a Minister, including any pre-legislation proposal, bill, motion, petition, vote or expenditure, other financial matter, report or paper. On 4 September 1991, the resolution of appointment was amended so that annual reports of government departments and statutory authorities stand referred automatically to the relevant Committee for any inquiry the Committee wishes to make.

On 12 June 1990, the Minister for Industry, Technology and Commerce wrote to the Committee proposing terms of reference for an inquiry into the development, use and release into the environment of genetically modified organisms. The terms of reference were subsequently amended on 3 July 1990 and are set out immediately following the *Table of Contents*.

The Committee received 167 submissions and 129 exhibits in the course of the inquiry. Over 1200 additional pages of evidence resulted from public hearings in Adelaide, Brisbane, Canberra, Melbourne and Sydney. On behalf of the Committee I wish to thank all those who gave their time and effort to contribute to the inquiry.

The Australian Conservation Foundation and the Law Reform Commission of Victoria allowed the Committee secretariat full access to their files on genetic manipulation. The CSIRO conducted Committee Members through research facilities in the ACT and gave a comprehensive briefing on the genetic manipulation work it is undertaking. The co-operation of those bodies is greatly appreciated. Dr Merilyn Sleigh of the CSIRO also greatly assisted the Committee by reading the draft report and checking on technical accuracy.

The inquiry into the development, use and release into the environment of genetically modified organisms has raised issues which are extremely broad in scope and complex in detail. Fundamental philosophical and ethical questions have had to be considered as well as possible environmental impacts, effects on human health, and legal issues such as patent rights, compensation for injury or property damage, and clearance and registration procedures for the sale of a wide range of products.

The development of biotechnology, of which genetic manipulation techniques are a part, promises to generate a revolution in industrial techniques. Nations around the world are grappling with the legal and institutional changes which will be required to cope with the new technology. I hope this report will contribute to the public debate on the important issues and help to provide some of the solutions.

MICHAEL J LEE, MP
Chairman
February 1992

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TERMS OF REFERENCE OF THE INQUIRY

On 12 June 1990, the Minister for Industry, Technology and Commerce wrote to the Committee proposing terms of reference for an inquiry into the development, use and release into the environment of genetically modified organisms. The terms of reference were amended on 3 July 1990. The amended terms of reference are as follows:

> Taking into account the existing and potential benefits to Australia of work involving the development, use and release of plants, animals and micro-organisms which have been modified by the new genetic manipulation techniques, and the existing guidelines and framework of regulations, and
>
> recognising the public concerns, including environmental, human and animal health and welfare that exist in relation to the release of such organisms and the need to raise the level of public understanding of the issues involved, and
>
> taking into consideration the evidence presented to, and recommendations of, the Victorian Law Reform Commission in its inquiry into genetic manipulation
>
> that the Committee
>
> > . identify and report on any national issues unique to the contained development and use of genetically manipulated organisms and their release into the environment; and
> >
> > . inquire into and report upon the adequacy of the current arrangements, and advise on future desirable legislative frameworks for the regulation of the contained development and use of genetically manipulated organisms, and their release into the environment, including imported material.

MEMBERSHIP OF THE COMMITTEE

Chairman:	Mr M J Lee MP
Deputy Chairman:	Mr F S McArthur MP
Members:	Mr G Campbell MP Mr M R Cobb MP Mr L D Ferguson MP Mr F A Ford MP Mr E L Grace MP Mr H A Jenkins MP Hon B O Jones MP Mr P E Nugent MP Hon N B Reid MP Mr L J Scott MP
Secretary:	Mr P McMahon
Research Officer:	Dr J Carter

Other staff who assisted the Committee in the course of the inquiry:

Ms M Bellgard
Ms D Denahy
Ms H Fyfe
Ms G Gould
Ms K Newton
Ms J Stuart

ACRONYMS/ABBREVIATIONS

AAC	Australian Agricultural Council
AAVCC	Australian Agricultural and Veterinary Chemicals Council
ACA	Australian Consumers' Association
ACF	Australian Conservation Foundation
ACNFP	Advisory Committee on Novel Foods and Processes
ACRE	Advisory Committee on Releases to the Environment (UK)
ACTU	Australian Council of Trade Unions
AEEC	Animal Experimentation Ethics Committee
AIRDIS	Australian Industrial Research and Development Incentives Scheme
AMLRDC	Australian Meat and Livestock Research and Development Corporation
ANZEC	Australian and New Zealand Environment Council
ANZFAS	Australian and New Zealand Federation of Animal Societies
AQIS	Australian Quarantine and Inspection Service
ARCBA	Australian Registered Cattle Breeders' Association
ASCORD	Academy of Science Committee on Recombinant DNA
AUBC	Adelaide University Biohazards Committee
CEPA	Commonwealth Environment Protection Authority
CEPANZO	Pan American Zoonoses Centre
CSIRO	Commonwealth Scientific and Industrial Research Organisation
DASETT	Department of the Arts, Sport, the Environment, Tourism and Territories
DITAC	Department of Industry, Technology and Commerce
DPIE	Department of Primary Industries and Energy
EPA	Environment Protection Authority
EPO	European Patent Office
FAC	Food Advisory Committee
FDA	Food and Drug Authority
FST	Food Science & Technology Subcommittee
GENHAZ	A system proposed by the UK Royal Commission on Environmental Pollution for appraising the possible hazards from releasing genetically modified organisms
GILSP	Good Industrial Large Scale Practice
GIRD	Grants for Industry Research and Development
GMAC	Genetic Manipulation Advisory Committee
GMO	Genetically modified organism
IBC	Institutional Biosafety Committee
NCCAW	National Consultative Committee on Animal Welfare
NFSC	National Foods Standards Council
NH&MRC	National Health and Medical Research Council
NIH	National Institutes of Health (USA)
NOHSC	National Occupational Health and Safety Commission
OECD	Organisation for Economic Cooperation and Development
PAHO	Pan American Health Organisation

RDMC	Recombinant DNA Monitoring Committee
TGA	Therapeutic Goods Administration
VLRC	Victorian Law Reform Commission/Law Reform Commission of Victoria

SUMMARY

1. This report consists of eight chapters. The first three are largely descriptive. Chapters 4 to 7 inclusive cover the philosophical/ethical/social, environmental, human health and legal issues raised in the course of the inquiry. Chapter 8 contains the Committee's recommendations for the kind of regulatory structure under which it believes the use of genetic manipulation techniques should be allowed to proceed.

2. The Committee has made 48 recommendations and these are listed after this summary in the order in which they appear in the report.

Background information

3. In Chapter 1 some background information is given about cell biology and genetic manipulation. A brief background history is presented concerning the growth in knowledge of genetics, genetic manipulation, and the development of regulations controlling the use of genetic manipulation techniques. A description is given of the Genetic Manipulation Advisory Committee (GMAC), its function and its membership. GMAC oversees the safe development of genetic manipulation techniques in Australia and the development of guidelines for such work.

4. The Committee has not considered it necessary for the purposes of this report to exhaustively define the techniques which are involved in genetic manipulation, although this may be necessary in regulations under any legislation which results. Any listing of the techniques which constitute genetic manipulation will need to be kept under review. This is very much a developing area and the need for flexibility in describing the techniques is essential.

5. In interpreting its terms of reference, the Committee decided not to consider the issue of making deliberate heritable changes to the genes of human beings but to recommend that this be examined in a separate inquiry (see recommendations 1 & 2).

Existing system of regulation

6. Chapter 2 of the report outlines the contents of the four existing sets of guidelines which are relevant to genetic manipulation technology. These are the three produced by GMAC or its predecessor, the Recombinant DNA Monitoring Committee (RDMC)

. *Guidelines for Small Scale Genetic Manipulation Work*
. *Guidelines for Large Scale Work with Recombinant DNA*
. *Procedures for Assessment of the Planned Release of Recombinant DNA Organisms*

and the fourth set of guidelines

. *the Australian code of practice for the care and use of animals for scientific purposes*

produced by a joint working party of the National Health and Medical Research Council (NH&MRC), the Commonwealth Scientific and Industrial Research Organisation (CSIRO) and the Australian Agricultural Council (AAC), together with representatives from various States.

7. The kinds of facilities required under the guidelines, the processes for gaining approval, the role of institutional biosafety committees, and the sanctions (such as they are) for breaches of the guidelines are described in Chapter 2.

8. The Committee considers that the guidelines are quite adequate for a voluntary code and are comprehensive in their coverage. The Committee's principal concern is that the guidelines at present have no legal force. Recommendations 3, 35 and 36 call for legal force to be given to the four sets of guidelines. The preferred option would be for the guidelines to be expressed in regulations under an Act of Parliament. This would allow for greater ease of amendment to keep up to date with changes in technology and experience. A wide range of sanctions should be available to act as a deterrent to breaches of the guidelines (recommendation 37).

Existing and potential benefits

9. Chapter 3 contains a fairly comprehensive description of the benefits which the new genetic manipulation techniques may be able to provide. A number of those who made submissions to the inquiry queried whether the techniques would produce these benefits and claimed that, on the contrary, there could be a number of deleterious effects.

10. The Committee believes that the possible economic, environmental and health benefits from applying genetic manipulation techniques are worth pursuing. Not all of the claimed benefits will materialise. Some applications of the techniques will have risks attached which may outweigh the benefits.

Philosophical/ethical/social issues

11. Chapter 4 contains an examination of the objections made to the use of genetic manipulation on philosophical, ethical or social impact grounds. This chapter also contains a discussion of the conflict between the principle of allowing public access to information about genetic manipulation projects and the argument for commercial confidentiality.

12. Questions based on moral, religious or philosophical belief are - and will continue to be - legitimate subjects of community debate. Many of these questions are fundamentally value judgements and do not stand or fall on questions of fact.

13. Basic philosophical concerns about these perceived attitudes: that human beings are separate 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 report. The existence of concerns at this quite fundamental level undoubtedly helps explain some of the strength of feeling of opponents of the technology.

14. 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.

15. Detailed suggestions concerning access to information about projects at both the research and release stage are contained in recommendations 12 and 13. The Committee recommends that at both the research stage and the release stage there should be a provision for the owners of information to claim commercial confidentiality in relation to that information. There should also be provision for others to seek access to such information. There should be a stronger presumption in favour of commercial confidentiality at the research stage than at the release stage. Throughout there must be full disclosure to the supervising authority, other than for small scale exempt work as is presently provided.

Environmental issues

16. Chapter 5 is the largest chapter in the report. It deals with the environmental issues which were raised in the course of the inquiry. The chapter examines the risks involved in contained work and in deliberate releases. The difficulties involved in the risk assessment process are discussed in detail. There is also a description of legislation in Australia at both the Commonwealth and State level which may be relevant for controlling genetic manipulation work and releases to the environment.

17. Three case studies are presented in some detail in Chapter 5 concerning instances where it was claimed that the relevant guidelines had been breached or where the existing clearance system had not worked satisfactorily. Two of these - the clearance for sale of the product *NoGall* and the transport of genetically modified pigs in Adelaide to the abattoir for slaughter and sale for human consumption - are Australian examples. The third involved work on the development of a rabies vaccine in Argentina. These are presented in detail because of the prominence they have received in press reports and in submissions from those who have expressed reservations about the technology. Briefer reference is made to the case of an experiment in New Zealand which involved attempting to incorporate nitrogen-fixing ability into a fungus.

18. The Committee believes that in some media reporting of breaches of guidelines the dangers have been exaggerated. However, there are lessons to be drawn from the case studies which are presented. The rules concerning approval for possibly dangerous work need to be clear. They need to be studied closely by those involved in such work. There needs to be reliable supervision and sanctions for deliberate breaches.

19. The Committee recommends a number of measures to assist in environmental protection. These include:

. the need for increased funding of basic environmental research (recommendation 15);
. monitoring of effluent (recommendations 17 & 21);
. improvements in the risk assessment process (recommendation 16);
. techniques to control the activity of inserted genes or their transference to other organisms (recommendations 19, 20 & 22); and
. improved supervision by institutional biosafety committees (recommendations 24 & 25).

Human health issues

20. Chapter 6 is concerned with human health aspects, such as the safety of food and pharmaceutical products developed using genetic manipulation techniques. The epidemic of eosinophilia-myalgia syndrome in 1989/90 associated with the use of L-tryptophan is examined as a case study of possible contamination of pharmaceuticals produced using genetic manipulation technology. The Committee recommends that new foods, new strains of existing foods and new food additives be submitted to a GMO Release Authority as a pre-condition before release (recommendation 26).

21. The chapter also discusses occupational health and safety issues. Recommendations are made concerning:

. training of laboratory personnel (recommendation 28);
. coverage of all employees by legislation (recommendation 29); and
. the compulsory notification of all potentially hazardous scientific work (recommendation 30).

Legal issues

22. The question of allowing patent rights over genetically modified organisms is examined in detail in Chapter 7. The Committee considers that there is no justification for denying the biotechnology industry the opportunity to use the Patents Act to seek a reward for effort. The Patents Act is not the appropriate vehicle for hindering, or preventing, the development of technologies to which society may have an objection. If that is the aim more direct legislative means should be used.

23. Chapter 7 also comments on product labelling and compensation for personal injury or property damage.

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

25. The Committee considers that those who release GMOs, without following the correct procedures, should not benefit from the difficulty of establishing a duty of care, experienced by plaintiffs in a common law action for negligence; nor should they benefit from the anomalies which appear to exist in other common law remedies. Accordingly, the Committee recommends strict liability for damages arising from deliberate releases which have not been authorised (recommendation 33).

26. The Committee also considers that, if those who are responsible for a release which results in loss or damage, obtained the required approval prior to release and fully complied with the conditions and procedures attached to the approval, this should mitigate their legal liability. A 'State of the Art' defence should be available to protect those who, acting with due diligence, authorise releases.

27. The Committee supports the broad thrust of the Government's proposed changes concerning product liability and their application to products involving the use of genetic modification techniques. The Committee notes, however, that recovery of loss arising from damage to property would be limited to property of a kind ordinarily acquired for personal, domestic or household use. The exclusion of property acquired for commercial use is not justified (recommendation 34).

The way ahead

28. Chapter 8 is concerned with the requirement for new legislation to control the use of genetic manipulation and the kind of regulatory structure which should be established.

29. The Committee considers that there is reason to doubt whether the existing product clearance and registration procedures are fully adequate to cope with products which consist of or include live GMOs.

30. The Committee recommends a two-tiered approach (recommendation 40). GMAC should be retained to grant approval for contained work and as a specialist body advising a broader based GMO Release Authority. Both bodies should be adequately funded.

31. Those who are seeking clearance for the release of GMOs for field trials, or of products containing live GMOs should be required to approach the Release Authority (recommendations 42 & 43). The Release Authority would forward applications to the appropriate existing Commonwealth and State bodies for parallel consideration. The Release Authority would have responsibility for conveying to the applicant the decision concerning whether the product had received both sets of clearances.

Provision should be made for possible public input before a decision is made concerning release of such products (recommendation 43).

32. Those who are seeking clearance for products which do not contain live GMOs, but which are produced by processes which involve the use of GMOs, should approach the existing product approval body, but that body would have to obtain the clearance of the GMO Release Authority before the sale or release of the product was authorised (recommendation 44).

RECOMMENDATIONS

Recommendation 1

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. (para 4.41)

Recommendation 2

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 (NH&MRC) guidelines and monitored by institutional ethics committees co-ordinated by the NH&MRC. (para 4.47)

Recommendation 3

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 Animal Experimentation Ethics Committees (AEECs) be required to submit annual reports (as in NSW). (para 4.91)

Recommendation 4

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. (para 4.92)

Recommendation 5

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. (para 4.104)

Recommendation 6

The Committee recommends that the Genetic Manipulation Advisory Committee (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. (para 4.107)

Recommendation 7

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. (para 4.126)

Recommendation 8

The Committee recommends that the Government support, through research grants and through funding for the Commonwealth Scientific and Industrial Research Organisation (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. (para 4.133)

Recommendation 9

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 Genetically Modified Organisms (GMO) Release Authority: recommendations 40 - 48). (para 4.138)

Recommendation 10

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. The Committee recommends that the Government ensure that there is a specific appropriation for the CSIRO to undertake such public information campaigns. (para 4.145)

Recommendation 11

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. (para 4.146)

Recommendation 12

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. (para 4.163)

Recommendation 13

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 is 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

. 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. (para 4.164)

Recommendation 14

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. (para 5.17)

Recommendation 15

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. (para 5.24)

Recommendation 16

The Committee recommends that the GENHAZ procedure (proposed by the UK Royal Commission on Environmental Pollution) 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. (para 5.47)

Recommendation 17

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. (para 5.69)

Recommendation 18

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. (para 5.70)

Recommendation 19

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 genetically modified organisms (GMOs) into the environment. (This might be appropriate for the release of a micro-organism.) (para 5.80)

Recommendation 20

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. (para 5.85)

Recommendation 21

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. (para 5.140)

Recommendation 22

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 transfer warrants 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. (para 5.154)

Recommendation 23

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. (para 5.185)

Recommendation 24

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 institutional biosafety committees (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. (para 5.276)

Recommendation 25

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.) (para 5.277)

Recommendation 26

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

Recommendation 27

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

Recommendation 28

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

Recommendation 29

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

Recommendation 30

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

Recommendation 31

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

Recommendation 32

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

Recommendation 33

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

Recommendation 34

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

Recommendation 35

The Committee recommends that adherence, by those proposing releases of GMOs to the environment, to the Recombinant DNA Monitoring Committee guidelines: *Procedures for Assessment of the Planned Release of Recombinant DNA Organisms*, or any subsequent replacement document, be made compulsory at an early date. (para 8.12)

Recommendation 36

The Committee recommends that GMAC guidelines be made mandatory for small and large scale genetic manipulation work at an early date. (para 8.31)

Recommendation 37

The Committee recommends that there be a wide range of penalties, including the withdrawal of Government grants and tax incentives, heavy fines, or imprisonment where appropriate, which might be imposed for breach of the guidelines. The right to sue for civil damages should remain. (para 8.34)

Recommendations 38

The Committee has already recommended that adherence to the guidelines appropriate to the stage and scale of the project be made mandatory (recommendations 35 and 36). To assist in the enforcement of this requirement the Committee recommends that those proposing to undertake contained genetic manipulation work, other than work which is exempt under the guidelines, either for research or commercial purposes, be required to make application to GMAC, who will notify the required level of containment under the appropriate guidelines. Work which is exempt from notification to GMAC under the guidelines should still require approval by the Institutional Biosafety Committee, as is presently the case. (para 8.43)

Recommendation 39

The Committee further recommends that if it is intended to change the scale of the project, for example, from small to large scale, further application to GMAC should be required. If it is intended to progress from contained work to field trial, application to the Release Authority should be required. (para 8.44)

Recommendation 40

The Committee recommends that a two-tiered approach be adopted for the release of GMOs to the environment. GMAC should be retained to grant approval for contained work (see recommendation 38) and as a specialist advisory body. In addition, a GMO Release Authority should be created by uniform complementary State and federal legislation. The GMO Release Authority should have responsibility for the authorisation of all releases of GMOs, whether for field trials at the pre-product stage (see recommendation 42) or for releases of products containing GMOs (see recommendation 43) and also for setting minimum standards and procedures. (para 8.69)

Recommendation 41

The Committee recommends that GMAC and the GMO Release Authority should be responsible to the Minister for Science and Technology. (para 8.70)

Recommendation 42

The Committee recommends that, concerning the release of GMOs at the field trial stage,

. it should be mandatory that those seeking approval for the release of GMOs in field trials should forward their applications to the GMO Release Authority
. the Release Authority should consider such applications with advice from GMAC and relevant State and Commonwealth authorities (such as Health or Environment Departments)
. the Release Authority should have the authority to publicly advertise proposed field trial releases if it considers this desirable and to allow a reasonable time (to be specified in regulations) for expressions of opinion before proceeding to a decision concerning approval
. the Minister should be advised of all proposed releases and have the discretion to order public hearings in relation to a proposed release
. the Release Authority should forward a copy of all applications to any appropriate existing State and Commonwealth bodies for parallel consideration
. these other State and Commonwealth bodies should indicate to the Release Authority whether the proposed release has their approval
. the approval of any other relevant State and Commonwealth bodies and of the Release Authority should be required before the GMO is released
. the Release Authority should be responsible for informing the applicant whether the release is authorised. (para 8.71)

Recommendation 43

The Committee recommends that, to ensure public confidence that concerns about the release of products containing live GMOs to the environment are fully considered:

. it should be mandatory that those seeking approval for the sale of such products should forward their applications to the GMO Release Authority
. the Release Authority should consider such applications with advice from GMAC
. the Release Authority should publicly advertise proposed releases and allow a reasonable time for expressions of opinion before proceeding to a decision concerning approval
. the Minister should be advised of all proposed releases and have the discretion to order public hearings in relation to a proposed release
. the Release Authority should forward a copy of all applications to the appropriate existing product approval body for parallel consideration
. the product approval body should indicate to the Release Authority whether the application has their approval
. the approval of both the product approval body and of the Release Authority should be required before the product is released
. the Release Authority should be responsible for informing the applicant whether the product meets all the requirements. (para 8.72)

Recommendation 44

The Committee recommends, in relation to products which do not contain live GMOs, but in the production of which the use of GMOs has been involved, that:

. all State or federal bodies with responsibility for product clearance or registration, as well as making their own evaluations, be required to refer any proposals made to them concerning such products to the GMO Release Authority

. the approval of the Release Authority be required before the product is authorised for release. (para 8.73)

Recommendation 45

The Committee recommends that legislation require:

. the notification of any unauthorised release of genetically modified organisms from contained facilities as soon as possible to the Institutional Biosafety Committee, the national GMO Release Authority and the responsible State and Commonwealth environment and health authorities

. the GMO Release Authority to co-ordinate any remedial action by the relevant authorities

. the keeping by the GMO Release Authority of a register of any unauthorised release of GMOs, indicating the nature of the organism, the quantities released, the location, and the institution involved. (para 8.74)

Recommendations 46

The Committee recommends that the membership of GMAC consist of people chosen by the Minister for their expertise in genetic manipulation technology and/or environmental science. (para 8.86)

Recommendation 47

The Committee recommends that the membership of the GMO Release Authority be selected by the Minister on the following basis:

. a chairperson

. the chairperson of GMAC

. two people chosen for their expertise in genetic manipulation technology

. two people chosen for their expertise in environmental science

. a nominee from each of the following Commonwealth Departments - Industry Technology and Commerce; Primary Industries and Energy; Arts Sport Environment and Territories; and Health Housing and Community Services

. two people chosen for their involvement in commercial development or use of genetically modified organisms

. two people chosen for their interest in environmental or consumer affairs issues.

. one person chosen for knowledge of law and/or philosophy. (para 8.87)

Recommendation 48

The Committee further recommends that the GMO Release Authority be able to propose to the Minister that their membership be temporarily supplemented by up to three additional people chosen for their expertise relevant to a particular release proposal. (para 8.88)

CHAPTER ONE

BACKGROUND INFORMATION

CHAPTER ONE

BACKGROUND INFORMATION

A. BIOLOGY

A.1 Genetic manipulation

1.1 Genetic manipulation involves altering (adding to, deleting from or re-arranging) the genetic information in an organism. It often can involve adding genetic information from other organisms/species. Cloning a gene is often, but not always, an essential part of genetic manipulation. This should not be confused with embryo cloning, in vitro fertilization and embryo transplants, which are separate techniques.[1]

1.2 One submission stated that the term 'genetically engineered organism' was to be preferred to 'genetically modified organism' to avoid confusion with conventional biotechnology such as traditional plant breeding. The kind of techniques it was claimed needed to be covered were "recombinant-DNA technology, as well as other techniques, including, but not limited to cell fusion, protoplast fusion, embryo mixing, chemical poration, ectroporation [sic], projectile transfer and microinjection."[2]

1.3 The UK Royal Commission on Environmental Pollution, which investigated this subject, used the term genetic engineering in its *Thirteenth Report*. The Royal Commission shifted to the phrase "genetically modified organism" instead of "genetically engineered organism" in its *Fourteenth Report*, dated June 1991, on the grounds that the former term has now become widely adopted.[3]

1.4 The Royal Commission commented on the difficulty of defining the subject matter, not only because of the sometimes different uses of the alternative terms but also because of the grey areas where traditional plant and animal breeding techniques overlap with the techniques which might now be called "engineering" or "manipulation".[4]

1.5 The Royal Commission decided that whether something comes within the scope of the term genetic engineering should be determined on the basis of the techniques used rather than whether the outcome could have occurred naturally. Techniques which the Royal Commission considered met this requirement included recombinant

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1 Cloning of a gene is the process of putting a vector carrying the gene into a host cell and allowing its numbers to increase by natural cell division.

2 Burch, Dr D et al.: Submission 106 p 12. "ectroporation" presumably means "electroporation".

3 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, footnote p 1

4 UK Royal Commission on Environmental Pollution, Thirteenth Report: *The release of genetically engineered organisms to the environment*, July 1989 paras 1.1 & 2.12

DNA techniques, micro-injection, and protoplast fusion. The Commission also stated that:

> "It is important that any definition should be kept under review by experts and amended as necessary both to clarify if necessary the position of new techniques and to modify the coverage in the light of experience".[5]

1.6 The Committee does not consider that there is any significant difference between the terms "genetic engineering" and "genetic manipulation". The phrases "genetic manipulation" and "genetically modified organisms" are used in this report rather than "genetic engineering" and "genetically engineered organisms" basically because these are the phrases present in the terms of reference given to the Committee for this inquiry.

1.7 The Committee also has not considered it necessary for the purposes of this report to exhaustively define the techniques which are involved, although this may be necessary in regulations under any legislation which results.

1.8 The Committee supports the comment of the UK Royal Commission that any listing of the techniques which constitute genetic manipulation will need to be kept under review. This is very much a developing area and the need for flexibility in describing the techniques is essential.

A.2 The cell

1.9 The cell is the building block of all forms of life. While there are some differences, cells are very similar, particularly in plant and animal life forms. Plant and animal cells consist of the nucleus containing paired chromosomes, and the cytoplasm, which contains a number of specialised parts or organelles. In animals the cell is bounded by a membrane and, in plants, by a cell wall. Bacterial cells on the other hand do not have organelles. They have a single chromosome which is not enclosed in a nucleus. Cells in a complex body, such as a human being, may be highly specialised in the functions they perform. For example, muscle cells and kidney cells perform different functions. In specialised cells only part of the genetic information those cells contain is used. The rest of the genetic information stays 'switched off'.

1.10 Where a nucleus is present, it contains chromosomes (or DNA). These determine what kind of work the cell will perform. It also contains the mechanism of self-replication.

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5 ibid., para 2.16

A.3 Chromosomes

1.11 Chromosomes are found in the nucleus of cells. They are composed of DNA and protein. The protein holds the DNA in a compacted form. When the protein is removed the DNA forms long threads. Apart from bacteria and viruses, which have only one chromosome, these long thread-like structures are found in higher forms of life as identical pairs.[6]

A.4 Nucleic acid

1.12 DNA (deoxyribonucleic acid) is the famous double helix shaped molecule found in the nucleus of the cell which is replicated during the process of cell division. It is a nucleic acid molecule. Nucleic acids, like proteins, are large molecules composed of smaller parts which are added together. There are two kinds of nucleic acid - deoxyribonucleic acid (DNA) and ribonucleic acid (RNA).

1.13 An important kind of RNA in genetics is messenger RNA (mRNA). It copies the information from the DNA molecule for the production of a protein when required. In specialised cells, only particular parts of the total genetic information in the cell (ie. from particular genes) will be copied and transported outside the cell nucleus by the mRNA. Targeting the mRNA in a specialised cell is then a useful way of finding a particular gene. An enzyme called reverse transcriptase can be used to get the mRNA to produce the DNA for which it carries the code. This copy DNA, or cDNA, can then be cloned by bacterial cell culture.

1.14 The smaller parts or building blocks of nucleic acids are called nucleotides. These consist of a base, a sugar and a phosphate group. The sugar and the phosphate group have a structural function. It is the bases which are of fundamental importance in conveying genetic information.

A.5 Bases

1.15 It is usually said that there are four bases, adenine (A), cytosine (C), guanine (G), and thymine (T), although RNA contains uracil (U) in place of the (T) base which is found in DNA. Genetic information is conveyed by the order in which the bases, (A), (C), (G), and (T)/(U) are arranged and repeated in the DNA molecule in the chromosomes contained in the nucleus of a cell. A sequence of three bases (which is called a codon) specifies the production of a particular amino acid during protein synthesis. Often it is only the first two bases in the codon which are crucial in the code for the particular amino acid.

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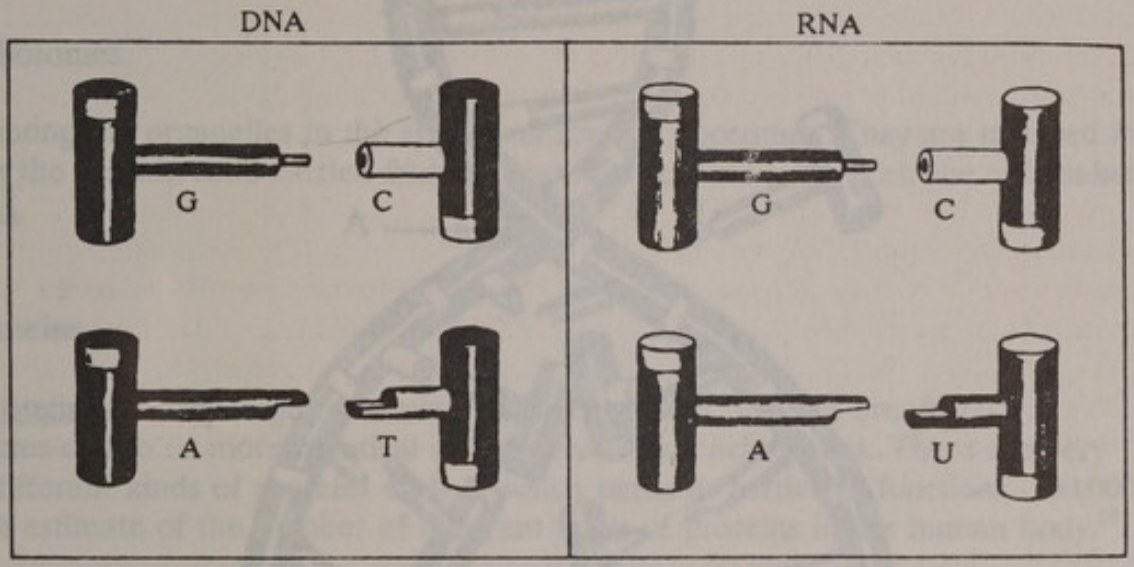
6 The sex chromosomes in a male mammal are not identical - one being an 'X' and the other a 'Y'.

1.16 In the double helix structure of a DNA molecule an (A) is always opposite a (T) and a (G) is always opposite a (C). This fact allows the molecule to be rebuilt exactly, after it splits in the process of cell division. To give an impression of the complexity of the genetic code, Nossal points out that a bacterial cell contains over 3 million pairs of bases while the number in a human cell would be perhaps 1000 times more.[7]

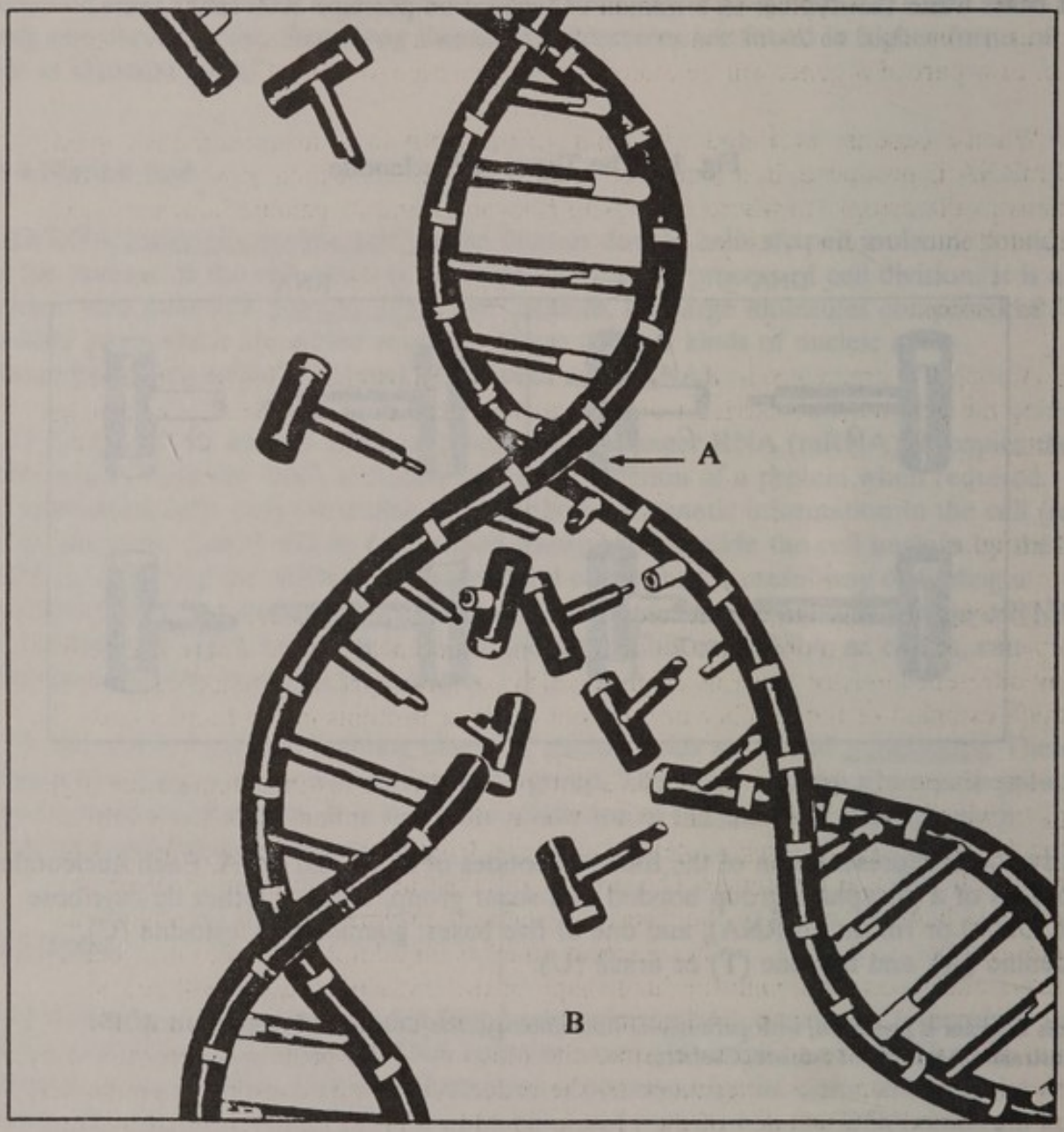
Fig. 1.1 The Types of Nucleotide



A symbolic representation of the four nucleotides of DNA and RNA. Each nucleotide consists of a phosphate group bonded to a sugar group, which is either de-oxyribose (in DNA) or ribose (in RNA), and one of five bases: guanine (G), cytosine (C), adenine (A), and thymine (T) or uracil (U).

7 Nossal, G: *Reshaping Life - Key Issues in Genetic Engineering*, Melbourne Uni Press, 1984 p 10

Fig. 1.2 The process of DNA replication



At point A, the two strands of the double helix begin to separate. Complementary nucleotides in solution within the nucleus move towards the bases that have been unpaired by the separation. They link with the unpaired bases and their sugar phosphate groups join to one another. Two exact replicas of DNA are therefore formed, as shown at B.

A.6 Genes

1.17 A gene is a piece of DNA with information for the construction of a specific protein. Genes are segments of chromosomes. They are not recognisable as physically separate entities.[8] A typical plant or animal cell contains perhaps 100,000 genes in its nucleus. From 1000 to 20,000 bases may be found in a single gene.[9] Usually only one gene, or a part of a gene, will be altered in the genetic modification process.

1.18 When a gene is 'activated', that part of the DNA in a chromosome is copied and mRNA is produced, in a two stage process. The mRNA then moves out of the nucleus to the cytoplasm where it binds to ribosomes and its genetic information is translated into protein by enzymes.

A.7 Ribosomes

1.19 Among the organelles in the cytoplasm are the ribosomes. They are involved in reading the genetic code carried from the nucleus according to which the cell makes proteins.

A.8 Proteins

1.20 Proteins are very large molecules. Many important proteins are, in fact, complexes of two or more identical or different amino acid chains. There are very many different kinds of proteins each of which perform particular functions. 100,000 is a rough estimate of the number of different kinds of proteins in the human body.[10]

1.21 The shape of a protein molecule is determined by the arrangement of the amino acids of which it is composed. There are twenty different amino acids, each with a particular shape. An average protein would have from 50 to 1000 amino acids. Clearly some also lie outside this range. The process of constructing a protein involves an amino acid being attached to the ribosome, then an enzyme attaches an additional amino acid beside it, then another enzyme attaches an additional amino acid beside that one and so on. Although the final shape of the protein molecule will not be linear but complex, its shape is determined by the sequential arrangement of the amino acids which are added to it. Since the function of the protein is determined by its shape and its shape is determined by the order in which its constituent amino acid parts are joined, the function of the protein could be said to be determined by both the constituent amino acids and the order in which they are added together.[11]

1.22 An enzyme is a protein which acts as a catalyst in chemical reactions within the cell; that is, it assists the reaction to occur. Enzymes play vital roles in reactions

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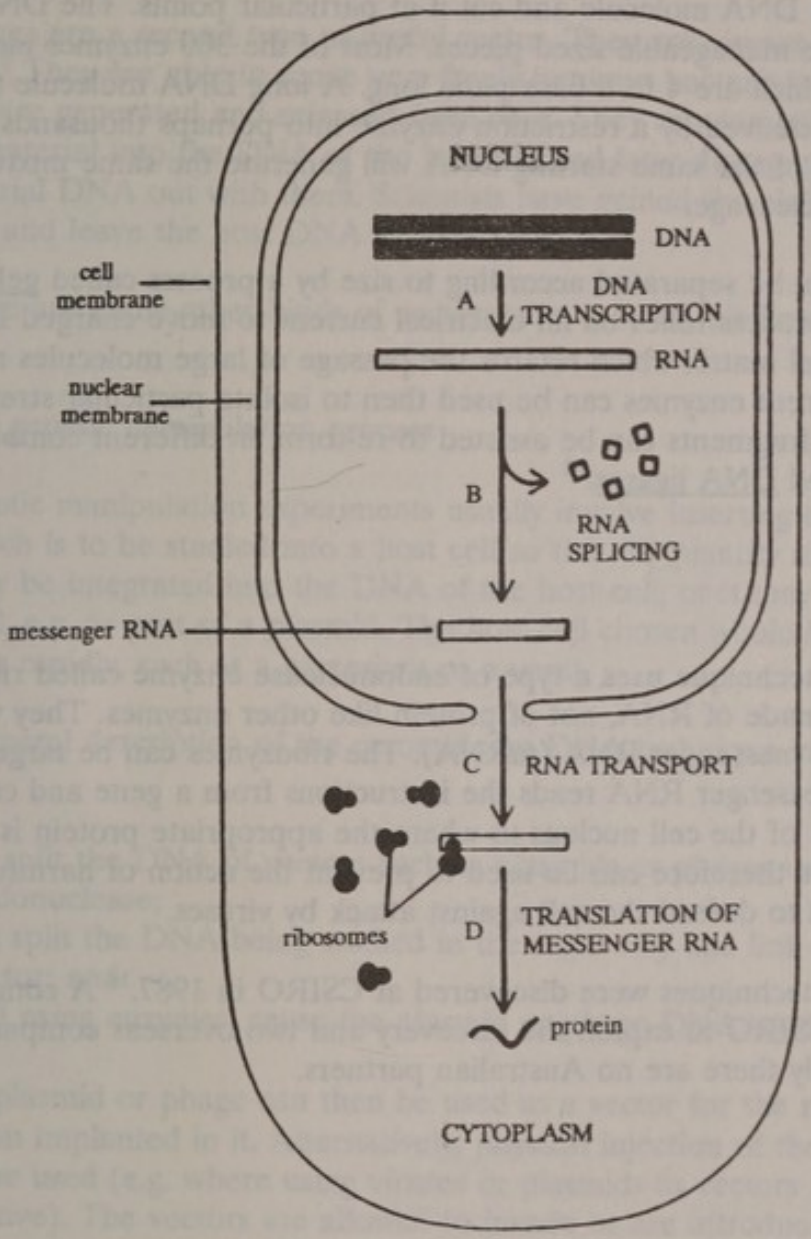
8 Stocker, Dr J, Chief Excutive, CSIRO: Submission 109 p 39
9 ibid.
10 Nossal, G: op. cit., p 10
11 ibid., p 13

involving the breaking down of food, the transport and storage of energy, the synthesising of large molecules and in cell replication. Each enzyme appears to have a quite specific role. The enzyme has a region on its surface which is complementary to a site on the molecule on which it acts. Once attached to the target molecule the enzyme can perform its function. A particular chemical process may require sequential reactions involving a number of enzymes. The shape of proteins is very important to their being able to perform their particular functions.[12]

12 ibid., p 11

Fig. 1.3 Protein synthesis



A: The DNA containing the code for a protein is used to make a molecule of RNA.

B: Non-coding portions of the RNA are removed. This process underlies the 'gene shears' technique (see section A.10).

C: The RNA leaves the nucleus as messenger RNA and attaches to a ribosome.

D: The ribosome produces the protein using the code provided by the messenger RNA.

This diagram is reproduced, with permission, from *The Molecular Biology of the Cell*, Alberts et al. 1989 Garland Publishing, New York

A.9 Restriction endonucleases

1.23 Restriction endonucleases are enzymes which can be used to locate a specific sequence of bases in a DNA molecule and cut it at particular points. The DNA being studied is then in more manageable sized pieces. Most of the 300 enzymes identified recognise sequences which are 4 to 6 base pairs long. A long DNA molecule (e.g. a chromosome) may be cleaved by a restriction enzyme into perhaps thousands of fragments. Every copy of the same starting DNA will generate the same mixture of DNA fragments after cleavage.

1.24 The fragments can be separated according to size by a process called gel electrophoresis. This process relies on an electrical current to move charged DNA molecules through a gel matrix which retards the passage of large molecules more than small ones. Different enzymes can be used then to isolate particular stretches of DNA of interest. The fragments can be assisted to re-form, in different combinations by using enzymes called DNA ligases.[13]

A.10 Gene shears

1.25 The gene shears technique uses a type of endonuclease enzyme called ribozymes. These molecules are made of RNA, not of protein like other enzymes. They work by cutting and destroying messenger RNA (mRNA). The ribozymes can be targeted at quite specific sites. Messenger RNA reads the instructions from a gene and carries these through the wall of the cell nucleus to where the appropriate protein is actually produced. Gene shears therefore can be used to prevent the action of harmful genes. They also can be used to defend the cell against attack by viruses.

1.26 The gene shears techniques were discovered at CSIRO in 1987.[14] A company has been formed by CSIRO to exploit the discovery and two overseas companies have invested in it. Currently there are no Australian partners.

A.11 Vectors

1.27 Vectors are molecules used to enable the movement of DNA of interest into a cell or organism, and often to facilitate the replication of that DNA within that cell.

1.28 Bacterial plasmids are one important kind of vector. They are small DNA molecules, found in many bacteria. They are much smaller than bacterial chromosomes, being from 2000 to a few hundred thousand base pairs long. Some plasmids can move from one cell to another including between cells of different species. This is a means by which the sort of changes which are made in a laboratory undertaking genetic modification can occur in nature. They can also reproduce

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13 ibid., pp 24-26

14 See Chapter 3: "Existing and Potential Benefits" Section B4

themselves inside the bacteria independently of the main bacterial DNA. They can sometimes fuse with the main DNA and later separate from it taking part of the main DNA with them.[15]

1.29 Phages are a second type of useful vector. They are viruses which attack bacteria.[16] They are able to move very freely between bacteria because infectious particles are generated and released from cells. They can sometimes integrate their genetic material into the DNA of the bacteria and later disengage, carrying some of the bacterial DNA out with them. Scientists have gained the ability to make phages integrate and leave the host DNA as they wish.

1.30 There are many other kinds of vectors now used in this field of research.

A.12 The genetic manipulation process

1.31 Genetic manipulation experiments usually involve inserting a particular piece of DNA which is to be studied into a host cell so that its quantity may be increased. The DNA may be integrated into the DNA of the host cell, or it may be carried separately in the cell, e.g. as part of a plasmid. The host cell chosen would be one which divides and grows rapidly, such as a bacterium or a yeast.

1.32 A general description of the recombinant DNA technique in this context would be:

(i) split the DNA of vectors such as plasmids or phages using restriction endonuclease;
(ii) split the DNA being studied in the same way and link it to the DNA of the vector; and
(iii) using enzymes, cause the plasmid or phage DNA to close up once again.

1.33 The plasmid or phage can then be used as a vector for the new genetic information implanted in it. Alternatively, physical injection of the DNA into the host cell may be used (e.g. where using viruses or plasmids as vectors is not found to be very effective). The vectors are allowed to invade or are introduced into a host cell. This process can be assisted in some cases by adding a special coating to the vector which enables it to penetrate the host.

1.34 When the host cell divides, the DNA and the vector carrying it are also reproduced. They may be present in single or multiple copies within the host cell.[17]

1.35 In most recombinant DNA experiments using bacteria or yeast cells, a mixed culture will result because only some of the cells will contain the gene of interest.

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15 Nossal, G: op. cit., p 28
16 The name 'phage' derives from 'bacteriophage' i.e. bacteria eater
17 Nossal, G: op. cit., p 28

These cells subsequently have to be found. One of the many ways of doing this is to use a radioactively labelled RNA probe which will bind to the stretch of DNA being sought, where the nucleotide sequence of the piece of DNA or even part of it, is known; or the protein product produced by the desired gene (if it is being made) can be found in the cultured material using antibodies to the protein. In this way individual cells containing the gene of interest can be identified, separated and concentrated.

1.36 A protein will only be made from DNA inserted into a host cell if the gene is complete, and the gene has been provided with signals that can be recognised by the RNA and protein-producing machineries of the host cell. Production of the protein coded for by a piece of DNA inserted in a host cell can be further increased or controlled by: taking a 'control element', for example the gene for the production of an enzyme to break down a particular sugar, which only triggers when that sugar is present; inserting it into a plasmid; and inserting the gene for the desired protein next to it. Bacteria containing this plasmid will then produce large amounts of the desired protein when fed the particular sugar.

1.37 There are many other mechanisms for increasing the rate of production of desired proteins. "Vectors that are suitable for switching on genes at will ... are known as expression vectors".[18]

1.38 It should be understood that the whole of this section on biology is a highly simplified explanation.[19]

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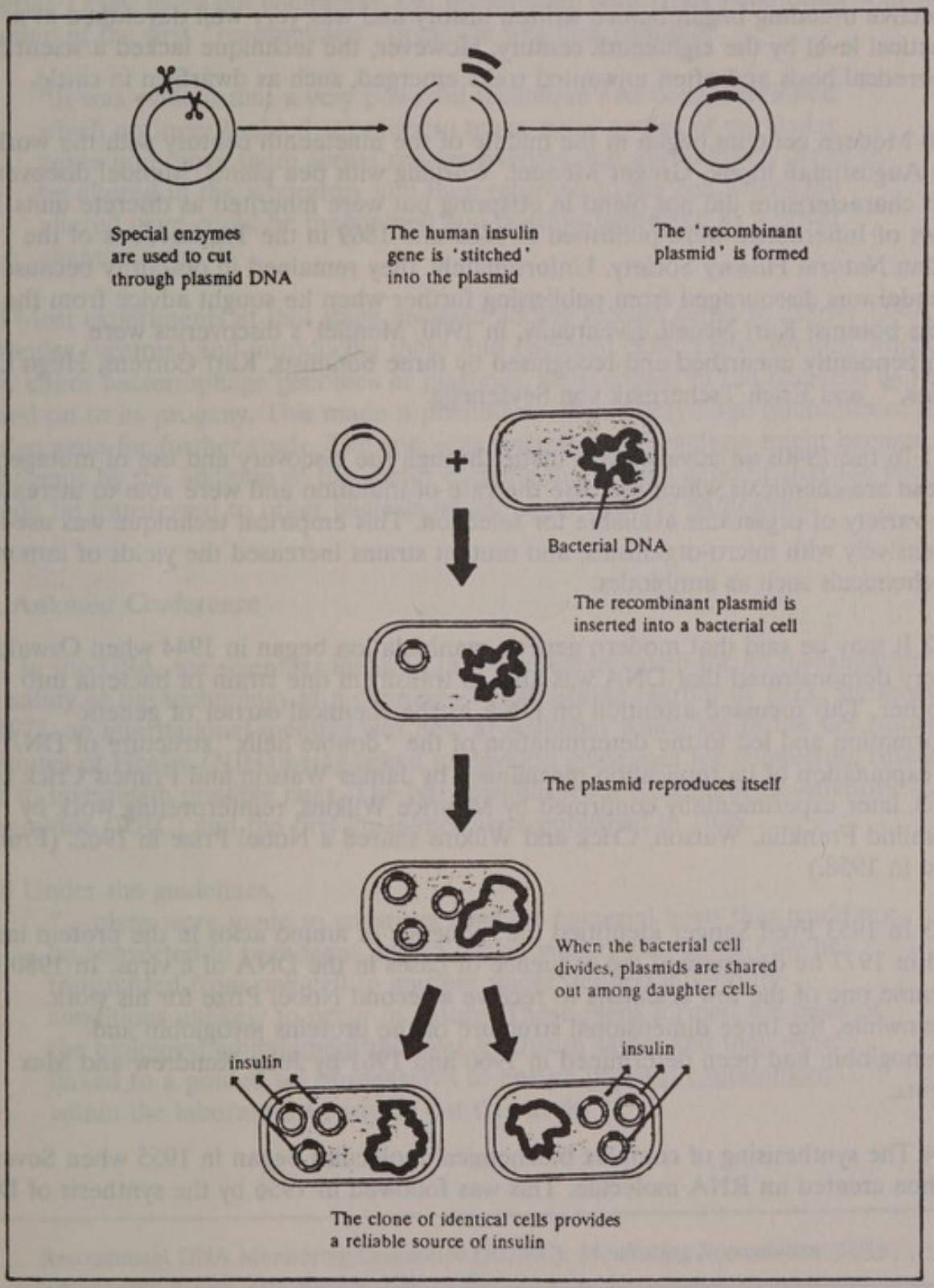
18 ibid., p 37

19 For more information see: Australian Academy of Science: *Biology, The Common Threads*, 1991 Part 2, and Nossal, G: *Reshaping Life - Key Issues in Genetic Engineering*, Melbourne University Press, 1984.

Fig. 1.4 Using Bacteria to Manufacture Human Insulin



This diagram is taken from *What is genetic engineering?* Information Sheet No 2 - 1990, supplied by the Australian Biotechnology Association.

B. History

1.39 Humanity has always desired to improve domesticated plants and animals and, traditionally this has been achieved through breeding from selected individuals. Selective breeding began before written history and was very well developed at a practical level by the eighteenth century. However, the technique lacked a scientific theoretical basis and often unwanted traits emerged, such as dwarfism in cattle.

1.40 Modern genetics began in the middle of the nineteenth century with the work of the Augustinian monk, Gregor Mendel. Working with pea plants, Mendel discovered that characteristics did not blend in offspring but were inherited as discrete units. His Laws of Inheritance were published in 1865 and 1869 in the Transactions of the Brünn Natural History Society. Unfortunately, they remained in obscurity because Mendel was discouraged from publicising further when he sought advice from the Swiss botanist Karl Nägeli. Eventually, in 1900, Mendel's discoveries were independently unearthed and recognised by three botanists, Karl Correns, Hugo De Vries,[20] and Erich Tschermak von Seysenegg.

1.41 In the 1940s an advance was made through the discovery and use of mutagens. These are chemicals which increase the rate of mutation and were able to increase the variety of organisms available for selection. This empirical technique was used extensively with micro-organisms, and mutant strains increased the yields of important biochemicals such as antibiotics.

1.42 It may be said that modern genetic manipulation began in 1944 when Oswald Avery demonstrated that DNA was able to transform one strain of bacteria into another. This focussed attention on DNA as the chemical carrier of genetic information and led to the determination of the 'double helix' structure of DNA and an explanation of its replication mechanism by James Watson and Francis Crick in 1953, later experimentally confirmed by Maurice Wilkins, reinterpreting work by Rosalind Franklin. Watson, Crick and Wilkins shared a Nobel Prize in 1962. (Franklin died in 1958.)

1.43 In 1953 Fred Sanger identified the sequence of amino acids in the protein insulin and in 1977 he determined the sequence of bases in the DNA of a virus. In 1980 he became one of the few scientists to receive a second Nobel Prize for his work. Meanwhile, the three dimensional structure of the proteins myoglobin and haemoglobin had been determined in 1960 and 1961 by John Kendrew and Max Perutz.

1.44 The synthesising of complex biochemical molecules began in 1955 when Severo Ochoa created an RNA molecule. This was followed in 1956 by the synthesis of DNA

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20 Asimov, I: *Biographical Encyclopedia of Science and Technology*, 2nd edition, Doubleday & Co, New York, 1982, contains information about most of the historical figures mentioned in this section.

by Arthur Kornberg. These discoveries enabled Marshall Nirenberg to identify the first triplet base sequence in the genetic code in 1961.

1.45 In the early 1970s the discovery of restriction enzymes enabled the genetic material, DNA, to be cut chemically and recombined with DNA from other sources. Creation of the first 'recombinant' organism was thus possible.

> "It was evident that a very powerful technique had been developed which not only enabled scientists to make many copies of particular genes and move them across species barriers, but also allowed genes to be altered in the laboratory and then returned to the cell where the altered gene could be maintained and possibly expressed as a novel characteristic."[21]

1.46 Most experiments at that stage involved adding foreign genes to carrier DNA molecules (vectors) and introducing these into bacterial cells. These vectors, which were either bacteriophage genomes or plasmids, were copied in the bacterial cell and passed on to its progeny. This made it possible to obtain very large quantities of the foreign gene for further study. The concerns were that the bacteria might become pathogenic by the addition of the vector carrying the foreign gene or that the vector "might be transferred to other bacteria which might become pathogenic."[22]

B.1 Asilomar Conference

1.47 In the USA, the scientists involved in the research called for an investigation into the safety of the technology at a meeting at Cold Spring Harbor in 1973. Subsequently in 1975, an international meeting was held at Asilomar which led to the US National Institutes of Health (NIH) being asked to develop guidelines for conducting research, and to investigate possible risks. The NIH established a Recombinant Advisory Committee (RAC) and the first guidelines were published in 1976.

1.48 Under the guidelines,

> "... plans were made to construct disabled bacterial hosts that could not be converted to pathogens and to design vectors that could only be transmitted from one cell to another under defined laboratory conditions unlikely to occur in nature. These plans formed the basis of the biological containment that was to ensure safety and they were linked to a graded set of measures to ensure physical containment ... within the laboratories carrying out this work."[23]

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21 Recombinant DNA Monitoring Committee (RDMC): *Monitoring Recombinant DNA Technology: A Five Year Review*, 1986 p 26

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

23 ibid., p 3

1.49 The Asilomar conference

> "... decided to prohibit experiments that involved the cloning of genes which coded for potential toxins ... The release of any organisms modified by [recombinant DNA techniques] was banned. Experiments which used human DNA were regarded as high risk requiring high levels of physical containment ... Other experiments were graded, taking into account the nature of the donor DNA and the host organism. Experiments using more than 10 litres of culture were not allowed. ... In the USA the National Institutes of Health took responsibility for administering and upgrading these guidelines."[24]

1.50 All institutions were required to create Institutional Biosafety Committees charged with authorizing research and ensuring that the guidelines were followed.

B.2 Regulation in Australia

B.2.(i) ASCORD and the RDMC

1.51 The Australian Academy of Sciences sent representatives to the Asilomar conference and subsequently appointed the Academy of Science Committee on Recombinant DNA molecules (ASCORD). ASCORD monitored work, advised on containment procedures, organised training, and established a set of guidelines for contained work. These guidelines were published in 1975 and were influenced by those of the US NIH and the UK.[25]

1.52 In 1980, due to the burgeoning of the techniques and the imminence of industrial applications, the Commonwealth Government established a committee chaired by Professor Frank Fenner to review the method of surveillance of biotechnology. In response to the Fenner Committee report the Recombinant DNA Monitoring Committee (RDMC) was established in 1981. [26]

> "Its task was to develop and review guidelines for large and small scale work, and to consider the problems associated with the planned release into the environment of organisms containing recombinant DNA. ... [It was required] to report within five years of its establishment on the need for monitoring to continue."[27]

1.53 Between its creation and the five year review, RDMC produced guidelines for small scale work (the first edition in May 1982), for large scale work in 1984, and an

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24 ibid.

25 RDMC: op. cit., p 28

26 Delroy, B, Biotechnology Section, Department of Industry, Technology and Commerce: Exhibit 128 p 2

27 Genetic Manipulation Advisory Committee (GMAC): *Report for the period 22 August 1988 to June 1989*, p 2

'interim and consultation' edition for planned release of GMOs in 1985. Annual reports were also produced as well as a document discussing recombinant DNA techniques in relation to Australian law.[28]

1.54 The RDMC's Five Year Review published in 1986 concluded, inter alia, that, although in some areas there were significant or unknown risks:

> "The majority of experiments using the recombinant DNA technique in Australia are of very low risk.
> The voluntary monitoring system, working through the RDMC and the institutional biosafety committees, has been effective for this technology and is likely to remain so for at least the next five years.
> Continued monitoring is desirable not only to ensure safety but also to reassure the community that the technology is indeed under expert surveillance."[29]

1.55 The Government accepted the report's recommendations and extended monitoring so that all innovative genetic manipulation technology was covered, not just research involving breaking and recombining DNA. The Genetic Manipulation Advisory Committee (GMAC), was set up in 1987 to replace the RDMC and charged to undertake this task.

1.56 In late 1981 the Department of Science and Technology and others sponsored a symposium in Sydney entitled: *Genetic Engineering - Commercial Opportunities in Australia.* The Department organised a workshop in Canberra in the following year.[30,31] Subsequently, the Australian Science and Technology Council

> "... recommended that the Government: (a) establish a national biotechnology research scheme to provide financial support for selected research and development programs in biotechnology; and (b) provide additional funds to the Australian Industrial Research and Development Incentives Scheme (AIRDIS) to be used solely for projects involving biotechnology."[32]

1.57 In 1983 these recommendations were incorporated into the National Biotechnology Program under which 20 grants had been awarded up to June 1986,

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28 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,* Department of Science and Technology 1984

29 RDMC: op. cit., p 3

30 Department of Science and Technology: *Genetic Engineering - Commercial Opportunities in Australia - Proceedings of a symposium held in Sydney 18-20 November 1981,* AGPS Canberra, 1982

31 Department of Science and Technology: *Biotechnology Appropriate areas for commercial exploitation in Australia - Proceedings and report of a Workshop held in Canberra 22-23 November 1982,* AGPS Canberra, 1983

32 Delroy, B, Biotechnology Section, Department of Industry, Technology and Commerce (DITAC): Exhibit 128 p 5

when the scheme was subsumed into the Grants for Industry Research and Development (GIRD) Scheme administered by the Department of Industry, Technology and Commerce.[33]

1.58 The GIRD Scheme has two components - a Discretionary Grants Scheme and a Generic Technology Scheme. The Discretionary Grants Scheme complements the general 150 per cent tax concession for research and development. It is available only to companies which are unable to take advantage of the tax concession.

1.59 Between 1987 and March 1991, some $10.7 million was granted to 22 projects which involve genetic manipulation in some way under the Generic Technology Scheme. Another project was allocated $281,600 under the Discretionary Grants Scheme. There may be other genetic manipulation projects receiving support through schemes administered in portfolios other than DITAC - such as the various research and development corporations within the Primary Industries and Energy portfolio.[34]

B.2.(ii) The Genetic Manipulation Advisory Committee (GMAC)

1.60 The RDMC's Five Year Review recommended that there should be a single national committee and stated that:

> "A committee including part-time members who are practising experts, is the only feasible option at present to ensure the necessary specialist knowledge is available for monitoring."[35]

1.61 Thus GMAC is a part-time body predominantly consisting of scientific experts served by a full-time Secretariat of five which includes a scientist who is the Secretary. Members of GMAC are all three year Ministerial appointments. To enable continuity, appointments are made on a staggered basis. Except for a representative from the Department of the Arts, Sport, the Environment, Tourism and Territories, members of GMAC are appointed on the basis of their personal expertise and not as representatives of universities, industry, lobby groups et cetera.[36] The members of GMAC, as of 30 June 1991, and the expertise which led to their appointment are shown below[37]:

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33 ibid., p 7

34 Clarke, B, Aerospace and Biological Industries Branch, DITAC: Submission 126.2. The figures include amounts actually paid to completed projects as well as the maximum approved grant amounts for uncompleted projects.

35 RDMC: op. cit., p 54

36 GMAC Secretariat: Exhibit 127

37 ibid.; Employment details given were those at time of appointment to GMAC (provided by GMAC secretariat)

Professor Nancy Millis (Chair)
Emeritus Professor of Microbiology, Department of Microbiology, University of Melbourne

Professor David Danks (Deputy Chair)
Paediatric Research and Director, Murdoch Institute for Research into Birth Defects, Royal Children's Hospital, Melbourne

Professor Randall Albury
Head of the Department of History and Philosophy of Science, University of New South Wales

Mr Eric Anderson
Environmental Consultant (1976-1988 Australian Government Environment Department Assistant Secretary)

Dr Annabelle Bennett
Barrister (corporate and commercial, equity, intellectual property)

Dr Brian Booth
Retired from full time work; Director, Enterovax Pty Ltd (1972-1984 Manager, Scientific Services Division and then Scientific Director, Wellcome Australia Ltd)

Dr Ashley Dunn
Laboratory Head, Tumour Biology Unit, Ludwig Institute of Cancer Research, Melbourne

Dr Wayne Gerlach
Principal Research Scientist, Division of Plant Industry, CSIRO

Professor Alastair Gilmour
Director, Centre for Environmental and Urban Studies, Macquarie University

Dr Peter Hudson
Principal Research Scientist, Division of Biotechnology, CSIRO

Professor Rhonda Jones
Professor of Zoology, James Cook University of North Queensland

Professor Kevin Marshall
Professor of Microbiology, School of Microbiology, University of New South Wales

Mr David Martin
Mechanical Engineer, Engineering Group, Australian Animal Health Laboratory, CSIRO

Dr John Oakeshott
Head of the Molecular Biology Section, CSIRO Division of Entomology

Dr Ian Parsonson
Retired in 1987 as Assistant Chief, Australian Animal Health Laboratory, CSIRO

Professor Jim Pittard
Professor of Microbiology, Department of Microbiology, University of Melbourne

Dr Margaret Roper
Senior Research Scientist, Microbiology Section, Division of Plant Industry, CSIRO

Mr Phillip Toyne
Lawyer (Aboriginal and conservation issues), Director, Australian Conservation Foundation

Mr John Whitelaw
Assistant Secretary, Environment Quality, Environment Division, Department of the Arts, Sport, the Environment, Tourism and Territories

1.62 GMAC's functions were developed for the submission which sought Cabinet approval to set up GMAC[38] and in September 1987 Cabinet decided to set up the regulatory committee with those functions.

1.63 GMAC's objectives are:

> ". to oversee the development and use of innovative genetic manipulation techniques in Australia so that any biosafety risk factors ... are identified and can be managed
> . to advise the Minister about matters affecting the regulation of ... [the] technology. ...
> The risk factors ... include those ... associated with the altered genetic capabilities ... which may give rise to safety concerns in public health, occupational health and safety, agricultural production or about the quality of the environment".[39]

1.64 Its functions are to:

> "1) maintain an overview of the biosafety factors ...
> 2) identify and keep under review classes of work ... (with) undefined risk levels
> 3) alert Australian regulatory authorities ... to the existence of novel risk factors
> 4) provide specialist technical advice ...
> 5) prepare, or ... assist with the preparation of, codes, standards or guidelines ...
> 6) participate in public discussions ...
> 7) liaise with agencies overseas to ensure that ... Australian guidelines and regulations are in harmony with international practice".[40]

1.65 GMAC is directed under its terms of reference to:

> "1) provide the Minister with an annual review of the risks ...
> 2) ... work through established regulatory agencies in preference to establishing its own ...
> 3) consult with interested organisations and individuals ...
> 4) institute procedures to protect commercially sensitive information ...

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38 ibid.
39 GMAC: *Report for the period 1 July 1989 to 30 June 1990*, Appendix B p 18
40 ibid., pp 18, 19

5) immediately advise the most appropriate ... agency ... of any project or activity in which biosafety is known or thought likely to be seriously compromised

6) work with the Group of Officials on Biotechnology Regulation to familiarise government agencies with the biosafety implications of these techniques ...

7) provide the Minister with an annual report ...

8) provide to the Minister by no later than December 1992 a report reviewing the risk levels associated with these techniques and advising on the need or otherwise for this specialised function to continue."[41]

1.66 GMAC has four sub-committees to which additional people may be co-opted because of their particular expertise (See Appendix VI for names)[42]:

. the Scientific Sub-committee reviews the molecular aspects of all proposals covered by the guidelines.

. the Large Scale Sub-committee reviews proposals for large scale work (that involving more than ten litres of material) which usually involves industrial scale production. It also inspects and issues certificates for facilities for large scale work and laboratories requiring higher than the minimum physical containment conditions.

. the Planned Release Sub-committee reviews proposals for releasing into the environment all genetically manipulated live organisms falling within the guidelines. It assesses the hazards involved, and advises the agency legally responsible for approving the release.

. the Public Liaison Sub-committee relates the activities of GMAC to the general public.

B.2.(iii) Discussion of genetic manipulation by government organisations

1.67 In September 1987, as a result of a Commonwealth Government Cabinet decision, the Group of Officials on Biotechnology Regulation (GOBR) was formed. The secretariat is within the Dept of Industry Technology and Commerce. Its role is to:

"... facilitate and encourage the development in Australia of a sensible and consistent regulatory environment ...

. alert regulatory agencies ... to consider whether their existing regulations and operations require updating ...

. encourage the development of compatible national and international assessment procedures and standards and the avoidance of ... duplication

. assist ... GMAC with the planning, design and conduct of its assessment and advisory activities".[43]

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41 ibid., p 19

42 ibid., p 4

43 Charter of Group of Officials on Biotechnology Regulations

1.68 GOBR held its first meeting in November 1988. Since October 1990 GOBR has been involved in the development of a national approach to biotechnology regulation firstly through the Australian Industry and Technology Council and subsequently through a joint effort of the Australian and New Zealand Environment Council, the Australian Agriculture Council, the Australian Health Ministers' Conference and the Australian Industry and Technology Council.

1.69 In March 1988 the Law Reform Commission of Victoria released its Discussion Paper No 11 *Genetic Manipulation*; in June of the following year its Report No 26, *Genetic Manipulation* was published.

1.70 The House of Representatives Standing Committee on Industry, Science and Technology began its Inquiry into Genetically Modified Organisms after receiving a reference from Senator Button, Minister for Industry, Technology and Commerce, in July 1990.

1.71 In the same month several working parties were set up to discuss aspects of genetic manipulation. A working party of the Australian and New Zealand Environment Council (ANZEC) was created "to develop a suggested national approach for regulatory arrangements covering pre-release assessment and post-release monitoring to minimise environmental hazards of GMOs."[44]

1.72 The Australian Agricultural Council (AAC) also set up working parties, to examine bioethical issues, and a second "to look at the application of genetic manipulation to plants and animals and relevant legislative issues".[45]

1.73 A special Premier's Conference was held in October 1990 which agreed "to the development of a national approach to assessment and control of GMOs."[46] In February 1991 a Joint Ministerial Councils Group meeting was hosted by ANZEC with representatives from AAC, the Australian Industry and Technology Council and the Australian Health Ministers' Conference. The aim was "to discuss the development of a common approach".[47]

> "The meeting recognised that the biotechnology industry is of great potential value to Australia, and its development should be facilitated without compromising good environmental management or public health. Due consideration must also be given to relevant social, economic, and ethical issues."[48]

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44 Department of Industry Technology and Commerce: Submission 126.1 p 1

45 ibid.

46 ibid., p 2

47 ibid.

48 ibid., Attachment A: *Report on First Meeting of Ministerial Council Representatives on the Development of a National Approach to Biotechnology Regulation*, p 1

CHAPTER TWO

EXISTING SYSTEM OF REGULATION

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A. The Australian Guidelines

2.1 There are four sets of guidelines relevant to genetic manipulation technology. Three have been produced by GMAC or its predecessor, RDMC. A fourth set of guidelines has been produced by a joint working party of the National Health and Medical Research Council (NH&MRC), CSIRO and the Australian Agricultural Council, together with representatives from various States, which covers work with animals.[1] This contains a section covering genetic manipulation experiments.

2.2 All the guidelines produced by RDMC and GMAC

> "... apply to any experiment involving the construction and/or propagation of viroids, viruses, cells or organisms of novel genotypes produced by genetic manipulation which are: *either* unlikely to occur in nature, *or* likely to pose a hazard to public health or to the environment."[2]

A.1 GMAC/RDMC Guidelines

A.1.(i) Guidelines for Small Scale Genetic Manipulation Work[3]

2.3 These guidelines concern work involving less than ten litres of cell culture and non-commercial production of:

- animals which are able to be contained within animal facilities
- plants contained within a single plant house
- fish accommodated in a laboratory aquarium
- insects which can be contained in an insectary.

Finally, if disease causing organisms are being produced, the quantity of their hosts should themselves fall within the criteria for the small scale work.

2.4 "Work with the debilitated K12 strain [of *Escherichia coli*], approved vectors and many of the genes from non-pathogens and non-pest species is exempt from the guidelines, as is work where genetic information is exchanged within one species, or between species known to do so in nature."[4]

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1 National Health & Medical Research Council/Commonwealth Scientific and Industrial Research Council/Australian Agricultural Council: *Australian code of practice for the care and use of animals for scientific purposes*, July 1990: Exhibit 47

2 Genetic Manipulation Advisory Committee (GMAC): *Guidelines for Small Scale Genetic Manipulation Work*, December 1989

3 ibid.

4 GMAC: Submission 88 p 5

2.5 The bacterium *Escherichia coli* (*E. coli*) is often used in small scale work because it has been extensively studied by molecular biologists. Consequently, its genetics and metabolism are well understood. The K12 strain is used because of its minimal survival outside the laboratory and its inability to transfer genetic information to other strains.

2.6 There were 1755 small scale proposals considered by RDMC or GMAC between 1981 and June 1990 - 1633 of which were considered to require only the lowest level of containment.[5]

A.1.(ii) Guidelines for Large Scale Work with Recombinant DNA[6]

2.7 These cover work with micro-organisms in volumes greater than 10 litres, or work with plants and animals which are housed in large facilities.

2.8 A category of GILSP (Good Industrial Large Scale Practice) covers work which is within the guidelines but of negligible risk. Such work merely requires the following of accepted safety practices for large scale industrial work.

2.9 There were 15 large scale projects reviewed by RDMC or GMAC between 1981 and June 1990.[7]

A.1.(iii) Procedures for Assessment of the Planned Release of Recombinant DNA Organisms[8]

2.10 Even though these guidelines refer to 'Recombinant DNA organisms', it is presently intended to cover the deliberate release into the environment of all genetically modified organisms.[9] GMAC is currently reviewing the document and revised guidelines are expected to be published in late 1991.[10]

2.11 Although research in certain areas can be exempt from the small and large scale guidelines "exemption from these guidelines does not mean exemption from the Planned Release Procedures."[11]

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5 ibid., p 6

6 GMAC: *Guidelines for large scale work with genetically manipulated organisms*, December 1990

7 GMAC: Submission 88 p 7

8 Recombinant DNA Monitoring Committee (RDMC): *Procedures for Assessment of the Planned Release of Recombinant DNA Organisms*, May 1987

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

10 ibid.

11 RDMC: *Planned release guidelines*, Section 3.2

2.12 The procedures also apply if a modified organism intended for release is imported into Australia.

2.13 The RDMC or GMAC have approved 10 proposals for release since 1987. (A list of the proposals is given in Appendix VI.)

A.2 Australian code of practice for the care and use of animals for scientific purposes[12]

2.14 The Code covers all live non-human vertebrates (animals with backbones). Sections 3.3.54 to 3.3.57 deal with the "Experimental manipulation of animals' genetic material".[13]

B. The Procedures at Work

2.15 If a company or research institution wishes to engage in research involving genetically modified organisms it has to take four major steps.

- . the facilities have to be adequately equipped and approved
- . an institutional biosafety committee has to be set up
- . approval has to be sought for projects
- . the guidelines for the research have to be followed.

B.1. The facilities for genetic manipulation

2.16 The requirements for physical containment vary depending on the scale of research contemplated. There are guidelines for small and large scale facilities. There are also levels of containment - one to three, with three being the highest containment. Higher containment levels include the requirements of lower containment but incorporate extra conditions. The containment needed for a project is decided by the IBC in consultation with GMAC. All laboratories and buildings such as animal houses must be clearly marked and the general public should not have direct access.

The increasing levels of security required in the facilities for contained work are shown in Figure 2.1.

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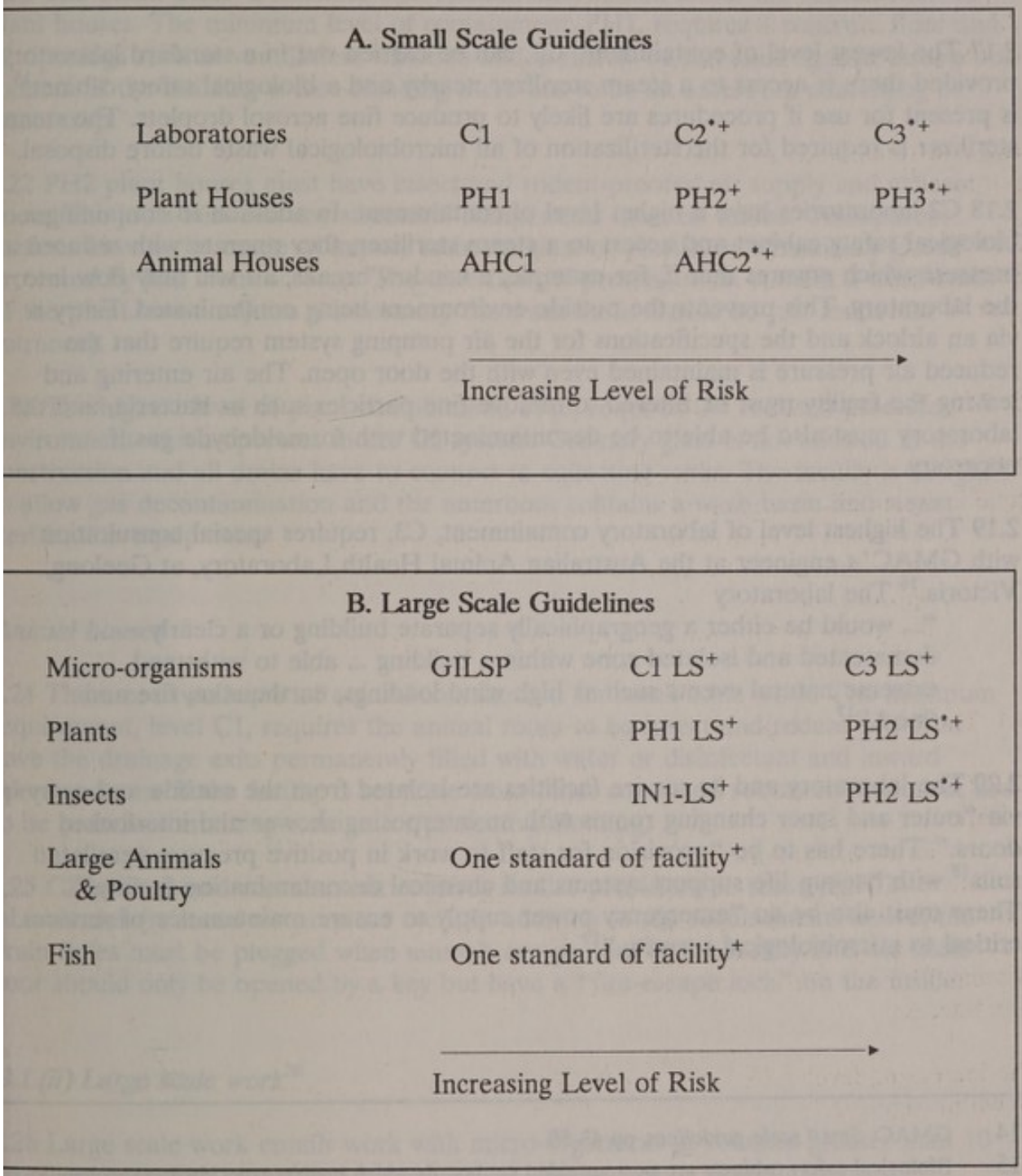
12 NH&MRC/CSIRO/AAC: *Australian code of practice*. Exhibit 47

13 ibid., p 29

Figure 2.1 Types of facilities for contained work



Facilities requiring a reduced air pressure working environment

Requires GMAC certification

B.1.(i) Small scale work[14]

Laboratories

2.17 The lowest level of containment, C1, can be carried out in a standard laboratory provided there is access to a steam sterilizer nearby and a biological safety cabinet[15] is present for use if procedures are likely to produce fine aerosol droplets. The steam sterilizer is required for the sterilization of all microbiological waste before disposal.

2.18 C2 laboratories have a higher level of containment. In addition to containing a biological safety cabinet and access to a steam sterilizer, they operate with reduced air pressure which ensures that if, for example, a window breaks, air will only flow into the laboratory. This prevents the outside environment being contaminated. Entry is via an airlock and the specifications for the air pumping system require that the reduced air pressure is maintained even with the door open. The air entering and leaving the facility must be filtered to remove fine particles such as bacteria, and the laboratory must also be able to be decontaminated with formaldehyde gas if necessary.

2.19 The highest level of laboratory containment, C3, requires special consultation with GMAC's engineer at the Australian Animal Health Laboratory, at Geelong, Victoria.[16] The laboratory

> "... would be either a geographically separate building or a clearly demarcated and isolated zone within a building ... able to withstand extreme natural events such as high wind loadings, earthquake, fire and flood."[17]

2.20 The laboratory and its service facilities are isolated from the outside and entry is via "outer and inner changing rooms with an interposing shower and interlocked doors." There has to be "provision for staff to work in positive pressure ventilated suits[18] with backup life support systems and chemical decontamination facility." There must also be an "emergency power supply to ensure maintenance of services critical to microbiological security."[19]

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14 GMAC: *Small scale guidelines*, pp 43-58

15 Biological safety cabinets are perspex-sided cupboards which enable experimenters to handle materials without breathing on them, or being exposed to gases or droplets coming from them. Even during use, air can only enter or leave the cabinet after passing through filters.

16 GMAC: *Small scale guidelines*, p 48

17 Martin, D, Australian Animal Health Laboratory, Geelong Victoria: Exhibit 129 p 1

18 A 'positive pressure ventilated suit' means that a worker is surrounded by air of a pressure greater than that of the laboratory. If the suit is damaged, air from the laboratory cannot enter, thus the worker is protected from any air-born hazards.

19 Further information about C3 laboratories and working procedures can be found in Exhibit 129: Martin, D, Australian Animal Health Laboratory, Geelong Victoria

Plant houses

2.21 The Small Scale Guidelines also contain information about the construction of plant houses. The minimum level of containment, PH1, requires a concrete floor and all openings such as ventilation, windows and drains to be screened against insects and rodents. If the building is free-standing there has to be an anteroom containing an insect trap.

2.22 PH2 plant houses must have insect and rodent-proofed air supply and exhaust ducts. The joins between any structural components must be sealed. Transparent sections have to be made of impact resistant glass or plastic, or of ordinary glass protected by hail stone screens. The anteroom, if present, must contain a wash basin (if the plant house adjoins a laboratory the wash basin should be just inside the entrance).

2.23 The highest level of plant containment, PH3, requires the reduced pressure environment which operates in the C2 system. Ordinary glass is not allowed in the construction and all drains have to connect to collecting tanks. The facility is designed to allow gas decontamination and the anteroom contains a wash basin and steam sterilization equipment.

Animal houses

2.24 There are two levels of animal containment for small scale work. The minimum requirement, level C1, requires the animal room to be insect and rodent proof, to have the drainage exits permanently filled with water or disinfectant and inward opening doors. If the facility is separate from other contained rooms an anteroom has to be present containing storage for protective clothing.

2.25 C2 level animal containment requires similar provisions to those for C2 laboratories (reduced air pressure etc.). In addition to the requirements above, the drain holes must be plugged when animals are present in the facility and the main door should only be opened by a key but have a "fire escape lock" on the inside.

B.1.(ii) Large scale work[20]

2.26 Large scale work entails work with micro-organisms in volumes greater than 10 litres, or work with plants and animals which are housed in large facilities.

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20 GMAC: *Large scale guidelines*, pp 23-38, p 60

Good Industrial Large Scale Practice (GILSP)

2.27 The GMAC guidelines recognise micro-organisms considered to be of low risk and therefore requiring minimal controls. GILSP means that the standard of safety precautions required to be taken is the same as for other organisms currently used in large scale industrial production. Examples of GILSP are included in the guidelines.[21]

2.28 The requirements have been developed from OECD guidelines.[22] Facilities have to incorporate treatment of air exhausts and liquid effluent (the latter requirement being added by GMAC), and should have washing and decontamination capabilities.

Containment for higher risk micro-organisms

2.29 For micro-organisms requiring more than GILSP safety precautions, there are several types of containment. C1-LS requires the exhaust gases from culture vessels etc. to be filtered or sterilized to prevent release of viable organisms. In addition the facility should be able to contain any material lost from culture vessels.

2.30 C3-LS (there is no C2-LS) requires, in addition, that the equipment be enclosed in a 'controlled area' subject to reduced air pressure. Other conditions match those of C2 in the Small Scale Guidelines.

Containment for large animals and poultry

2.31 Two layers of containment are required: primary and secondary. The requirements of the primary containment area are similar to those in the Small Scale Guidelines. It is used to isolate animals which have had foreign DNA inserted by an infectious agent. Those animals shown to be non-infectious can be housed in a 'secure area' within a secondary containment area. This consists of a 2 metre security mesh fence designed to prevent animals burrowing underneath or flying over the top.

Containment for plants and insects

2.32 There are two levels of containment for large scale work with plants, PH1-LS and PH2-LS. These are similar to those of the Small Scale Guidelines. The PH2-LS facility operates under reduced air pressure as does the PH3 plant house under the Small Scale Guidelines.

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21 ibid., Appendix 6.7, p 60

22 Organisation for Economic Cooperation and Development (OECD): *Recombinant DNA Safety Considerations*, 1986 p 34-35

2.33 There are specifications for large scale insect houses, but these are not highly detailed, owing to the likely diversity of the insects and their associated pathogens. The minimum standard, IN1-LS requires the building to have an anteroom with self-locking doors and enough space to allow decontamination of materials and personnel. Construction should allow the building to be decontaminated with appropriate liquids and gases and any openings should not permit the entry of insects or rodents. If air conditioners are installed they should be capable of recirculating the air so that no air is released to the outside. Drainage and waste material should be collected for decontamination before removal. Facilities that meet the PH2-LS or insect quarantine standards can also be used as insect houses.[23]

Containment for fish

2.34 For the production of transgenic fish, the principle is to prevent the escape of the smallest viable particles such as sperm - 5 micron in size.[24] In fish reproduction, eggs are usually released into the water and are fertilized by sperm which is also released. If sperm from a genetically modified fish escaped in discharge water they might fertilize the eggs of unmodified local fish. Thus, although transgenic fish might not escape, their modified genes could.

2.35 Accordingly, water is recirculated, or sterilized before discharge. Hatchlings and fingerlings have to be raised in entirely enclosed rodent and amphibian proof buildings with airlock entrances. For growing out, the use of net cages suspended in either fresh or salt water is prohibited. In addition, the facility must not be located in an area prone to flooding or naturally draining into a water course or the sea. Moreover:

> "To protect aquaria, outside ponds and raceways from theft and vandalism, movement sensors, light beams and alarms are required, as perimeter fencing alone is not an effective deterrent."[25]

B.1.(iii) Facility inspections

2.36 All facilities once constructed have to be certified. GMAC advises that:

> "Organisations planning new containment facilities or making amendments to upgrade levels of existing facilities are advised to submit plans to GMAC before commencement of work. This process may save the organisation costly mistakes."[26]

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23 GMAC: *Large scale guidelines*, pp 36-38
24 5 micron is 5 one thousandths of a millimetre
25 GMAC: *Large scale guidelines*, p 35
26 ibid., p 10

2.37 The IBC certifies all Level 1 and GILSP facilities; GMAC certifies all the other facilities. The laboratory manager is notified about the visit in advance.[27]

2.38 The guidelines indicate that certified laboratories should be inspected regularly. Furthermore, "GMAC reserves the right to inspect laboratories and facilities at any time without notice."[28] To date, GMAC has not exercised this right to inspect facilities.[29] Although IBCs have to provide an annual report, the details which are required do not include a record of facility inspections.[30]

B.2 Institutional Biosafety Committees

2.39 The role of the Institutional Biosafety Committee system is to provide for the monitoring of the day-to-day work of bodies involved in genetic manipulation and ensure the GMAC guidelines are followed. There are over 70 IBCs in Australia.[31]

2.40 The Institutional Biosafety Committee classifies proposed genetic manipulation work into one of four categories:

. 'Exempted work' (see paragraphs 2.65 - 2.67): this involves negligible risk, is exempt from the GMAC guidelines, but has to be carried out under normal microbiological laboratory conditions

. 'Specially exempted work' (see paragraphs 2.65 -2.67)[32] researchers may apply for their work to be exempted if they consider it to pose no significant risk. A request has to be endorsed by the IBC and GMAC

. 'Category B work' (see paragraphs 2.68 - 2.69): this involves low but not negligible risk to laboratory personnel, the community or the environment. The IBC assesses the level of containment required, and notifies the project to GMAC for information

. 'Category A work' (see paragraphs 2.70 - 2.71): this is more hazardous work or work of uncertain risk and requires GMAC assessment before work may proceed.

2.41 There are two types of containment that can be used

. physical - closed containers, safety cabinets, specially designed equipment

. biological - using host organisms that would not survive outside the laboratory.

2.42 GMAC emphasises the importance of the IBC in the regulation of genetic manipulation work. It is stated: "The calibre and expertise of members on the IBC should be such that it can competently carry out its duties. The Chairman of the

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27 Correspondence from GMAC, 5 Aug. 1991

28 GMAC: *Small scale guidelines*, p 12

29 Correspondence from GMAC, 5 Aug. 1991

30 GMAC: *Small scale guidelines*, p 17

31 GMAC: *Report for the period 1 July 1989 to 30 June 1990*, p 3

32 GMAC: *Small scale guidelines*, p 9

Committee should be of sufficient standing in the institution for decisions and advice by the IBC to be effectively implemented."[33]

B.2.(i) The composition of the IBC

2.43 The membership of the IBC is defined in the guidelines and includes a Biological Safety Officer where applicable, an engineer able to test the safety aspects of the facilities and equipment, and "at least one informed or interested external member from the wider community who need not have a technical background."[34]

2.44 Unfortunately, it has become apparent during evidence that this requirement may not always be met. The Queensland Department of Primary Industry IBC has no lay person[35] and the IBC of the University of Queensland has "a person from [the] geology and mineralogy [department]" of the University to represent the 'wider community'.[36] The IBC which covers Arthur Webster Pty Ltd consists solely of company employees, although there is a "non-technical representative ... [who] is a person from ... within the administrative or accounts division of the company".[37]

2.45 However, not all company IBCs are 'in house' committees. For example, Burns Philp and Co. Ltd is covered by two IBCs: yeast strain development is covered by the IBC from the nearby CSIRO Division of Biomolecular Engineering (with only one Burns Philp representative); cheese starter research is covered by the University of New South Wales IBC.[38]

2.46 If large scale work is contemplated, there should be a member able to advise on the relevant legislation and regulatory practice. An external member with technical expertise is also needed. (IBCs fearing breaches of confidentiality are advised to include a consultant who is independent of the project or organisation.)[39]

2.47 If release of a live modified organism is envisaged, the IBC needs to include an ecologist with expertise relevant to the organism.[40]

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33 ibid., p 14
34 ibid.
35 Dalgliesh, R: Deputy Director, Pathology Branch, Animal Research Institute, DPI Queensland: Transcript p 1026
36 Pemberton, Dr J, Institutional Biosafety Committee, University of Queensland: Transcript p 974
37 Lehrbach, Dr P, Genetic Research, Arthur Webster Pty Ltd: Transcript p 875
38 Evans, Dr R and Friend, Dr J, Burns Philp & Co Ltd: Transcript p 905
39 GMAC: *Large scale guidelines*, p 12
40 RDMC: *Planned release guidelines*, Section 4.2

B.2.(ii) The responsibilities of the IBC

2.48 The chairperson of the IBC informs GMAC of the membership of the Committee and provides yearly updates.[41] The yearly update, which is initiated by GMAC, also requires a listing of the current proposals, certified facilities, and a report of any significant incidents. As well:

> "If the IBC Chairperson is satisfied that an accident or incident occurred which was directly attributable to work with genetically manipulated organisms, and was of sufficient significance, he/she **should make a report to GMAC and the head of the organisation as soon as the information comes available.** An example of such an incident might be a deliberate failure to comply with these Guidelines, or an incident or accident which may have resulted in a risk to human health or to the environment."[42]

2.49 The major role of the IBC is to receive all proposals for genetic manipulation research and send a copy to GMAC together with an assessment, both of the potential hazards and the suitable level of containment. There are several categories of work - some small scale work can proceed after IBC approval only; others with IBC approval and GMAC notification; other small scale work has to be approved by GMAC before work can commence. Unless specifically exempted in the Large Scale Guidelines all large scale work "must be submitted to the IBC for assessment, and subsequently to GMAC for review. ... Project supervisors **must not begin work** until specifically advised by the IBC, after GMAC review."[43]

2.50 The 'exempted work' must, nevertheless, be submitted to the IBC for its endorsement before work commences. GMAC is notified of the exempted work.

2.51 All release proposals have to be submitted to GMAC, via the IBC, which also advises the relevant government regulatory authority. GMAC does not have the power to approve the release of genetically modified organisms.

2.52 GMAC provides advice concerning the safety of the proposal and adequacy of the level of containment suggested. The IBC has to ensure that GMAC's advice is acted upon. The IBC is also able to impose additional rules for projects provided they are consistent with the Guidelines.

2.53 All projects and facilities have to be monitored. "At least annual inspections of all facilities should be undertaken to ensure that they continue to meet the relevant containment requirements."[44]

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41 A form - *Institutional Biosafety Committee Information Form* - is provided by GMAC for this purpose.

42 GMAC: *Large scale guidelines*, p 17

43 ibid., p 6

44 ibid., p 13

2.54 For projects involving the release of organisms the IBC has to:

> "... monitor the progress of the release and immediately report any significant unforeseen occurrences to [GMAC]. At the end of any field trial a report on the work should be submitted ... Should any significant longer term effect, such as an adverse environmental effect, become apparent after the monitoring period then [GMAC] should be informed by the IBC."[45]

2.55 In addition, the IBC has to review the qualifications and experience of personnel working on projects and maintain a register of projects and personnel.

2.56 For large scale work an operating manual has to be produced for each project. This includes operating instructions as well as emergency procedures, and information relevant to worker and environment safety. The Standard Operating Procedures outlined in the manual are checked by the GMAC inspection team when they certify the facilities. The IBC is responsible for carrying out annual audits of the procedures and of the operating manual.

2.57 The IBCs have to ensure that organisations undertaking large scale work keep permanent records which are available for inspection by GMAC. Records of the processes used are kept for the life of the project, whilst medical records are kept indefinitely.

2.58 Serum samples are obtained from workers involved in C3-LS projects before the work commences and samples are then taken at a biennial medical examination. The samples would be available if any unforeseen long term adverse affects became apparent.

2.59 For small scale work the keeping of medical records is only recommended for C3 work, however, many organisations working with micro-organisms undertake routine monitoring.[46]

B.3 Gaining approval for projects

2.60 Once the facilities have been built and certified and the IBC instituted, an organisation has to undergo an approval procedure for its projects. A description of the procedure relevant to the different categories of work is contained in this section paragraph 2.62 to paragraph 2.85.

2.61 With all proposals the IBC provides an assessment of the suggested research, the category into which it falls and the competence of the researchers. If GMAC is notified, or its approval sought, the assessment is forwarded to GMAC with the original proposal. The categories for contained work are shown in Figure 2.2.

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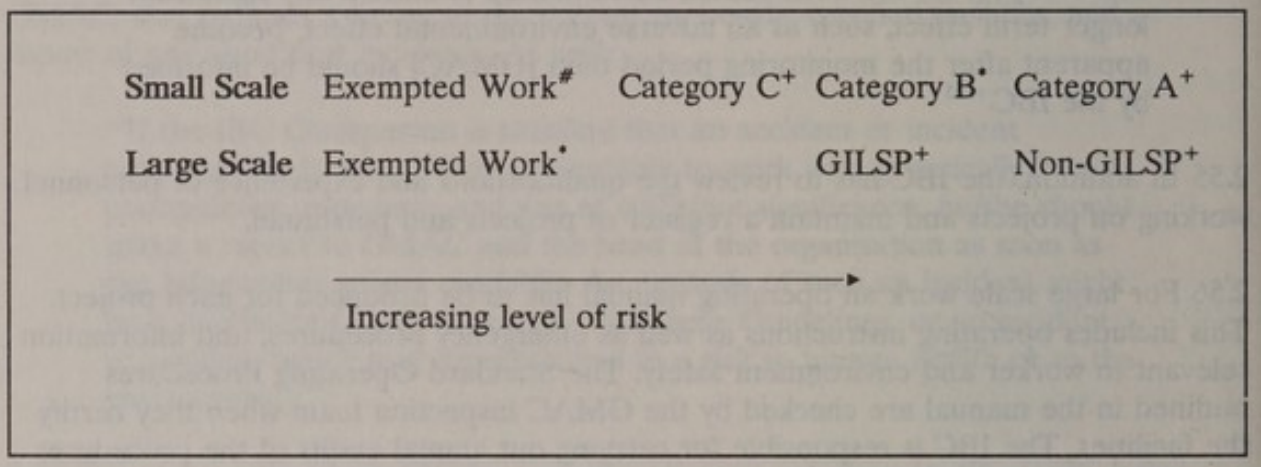
45 RDMC: *Planned release guidelines*, Section 4.8

46 GMAC: *Small scale guidelines*, p 17

Figure 2.2 Categories of contained work



- IBC approval only
* - IBC approval needed; GMAC is notified
+ - IBC and GMAC approval is needed.
GILSP - "Good Industrial Large Scale Practice"

B.3.(i) Proposals for small scale work

2.62 The proposer has to provide a brief description of the main steps involved in the work. This includes:

. the source of the DNA used or, if the DNA is already available, details of who made it, how it was obtained and a description of its properties
. the details of the host organism to which the DNA is added, as well as the method to be used - the `vector'
. a written description of the vector, and, if it is a retrovirus, a detailed description of its genetic content
. the category into which the proposer feels the project falls (this would determine the level of containment envisaged)
. the location of the proposed work and its certified containment level.

2.63 The IBC assesses the proposal and comments on the category into which it falls. If the proposal falls into two categories, GMAC emphasises that it should be dealt with under the category requiring the highest containment. The proposal and the IBC assessment are forwarded to GMAC, unless the work falls into an exempted category. For the higher risk category, work can only proceed after GMAC has assessed the proposal and advised on the level of containment.

2.64 There are three categories of work falling under the Small Scale Guidelines. They are discussed here in order of increasing risk.

Category C - Special exemptions, and Exempted work

2.65 These experiments are of low risk because they involve
. non-pathogenic organisms
. micro-organisms which are known to naturally exchange genetic information
. experiments with approved host/vector systems[47] and which do not carry the possibility of creating infectious agents or growth regulating chemicals.

2.66 Researchers may feel that their project falls outside this description but still carries negligible risk. If they can demonstrate to GMAC that it carries minimal risk, they can be granted a 'Category C - Special Exemption'.

2.67 Notwithstanding the low risk, and the fact that GMAC notification is not required for such work, 'exempt experiments' must receive IBC approval before work commences.

Category B - Experiments which require GMAC notification and IBC approval

2.68 The experiments in this category involve
. whole animals and plants but not micro-organisms
. work with non-approved host/vector[48] systems
. work with approved host/vector systems but involving genes able to create pathogenicity, cell growth regulators, or using DNA from micro-organisms able to cause disease.

2.69 The work carries low risks to laboratory personnel, the community and environment. The containment is usually C1, or PH1. However, the work is only able to proceed after IBC approval.

Category A - Experiments which require GMAC advice and IBC approval

2.70 The experiments in this category involve
. agents or organisms which can infect human, animal or plant cells
. DNA which encodes for a growth regulator, pathogenicity, or chemicals of high toxicity
. human gene therapy experiments.

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47 Approved host/vector systems are designed to confer biological containment. The host organism is unlikely to survive outside the laboratory and the vector is unable to transfer to organisms not involved in the experiment. A list of approved systems is given in Appendix 5.3 pp 28, 29 of the Small scale guidelines

48 ibid.

2.71 The category includes work which has known or uncertain hazards to researchers, community, environment or a patient.
GMAC assesses the proposed work and decides the level of appropriate containment; C1 may be considered sufficient. If GMAC raises any concerns they have to be addressed. The researchers must not commence work until GMAC's advice is conveyed to them via the IBC.[49]

B.3.(ii) Proposals for large scale work

2.72 In addition to information similar to that supplied for a small scale project, the proposal has to include the following:

. the nature of the products, contaminants or wastes
. the procedures for disposing of any animals or plants that are used
. the procedures for checking the genetic stability of the organisms
. arrangements for supervising, training and monitoring the health of personnel
. the transport arrangements if DNA material is to be transported both within the organization or between facilities

2.73 Finally the proposal must include information about "any aspect which may adversely affect workers, the public or the environment."[50]

2.74 There are three categories which fall under the large scale guidelines and they all require IBC assessment and approval. The IBC assessments are forwarded to GMAC. Work entailing higher risk needs GMAC approval before the project can commence, whereas the lowest risk category - exempt work - only requires GMAC notification.

Exempted work

2.75 The criteria for exemption are the same as for small scale work. The Guidelines specify that if a release of live genetically modified organisms is involved, the work falls within the purview of the Release Guidelines. Moreover the work must comply with any relevant statutory provisions.[51] An example of such work is the production of vaccine doses for pig trials by Enterovax Pty Ltd in 1987.[52]

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49 GMAC: *Small scale guidelines*, p 6
50 GMAC: *Large scale guidelines*, Appendix 6.5: Form DAS 1329 (9/90), *Proposal for Assessment of Large Scale Work*, Question 24.
51 GMAC: *Large scale guidelines*, p 5
52 Correspondence from GMAC, 5 Aug. 1991

Good Industrial Large Scale Practice (GILSP)

2.76 GILSP projects are considered not to pose significant risk to workers, the public or the environment because the DNA involved does not introduce a hazard and the host/vector system employed provides biological containment.[53] The production of human growth hormone by the Commonwealth Serum Laboratories, approved in August 1990, is an example of a GILSP project.[54]

Non-GILSP work

2.77 All other large scale work falls under this category and requires IBC endorsement and GMAC approval before work can commence. An example of such work is the production of a tick vaccine by Biotech Australia Pty Ltd in 1988.[55]

B.3.(iii) Proposals for releasing genetically modified organisms

2.78 The range of information required in the proposal is comprehensive, covering, inter alia:

. the aims of the proposal and why other methods, especially those not involving release, are inferior
. details of the genetic modification and its effect; the stability of the modification and the chances that genetic material could be transferred into other organisms in the release area
. the known effects of the unmodified parent organism, and an assessment of the possible effects of the modified organism on human, animal and plant health, agricultural productivity and the environment
. evidence relating to the persistence, viability and potential for the modified organism to disperse in the release area
. details of the actual release experiment and how any potential adverse effects would be monitored in both the short and long term
. details of contingency plans in case of environmental extremes, such as floods, and control methods if it was decided to eliminate the organism at some stage

2.79 In addition, the proposal has to answer questions relating to the particular organism or end uses. The categories are:

. live vaccines
. micro-organisms associated with plants
. micro-organisms associated with animals (e.g. ruminants)

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53 Approved host/vector systems are designed to confer biological containment. The host organism is unlikely to survive outside the laboratory and the vector is unable to transfer DNA to organisms not involved in the experiment. A list of approved systems is given in Appendix 5.3, pp 28, 29 of the Small Scale guidelines.

54 Correspondence from GMAC, 5 Aug. 1991

55 ibid.

. micro-organisms used to modify the environment (e.g. biological or pollution control)
. micro-organisms to be used in food
. domesticated or farm animals
. crop or pasture plants

2.80 For each category, the proposer has to answer 23 questions; there are between 2 and 13 additional questions depending on the category of organism being assessed. The questions concern aspects of the organism, the experiment and possible effects on the release environment.

2.81 The process by which a proposal to release a GMO is presently considered is set out below:

> "(1) ... the proposal must be endorsed by the institution's biosafety committee (IBC)
> (2) the IBC sends the endorsed proposal to GMAC for consideration
> (3) the scientific committee of GMAC considers the genetic aspects of the construct and the planned release committee considers the genetic aspects and the environmental issues associated with the release. These committees review the proposal bearing in mind a set of criteria listed in the GMAC Guidelines ...
> (4) their report is sent to the responsible IBC and to the agency which currently has regulatory authority for the release of that type of novel organism, for example, a Department of Health for a novel vaccine, or an environment agency if the proposal is related to an organism which has special properties to degrade a pollutant such as chlorinated hydrocarbon
> (5) GMAC does not give approval for the release - this is given by the legally responsible agency. That agency will add the advice from GMAC to other information it considers. At this point, the agency may seek public opinion or the views of special groups. The agency ... will decide whether to grant permission. If it does so, it may also define particular conditions, monitoring and reporting."[56]

> "... it is suggested that an IBC have enough scientific members so it is not totally dependent on the advice of the persons submitting a proposal ... in planned release work the IBC should include members experienced in ecological assessment appropriate to the release projects under the IBC's supervision."[57]

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56 Millis, Prof N, Chairman, GMAC: *Adequate Guidelines are already in Place*, in *Search*, Vol 20(3) May/June 1989 pp 80, 81

57 RDMC: *Planned release guidelines*, Section 4.2

> "[GMAC] must be notified in advance by the IBC if it is proposed that [a GMAC] recommendation not be implemented."[58]

2.82 If GMAC is concerned about an IBC intending not to implement a GMAC recommendation it is prepared to consult with the regulatory agency and, if the problem remains unresolved, advise the Minister.[59]

2.83 There are no procedures in the Guidelines for public involvement in this assessment process. However,

> "[GMAC] recognises that public participation in decision-making on planned release proposals can be a significant issue. The lead role in any program of public participation would be handled by the appropriate regulatory authority. [GMAC] will assist the responsible agency, if requested, in any public participation programme."[60]

B.3.(iv) Proposals involving 'all live non-human vertebrates'

2.84 These proposals fall within ambit of the *Australian code of practice for the care and use of animals for scientific purposes.* The Code requires that the proposal must be submitted to an Animal Experimentation Ethics Committee (AEEC) for approval and must be carried out in accordance with guidelines issued by GMAC and the institution's biohazards committee. All institutions using animals for scientific purposes are required under the Code to "establish one or more AEECs or their equivalents".[61] 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".[62]

2.85 Consequently, an AEEC must have a broad membership which may include a representative from an animal welfare group.[63] "Investigators must inform the AEEC of the known potential adverse effects on the well-being of the animals."[64]

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58 ibid., Section 4.13

59 ibid., Section 4.7

60 ibid., Section 4.11

61 NH&MRC/CSIRO/AAC: *Australian code of practice*: Exhibit 47 p 9

62 ibid., p 10

63 The Code suggests the following membership for the AEEC: a member qualified in veterinary science; a person with substantial recent experience in animal experimentation; an independent person with a demonstrated commitment to animal welfare, preferably a member of an animal welfare group; an independent person who has not conducted animal experiments, preferably not employed by the institution.

64 NH&MRC/CSIRO/AAC: *Australian code of practice*: Exhibit 47 p 29

B.4 Following the guidelines

2.86 The institutions undertaking genetic modification research are obliged to acquaint researchers with the guidelines.

> "An institution, firm or its recruitment section should ensure that staff recruited to work in laboratories are informed of hazards, have adequate training to ensure that their work is carried out under these Guidelines, and have access to the IBC Chairman or Biological Safety Officer for advice."[65]

2.87 Both the small and large scale guidelines contain detailed procedures to be carried out in each of the containment areas. They are comprehensive and akin to 'Laboratory Rules', prescribing what can and cannot be done.[66] Many of the procedures would be regarded as sensible microbiological practice, for example: "Hands must be washed with liquid soap and water when leaving the laboratory and after handling cultures. All microbiological waste must be steam sterilized before disposal."[67]

2.88 There are specific recommendations for handling retroviruses and DNA fragments such as oncogenes.[68,69]

2.89 Both the Small and Large Scale Guidelines contain procedures for transporting material within the institution and between facilities.

> "Any container of viable organisms must be transported within a secondary unbreakable and closed container which can be readily decontaminated. Workers who wish to transfer material between institutions are advised to pay particular attention to the various statutory regulations regarding the transport of biological materials regarded as infectious."[70]

2.90 Concerning the transport of transgenic animals, both guidelines emphasise:

> "... the need to prevent the animals escaping ... the need to ensure that they are properly identified and duly arrive at the intended destination, and to ensure that a competent biologist with some experience in handling transgenic animals takes delivery of them. The IBC may institute whatever procedures or rules it considers appropriate to meet

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65 GMAC: *Small scale guidelines*, p 13

66 GMAC: *Small scale guidelines*, Appendix 5.9 to 5.19, pp 43-66; GMAC: *Large scale guidelines*, pp 22-38

67 GMAC: *Small scale guidelines*, p 43

68 An oncogene is a gene or genes which, when inappropriately activated, can be involved in the production of cancer. (See Chapter 6 Section *C.2.(iii)*)

69 GMAC: *Small scale guidelines*, pp 33-38

70 GMAC: *Small scale guidelines*, p 20; GMAC: *Large scale guidelines*, pp 39, 40

> these conditions. It may be necessary for the IBC to inspect the arrangements for transport, to satisfy that the above conditions are adhered to".[71]

2.91 Thus it is clear that the IBC must be involved in approving any movement of transgenic animals out of the facility.

2.92 If material is supplied to other researchers it is emphasised that the recipients "are made aware of the existence of these Guidelines and of the need to comply with them."[72]

2.93 The Department of Primary Industries and Energy is responsible for all quarantine matters. If genetically modified material is to be imported the IBC has to be consulted and permission sought from the Australian Quarantine and Inspection Service so that it can be assessed under the appropriate regulations for importing exotic organisms.

2.94 Where activities involve non-human vertebrate animals, "the clinical status of animals ... must be monitored for unusual or unexpected adverse effects. Investigators must report such effects to the AEEC."[73]

C. Sanctions for failure to adhere to the guidelines

2.95 Adherence to the guidelines is voluntary. There can be sanctions although these are more punitive for publicly funded institutions than for privately funded research bodies:

> "Non-compliance ... may result in withdrawal of grants by the major Commonwealth Government funding authorities. ... Registration for tax incentives for private sector funding of research and development may also be conditional upon compliance with GMAC Guidelines. ... Non-compliance will be reported to the Minister who may make a public statement. [Establishments] may also be named for non-compliance under GMAC's annual reporting requirements."[74]

2.96 Furthermore continual breaches of substantive requirements could result in an inquiry under public health and occupational health and safety legislation.

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71 GMAC: *Small scale guidelines*, p 21; GMAC: *Large scale guidelines*, p 41
72 GMAC: *Small scale guidelines*, p 21; GMAC: *Large scale guidelines*, p 39
73 NH&MRC/CSIRO/AAC: *Australian code of practice*: Exhibit 47 p 29
74 GMAC: *Small scale guidelines*, p 19; GMAC: *Large scale guidelines*, p 19

2.97 In evidence companies stated that they are willing to follow the voluntary guidelines:

> "You would not endanger the whole project by ignoring the advice of an advisory body, such as GMAC, at an early stage. I do not think you would bypass it, if eventually you were to commercialise it [a product]. I do not see you would gain from that. ... How are you ever going to prove it to be safe and efficacious when it comes up for registration [under existing end use legislation] if you have not taken the early precautions. ... I think there is too much at risk commercially to go outside the system."[75]

2.98 Indeed, some companies stated they were prepared to go beyond the guidelines.

> "It is certainly our attitude that, as a company, we should be whiter than white; we are very anxious to do as much, or more, than GMAC requires. I think that as a commercial company you are more visible than an academic institute in fact and more is expected of you, and we certainly try to accomplish that."[76]

> "Right from the beginning we set out to set standards which went beyond those of the accepted guidelines because we thought we would then be safe and we have always done that. At the moment I think it would be true to say that most of the projects we are working on would be exempted under the current GMAC guidelines but we still apply the full guidelines to all those projects. ... I have to say that I know of no case where I could say that [a competitor has taken a shortcut] ... but obviously the potential would be there for somebody to say, 'Well I will ignore the guidelines and set up a backyard operation', but as far as I know it has never been an issue."[77]

2.99 In general, companies have not indicated a difficulty with compliance to the current GMAC guidelines being made mandatory. The witness from Monsanto Australia Ltd stated:

> "There is a pressing need for a comprehensive regulatory system to be put in place. ... it should operate in a 'predictable and efficient manner'. Even onerous regulation can be handled as long as it is predictable and efficient so that you have a framework for planning that will allow long term investment. ... we agree that specific federal

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75 Lehrbach, Dr P, Genetic Research, Arthur Webster Pty Ltd: Transcript p 878
76 Willetts, Dr N, Research and Development, Biotech Australia Pty Ltd: Transcript p 772
77 Harrison, Dr D, Managing Director, Biotech Australia Pty Ltd: Transcript p 772

> legislation should be enacted, notifications should be mandatory and no release of GMOs should take place without a permit. ...[78]
>
> We are not looking for a weakening of rules. We are looking for a firming up of rules. ... it is the lack of regulations that is discouraging it [investment in Australia]. We do not have a predictable framework in which to operate."[79]

The Calgene Pacific representative said:

> "We would like to emphasise the potential role of the Institutional Biosafety Committee and the role that this group can play in monitoring and guiding the research activities of the company. We suggest that perhaps there is scope for making members of that committee accountable in a similar fashion to directors of companies, in that they be responsible for ensuring that work carried out in an organisation or a company is carried out according to the recommendations of GMAC, and that they be liable if the company or the institution does not comply with those recommendations."[80]

D. Adequacy of the Guidelines

2.100 The Committee considers that the guidelines are quite adequate for a voluntary code and are quite comprehensive. The Committee's principal concern is that the guidelines at present have no legal force. Recommendations 3, 35 and 36 in this report call for legal force to be given to the four sets of guidelines. The preferred option would be for the guidelines to be expressed in regulations under an Act of Parliament. This would allow for greater ease of amendment to keep up to date with changes in technology and experience. A wide range of sanctions should be available to act as a deterrent to breaches of the guidelines (recommendation 37).

2.101 In chapter 5, dealing with environmental concerns raised in the course of the inquiry, the Committee recommends changes in risk assessment procedures for the release of genetically modified organisms. Implementation of these recommendations would require redrafting the *Procedures for Assessment of the Planned Release of Recombinant DNA Organisms.*

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78 Sheers, M, Regulatory and Environmental Affairs Manager, Monsanto Australia Ltd: Transcript p 444

79 ibid. p 456

80 Cornish, Dr E, Principle Research Scientist, Calgene Pacific: Transcript pp 431, 432

CHAPTER THREE

EXISTING AND POTENTIAL BENEFITS

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3.1 The proponents of the new genetic manipulation techniques believe that a wide range of benefits are possible. These include a much greater understanding of basic biological processes with the potential for future practical uses as yet unspecified. The potential for productivity gains in the food, agricultural, pharmaceutical, and mining industries has been suggested. It is also stated that there will be major benefits for human health and for protection of the natural environment.

3.2 Genetic manipulation techniques may be applied to somatic cells or to germline cells. The possibility exists of using these techniques on human patients just as they may be used on other forms of life. The therapies are described briefly in sections *C.1.(i)* and *(ii)* below. In 1987 the National Health and Medical Research Council adopted a policy statement which accepted that somatic cell gene therapy may be acceptable for human beings under certain conditions, but that germline cell gene therapy is not.[1] In interpreting its terms of reference the Committee decided not to consider the issue of germline cell gene therapy on humans.

3.3 There are those who say that the benefits of genetic manipulation may be illusory and are influenced by naive economic assumptions. Moreover, it has been suggested that the question of society's priorities should be addressed when evaluating the benefits of the technology.[2]

3.4 The Committee believes that the possible economic, environmental and health benefits from applying genetic manipulation techniques are worth pursuing. Not all of the claimed benefits will materialise. Some applications of the techniques will have risks attached which may outweigh the benefits.

3.5 Some of the possible benefits of genetic modification techniques, as well as some counter-arguments to these claimed benefits, are set out in the rest of this chapter. Additional concerns which have been raised are examined in chapters 5 and 6: 'Environmental Concerns' and 'Human Health Issues'.

A. Increased knowledge of cell structure and function

3.6 With the discovery of the structure of DNA in 1953 and, subsequently, the genetic code, there appeared the potential to isolate and analyse specific genes. If a way could be discovered to manufacture in large quantity the products of these genes, their effect on the body could be researched.

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1 Victorian Law Reform Commission: Discusion Paper No 11, *Genetic manipulation*, March 1988 p 14

2 Phelps, R, Australian Conservation Foundation: Transcript pp 514, 515

> "... through these new approaches the great secrets of differentiation and development, of behaviour and the function of the nervous system, of the mechanisms underlying the major remaining diseases of our time including heart disease, cancer and the auto-immune chronic diseases, and finally even of the mysterious process of ageing itself, may eventually be unravelled."[3]

3.7 Chemicals which normally exist in infinitesimal amounts in the cell can now be produced in sufficient quantities to enable research to be carried out. For example:

> "Until recently, all information pertaining to relaxin[4] came from experimental animals. Through studying the structure of relaxin, and the genes responsible for its synthesis in animals, scientists ... were able to find the gene for the human hormone in a gene library, and thus to work out the structure of human relaxin, and to make it through genetic engineering. So a molecule about which literally nothing was known beforehand becomes available for study, and possible later clinical application."[5]

3.8 The technology of genetic manipulation has, therefore, become an integral component of research and university instruction and in unravelling the intricacies of cellular processes.[6] The expertise gained through research into the technology would become available in laboratories throughout Australia and could be applied in future projects.[7]

B. New Techniques become available

3.9 The discoveries of basic research, for example restriction enzymes, the polymerase chain reaction and gene shears or ribozymes create the opportunity to increase knowledge and are able to be applied to create useful products.

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3 Bodmer, W: *Implications of Advances in Genetics for the Future* in *The Biological Manipulation of Life*, Ed. Messel, H. Pergamon Press, 1981 p 310

4 Relaxin is a hormone allowing the pelvis to become more flexible during childbirth.

5 Nossal, G: *Reshaping Life - Key issues in genetic engineering*, Melbourne University Press, 1984 p 49

6 Faine, Prof S, Monash University, Department of Microbiology: Submission 55 p 1

7 Hackett, Dr J, Australian Meat and Livestock Research and Development Corporation: Transcript p 804

B.1 Monoclonal antibodies

3.10 Monoclonal antibodies are produced from cells which result from the fusing of an individual antibody-producing cell with a tumour cell. The resulting 'hybridoma cell' is able to grow and divide indefinitely while simultaneously producing the antibody. Large quantities of antibody can be produced which are able to attach to a specific chemical which might have resulted from, for example, a medical condition. Monoclonal antibodies could thus be used for a variety of diagnostic tests, including pregnancy tests, and screening for cancer and other diseases. In addition, it might be possible to produce large numbers of antibodies to be directed at particular disease organisms or cancer cells.

3.11 Research into the use of monoclonal antibodies to fight cancer initially involved the use of antibodies produced by mice in response to being inoculated with cancer cells. Unfortunately, an allergy reaction eventually occurs when the antibodies are administered to the patient. The current aim is to swap the non-essential mice components of the antibody with the equivalent human components so the now composite antibody does not cause a reaction.[8] This swapping process makes use of genetic modification technology.

B.2 DNA probes

3.12 DNA probes are made to find particular sequences on chromosome fragments. The probe is attached to a chemical which allows the position of the probe on the chromosome to be revealed, or the probe/chromosome fragment to be extracted and thus purified. Chromosome fragments would be detached from their probes prior to incorporation into another organism.

3.13 Probes have been used to identify carriers of genetic diseases such as Huntingdon's Disease,[9] and are the basis for 'DNA fingerprinting'. They may also enable the identification and isolation of desirable genes in organisms such as those responsible for 'high protein' cows. There is also the potential for probes to be used in identifying the sex of embryos and semen.[10] DNA probes can also be used to detect animal and plant diseases and food contaminants such as botulism.[11]

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8 Coghlan, A: *A second chance for antibodies*, in *New Scientist*, 9 February 1991, p 27

9 Huntingdon's Disease is a genetic disorder causing loss of mental capacity and physical co-ordination in late middle age. The symptoms are usually manifested after the child bearing years. The disease results from a dominant gene so everyone with the gene will develop symptoms. Early identification of carriers of the gene enables counselling and an informed choice about having children.

10 Fenwick, T, Queensland Department of Primary Industries: Submission 104 p 4

11 Dalgliesh, R, Queensland Department of Primary Industries, Animal Research Institute, Pathology Branch: Transcript p 1013; Submission 104 p 5

3.14 DNA probes can be made to find particular genes and detect the presence of disease-causing defects in tissue samples or in embryos, using amniocentesis. A DNA probe is a molecule, marked by some means such as a dye or radioactively, which will become attached to a specific gene in a DNA molecule. There are a large range of diseases caused by the presence of some genetic abnormality. Using gene probes allows detection of the defect without having to wait for the disease to manifest itself. They "present no threat to personal safety (since) they are used in the laboratory and not in the patient's body".[12]

B.3 Polymerase chain reaction

3.15 The polymerase chain reaction enables genetic sequences to be multiplied in the test tube. Previous methods involved the multiplication of bacteria into which the sequence had been incorporated. The procedure is intrinsically safer because it does not involve entire organisms which could escape.[13] The technique can be used to obtain measurable quantities of a DNA sequence which would normally be undetectable, while avoiding the presence of extraneous DNA. The reaction is thus more precise and can be used in medical diagnosis.

> "[The reaction] was used recently to identify the AIDS virus in the preserved tissues of a Manchester seaman who died of an AIDS-like syndrome in the 1950's. This is the earliest documented case of AIDS in a European and has led to a search of medical records and specimens to determine whether the virus occurred earlier and whether it has evolved substantially since its first appearance in humans."[14]

3.16 The polymerase chain reaction also has the potential to replace more time-consuming diagnostic tests. Tests for botulism, which employ 'conventional' methods using bacteria, can take two weeks, whereas tests using the polymerase chain reaction could take half a day.[15]

3.17 The technique also has potential in risk assessment procedures.

> "... it is now possible to detect target cells in the environment at a level of 1 cell per 1 gram of soil sediment, with a background noise level of 10^9 diverse nontarget organisms (Steffan and Atlas 1988).[16] ... Using these techniques, it is possible to track and identify not only the presence of an organism in the environment, but the presence and

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12 VLRC: Discussion Paper No 11 p 11

13 Pemberton, Dr J, Institutional Biosafety Committee, University of Queensland: Transcript p 981

14 Stocker, Dr J, Chief Executive, CSIRO: Submission 109 p 5

15 Pemberton, Dr J, Institutional Biosafety Committee, University of Queensland: Transcript p 981

16 Steffan R and Atlas R: *DNA amplification to enhance detection of genetically engineered bacteria in environmental samples*, in *Appl. & Env. Microbiol*, Vol 54, 1988 p 2185-2191

movement of a single gene, that may or may not have remained in the organism in which it was introduced."[17]

B.4 Gene Shears

3.18 The 'gene shears' technique involves the use of a type of endonuclease called a ribozyme and was developed from the discovery that functional stretches of DNA (exons) are interrupted by apparently nonsensical stretches (introns).

3.19 Thomas Cech, studying the DNA of a micro-organism called *Tetrahymena thermophilia*, found that the RNA molecule produced from DNA containing 'nonsense' introns automatically rearranged itself so that the introns were removed and the exons joined up. Surprisingly, the sequence of the RNA molecule corresponding to the DNA intron, contained the information to effect this reassembly. Furthermore, once removed, this RNA could act as an enzyme. This new type of enzyme which he called 'ribozyme', was unusual because it was not made of protein.[18]

3.20 Two researchers at the CSIRO, Wayne Gerlach and Jim Haseloff, developed the idea further by suggesting "a means by which efficient ribozymes may be constructed from synthetic RNA".[19] The term 'gene shears' was coined to describe the production of a ribozyme which could be directed at a specific stretch of RNA. Thus a gene (made of DNA) could be deactivated because the RNA molecule made from it is destroyed by the gene shears ribozyme.

3.21 The technique has a wide range of applications: "infectious mammalian viruses might be inactivated by the direct administration of appropriate ribozymes"; the ability to produce gene shears molecules could be inserted into an organism "to neutralize the effects of unwanted gene activity ... even to the extent of engineering plants that produce fruit without stones, as well as to treat genetic disease in people where the underlying effect is the overproduction of a protein".[20]

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17 Keating, Dr P, and Rainford, A, Biotech International Australia Pty Ltd: Submission 90, Appendix 3 p 4

18 Maddox, J: *The great gene shears story*, in *Nature*, 7 Dec 1989 p 609

19 ibid., p 611

20 ibid., p 612

C. Benefits to Human and Animal Health

C.1 Genetic manipulation in humans

3.22 **In interpreting its terms of reference and for reasons more fully explained in chapter 4 section A.3, the Committee has decided not to consider the issue of making deliberate heritable changes to the genes of human beings but to recommend that this be examined in a separate inquiry (see recommendation 1 in chapter 4, section A.3).** This section is included in the report mainly for background information and for the sake of completeness in describing the potential benefits of the technology.

3.23 In January 1989 initial steps were taken in the US to establish a program to map the human genome.[21] The intention is to provide a genetic and physical map of the chromosomes and ultimately to identify the complete sequence of bases. A related project has also started in the UK to produce a gene map consisting of "the sequence of base pairs making up individual genes and their positions within the complete genome".[22]

3.24 One possible benefit from knowledge of the human genome could be to enable the identification and possible correction of genes causing certain health disorders.

3.25 The Victorian Law Reform Commission estimated that "there are more than 4,000 currently recognised single gene defects ... [affecting] at least one per cent of all humans" and half of these defects produce serious consequences.[23] Genetic modification offers the prospect of altering the genetic composition of an organism in order to overcome these genetic defects.

C.1.(i) Germ cell gene therapy

3.26 This involves making a change in the germ cells - that is the modification would be passed on to subsequent generations. This technique would involve the diagnosis and correction of genetic disease in gametes or embryos.

3.27 Most inherited diseases are the result of both parents being carriers of a recessive gene for the disease and both of them passing that gene on to the offspring. Only then does the disease become expressed in the child.

3.28 For humans, germ cell gene therapy:

> "... has been rejected around the world on the basis of a number of medical/scientific considerations, in addition to the obvious ethical factors. ... Germline gene therapy using human embryos is a practical

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21 Roberts, L: *Genome Project Under Way, at Last*, in *Science*, Vol 243 pp 167-168

22 Galloway, J: *Britain and the human genome*, in *New Scientist*, 28 July 1990 p 25

23 VLRC: Discussion Paper No 11 p 11

> possibility given current technology, but no medical or scientific justification for taking such an approach has emerged."[24]

3.29 This position has also been adopted in Australia with the NH&MRC actively discouraging germ cell gene therapy.

C.1.(ii) Somatic cell gene therapy

3.30 The aim of this treatment is to correct the genes in particular body cells without the alteration being inherited by subsequent generations.

> "This approach is likely to be limited to cells that can be removed from the body, manipulated and reimplanted, such as the cells of the bone marrow. ... If this approach is effective, a small but significant number of diseases may be effectively cured in individual sufferers. This will have enormous benefits to individuals in providing a relatively normal life style while the burden to society in providing life-long care for such patients, expensive drug treatments, special diets etc., will be greatly reduced."[25]

3.31 Using somatic cell therapy, for example, it might be possible to introduce genes enabling insulin production into patients suffering from diabetes. If successful this would obviate the need for continuously supplying the hormone or transplanting pancreatic cells.

3.32 In April 1991 it was reported that the first somatic cell gene therapy trials in Europe would begin in France. A gene for a cancer-killing hormone would be incorporated into white blood cells for use in patients with terminal skin cancer.[26] In July 1991 the initial phase was completed of a trial to correct an hereditary disease in a four year old girl in the US. Again, genetically altered blood cells had been infused into the patient who suffers from a potentially lethal immune deficiency disorder.[27]

3.33 There is concern that somatic cell gene therapy using retroviruses may inadvertently transfer oncogenes causing cancer. For example, Dr Ditta Bartels expressed such concern to the VLRC inquiry.[28]

3.34 Scientists reportedly replied that this danger can be easily overcome by making the virus unable to replicate after insertion in the patient's cells and that it is easy to determine whether the virus is carrying an oncogene. However, it is conceded that

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24 Stocker, Dr J, Chief Executive, CSIRO: Submission 109 p 6

25 ibid.

26 *French gene trials*, in *New Scientist*, 6 April 1991 p 14

27 Angier, N: *Gene therapy trial shows promise, scientists say*, in *The Age*, 29 July 1991 (Quoting an article in the *New York Times*)

28 VLRC: Discussion Paper No 11 p 7

there is some risk of cancer since it is not possible to control the site of insertion of the gene in the chromosome.[29] Stringent laboratory and animal tests would help reduce the risk.

C.2 New pharmaceuticals

C.2.(i) Hormones and other chemicals

3.35 Genes exert their effect because they code for the proteins which are manufactured by the cell. Many chemicals which are important to the human body are proteins, thus it has been possible to incorporate the genes coding for them into bacteria. These bacteria are subsequently grown in large quantities and the hormone is extracted from the cells or culture fluid.

3.36 Genetic modification procedures supersede the traditional method of extracting the chemical from large quantities of tissue of human origin, e.g. in the case of blood products, or from animals, in the case of insulin. The technique has the added advantage of producing uncontaminated products. For example, to replace the: "human growth hormone which was taken off the market because it carried one of those slow viruses which gave rise to Creutzfeldt-Jakob syndrome[30] in several kids and they died as a result."[31]

3.37 A further example is the production of blood components such as Factor VIII[32] which, if extracted from large quantities of blood, could be contaminated with the AIDS virus.[33]

3.38 A second advantage is that the product is of human type and so allergic reactions are unlikely, for example, reactions caused by the use of insulin extracted from slaughtered pigs.[34]

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29 VLRC: Report No 26, *Genetic manipulation*, June 1989 p 5

30 Creutzfeldt-Jakob disease is a rapidly progessing disease of middle life. Symptoms include mental disorientation, dementia, and neurological disturbances such as tremor and other involuntary movements. Death usually ensues within a year.

31 Willetts, Dr N, Research and Development, Biotech Australia Pty Ltd: Transcript p 787

32 Factor VIII is a blood component which is essential for blood clotting. The component is deficient in haemophiliacs and was extracted from donated blood. Before sterilization techniques were altered, Factor VIII preparations could have contained HIV thereby transmitting AIDS to haemophiliacs.

33 Stocker, Dr J, Chief Executive, CSIRO: Submission 109 p 5

34 Sylvester, E and Klotz, L: *The Gene Age*, Charles Scribner's Sons, New York, 1983 p 9

C.2.(ii) Vaccines

3.39 Already vaccines produced using genetic manipulation techniques are having a significant impact:

> "Over the last 10 years we have heard of numerous success stories associated with the safe and efficacious vaccines produced by genetically manipulated organisms. I refer here to the trialling of the rabies vaccine in Europe and in the States, and the virtual eradication of pseudo rabies disease in pigs in Europe".[35]

3.40 Often genetic modification offers the only way to create a vaccine. For example, for those designed to provide protection against parasites:

> "It is simply totally impossible to think of making a vaccine by traditional methods from parasite material itself. You cannot grow enough [parasites]; it is too complex in nature. The only way to produce a vaccine against the cattle tick or against the nematodes which affect sheep in Victoria and other parts of Australia is via a recombinant DNA route[36]. ... One hopes that these vaccines will obviate the need for so many chemicals which have problems in terms of resistance, so they have to find more chemicals. It is very difficult to prove the safety of chemicals, so the vaccines should provide a much more safe control of these organisms."[37]

3.41 Genetic modification can provide three types of vaccine:

- . subunit or killed vaccines
- . live vaccines using attenuated disease organisms
- . live vaccines using non-pathogenic vectors.

3.42 Subunit or killed vaccines - These vaccines consist of dead material or just the disease organism's chemicals (antigens) which stimulate antibody production in the vaccinated animal. Research is being conducted in producing vaccines against ovine footrot and other diseases in cattle and poultry.[38]

3.43 Live vaccines using attenuated disease organisms - The disease organism is modified so that its virulence genes are deleted. In Australia research is being conducted by Arthur Webster Pty Ltd, in collaboration with the Queensland Department of Primary Industries, into producing a vaccine against infectious bovine rhinotracheitis.

> "The particular agent that causes this disease is a virus; it is a herpes virus. We know that the reason this virus is pathogenic, or causes

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35 Lehrbach, Dr P, Genetic Research, Arthur Webster Pty Ltd: Transcript, p 872
36 Willetts, Dr N, Research and Development, Biotech Australia Pty Ltd: Transcript p 769
37 Harrison, Dr D, Managing Director, Biotech Australia Pty Ltd: Transcript p 769
38 Lehrbach, Dr P, Genetic Research, Arthur Webster Pty Ltd: Submission 68 p 5

> disease, is that it expresses thymidine kinase, which is an enzyme that is expressed by a particular gene in that virus. ... So the idea of our project was ... to identify the gene, remove it from the virus and use that genetically modified virus as a vaccine."[39]

3.44 Live vaccines using non-pathogenic vectors - These vaccines are made by adding immunity inducing genes to organisms which "are either currently used as live vaccine strains or are known to be non-pathogenic"[40] The technique allows the development of 'one shot' vaccines where a single genetically modified vector would carry a variety of antigens and thus would confer immunity to several diseases. Such 'multivalent vaccines' would greatly simplify disease control regimes, especially in the poultry industry.[41]

C.3 Novel ways of treating diseases

3.45 Because genetic modification allows the large scale production of several types of complicated biological molecules, the opportunity to create new ways of fighting diseases has arisen.

C.3.(i) Complementary sequences

3.46 It has been suggested that a single strand of DNA could be created that is able to attach itself to a stretch of the double helix structure of a gene. This third strand might, for example, deactivate genes causing the growth of cancers, or neutralize the genetic information of viruses such as those responsible for AIDS and herpes.[42]

3.47 'Antisense' RNAs are synthetic RNA molecules able to bind to important RNA molecules produced by the cell and resulting in their degradation by cellular enzymes. Ribozymes extend this possibility by incorporating enzymic activity into the antisense RNA molecule itself.[43]

3.48 Another possible application of a complementary sequence involves an attempt to create a matching protein to chemically cover up the 'CD4 receptor' on the AIDS virus. The receptor is a surface chemical which is thought to enable the virus to attack body cells.[44]

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39 Dalgliesh, R, Queensland Department of Primary Industry, Animal Research Institute, Pathology Branch: Transcript p 1015

40 Lehrbach, Dr P, Genetic Research, Arthur Webster Pty Ltd: Submission 68 p 6

41 Lehrbach, Dr P, Genetic Research, Arthur Webster Pty Ltd: Transcript p 871

42 Charles, D: *A triple helix to cripple viruses*, in *New Scientist*, 13 April 1991 p 15

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

44 Kingman, S: *Altered antibody could keep AIDS at bay*, in *New Scientist*, 11 February 1989 p 25

D. Increased Efficiency in Breeding Animals and Plants

3.49 Traditional animal breeding programs are limited by the imprecision of the process and the time it takes for organisms to reach reproductive maturity. Genetic manipulation offers the prospect of achieving "in one year what might take 30 years to do by normal breeding programs."[45]

3.50 Moreover, traditional methods are not always immediately successful.

> "In France over the last 18 months researchers have been using the very prolific pigs out of China that have litter sizes of 22 and 23. They have been crossbreeding them with their own high meat-yielding pigs to try to get feed efficiency and lean meat conversion improvements in the Chinese pigs. ... by the time they got their carcass quality-feed efficiency where they were looking for, the litter size was back down to 10s and 12s where they were already. Nothing had been gained in that exercise. With genetic engineering, there is the possibility of inserting into those Chinese pigs ... the genes for the desired effect without the deletion of the reproductive genes."[46]

3.51 Traditional breeding can also have unexpected consequences:

> "[Breeders] pick a trait and then select for it. That trait which may have four or five genes controlling it may be associated with a piece of DNA that has a recessive lethal gene which is never seen in the normal population. You concentrate it with the characteristics you are after. If you insert an individual gene through transgenic technology, all you do is put one [gene] in with the other hundred thousand genes."[47]

3.52 Often traditional long-term breeding programs have been unsuccessful:

> "... in the Philippines ... is a disease called bacterial wilt which exists in the soil and attacks plants ranging from bananas to potatoes to tomatoes to ginger and to teak. Breeding experiments over twenty or thirty years have failed to produce any control of that disease whatsoever. ... That organism is in the soil. To us it seems as though the only way is to genetically engineer that bacterium so that we can identify what is happening between the plant and the root and release another organism so that we get a preferential result rather than the disease."[48]

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45 Wells, Dr. J, Bresatec/Metrotec: Transcript p 602

46 Lloyd, Dr B, Managing Director, Metrotec: Transcript p 602

47 Campbell, Dr R, Pig Research and Development Corporation: Transcript p 71

48 Holloway, Prof B: Transcript pp 335, 336

3.53 The Angus and Hereford cattle industry experienced significant problems with the unwanted 'Snorter dwarf' characteristic appearing in breeding stock in the 1940s and 1950s in the USA. The underlying gene is a recessive but the heterozygote bull "more nearly approach[ed] the conformational standards [for the breed, and] ... cattle judges and breeders, apparently unknowingly, favoured the heterozygote[49] during the 15- to 20 year period prior to the mid-1950's."[50]

3.54 However, once the genetic basis of this condition was recognised it was possible to remove this trait from herds by the strict adherence to a detailed breeding program.

3.55 Genetic modification allows the transferring of genes between species to create combinations which would not occur naturally. This means that animal and plant breeders no longer need to rely solely on chance mutations as a source of new genetic material for their programs.

E. Increased Resistance to Diseases, Pests and Environmental Extremes

3.56 Traditional cross-breeding techniques may be 'hit or miss'. Genetic modification is a far more powerful tool.

E.1 Micro-organisms

3.57 Many micro-organisms are beneficial but are subject to attack from viruses or are susceptible to agricultural pesticides. Research is being conducted into making cheese starter bacteria resistant to viruses:

> "[Viral] attack of these very delicate bacteria, used to convert milk to cheese or yoghurt is a frequent and very costly problem to the dairy industry. ... In all cases relatively minor changes in the total genetic makeup of the strains will be involved and only genetic material from similar organisms will be utilised ... only cheese-starter DNA [would be used] to improve cheese starters. In other words, the engineered changes could - in theory - occur under suitable conditions in nature".[51]

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49 Individuals carry two copies of a particular gene. If these copies are different the individual is said to be a 'heterozygote'. In the case of Snorter dwarfism, the gene causing the condition will be masked by the normal gene when it is present i.e. in the heterozygote. Cattle possessing two copies of the Snorter gene are dwarfs because the normal gene cannot be present.

50 Marlowe, T: *Evidence of selection for the snorter dwarf gene in cattle*, in *Journal of Animal Science*, Vol 23 1964 pp 454-460

51 Friend, Dr J, Technology and Research, Food and Fermentation Division, Burns Philp & Co Ltd: Submission 72 p 6

3.58 The efficiency of bacteria can be influenced by fungicides. Consequently, there is research to improve the fungicide resistance of the nitrogen-fixing bacterium rhizobium. The use of leguminous plants containing such bacteria decreases the need for Australian farmers to use nitrogenous fertilizers on pastures.

> "Rhizobium is the bacterium that causes nodules on legumes and increases nitrogen levels in the soil through that means. We have to use fungicides to control root diseases on legumes. If we can put a plasmid with fungicide resistance into rhizobium it will confer much more sustainable nitrogen nodulation on the plant. ... we would also ... have to involve a genetic change to stop transfer of plasmids, because otherwise we would create fungicide resistance in a lot of organisms in the soil where we really want to be able to use fungicides to control them."[52]

E.2 Animals resistant to parasites

3.59 The control of parasites in primary production is a costly and often only a partially effective process. It also involves the use of hazardous chemicals which may leave residues in meat and contaminate the environment. CSIRO is undertaking research to create blowfly-resistant sheep.

> "... the sheep blowfly lays its eggs on the skin of the animal and the larvae which subsequently hatch, burrow into the skin to feed off the underlying tissues. ... This project aims to provide the secretion on the sheep skin of an enzyme which is able to destroy the newly hatched larvae ... The source of the anti-blowfly enzyme is a gene isolated from plants ... it is totally harmless to all mammals, unlikely to result in any significant disturbance to the general ecology, and will prove difficult for blowflies to develop resistance to its action."[53]

3.60 It has also been suggested that rumen micro-organisms could be genetically modified to confer resistance to parasites.[54]

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52 Green, Dr C, Plant Pathology, NSW Department of Agriculture and Fisheries, Biological and Chemical Research Institute: Transcript pp 753, 754

53 Stocker, Dr J, Chief Executive, CSIRO: Submission 109 p 43

54 Australian Registered Cattle Breeders' Association: Submission 60.1 p 5

E.3 Plants resistant to pests and diseases

3.61 The development of plants able to produce insecticides might allow the quantity of insecticides sprayed on plants to be reduced and this could allow major cost reductions.

> "As long as these plants did not kill insects that played an important and positive role in the ecology and as long as these plants were not in any way toxic or dangerous to animals and humans when consumed over a number of years, this may also be a highly useful development. Clearly however, one that requires very careful scrutiny."[55]

3.62 Reducing the use of pesticides could considerably decrease food production costs. The cotton industry allegedly spends over $100 million annually in chemical pesticides to protect the crop against the caterpillars of the moth *Heliothis armigera*. "This makes the industry Australia's largest chemical pesticide user and not only puts a financial strain on the growers, but also puts a heavy chemical burden on the environment."[56]

3.63 It has been estimated that "the induction of virus resistance [in plants] could increase yields for some crops by as much as 30% as shown in field tests with tomatoes".[57] Similarly, the fungus Take-All in the soils of Australia causes an estimated 20 per cent loss of wheat production.[58]

3.64 The CSIRO is undertaking research to control a virus which attacks wheat and a second which attacks potatoes by causing the cells of the plant to produce small amounts of the virus's coat protein. This appears to protect the plant.

> "... it is thought that when a virus enters a healthy cell it has to uncoat and release its genetic material into the cell. If there is already a lot of its coat protein present then the genetic material gets repackaged before it can start to grow and reproduce itself. This probably gives the plant sufficient time to mount its own defences against the virus".[59]

3.65 The amount of virus protein, although significant relative to the virus attacking the cell, is only a small proportion of the plant's protein content - about 0.01 to 0.2 per cent. "That is negligible compared to the amount of virus or virus coat protein you find in a virus-infected plant."[60]

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

56 Stocker, Dr J, Chief Executive, CSIRO: Submission 109 p 44

57 ibid., p 8

58 Holloway, Prof B: Transcript p 335

59 Stocker, Dr J, Chief Executive, CSIRO: Submission 109 p 45

60 Dietzgen, Dr R, Plant Pathologist, Queensland Department of Primary Industries: Transcript p 1031

3.66 The main toxin which is being incorporated into plants is *Bacillus thuringiensis* toxin (BT toxin). It is an insecticidal protein produced by a bacterium, which is currently registered as a safe biological insecticide. ('Dipel' and 'Thuricide'). "So there is already toxicological evidence that [it] is not toxic to humans. It is a highly specific toxin, only specific to insects and within the insects only to a very narrow range of species of insects."[61]

3.67 There is always the possibility that insects will develop resistance to these proteins. The claim was made that genetically modified resistance may be effective only for between 5 and 15 years before the disease causing organism or pest will evolve to counter the resistance.[62] However, in the case of BT, at least, it has been argued: "*Bacillus thuringiensis* and strains that are associated with it have a whole variety of sub-types of the toxin, which you direct against the different insects so that you may be able to use a combination or change the combination at will."[63]

3.68 In its project to incorporate insect resistance into cotton, CSIRO intends to:

> "... produce cotton plants containing multiple insect resistance genes so that if the insects overcome one gene then the others will be present to control them. The probability of insects gaining resistance to several genes simultaneously will be very small indeed."[64]

3.69 A number of warnings were made that the benefits of incorporating disease or pest resistance into plants might not be easy to obtain. Some resistances may involve more than one gene, making the process more complicated.

3.70 Also Dr Murray argued that "the exact consequences of introducing a novel gene ... into a plant cannot be predicted with absolute certainty" - the yield of the modified crop may fall.[65]

E.4 Plants resistant to environmental extremes

3.71 It may be possible to modify plants to improve tolerance to drought and salinity.[66] These plants could supplement naturally occurring varieties in land reclamation work and in forestry. "An important component of land reclamation strategies is the establishment of salt-tolerant trees. Genes controlling ion

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

62 Burch, Dr D, et al.: Submission 106 p 35

63 Pemberton, Dr J, Institutional Biosafety Committee, University of Queensland: Transcript p 1175

64 Stocker, Dr J, Chief Executive, CSIRO: Submission 109 p 44

65 Murray, Dr D: Submission 11 p 4

66 Kerr, Prof A, Department of Plant Pathology, Waite Agricultural Research Institute, University of Adelaide: Transcript p 577

pumping/exchange, and the production of compatible solutes are available, and these could be incorporated into trees."[67]

3.72 It was also argued that plants genetically modified to tolerate harsh environments, such as high salt content soils or high acidity soils, or with a reduced need for fertilisers - may allow greater utilisation of marginal land.[68]

3.73 There does appear to be a danger that the growth of crops or the grazing of animals on marginal land could then deplete those soils of vital but scarce micro-nutrients.[69] The need for sensible land management practices remains, regardless of the advances which may be made through genetic modification techniques.

3.74 Research is also being initiated to create cotton plants with increased tolerance to flooding.[70]

F. Improved Production Efficiency

3.75 Production efficiency can mean either greater outputs for the same level of inputs or the same level of output with a reduction in inputs. This might be possible through improved conversion of raw materials into a marketable product leaving less waste, or by speeding up the actual process of conversion.

> "... it is no longer feasible on economic and ecological grounds to increase agricultural outputs by simply bringing new land into production. There is a need for productivity growth which will most likely result from the application of new technology."[71]

> "The alternative, where we allow these [improved productivity] developments to occur overseas, with Australia being a follower rather than leader, will result in our industries struggling to maintain their niche in what is likely to be a market place of rapidly improving efficiency."[72]

3.76 One basis of the argument for increased efficiency in food production, is the need to feed a growing human population. It was claimed that data from the United Nations Food and Agriculture Organisation (FAO) showed that in 1989 the world reserves of small grain cereals fell below the sixty day mark for the first time in the

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67 Briggs, W, A.P.M. Forests Pty Ltd: Submission 89 p 2

68 Australian Registered Cattle Breeders' Association: Submission 60 p 4; Cornish, Dr E, Calgene Pacific Pty Ltd: Transcript p 431; DASETT: Submission 138 p 6

69 Burch, Dr D, et al.: Submission 106 p 33

70 Jenkins, E, Cotton Research and Development Corporation: Submission 101 p 3

71 Fenwick, T, Queensland Department of Primary Industries: Submission 104 p 2

72 Smeaton Dr J, Managing Director, Bresatec: Submission 61 p 1

1980s. Consequently, human ingenuity and technology was needed to maintain food supplies.[73]

3.77 The United Scientists for Environmental Responsibility and Protection, South Australia, argued that claims that genetic manipulation would help solve world food problems were overstated - an example of some scientists overestimating the benefits and underestimating the risks. They said that similar claims were made about the green revolution and pesticides but that these did not prove to be well founded. They claimed that food production is adequate but that distribution is the main cause of malnutrition and hunger.[74]

3.78 **The Committee accepts that there are substantial inefficiencies in the distribution of the world's food supplies and that these must be addressed. Those problems have proved, however, to be highly intractable. Their existence certainly does not preclude taking measures to improve the efficiency of food production. The desirability of greater efficiency in the use of scarce or costly resources would seem to be obvious.**

3.79 Increased efficiency of food production could involve modifying plants so that they can more efficiently convert sunlight into sugars, modifying plants so that they are more digestible to animals, modifying animals so that they can extract more nutrients from the plants they eat, or modifying the bacteria which inhabit the digestive tracts of animals to increase their efficiency at breaking down food which is ingested.

F.1 Improving the efficiency of crop production

3.80 There is considerable interest in improving the performance of the nitrogen-fixing bacterium, rhizobium, or enabling plants other than legumes to incorporate the bacterium. A benefit would be that: "the farmer would not have the need to add nitrogenous fertiliser and he could get a better pasture, and hence better sheep and cattle. ... you have increased your productivity without any capital input whatsoever."[75]

3.81 Doubt has been expressed, however, concerning the feasibility of endowing non-leguminous plants with the ability to incorporate the bacterium and thus fix nitrogen - in effect making their own fertilizer.[76] It was also suggested that improving the nitrogen-fixing qualities of crops could deplete soils of nitrogen or increase the

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73 Poole, Prof N, ICI Seeds and Pacific Seeds Pty Ltd, Biotechnology and Regulatory Affairs: Transcript p 421

74 Nable, Dr R, United Scientists for Environmental Responsibility and Protection: Transcript p 635

75 Holloway, Prof B: Transcript p 337

76 Green, Dr C, Plant Pathology, NSW Department of Agriculture and Fisheries, Biological and Chemical Research Institute: Transcript p 755

amount of nitrogen run-off into waterways or even conceivably upset the whole nitrogen cycle resulting in atmospheric problems.[77]

3.82 It was also argued that improving the ability of crops to utilise applied fertilisers would lead to greater quantities of fertilisers being used - particularly if the improvement to the plant involved increasing its ability to absorb those fertilisers.[78]

3.83 Improving the efficiency with which crops make use of fertiliser would not necessarily lead to increased quantities of fertiliser being applied. Rather, the opposite could well be the case. The farmer still has to make an economic decision concerning the optimum level of expenditure on fertiliser. The increased efficiency of the plant could lead to cost cutting through decreased usage of fertiliser for the same output. Alternatively, there could be some increase in output with the level of fertiliser used remaining constant.

3.84 It was stated that high yield varieties of plants need higher doses of fertilisers and may be more vulnerable to disease and pests.[79]

3.85 The Committee considers that the costs and benefits need to be assessed on a case by case basis. No decision should be made on the worth of a particular form of genetically modified crop without information about the expected increase in yield and the expected increase, if any, in the input costs such as fertiliser and pesticide.

F.2 Improving the productivity of the cattle industry

3.86 As mentioned above, one avenue for improvement is in the area of efficiency of forage use. The Australian Meat and Life-stock Research and Development Corporation (AMLRDC) has recently decided to fund, under the Rumen Modification Program, research into the development of strains of bacteria which are more efficient at digesting grasses in the forestomachs of cattle and sheep. It is estimated that at present up to 70% of the energy value of dry tropical grass eaten is unused and lost to the animal.

3.87 The Corporation argues that this method of increasing production efficiency is a more environmentally sound way of increasing output than increasing stocking levels or using herbicides or fertilisers.[80]

3.88 The AMLRDC has estimated that: "a 5% increase in the ability of ruminants to digest plant cellulose would result in at least 53% return on investment within 10

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77 Burch, Dr D et al.: Submission 106 p 33;
United Scientists for Environmental Responsibility and Protection, Sth Aust: Transcript p 647

78 Burch, Dr D et al.: Submission 106 p 33

79 ibid., p 35

80 Johnsson, Dr I, Australian Meat and Live-stock Research and Development Corporation: Submission 14 pp 1, 2

years, but possibly 69% in 5 years."[81] This is equivalent to a return of "something like $120m to the beef industry, and perhaps $60m-odd to the sheep industry".[82]

3.89 The net result of the project could be an increased 'turn off' rate for the cattle industry.

> "... at the moment it might take five years to grow an animal to a suitable market weight. If we can cut that back to three or four years you will turn your sale animals over at a far faster rate and therefore you can decrease the number of breeding cows you have in your herd."[83]

3.90 A further possibility with rumen micro-organisms is to modify them so they remove toxins in fodder. The potential for improvement is illustrated by an example concerning a naturally occurring rumen micro-organism.

> "... there was an introduction made from overseas to enable beef animals to eat leucaena, a productive tree legume in the north. ... Initially when it [leucaena] was introduced we found that it has a substance called mimosine, which is not exactly a toxin but it limits the intake of animals and they perform only moderately well. It was identified that similar animals grazing a similar plant in Hawaii were performing much better; there was about a 20 or 30 per cent better growth rate."[84]

3.91 By introducing an inoculum containing micro-organisms originating from Hawaii, the performance of Australian animals feeding on leucaena now matches that of Hawaiian animals.[85]

3.92 There is research to modify rumen micro-organisms so they can detoxify fluoroacetate.

> "... fluoroacetate is a component of [the] gidgee [plant] and is toxic to animals grazing it. ... a group under Keith Gregg at the University of New England ... is identifying the principle present in certain bacteria which allows fluoroacetate to be detoxified and is trying to transfer that to rumen bacteria so the sheep can now graze the material with impunity."[86]

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81 Australian Registered Cattle Breeders' Association: Submission 60.1 p 5

82 Johnsson, Dr I, Australian Meat and Live-stock Research and Development Corporation: Transcript p 794

83 ibid., p 798

84 ibid., p 801

85 ibid.,

86 Hackett, Dr J, Australian Meat and Livestock Research and Development Corporation: Transcript p 806

F.3 Improving the productivity of the sheep industry

3.93 Despite the downturn in the wool industry, increased efficiency is a desirable goal. Sheep which grew faster and produced more wool per animal for the same amount of food could enable a lower stocking rate whilst maintaining income. The industry could react more quickly to an expanding market since fewer sheep would have to be bred to meet increasing demand.

3.94 The CSIRO is attempting to modify the genes of sheep in three ways[87]:

. to enable the sheep to make an amino acid critical to wool production

. to enable the sheep to make use of a waste chemical which is produced in large amounts in their rumen

. adding genes to increase the amount of growth hormone in sheep to increase growth rate

3.95 A further method of increasing productivity is via the indirect route of improving the fodder available to sheep. CSIRO is attempting to incorporate genes for sulphur-rich proteins into lucerne and sub-clover. Sulphur containing proteins are important for wool production and supplementary feeding, directly into the sheep's true stomach can increase wool production by 30%.

3.96 Unfortunately:

> "... the micro-organisms that live in their fore-stomachs ... convert a lot of the high quality plant proteins into low quality microbial proteins which are then redigested in the sheep's true stomach. These microbial proteins are often deficient in essential sulphur-containing amino acids ... [the sulphur-rich proteins which would be made by the modified plants] are also resistant to degradation by the microbes in the sheep's fore-stomach and so pass quickly into the true stomach".[88]

3.97 The question has been raised whether attempts by the CSIRO to modify sheep in order to produce more wool are economically wise at present. The argument is that it is simpler and cheaper to increase or decrease the number of sheep to control wool supply.[89] It might be countered that, regardless of whether there is presently a glut of wool, more efficient production of the same quantity of wool would mean lower costs and greater competitiveness on world markets and less environmental pressure.

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87 Mayo, O, Division of Animal Protection, CSIRO: Submission 43 p 2; Stocker, Dr J, Chief Executive, CSIRO: Submission 109 p 42

88 Stocker, Dr J, Chief Executive, CSIRO: Submission 109 p 45

89 Murray, Dr D: Submission 11 p 1

F.4 Improving the efficiency of pork production

3.98 In Australia over 53 per cent of the total pig herd is managed in holdings consisting of over 1000 animals.[90] Intensive conditions are fertile breeding grounds for disease and, thus, disease control is a major cost. Studies by the Pig Research and Development Corporation suggest the cost to be "an average of $100/sow/year."[91]

3.99 With such a high level of disease control measures involving the use of antibiotics there is always concern about antibiotic residues in the meat. Consequently:

> "The development of vaccines using genetically modified bacterial or virus vectors provides some considerable potential for disease control using techniques which are more likely to be more effective and which are safer for the environment and consumer than current antibiotics."[92]

3.100 The other area where major improvements in efficiency could be achieved is in the conversion of pig feed into meat.

> "Feed is the major cost component of pig production - some 60 - 65% of total production costs. Feed prices have increased more than meat prices in recent years ... and generally the terms of trade for pig producers have been in decline."[93]

3.101 Selective breeding has increased feed conversion rates. However, without an influx of genetic material from overseas, there is a limit to possible improvement.

> "... the big advantage that the UK has over us, is that they have much better genotypes than we do. ... We have not had a really good gene influx for a while. We have hit intrinsic constraint in our animals a lot earlier, and unfortunately at a lot lower level than some other countries in the world."[94]

3.102 A possible strategy is to introduce genes into the Australian pig herd via genetic modification. Growth hormone genes have been incorporated into pigs. "Some of these pigs have proceeded to express additional growth hormone production and have demonstrated substantial improvements in growth performance, feed conversion efficiency and carcass quality."[95] (For a discussion of the incident involving transgenic pigs in Adelaide see Chapter 5 *F.2.(iii)*.)

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90 Taverner, Dr M, Pig Research and Development Corporation: Submission 57 p 2
91 ibid., p 5
92 ibid.
93 ibid., p 3
94 Campbell, Dr R, Pig Research and Development Corporation: Transcript p 73
95 Taverner, Dr M, Pig Research and Development Corporation: Submission 57 p 4

F.5 Potential for increased efficiency in the poultry industry

3.103 Genetically modifying poultry appears to be a difficult process, although some researchers have apparently succeeded in doing so. "It is very difficult to actually insert the new genes into the ovum. Even though they have got a big egg, it has already gone past some critical processes before it is available to you."[96]

3.104 There is scope, however, in improving disease control in flocks.

> "It is also going to help us to simplify vaccine regimes within the poultry industry by the use of multivalent vaccines. ... We will end up with a single virus that can immunise against a whole variety of diseases in the one vaccine regime, whereas today they are either done separately or they are done in combination with two viruses put together in the one vaccine solution."[97]

F.6 Improvements to aquaculture

3.105 Many fish and other aquatic animals are produced in 'fish farms', and hence may be subject to crowding. Genetic modification techniques could improve growth rates, disease resistance, tolerance to high densities and increase the range of conditions under which the animal could be grown.[98]

F.7 Improving production efficiency in food processing

3.106 Approval has been granted to a company in the UK to release a genetically modified yeast and approval for its use in Australia is being sought.[99] Consequently, its Australian competitors are compelled to maintain their research effort.

> "It is our view that unless we continue to work in the area and in the long term begin to introduce the fruits of this technology into the market place, our competitive position will be eroded. As a minimum position we must be able to respond on a case-by-case basis to the introduction of strains into the market place by our competitors."[100]

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96 Campbell, Dr R, Pig Research and Development Corporation: Transcript p 75

97 Lehrbach, Dr P, Genetic Research, Arthur Webster Pty Ltd: Transcript pp 871, 874

98 Department of Primary Industries and Energy: Submission 143 pp 29, 30

99 Friend, Dr J, Technology and Research, Food and Fermentation Division, Burns Philp & Co Ltd: Transcript pp 895, 897

100 Friend, Dr J, Technology and Research, Food and Fermentation Division, Burns Philp & Co Ltd: Submission 72 p 5

3.107 There is research to increase the tolerance of yeasts to the preservatives that are used in bread making to inhibit fungal growth.[101] A second avenue of research is preventing a 'maltose lag' when bakers' yeast switches over to use the major sugar in wheat, maltose. This lag slows the rising of the dough.[102]

3.108 There is also active research into improving cheese starter cultures. A virus gene has been incorporated into a cheese-making bacterium to cause it to disintegrate upon maturity. The bacterial enzymes which are released impart the flavour to the cheese. The process of bacterial breakdown is a natural part of cheese-making but the inserted gene would enable cheeses to mature "in days instead of months."[103]

F.8 Increased productivity in the minerals and energy sector

3.109 Many processes in nature are mediated by micro-organisms and several, such as fermentation, have been exploited and form the basis for industrial processes.

3.110 The genetic modification of micro-organisms is well established, so increasing the efficiency of microbial action is feasible:

> "... including the conversion of biomass through fermentation processes to biofuels, for example, methane and ethanol and microbial removal of sulphur and sulphides from coal. In the case of enhanced oil recovery, work is undertaken in Australia using naturally occurring organisms from sewage farms."[104]

3.111 Micro-organisms living in mine waste heaps could be modified to enhance their ability to cause leaching of minerals, thereby increasing extraction efficiency.

3.112 In the US, naturally occurring micro-organisms are used to extract copper from low grade ores. By 1989 over 30 per cent of copper production resulted from this process. Sulphuric acid is sprayed over the top of an ore heap and the water percolating through the heap is collected when it emerges and the copper extracted using solvents.[105]

3.113 The process provides the opportunity to develop the in situ mining of ore bodies.

> "Once an ore body had been identified and deemed economic to develop, wells would be drilled into it and the ore fractured. Then the

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101 Friend, Dr J, Technology and Research, Food and Fermentation Division, Burns Philp & Co Ltd: Transcript p 894

102 Evans, Dr R, Food and Fermentation Division, Burns Philp & Co Ltd: Transcript p 896

103 Coghlan, A: *An explosive start to fast maturing cheeses*, in *New Scientist*, 16 March 1991 p 24

104 Department of Primary Industries and Energy: Submission 143 p 30

105 Debus, K: *Mining with microbes*, in *Technology Review*, Vol 93(6) 1990 pp 52, 53

> ore would be inoculated with either a naturally occurring bacteria ... or one engineered for extracting a specific metal, and the ore would be flooded with water. This water would be collected and pumped to the surface pregnant with the desired metals. The top of the mine would show little environmental or aesthetic damage, and inside the earth, the ore deposit would remain intact minus a small fraction of the valuable metal. The only lasting impact on the site would be several capped holes."[106]

3.114 A possible danger could be enhanced generation of sulphuric acid and concentration in water sources.[107]

G. Improved Quality of Products

G.1 Purity of drugs and pharmaceuticals

3.115 Chemicals made by genetically modified organisms can meet very stringent purity standards.

> "The current commercial recombinant DNA insulin has seven parts per million impurities. For many decades people were treated with materials that had hundreds to thousands of parts per million of impurities. The degree of purity that is required of these products is way in excess of anything that previously occurred."[108]

> "... a general advantage that recombinant products have is that you can make vaccines in a way that does not involve growing pathogenic organisms, so you avoid all use of those. ... replacing a natural product that is purified from natural sources such as human growth hormone, with a recombinant product, then you avoid that potential for contamination from viruses or other entities which we are not aware of or not familiar with."[109]

3.116 It could also be argued that these safety concerns should be reflected by labelling. "I think that would be a very good argument to label products from human and animal original because there is clearly more danger of contamination there than there is from a recombinant DNA product."[110]

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106 ibid., pp 55, 56
107 Burch, Dr D et al.: Submission 106 p 34
108 Gray, Prof P, Australian Biotechnology Association: Transcript p 703
109 Willetts, Dr N, Research and Development, Biotech Australia Pty Ltd: Transcript pp 787, 788
110 ibid., p 789

G.2 Wool quality

3.117 CSIRO is aiming to genetically modify sheep that do not produce small tufts of black fibres in their fleece.

> "These fibres, while small in number, can create large problems in the appearance of the final garments produced from wool. ... An effective solution to the problem would be to inhibit the enzyme pathway that is responsible for the production of the black pigment in the wool fibres. ... When successful, downgrading of the wool clip because of 'black fibre' will not occur, thus saving many millions of dollars."[111]

G.3 Reduction of chemical residues in food

3.118 Developments in vaccines and genetically modifying pest resistance into animals and plants has the potential to reduce pesticide use.

> "Many compounds used as pesticides are broad spectrum nerve poisons, or actual or suspected carcinogens. Residues of these compounds, especially the more durable fat-soluble organochlorines, contaminate plant foods and become concentrated with subsequent steps in the human food chain. ... Compounds used as insecticides, nematicides [compounds that kill nematode worms in the soil] and miticides are continually being removed from the range permitted, either because they are hazardous[112] or they are no longer effective, or both."[113]

G.4 Low fat meat

3.119 One of the goals of research into adding genes for growth hormone into animals is the production of low fat meat. Consumers are aware of the health value of low fat products and the pig industry is endeavouring to meet this need. Experiments in which pigs were injected with extra growth hormone have shown a reduction of "body fat content by more than 30%"[114] hence incorporating growth hormone genes into pigs could have a significant effect. CSIRO is also attempting to insert extra growth hormone genes into sheep to alter, inter alia, carcass composition.[115]

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111 Stocker, Dr J, Chief Executive, CSIRO: Submission 109 p 43

112 Feldmesser, J et al., in *Agricultural Chemicals of the Future,* Ed. Hilton, J, Rowman & Allanheld, Totowa, 1985 pp 327-344

113 Murray, Dr D: Submission 11 p 3

114 Taverner, Dr M, Pig Research and Development Corporation: Submission 57 p 4

115 Stocker, Dr J, Chief Executive, CSIRO: Submission 109 p 42

G.5 High protein milk

3.120 Traditionally, dairy farmers were paid for the fat content of their milk. However, recognising public demand for high protein and low fat milk, payment is now made on protein content. It is possible to process the milk to increase its protein content but an excess of milk is needed to concentrate the protein. This would be undesirable in times of milk shortage.[116]

> "Conventional selection procedures in dairy cows are extremely inefficient in some areas. The most evident is the milk composition [protein percentage] ... Economics dictate the farmer select for total production, but milk composition does not necessarily improve and, in fact, can deteriorate. This is a clear instance of where genetic engineering could overcome a natural obstacle to improvement".[117]

G.6 Protein enriched produce

3.121 It is feasible to incorporate genes into plants coding for additional proteins rich in essential amino acids. It has been predicted that: "Five years from now ... people will be eating protein enhanced beans, corn, soybeans and wheat, and livestock will chow down on altered corn, soybeans, wheat, alfalfa, rapeseed and sunflower."[118]

G.7 Improved keeping qualities of harvested crops

3.122 A common complaint concerning vegetables is that early harvest and storage results in a loss of flavour. Ripe fruit and vegetables are often subject to bruising because of soft cell walls.

3.123 Tomatoes have been modified so that the enzyme responsible for cell wall softening has been deactivated. Such tomatoes:

> "... remain firm for longer during ripening and post harvest storage. This means that tomatoes for the fruit and vegetable market can be picked later than usual, i.e. when they are red rather than green. Hence they should have better flavour and vitamin C content".[119]

3.124 It may also be possible to create "fruits and vegetables with reduced browning on exposure of cut surfaces to air - a benefit to food processors and consumers".[120]

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116 Nieper, R, Division of Animal Industries, Queensland Department of Primary Industries: Transcript p 1022

117 Fenwick, T, Queensland Department of Primary Industries: Submission 104 p 3

118 Wickelgren, I: *Please pass the genes*, in *Science News*, Vol 136 1989 p 124

119 Murray, Dr D: Submission 11 p 5

120 Stocker, Dr J, Chief Executive, CSIRO: Submission 109 p 8

H. Potential for New Products and Processes

H.1 Production of biological pesticides

3.125 A biological pesticide is an organism which is used to kill pests. For example, 'Dipel' and 'Thuricide' contain spores of a naturally occurring bacterium which kills caterpillars which eat it. The genetically modified organism 'NoGall' was recently released in Australia as a pesticide.

> "The bacterium involved had already been in use for many years for control of crown gall on plants. They made a genetic modification ... and applied for the registration of that particular strain as a pesticide. ... The change in NoGall that had been made was in fact to delete a gene that allowed it to transfer fungicide resistance from a plasmid. ... this plasmic transfer was occurring which was defeating the value of the NoGall inoculant ... [the deletion] makes the organism far more safe in the environment".[121]

3.126 Research to develop another bacterium, to control Take-All in wheat, is being conducted by CSIRO. The intention is: "to use a micro-organism and to engineer it so that it will consistently make a product which will kill the fungus which causes take-all of wheat."[122]

3.127 Approval has been given for a field trial to study the behaviour of the micro-organism in the environment. The wild form of the bacterium has been modified by the addition of a small genetic tag to assist in tracing its movement in the environment.[123]

H.2 Production of pharmaceuticals by animals and plants

3.128 A problem with the production of proteins by bacteria is that bacteria lack the chemical machinery necessary to add 'side chains' to the manufactured protein. Side chains are vital to the folding of protein and the protein's final shape affects its activity. Consequently, there is research into genetically modifying animals and plants, which have the necessary biochemical pathways, and using them to produce complex proteins. For example, genetically modified cows and sheep could produce these chemicals in their milk.

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121 Green, Dr C, Plant Pathology, NSW Department of Agriculture and Fisheries, Biological and Chemical Research Institute: Transcript pp 752, 753

122 Holloway, Prof B: Transcript p 335

123 Stocker, Dr J, Chief Executive, CSIRO: Submission 109 p 8

3.129 The use of milk producing animals such as cows may cause concern. However:

> "There may be no animal welfare issues ... providing that the genetic information that is inserted into the cow does not affect the physiology of the cow other than by having the cow secrete the pharmaceutical in the milk."[124]

3.130 An alternative may be to use plants as pharmaceutical factories. Mouse antibodies have been obtained from genetically modified tobacco plants, the antibody constituting 1.3 per cent of total leaf protein.[125]

3.131 The costs of these novel process would have to be weighed against using mammalian cell cultures and other potential organisms such as yeasts.

H.3 Production of novel foods and other products

H.3.(i) Low carbohydrate beer

3.132 There has been a traditional breeding program to incorporate in brewer's yeast the ability to ferment a wider range of sugars. Unfortunately:

> "... unwanted flavour characteristics were also transferred ... An alternative approach to the same problem is to isolate the gene responsible for the extra sugar utilising ability [from other yeasts] and introduce it into the brewers's yeast ... This [modified] strain has the required new property ... and is much better characterised than its traditionally produced cousin."[126]

3.133 In the UK the Advisory Committee on Novel Foods and Processes (ACNFP) "has entered into detailed correspondence with the brewing industry about the need for referral of taste trials to ethics committees". ACNFP is presently establishing procedures for taste trials which would cover all types of food.[127]

H.3.(ii) Cheeses

3.134 The genetically modified cheese starter bacteria (see para 3.108) may allow food technologists "to broaden the choice of starter cultures, allowing cheese makers to make tasty new cheeses in a fraction of the time it takes normally".[128]

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124 Sleigh, Dr M, Division of Biomolecular Engineering, CSIRO: Transcript p 1073

125 Hiatt, A: *Production of antibodies in transgenic plants*, in *Nature*, Vol 342 1989, p 76

126 Hammond, Dr J, Brewing Research Foundation (UK): Exhibit 30 p 4

127 Department of Health (UK), Ministry of Agriculture, Fisheries and Food, Advisory Committee on Novel Foods and Processes: *Annual report 1990*, p 2

128 Coghlan, A: op. cit. p 24

H.3.(iii) Other novel biological products

3.135 ICI has a division devoted to novel biological products.

> "Many of the products are manufactured by large scale fermentation of micro-organisms, for example:
> Biopol (PHB) - a plastic which is biodegradable and can also be recycled.
> Quorn - a mycoprotein, a health food meat substitute.
> Ecosyl - a silage additive."[129]

H.4 Novel processes

3.136 In evidence, mention was made of the potential for genetically modified micro-organisms to be involved in novel industrial processes.

> "... in the area of the pulp and paper industry, looking at high temperature bacteria which allow the non-use of existing bleaching techniques. ...[using] hot-spring source bacteria, which replace the existing techniques. The idea is to produce a less damaging and more acceptable industrial process."[130]

3.137 There is also work in "applying microbial techniques to metal plating and therefore bypassing the current processes of using chemicals".[131]

I. Potential Benefits to the Environment

I.1 Reducing biocide use

3.138 Genetically modifying pest resistance into organisms and producing new vaccines may benefit the environment through a reduction in the use of hazardous pesticides and drugs. Consequently, there could be less chemical residue in the soil, or entering watercourses and food chains. It has been argued that herbicide resistant plants will have a similar effect on the environment. Several herbicide resistant plants have been created by traditional mutant selection techniques,[132] but it is genetic manipulation that will maximise this development.

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129 Davies, R, ICI Australia Ltd, et al.: Submission 121 p 6
130 Campbell, Dr R, Pig Research and Development Corporation: Transcript p 469
131 Davidge, M, Scientific and Technical Services Division, Bunge (Australia) Pty Ltd: Transcript p 478
132 Nieper, R, Division of Animal Industries, Queensland Department of Primary Industries: Exhibit 113 p 1

3.139 The subject of herbicide resistant plants and whether their development will be an environmental benefit or cost is discussed in Chapter 5.

I.2 Reducing soil erosion

3.140 In Australia "soil erosion is a much more serious problem than pollution through herbicides".[133]

> "While cultivation is a means of removing weeds the frequent running of machinery over damp soil can cause compaction and reductions in productivity due to destruction of the soil profile. Frequent cultivation can also lead to significant soil erosion".[134]

> "The soil conservation cost of these farming methods has been great and in many areas of the world they threaten the whole viability of the local agricultural industry. In addition, the loss of top-soil through cultivation-induced degradation of the top-soil and subsequent erosion will exacerbate other important phenomenon such as salination and water catchment management."[135]

3.141 Minimum tillage, coupled with the strategic use of herbicides, is aimed to facilitate sustainable agriculture in Australia's vulnerable soils. The use of herbicide resistant plants may complement this strategy.

I.3 Biological control

3.142 Biological control entails using organisms to control pests. The advantage of such control is that it can be highly specific to the target organism and offer a permanent solution. Unfortunately, if disease organisms are used as control agents, natural selection may produce immunity in the target species and a reduction in virulence in the control agent. (These reasons have contributed to the re-emergence of Australia's rabbit problem because rabbits have become more resistant to myxomatosis and the disease itself has become weaker.[136])

3.143 The fox is a serious pest in Australia.

> "The opinion of the people working on fox control around the country is that conventional control techniques are not sufficient. ... The

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133 Kerr, Prof A, Department of Plant Pathology, Waite Agricultural Research Institute, University of Adelaide: Transcript p 580

134 Stocker, Dr J, Chief Executive, CSIRO: Submission 109 p 22

135 Dalling, M, Calgene Pacific: Submission 23 p 4

136 CSIRO Division of Wildlife and Ecology: Information Sheet - *Research into the rabbit problem*

reduction in diversity that the fox is doing, in terms of our unique native fauna, is quite horrendous according to much biological opinion."[137]

3.144 Genetic manipulation will play a pivotal role in the measures being developed by CSIRO to control foxes through induced sterility. The goal is to incorporate into a fox-specific virus, a gene for a protein that would stimulate foxes to make antibodies against their own reproductive proteins.[138]

> "The use of fox-specific proteins and a fox-specific virus should prevent the recombinant virus sterilising other canids ... such as dingos and domestic dogs. The recombinant virus must not have containment properties which pose problems to foxes or related species in other parts of the world".[139]

3.145 A similar approach is envisaged with rabbit control using the myxoma virus which is specific to rabbits. "It is expected recombinant viruses will be available for field trials by 1992".[140]

3.146 Genetic manipulation could also be used to increase the virulence of the diseases of pests. An example is research into a virus which attacks an insect which is a serious pest of cotton.[141]

I.4 Bioremediation

3.147 Bacteria are small, genetically diverse and capable of rapidly increasing in number under the right conditions. For this reason, a small number of appropriately modified bacteria which were added to the site of a chemical spill would have the potential for removing the contamination. It may be possible to discover the genes which enable certain bacteria to use a noxious chemical as a food source and transfer them into other bacteria which have a better growth rate or wider adaptability.

> "From an environmental perspective, great potential exists for GMOs to:
> - treat wastes, particularly by engineering microbes capable of breaking down toxic chemicals such as dioxins/PCB's
> - clean up spills; bacteria have already been used on oil spills and their efficiency may be greatly increased through genetic engineering
> - provide cheap and effective methods for *in situ* treatment of contaminated sites. Biotechnology may provide the only effective means

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137 Reville, Dr B, Endangered Species Unit, Australian National Parks and Wildlife Service: Transcript pp 152-154

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

139 Bridgewater, P, Australian National Parks and Wildlife Service: Submission 87 p 10

140 CSIRO Division of Wildlife and Ecology: op. cit.

141 Jenkins, E, Cotton Research and Development Corporation: Submission 101 p 2

> of cleaning up ground water contaminated by hazardous chemicals".[142]

3.148 In 1980 a genetically modified organism was the subject of a landmark decision concerning patenting. Ananda Chakrabarty added plasmids to a bacterium so it was able to break down four of the components of crude oil.[143,144] Research into creating other micro-organisms able to attack toxic waste has also been reported.[145]

3.149 It may also be possible to use modified bacteria to reduce erosion and reclaim degraded grazing land.

> "Soil bacteria are important in maintaining soil structure by exudation of polysaccharides which allow soil particles to aggregate. Soil aggregation is important because it allows aeration of soil, drainage of water and penetration of plant roots through the soil. Grazing by sheep and cattle tends to pack the soil and over-grazing leads to destruction of the soil structure and significant decreases in plant growth. ... Development of soil bacteria that have lower nutritional requirements and more efficient secretion of polysaccharides may allow reclamation of soils from grazing lands that have lost much of their ability to support cattle and reduce the rate of soil erosion".[146]

3.150 A possible danger could be toxic organometallic compounds entering the food chain.[147]

J. Potential for Economic Benefit for Australia

J.1 Investment

3.151 The biotechnology industry is expanding worldwide and it has been estimated that "by the year 2000 biotechnology would be worth at least $US 9 billion and possibly as much as $US 100 billion per annum to world industry".[148]

3.152 Multinational companies have already started to invest in Australian companies (Suntory Ltd has 10% of Calgene Pacific shares[149]), establish research facilities in

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142 Quinn, N, Environment Protection Division, Department of the Arts, Sports, Environment, Tourism and Territories: Submission 138 p 6

143 Sylvester, E and Klotz, L: *The gene age*, Charles Scribner's Sons, New York 1983

144 Slattery, J, The Institute of Patent Attorneys of Australia: Submission 44 p 6

145 Joyce, C: *Microbial dustmen clean up toxic waste*, in *New Scientist*, 6 May 1983 p 288

146 Australian Registered Cattle Breeders' Association: Submission 60.1 p 7

147 Burch, Dr D et al.: Submission 106 p 34

148 Department of Industry, Technology and Commerce: Submission 126 p 2

149 Dalling, M, Calgene Pacific: Submission 23 p 23

Australia (ICI employs 56 R&D professional staff in several facilities[150]), or have formed joint ventures (Groupe Limagrain and Johnson & Johnson have recently entered into a partnership with CSIRO to form Gene Shears Pty Ltd).

3.153 Biotechnology companies are thus well placed, with access to substantial overseas investment funds, should the regulatory climate in Australia remain at least as conducive to the development of genetic modification technology as elsewhere.

J.2 Export opportunities

3.154 With the expected increase in the industry worldwide there is opportunity for Australia to exploit its expertise. An example is in the area of waste treatment and bioremediation.

> "The British released their White Paper at the end of September this year and the Government owned up purely to water and waste clean-up of £28 billion ... So I see a huge new potential industry in the Northern Hemisphere for Australia to be involved in and that will involve microbiology and molecular biology".[151]

3.155 The changes in Eastern Europe have revealed the scale of the environmental problems in the region so that opportunities for exporting bioremediation technology should be substantial.

3.156 It has also been suggested that a "substantial trade opportunity for Australia" exists in the production of primary products free of chemical residues.[152] This would result from the use of genetically modified vaccines, and animals and plants modified to resist pests.

J.3 Maintaining market position

3.157 Adopting genetic manipulation technology may not necessarily increase Australia's worldwide market share. Nevertheless:

> "... Australia does not operate in a vacuum. We are subject to major competition from other parts of the world. ... The application of this modern technology does have the potential to maintain production, increase production levels and therefore keep costs down and maintain the industry in a competitive state. So all of that would potentially fall by the wayside if you deprived yourself of a technology which was going to contribute in other parts of the world".[153]

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150 Davies, R et al., ICI Australia Ltd: Submission 121 p 7
151 Rolfe, Prof B: Transcript p 220
152 Dalling, M, Calgene Pacific: Submission 23 p 3
153 Willetts, Dr N, Research and Development, Biotech Australia Pty Ltd: Transcript p 784

3.158 As the Committee was concluding its deliberations, its attention was drawn to an announcement by the President of the United States of America, George Bush, that biotechnology products should not receive too much scrutiny from Federal regulators.[154]

154 Hilts, P: *Bush to ease rules on products made by altering genes* in *The New York Times* 25 February 1992

CHAPTER FOUR

PHILOSOPHICAL/ETHICAL/SOCIAL ISSUES

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PHILOSOPHICAL/ETHICAL/SOCIAL ISSUES

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, F 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

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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.**

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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

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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.

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287 Wells, Dr J, Bresatec/Metrotec: Transcript p 596

CHAPTER SIX

HUMAN HEALTH ISSUES

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HUMAN HEALTH ISSUES

A. Food and Pharmaceuticals

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

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

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

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

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

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

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

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

A.1 Food safety

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

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

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

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

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

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

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

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

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

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

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

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

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

A.2 Food sources modified to contain additional chemicals

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

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

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

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

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

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

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

10 ibid.

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

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

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

A.3 Unintentional contamination of food or pharmaceutical products

A.3.(i) Hormone contamination of food

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

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

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

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

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

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

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

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

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

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

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

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

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

17 ibid.

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

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

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

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

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

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

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

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

6.27 This argument has been supported.

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

6.28 However contrary arguments have been made by industry.

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

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

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

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23 Hulsman, Dr K: Transcript p 1209

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

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

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

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

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

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

A.3.(iii) Contamination of pharmaceuticals

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

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

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

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

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

29 ibid.

The L-tryptophan case

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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38 Belongia, E et al.: op. cit., p 360
39 Roberts, L: *L-Tryptophan Puzzle Takes New Twist*, in *Science*, Vol 249, 1990 p 988
40 Raphals, P: *Does Medical Mystery Threaten Biotech?* in *Science*, Vol 250, 1990 p 619
41 ibid.
42 Belongia, E et al.: op. cit., p 363
43 *S-Denko confirms contaminant*, in *SCRIP*, No 1560, 24 October 1990 p 24
44 *Showa Denko settles L-tryptophan suits in Japan*, in *SCRIP*, No 1595, 1 March 1991 p 10

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

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

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

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

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

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

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

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

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

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

B. Existing regulations addressing safety

B.1 The regulation of foods

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

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

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

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

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

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

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

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

6.52 The Authority will consist of

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

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

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

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

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

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

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

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

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

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

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

Recommendation 26

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

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

B.2 The regulation of food additives

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

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

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58 ibid., p 6

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

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

61 ibid., p 13

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

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

B.3 The Codex Alimentarius

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

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

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

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

64 ibid., p 5

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

6.64 The Codex Alimentarius Commission has stated:

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

Recommendation 27

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

B.4 The regulation of pharmaceuticals

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

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

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

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

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

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

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

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

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

6.72 As part of an application:

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

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

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

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

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

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

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

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

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

C. Occupational Health and Safety

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

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

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

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

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

Recommendation 28

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

C.1 Existing legislation and guidelines

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

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

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

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

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79 VLRC: Report No 26 p vi, Recommendation 9

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Recommendation 29

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

Recommendation 30

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

C.2 The risks associated with laboratory and industrial processes

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

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

6.99 Some of the possible hazards are outlined below.

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

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

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

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

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

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

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

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

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

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89 ibid., p 88

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

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

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

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

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

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

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

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

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

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

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

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

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

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

95 ibid.

96 ibid.

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

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

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

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

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

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

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

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98 Bartels, D: *Organisational hazards in biotechnology - towards a new risk assessment program*, in *Prometheus*, Vol 4(2) 1986 p 281
99 Bartels, D: *Escape of the cancer genes?* in *New Scientist*, 30 July 1987 p 53
100 Sleigh, Dr M, Division of Biomolecular Engineering, CSIRO: pers. comm.
101 Walgate, R: *Inquiry into lab's bone cancers*, in *Nature*, Vol 321, 1986 p 643
102 Coles, P: *Inquiry into Pasteur deaths*, in *Nature*, Vol 338, 1989 p 607
103 Roosa, N: *The Pasteur syndrome*, in *Omni*, October 1988 p 28
104 Bartels, D: *Escape of the cancer genes?* in *New Scientist*, 30 July 1987 p 54
105 Roosa, N: op. cit., p 28
106 Walgate, R: *Inquiry into lab's bone cancers*, in *Nature*, Vol 321, 1986 p 643
107 Coles, P: op. cit., p 583

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

Conclusion

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

C.3 The potential risks associated with changed agricultural practices

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

115 ibid., p 7

116 ibid.

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

118 ibid., pp 1141, 1146

D. Biological Warfare

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

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

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119 Phelps, R, Australian Conservation Foundation: Submission 140 p 54
120 ibid., p 52
121 United Scientists for Environmental Responsibility and Protection: Transcript p 638
122 VLRC: Report No 26 p 9

CHAPTER SEVEN

LEGAL ISSUES

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LEGAL ISSUES

A. PROPERTY RIGHTS - THE PATENTING OF LIVING ORGANISMS

A.1 The nature of patents

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

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

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

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

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

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

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

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

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

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

5 ibid., p 9

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

A.2 Requirements of patents

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

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

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

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

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

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

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

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

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

8 ibid., p 9

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

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

11 Australian Official Journal of Patents, 1980 p 1162

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

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

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

Recommendation 31

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

A.3 The obligations of a patentee

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

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

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

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

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

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

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

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

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

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

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

A.4 The patenting of organisms overseas

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

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

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

17 ibid.

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

19 ibid.

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

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

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

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

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

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

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

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

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

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

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

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

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

24 ibid.

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

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

27 ibid.

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

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

A.5 Consideration of the arguments against patenting

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

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

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

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

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

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

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28 ibid.

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

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

31 Murray, Dr D: Transcript p 815

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

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

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

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

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

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

7.39 Professor Singer argued that:

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

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

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

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

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34 ibid., p 49
35 Singer, Prof P: Transcript p 254
36 ibid., p 262
37 Holmes, P, Legal Research Project, Macquarie University: Submission 146 p 77
38 Patent Trade Marks and Design Office: Submission 127 p 8 - referring to Curry, J, *The Patentability of Genetically Engineered Plants and Animals in the US and Europe*, IPPL, London 1987

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

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

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

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

7.45 Animal research is also controlled and monitored.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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47 ibid.

48 ibid., p 12

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

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

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

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

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

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

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

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

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

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

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

52 ibid., p 3

53 ibid.

54 ibid.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

7.84 A contrary argument has been put that patenting:

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

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

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

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

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

7.88 One submission proposed that there be created:

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

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

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

64 ibid., p 15

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

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

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

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

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

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

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

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

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

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66 ibid., p 3

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

A.6 Is patenting a commercially sensible option?

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

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

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

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

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

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

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

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

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

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

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

7.106 Nevertheless, it was suggested that:

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

7.107 There are

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

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

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76 Harrison, Dr D: Transcript p 776

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

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

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

A.7 Summary

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

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

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

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

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

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

B. Regulation of Product or Process

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

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

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

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

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

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

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

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

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

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

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

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

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

84 ibid., pp 37, 38

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

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

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

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

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

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

Recommendation 32

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

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

C. PRODUCT LABELLING

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

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

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

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

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

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

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

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

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87 Australian Consumers' Association: Submission 132 p 13

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

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

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

91 Hulsman, Dr K: Transcript p 1209

C.1 Current product labelling regulations

C.1.(i) Regulations concerning food

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

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

C.1.(ii) Regulations concerning pharmaceuticals

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

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

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

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

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

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

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

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

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

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

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

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

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

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

97 ibid., pp 3, 4

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

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

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

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

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

C.2 Practical difficulties

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

C.2.(i) The problem of identity

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C.2.(iv) The problem of consistency

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

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

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

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

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

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

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

C.3 The UK Food Advisory Committee

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

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

7.155 The four categories of food are:

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

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

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

110 ibid., p 2

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

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

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

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

C.4 Conclusion

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

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

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

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

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

112 ibid., Annex III p 1

113 ibid., Annex III p 2

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

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

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

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

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

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

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

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114 VLRC: Report No 26 p vi

115 ibid., p 22

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

117 ibid., p 89

118 ibid., pp 88, 89

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

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

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

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

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

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

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119 ibid., p 88

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

121 ibid., p 55

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

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

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

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

Recommendation 33

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

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

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

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

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

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124 Burch, Dr D et al.: Submission 106 p 50
125 Phelps, R, Australian Conservation Foundation: Submission 140 p 80
126 Burch, Dr D et al.: Submission 106 p 2
127 UK Royal Commission on Environmental Pollution: op. cit., para. 12.24 p 94
128 ibid., p 95

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

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

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

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

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

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

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

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

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

131 ibid. p 7

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

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

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

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

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

Recommendation 34

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

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

CHAPTER EIGHT

THE WAY AHEAD

CHAPTER EIGHT

THE WAY AHEAD

A. Requirement for Legislation

8.1 There are three main reasons why legislative action might be needed as a result of the development of genetic manipulation techniques. Firstly, to ensure that there are adequate controls to protect the environment from the accidental or intentional release of genetically modified organisms. Secondly, to fill in any apparent gaps in existing legislation governing the clearance and registration of products which may now contain, or be produced by, genetically modified organisms. Thirdly, if it is considered that adherence to the existing voluntary guidelines concerning contained genetic manipulation work should be made mandatory, any new legislation must clarify the administrative framework.

A.1 Accidental or deliberate releases

8.2 Chapter 5 in this report dealt with the environmental issues relevant to the inquiry in some detail. Existing Commonwealth and State legislation which might be applicable to the environmental impact of releases of GMOs was outlined. A number of recommendations were made for measures to help reduce the risks.

8.3 One possible eventuality is the accidental release of GMOs from commercial or research premises. Recommendations 36 to 39 and recommendation 45 in this report concerning the regulation of contained work with GMOs, should help to minimise the chance of accidental release and to minimise any dangers if release does occur.

8.4 Reference was made in chapter 5 to various State Acts concerning air and water quality, waste management, or sewerage, or health matters which might be applicable to escapes of GMOs. The polluter could be subject to certain sanctions under these Acts and there may be provisions concerning the removal of the polluting substance. Mention was also made of common law actions which might apply.

8.5 The VLRC felt that there was adequate power under existing legislation to deal with any emergency that may arise from a release of GMOs to the environment. They acknowledged, however, concerns expressed to them that "criteria for invoking these laws are generally commercial loss or public health damage" rather than environmental damage.[1]

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1 VLRC: Report No 26, *Genetic Manipulation*, June 1989 p 35

8.6 Dr David Burch et al. recommended provision for an emergency disaster safety net program, "allowing seizure and destruction of bioproducts, sterilisation of fields and clean-up of spills."[2]

8.7 Dr Chris Green, Director of Plant Pathology, NSW Department of Agriculture and Fisheries, commented on the need for contingency planning to allow rapid responses to accidents. He mentioned that, for outbreaks of disease or occurrences of exotic pests, rapid decisions and responses are required. The same could be necessary in relation to escapes of GMOs or when unintended effects resulted from authorised releases.

> "... action has to be taken very often within days if it is a bacterial infection. This is mostly done by departments in the States being fairly ready to take the immediate action and take the cost. The departments hope to recover costs by Federal-State partitioning of costs.
>
> ... Until now the State departments have generally borne this. ... State department finance is getting tighter and tighter. ...
>
> If we are taking genetic engineering organisms, it is almost the same. I regard a genetically modified organism as being an exotic. It is a different gene combination to what occurs in nature. You have got exactly the same problem. If you do get an escape, who is going to deal with it? Who is going to pay for it and who is going to make the decisions as to whether we try to eradicate it or whether we let it run loose? I am not going to try to make those decisions."[3]

8.8 The VLRC report recommended specific legislation to control the experimental releases of altered organisms - enacted by Commonwealth, or complementary State/Commonwealth legislation. The VLRC said this legislation should:

> . include mandatory notification to GMAC and relevant State and Federal Government Departments of proposed releases;
> . require the supervising agency to conduct an environmental impact assessment on proposed releases;
> . require advertisement by the supervising agency and public input before any approval;
> .provide for the supervising agency to have power to impose conditions, such as containment and monitoring requirements, when approving a release proposal and power to "take steps to prevent injury or damage to people or property and to eradicate or otherwise deal with organisms in the environment".[4]

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2 Burch, Dr D et al.: Submission 106 pp 5 & 56

3 Green, Dr C, Director of Plant Pathology, NSW Department of Agriculture and Fisheries: Transcript pp 757, 756

4 VLRC: Report No 26 p vi, Recommendation 13

8.9 The VLRC emphasised the importance of Federal co-ordination of "advice, assessment, approval, and monitoring of proposed releases" through GMAC and the Group of Officials on Biotechnology Regulations.[5]

8.10 There was broad support among those who made submissions to the inquiry for many of the measures included in the above VLRC recommendations, and in particular for: a uniform national approach; mandatory notification of proposed releases; an approval procedure (although not uniform support for a detailed environmental impact assessment in every case); public input into decision making about releases; and provision for the supervisory agency to impose conditions as part of the approval for release.

8.11 Biotechnology companies stated a preference for a comprehensive national regulatory system over one which was less uniform and more uncertain. Monsanto Australia Ltd commented that uncertainty about regulatory requirements at present was inhibiting commercialisation of biotechnology in Australia.[6]

Recommendation 35

8.12 The Committee recommends that adherence, by those proposing releases of GMOs to the environment, to the Recombinant DNA Monitoring Committee guidelines: *Procedures for Assessment of the Planned Release of Recombinant DNA Organisms*, or any subsequent replacement document, be made compulsory at an early date.

A.2 Existing product legislation - gaps

8.13 The VLRC inquiry found that, in the State of Victoria at least:

> "Most of the potential applications of genetic manipulation probably fall within existing legislation and the responsibilities of Government Departments ... Although produced by genetic manipulation techniques, they are not radically different from products produced by other means....
> It is essential, however, that every proposed release falls within the responsibility of some Department. ... legislation generally requires that a new product may not be sold or used unless it is registered, or the subject of a permit.
> There are ... some agricultural activities that are subject to few controls, such as the breeding of transgenic animals and the propagation and sale of new plants. Also, it is conceivable that, as new products are

5 ibid., p vii, Recommendation 14

6 Sheers, M, Regulatory and Environmental Affairs, Monsanto Australia Ltd: Transcript pp 443-445

> developed, or are used in novel ways, they will not fall readily, or at all, within the review responsibilities of a Government Department. ...
> ... It is evident from the Commission's discussions with representatives of various Government Departments that even they are uncertain about some of the matters that might fall within their responsibilities and the applicability of the legislation they administer to the new technology."[7]

8.14 Prof Nancy Millis, from GMAC, like Mrs Loane Skene from the VLRC, referred to existing legislation being inadequate to cover the case of releases of live plants which have been genetically modified.[8] The GMAC submission commented that

> "Although there are many Acts and sets of regulations that are directly applicable or can be readily invoked, there is great variability and lack of a clear path for clearance, and uncertainty about responsibilities within State and Commonwealth agencies."[9]

8.15 Previous chapters in this report have included discussion of the existing regulatory framework in the following areas: food, food additives and pharmaceuticals (in chapter 6); product labelling requirements for food, pharmaceuticals, and agricultural and veterinary chemicals (in chapter 7).

8.16 The Committee has already commented that there was an apparent gap in the food clearance procedures. The Committee has accordingly recommended in chapter 6 that new foods, new strains of existing foods, or new food additives which are developed using genetic manipulation techniques should be referred to GMAC before release.

8.17 It was noted in chapter 6 that the procedures for clearance of therapeutic goods, although focussed on the type of product and its intended use, allow consideration of the process of manufacture to be taken into account. Indeed, recent amendments to the Health Department guidelines specifically relate to the information required for the products of genetic manipulation. There may be scope, however, for 'dietary supplements,' which are marketed without making claims about therapeutic properties, to slip through without the same consideration which therapeutic goods receive.

8.18 It was noted in chapter 7 that the Australian Agricultural and Veterinary Chemicals Council (AAVCC) has been established to co-ordinate the pre-registration assessment and clearance process for agricultural and veterinary chemicals. It was also noted that such chemicals can include biological agents, either naturally occurring or genetically modified. The working procedures of the AAVCC involves GMAC in an assessment of the possible hazards which might result from any manufacturing process involving GMOs.

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7 VLRC: Report No 26 pp 29, 30
8 Millis, Prof N, Chairman, GMAC: Transcript p 80
9 GMAC: Submission 88.1

8.19 There were conflicting opinions expressed concerning the adequacy of the AAVCC process when dealing with GMOs.

8.20 "ICI Australia would like to emphasise that a competent regulatory framework already exists for farm chemicals and pharmaceuticals. ... [The authorities] have developed the experience and flexibility to establish the safety of products and processes involving biotechnology."[10]

8.21 However, Biotech International did not share this satisfaction with the applicability of the procedures.

> "Many sections of the data required ... are not applicable to living organisms. Many of the questions that should be answered when assessing biological control agents are not asked. A great deal of space in the submission is taken up in defining ... chemical and physical properties (boiling point, solubility etc) of constituent compounds and end products."[11]

8.22 The Committee indicated in chapter 7 that it favours an approach whereby products are regulated on the basis of their intended use rather than on the basis of the manufacturing process employed in their production. The Committee recommended in chapter 7 that those seeking approval for registration or sale of new products should indicate the method of manufacture so that this could be taken into account in considering the safety or efficacy of the product.

8.23 A distinction could be made between products which are merely chemical products and those which do or could include live organisms. Existing approval procedures for some types of products have been developed including consideration of the possibility of the inclusion of live organisms in the product. For example, clearance procedures for vaccines have long had to encompass vaccines incorporating live organisms. It should not be difficult to adapt these kinds of procedures to allow appropriate consideration of products incorporating live genetically modified organisms.

8.24 The approval procedures for other types of products, such as agricultural chemicals, have been developed with non-living products in mind. It may be more difficult to accommodate consideration of GMOs within such procedures.

8.25 **The Committee considers that existing product clearance and registration procedures are not fully adequate to cope with products which consist of or include live GMOs.**

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10 ICI Australia Ltd: Submission 121 p 12

11 Biotech International Ltd: Submission 90 p 6

A.3 Existing guidelines for contained work - voluntary or compulsory adherence

8.26 In chapter 2 of this report the existing GMAC guidelines for small and large scale genetic manipulation work, and the *Australian code of practice for the care and use of animals for scientific purposes* were described. The Committee has already recommended in chapter 4 of this report that legislative force be given to the *Australian code of practice.*

8.27 It was noted in chapter 2 that adherence to the GMAC guidelines is voluntary; although there are some sanctions which could be applied such as withdrawal of government grants or tax incentives. There were different opinions among those who made submissions to the inquiry concerning the need to make adherence to the guidelines compulsory.

8.28 Prof Jim Pittard, Chairman of the Scientific Sub-Committee of GMAC, argued that the fifteen year history of regulation of contained work by voluntary guidelines, "without any major mishap or non-compliance", indicated that no new legislation was necessary.[12] The Australian Veterinary Association,[13] the Australian Academy of Science,[14] the Department of Microbiology, Monash University,[15] and the Department of Industry, Technology and Commerce[16] similarly argued against the need for compulsory adherence to guidelines for contained work.

8.29 On the other hand, the Australian Conservation Foundation,[17] the Department of Primary Industries and Energy,[18] the Biotechnology Industry Association[19] among others argued in favour of mandatory guidelines. It was argued that the limited existing sanctions will not be sufficient to ensure compliance as the use of the technology becomes more widespread. Mr Nelson Quinn, First Assistant Secretary of the Environment Protection Division of the Department of the Arts, Sport, the Environment, Tourism and Territories stated:

> "I think our expectation would be that the demands of the public and probably parliaments and so on would make it pretty much inevitable that there would have to be some kind of formality attaching to those guidelines. The level of it would be an issue for decision, I guess. You would expect to find at least codes of conduct and so on endorsed by

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12 Pittard, A J, Professor of Microbiology, University of Melbourne and Chairman of Scientific Sub-Committee, GMAC: Submission 2, p 12

13 The Australian Veterinary Association Ltd: Submission 133 p 3

14 Gibson, Prof F, Australian Academy of Science: Transcript p 5

15 Bayley, Prof R, Chairman, Department of Microbiology, Monash University: Submission 59 p 2

16 Delroy, B and Clarke, B; Department of Industry, Technology and Commerce: Transcript p 1100

17 Phelps, R, Australian Conservation Foundation: Submission 140 p 28

18 McLean, Dr G, Bureau of Rural Resources, Primary Industries and Energy: Transcript p 1148

19 Biotechnology Industry Association: Submission 157 p 10

the Authority. In the real world that really would amount to a mandatory system."[20]

8.30 The Committee considers that there is no substantial argument against adherence to the GMAC guidelines for small and large scale genetic manipulation work being made compulsory. Giving those guidelines statutory backing will help improve public confidence in the system, without making more stringent the requirements that researchers and commercial operators state that they already meet in practice.

Recommendation 36

8.31 The Committee recommends that GMAC guidelines be made mandatory for small and large scale genetic manipulation work at an early date.

A.3.(i) Sanctions

8.32 Making adherence to the guidelines mandatory raises the question of the sanctions which might be imposed.[21] The VLRC report recommended that: "Research funding and taxation incentives for genetic manipulation work should be conditional on compliance with Genetic Manipulation Advisory Committee guidelines."[22]

8.33 Biotech Australia went slightly further suggesting that sanctions for non-compliance could be "withdrawal of Government grants, tax incentives" as well as withdrawing "the right to conduct research or manufacturing until GMAC is satisfied there is compliance".

Recommendation 37

8.34 The Committee recommends that there be a wide range of penalties, including the withdrawal of Government grants and tax incentives, heavy fines, or imprisonment where appropriate, which might be imposed for breach of the guidelines. The right to sue for civil damages should remain.

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20 Quinn, N, Environment Protection Division, Department of the Arts, Sport, the Environment, Tourism and Territories: Transcript p 1116

21 Biotech Australia Pty Ltd: Submission 37 p 5

22 VLRC: Report No 26 p vi, Recommendation 10

A.3.(ii) Registration of researchers, premises or projects

8.35 The sanction of withdrawing the right to conduct research or manufacturing would imply a process of registration of individuals, companies, laboratories or manufacturing premises, or of projects.

8.36 Dr John Davies and Prof Bruce Holloway from Monash University advocated, on the grounds of efficiency, that any regulation of GMO work should involve licensing experimenters and facilities to carry out certain kinds of experiments, rather than requiring approval for individual projects. The penalty for failing to follow the appropriate guidelines would be to lose the licence.[23]

8.37 Professor Barry Rolfe also advocated the registration with GMAC of people and laboratories working in molecular biology. One result of such registration would be increased control over the purchase of equipment and chemicals used in molecular biology.[24]

8.38 The VLRC did not consider that genetic manipulation work was "so intrinsically dangerous that it should only be conducted in specially certified or licensed laboratories or by specially certified or licensed researchers".[25] However, the Commission stated that, "in order to appease community concern", legislation should be introduced in relation to "potentially hazardous scientific work" in general.[26]

8.39 The VLRC recommended legislation to require prior notification of potentially hazardous scientific work in Victoria to the State Department of Labour at least 30 days before commencement.[27] This could include genetic manipulation work if GMAC considered that the proposed work warranted it.[28] The Department of Labour would be empowered to "prohibit or to impose conditions on proposed projects".[29]

8.40 The VLRC noted that such a requirement would assist the Department of Labour in enforcing occupational health and safety laws. The Committee agrees that such a requirement would be useful from an occupational health and safety view-point and has recommended, in chapter 6, that State Governments be encouraged to require the notification of all potentially hazardous scientific work to the responsible authorities.

8.41 The ACF recommended not only the notification of all genetic modification research proposals, and their registration with the Commonwealth Environment

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23 Davies, Dr R; Holloway, Prof B: Transcript pp 348, 349
24 Rolfe, Prof B: Transcript pp 209-211
25 VLRC: Report No 26 p 19
26 ibid., pp 16, 17
27 ibid., p v, Recommendation 3
28 ibid., Recommendation 4
29 ibid., Recommendation 5

Protection Authority,[30] but also the notification of each stage in the transition of a project from initial research proposal to commercial production with penalties for non-compliance. Such notifications should be kept in a public register. This would make it easier to trace any unauthorised releases.[31]

8.42 The ACF further recommended that State environment protection authorities should have responsibility for assessing and monitoring the establishment and operation of all laboratories and factories using GMOs. The GMAC Scientific sub-committee, the National Association of Testing Authorities, the Standards Association and other like bodies could be involved in an advisory capacity.[32]

Recommendation 38

8.43 The Committee has already recommended that adherence to the guidelines appropriate to the stage and scale of the project be made mandatory (recommendations 35 and 36). To assist in the enforcement of this requirement the Committee recommends that those proposing to undertake contained genetic manipulation work, other than work which is exempt under the guidelines, either for research or commercial purposes, be required to make application to GMAC, who will notify the required level of containment under the appropriate guidelines. Work which is exempt from notification to GMAC under the guidelines should still require approval by the Institutional Biosafety Committee, as is presently the case.

Recommendation 39

8.44 The Committee further recommends that if it is intended to change the scale of the project, for example, from small to large scale, further application to GMAC should be required. If it is intended to progress from contained work to field trial, application to the Release Authority should be required.

8.45 The Committee considers that if the above recommendations and recommendation 25 (para 5.277) (to impose legal responsibilities on IBCs for supervision and control of projects) are implemented, registration of researchers and/or premises should not be necessary.

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30 Phelps, R, Australian Conservation Foundation: Submission 140 p 27
31 ibid., p 30
32 ibid., p 28

A.3.(iii) Guidelines - by legislation or regulations

8.46 There was broad support for the idea that, if compliance with the guidelines was to be made compulsory, the guidelines should be set out in regulations under the Act rather than incorporated in it. This would enable them to be more easily amended to keep pace with developments in technology.

> "... if there were new technological developments which were demonstrably safe or which significantly reduced the level of risk yet fell outside ... the legislative framework, delays [would be] incurred due to the need to make changes to the law ...
>
> ... legally obligating all institutions and individuals to operate through GMAC and according to the guidelines ... would retain the necessary flexibility [allowing] decisions on a case-by-case basis without the need to resort to changes in the law."[33]

8.47 A contrary view - that the code of practice or guidelines should "have some basis in the legislation itself" - was expressed by Mr Kevin Andrews, Acting Director of the Bioethics Centre of St Vincent's Hospital.

> "Parliament ultimately is the final barometer, if one can put it that way, of public concerns in this area and public acceptability of new technology and therefore the code of practice ought to have some basis in the legislation itself. ... the Parliament then can place parameters upon the way in which it says this technology can go forward. If one is looking at it from, say, an environmental concern, then that environmental concern ought to fundamentally, in my opinion, be the principle that there is no degradation of the environment. That principle could be embodied in the legislation, just as, in an analogous situation, the principle of the best interests of the child is contained in the Family Law Act".[34]

8.48 The Committee considers that, while a general statement of principles could be included in legislation, the detailed guidelines themselves should be contained in regulations issued under the Act. This would allow the flexibility needed to update the guidelines in accordance with changes in technology and experience.

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33 Biotech Australia Pty Ltd: Submission 37 pp 4, 5

34 Andrews, K, Acting Director, Bioethics Centre, St Vincent's Hospital, Fitzroy: Transcript pp 487, 488

B. Options for National Supervisory Body

8.49 There are three broad alternatives for a national body to regulate the release of GMOs: an expanded GMAC; or some other existing body, perhaps in an enhanced form; or a new federal body.

B.1 A new enlarged GMAC

8.50 The VLRC report recommended a continuing advisory and monitoring role for GMAC.[35]

8.51 In the case of planned releases, Prof Jim Pittard felt that if GMAC is not to be the body making the final decision on releases then: "there needs to be a detailed identification of the appropriate government bodies for all the types of release and they need to be contacted and made aware of the necessity of GMAC's involvement (as the chief advisory body)."[36]

8.52 The Australian Academy of Science suggested that GMAC be responsible for overseeing approvals for release because "it will usually be familiar with the previous history of the project, having been concerned with the work during the research phase. It has also been concerned with formulating the existing guidelines for release proposals."[37]

8.53 Biotech International argued: "Extension and modification of the existing system is likely to be more cost effective and practical than the formation of an entirely new structure."[38]

8.54 Metrotec recommended a coordinating role for GMAC.

> "GMAC should act as a clearing house, streamlining the collection and dissemination of information between research groups and Government regulatory bodies. It should be GMAC's responsibility to ensure that research groups target all the required regulatory groups in the correct format and to co-ordinate the response. This clearing house system should operate nationally".[39]

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35 VLRC: Report No 26 p v, Recommendation 7

36 Pittard, Prof A J, Professor of Microbiology, University of Melbourne; Chairman of Scientific Sub-Committee GMAC: Submission 2 p 13

37 Australian Academy of Science: Submission 118 p 6

38 Biotech International Ltd: Submission 90 p 6

39 Metrotec Pty Ltd: Submission 61 p 3

8.55 Should this option be pursued, the membership of GMAC might need broadening.

> "As the membership of GMAC ... is limited and the opportunity for public debate and input into the regulatory making process is inadequate, the body remains technically oriented. Nor are the deliberations of the Committee generally open to members of the Australian public. In contrast, the operation of the American Recombinant DNA Advisory Committee is much more inviting of public participation."[40]

B.2 Existing bodies other than GMAC which could regulate releases

8.56 It was suggested that existing or proposed environmental bodies, such as the Environmental Protection Agency (EPA), could fulfil the function of regulating releases.

> "... the Australian and New Zealand Environment Council (ANZEC) could play a more formal role ... [a] working party within ANZEC would be appropriate (or within an appropriate federal agency or EPA, in liaison with ANZEC)."[41]

> "The proposed federal EPA would be the ideal body to coordinate and respond to biotechnology proposals. This would include mechanisms which would allow public participation, conflict resolution and principles for evaluation of GMOs in an ecologically sustainable framework."[42]

8.57 The ACF suggested that the proposed Commonwealth Environment Protection Authority should have responsibility for national aspects including:

> ". receiving notification and registering all GE research proposals
> . informing the public and nationally advertising all proposed GMO releases
> . commissioning and receiving the GMAC's genetic assessment
> . commissioning and co-ordinating all non-genetic (environmental and social) assessments
> . establishing forums in which public interest representatives can contribute to decision-making
> . maintaining a public register and information base of all work, especially deliberate releases."[43]

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40 Andrews, K, Director, St Vincent's Bioethics Centre: Submission 112 p 8
41 Burch, Dr D et al.: Submission 106 p 57
42 Queensland Department of Environment and Heritage: Submission 73 p 4
43 Phelps, R, Australian Conservation Foundation: Submission 140 p 27

8.58 State Departments of the Environment would have responsibility for implementing Commonwealth decisions concerning GMOs - in particular post-release monitoring with assistance from GMAC's Live Release sub-committee.[44]

8.59 A different review agency was raised during evidence by Prof Nancy Millis.

> "I think we should consider whether we need anything further than the existing quarantine regulations. ... I believe it is appropriate for quarantine for all novel organisms, be they genetically modified or otherwise. At present there is a mechanism for handling them ... It seems to me that anything coming in as a totally novel organism is probably best handled by the group that is accustomed to that activity."[45]

8.60 A major advantage of using the Australian Quarantine and Inspection Service to regulate the release of all novel organisms would be that an Australia-wide organisation already exists. AQIS has evaluation and monitoring expertise and experience and its State offices could act as a conduit through which release proposals could be submitted to a central body.

8.61 Legislation would need to be enacted to alter AQIS's charter and to broaden its membership so that the broad issues surrounding release of novel organisms could be canvassed.

B.3 A new body to control releases

8.62 A number of submissions proposed that a two-tiered system be established. There would be a scientific advisory body like the present GMAC and another body with broader membership which would have the responsibility for decisions about releases of GMOs to the environment.[46] DITAC envisaged that there would be community representatives on the regulatory body as well as people with environmental expertise.[47]

8.63 A model for the regulation of releases was proposed by CSIRO.

> "(1) A Federal Registration Board to be established as the focal point for receipt of all release proposals. Notification of proposed releases to the Board to be made mandatory.
> (2) Regulations governing GMO release to be prepared and updated by this Board.

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44 ibid., p 28

45 Millis, Prof N, Chairman, GMAC: Transcript pp 1213, 1214

46 Sleigh, Dr M, Division of Biomolecular Engineering, CSIRO: Transcript pp 1065, 1066

47 Clarke, B, Aerospace and Biological Industries Branch, Department of Industry, Technology and Commerce: Transcript pp 1095, 1096

(3) Provisions for public notification of proposed releases but for extended public involvement (e.g. public hearings) only when this is warranted by public response.
(4) A time frame for decision-making.
(5) Assessment of proposals to be carried out by expert committees advising the Board (e.g. GMAC). GMAC could become, in effect, a subcommittee of the Board.
(6) The Board to act as a point of despatch of proposals to other State and Federal agencies either to provide expert advice or assessment or to give final approval for release where this falls under existing legislation.
...
(7) All final permits for releases, endorsed by other bodies as required, to be issued by the Board."[48]

8.64 Government Departments, both State and Federal, indicated their support for this type of arrangement which would use, where possible, existing clearance procedures:

> "Wherever possible, [the Board] refers the GMO to the lead agency of an existing scheme for assessment. Control is achieved through existing [State or Territory] mechanisms ... [if this is not possible, the Board] has statutory requirements to ensure a suitable assessment is done."[49]

8.65 Thus existing clearance procedures would be used; an advantage because they would be familiar to industry.

8.66 If CSIRO's Release Board model were to be adopted, there would be a need to amend existing legislation to ensure referral to the Board, and accommodate the particular characteristics of genetically modified organisms or, alternatively, enable the Board to cover the deficiencies of existing procedures.

8.67 GMAC recommended that:

. there should be a Commonwealth Committee with legal responsibility for making determinations concerning the release of novel living organisms and its permission should be a legal requirement before releases can occur
. permission by the Release Committee would not remove the responsibility to obtain other permits
. the Release Committee would have members appointed for their knowledge of environmental and ecological matters, including one representative from GMAC
. GMAC would advise the Release Committee, which would also be free to seek advice from other relevant agencies

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48 Stocker, Dr J, Chief Executive, CSIRO: Submission 109 p 29
49 Department of the Arts, Sport, the Environment, Tourism and Territories: Submission 138 p 25

. the Release Committee should have responsibility for producing minimal standards and procedures associated with releases where such do not already exist; but State authorities would be free to make further conditions.[50]

8.68 Prof Millis stated that under the system recommended above, a proponent of a release would have to apply to the relevant IBC which would have to come to GMAC for advice. GMAC then would have to refer the proposal to the Release Committee, which then would have to consult the relevant State agencies. The Release Committee, together with the State agencies, would make a decision. The Release Committee would inform the proponent of the outcome. This would provide a one-stop-shop for the proponent.[51]

Recommendation 40

8.69 The Committee recommends that a two-tiered approach be adopted for the release of GMOs to the environment. GMAC should be retained to grant approval for contained work (see recommendation 38) and as a specialist advisory body. In addition, a GMO Release Authority should be created by uniform complementary State and federal legislation. The GMO Release Authority should have responsibility for the authorisation of all releases of GMOs, whether for field trials at the pre-product stage (see recommendation 42) or for releases of products containing GMOs (see recommendation 43) and also for setting minimum standards and procedures.

Recommendation 41

8.70 The Committee recommends that GMAC and the GMO Release Authority should be responsible to the Minister for Science and Technology.

50 GMAC: Submission 88.1

51 Millis, Prof N, Chairman, GMAC: Transcript p 80

Recommendation 42

8.71 The Committee recommends that, concerning the release of GMOs at the field trial stage,

. it should be mandatory that those seeking approval for the release of GMOs in field trials should forward their applications to the GMO Release Authority

. the Release Authority should consider such applications with advice from GMAC and relevant State and Commonwealth authorities (such as Health or Environment Departments)

. the Release Authority should have the authority to publicly advertise proposed field trial releases if it considers this desirable and to allow a reasonable time (to be specified in regulations) for expressions of opinion before proceeding to a decision concerning approval

. the Minister should be advised of all proposed releases and have the discretion to order public hearings in relation to a proposed release

. the Release Authority should forward a copy of all applications to any appropriate existing State and Commonwealth bodies for parallel consideration

. these other State and Commonwealth bodies should indicate to the Release Authority whether the proposed release has their approval

. the approval of any other relevant State and Commonwealth bodies and of the Release Authority should be required before the GMO is released

. the Release Authority should be responsible for informing the applicant whether the release is authorised.

Recommendation 43

8.72 The Committee recommends that, to ensure public confidence that concerns about the release of products containing live GMOs to the environment are fully considered:

. it should be mandatory that those seeking approval for the sale of such products should forward their applications to the GMO Release Authority
. the Release Authority should consider such applications with advice from GMAC
. the Release Authority should publicly advertise proposed releases and allow a reasonable time for expressions of opinion before proceeding to a decision concerning approval
. the Minister should be advised of all proposed releases and have the discretion to order public hearings in relation to a proposed release
. the Release Authority should forward a copy of all applications to the appropriate existing product approval body for parallel consideration
. the product approval body should indicate to the Release Authority whether the application has their approval
. the approval of both the product approval body and of the Release Authority should be required before the product is released
. the Release Authority should be responsible for informing the applicant whether the product meets all the requirements.

Recommendation 44

8.73 The Committee recommends, in relation to products which do not contain live GMOs, but in the production of which the use of GMOs has been involved, that:

. all State or federal bodies with responsibility for product clearance or registration, as well as making their own evaluations, be required to refer any proposals made to them concerning such products to the GMO Release Authority
. the approval of the Release Authority be required before the product is authorised for release.

Recommendation 45

8.74 The Committee recommends that legislation require:

. the notification of any unauthorised release of genetically modified organisms from contained facilities as soon as possible to the Institutional Biosafety Committee, the national GMO Release Authority and the responsible State and Commonwealth environment and health authorities

. the GMO Release Authority to co-ordinate any remedial action by the relevant authorities

. the keeping by the GMO Release Authority of a register of any unauthorised releases of GMOs, indicating the nature of the organism, the quantities released, the location, and the institution involved.

B.4 Membership of the Release Authority

8.75 Calls were made for tight regulation, with a committee to monitor experiments composed of community representatives such as environmentalists and animal health and welfare people as well as scientists. The ACF wanted a "decision-making body representing a broad range of interest groups and the general public".[52] Similar comments were made by Dr David Burch et al.[53]

8.76 The Department of Primary Industries and Energy (DPIE) suggested that the "receiving and approving authority" for environmental release proposals should be

> "... comprised of persons of standing in the community and preferably with no more than two or three members ... After taking into account all relevant factors, (Scientific, economic and social expert advice, and public input) the ultimate approvals would need to be [their] responsibility".[54]

8.77 DPIE did not have a firm position on whether the public should be represented on the regulatory body but one of the Departmental witnesses stated:

> "I think our view so far ... has largely been that the members of a group like that would need to be certainly expert based. We would not see all the expertise needing to be scientific - clearly there are economic and social concerns. But having a representative of particular public interest groups I think is probably something that we do not particularly like. We see it more as needing people who have sufficient stature in the

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52 Phelps, R, Australian Conservation Foundation: Submission 140 p 17

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

54 Department of Primary Industries and Energy: Submission 143 p 21

> field to gain public confidence that they are in fact impartial and that they are not driven by a particular group".[55]

8.78 A small authority was also suggested by the Department of the Arts, Sport, the Environment, Tourism and Territories. They proposed:

> "... between three and five members, which would be appointed on the basis of the expertise the members could bring to bear in making the decisions the authority was required to take. ... such a body would not, in any sense, be representative of interest groups. ... [the authority] can have paraded before them whatever kind of information ... that the authority would be dealing with".[56]

8.79 The CSIRO submission suggested that "membership should include scientific representation as well as other experts and public representatives"[57], a view supported by the Australian Biotechnology Association[58].

8.80 Dr Merilyn Sleigh from the CSIRO commented in oral evidence:

> "... whether particular interest or lobby groups should be represented on an overall decision making body. My instinct on this is to say, 'No, they should not', because, after all, what you are really after there is people who are there to make decisions rather than, in a sense, to represent particular constituencies or the policies of those constituencies.
> On the other hand, the British ACRE committee has, in fact, representatives of such interest groups in its membership. Their perception seems to be that this functions very well....
> I think that, on balance, there would be advantages in having different viewpoints represented, as far as possible, on an actual decision making body, while still reinforcing the view that that body needs to be receiving excellent scientific advice, and also containing scientific representation as a fairly strong element within it."[59]"

8.81 The ACRE committee which regulates releases in the UK has a membership which "comprises academics, experts, representatives of trade unions, representatives of employees, and also around the table we have assessors from all the relevant government departments".[60]

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55 Quinn, A, Research and Development Policy, Corporate Policy Division, Department of Primary Industries and Energy: Transcript pp 1140

56 ibid., p 1110

57 Stocker, Dr J, Chief Executive, CSIRO: Submission 109 p 30

58 Australian Biotechnology Association: Submission 142 p v, Recommendation 5

59 Sleigh, Dr M, Division of Biomolecular Engineering, CSIRO: Transcript pp 1066-1068

60 Poole, Prof N, Manager, Biotechnology and Regulatory Affairs, ICI Seeds and Pacific Seeds Pty Ltd: Transcript p 407

8.82 Monsanto Australia Ltd considered that

> "... the board should include wide representation so that ethical, social and economic views - all views - can be adequately addressed. ... there is a place for the wider interest of the public to be represented by people adequately qualified to make those representations ... for people with wide interests but specific qualifications."[61]

8.83 Monsanto also argued that the science aspects of a proposal should be separated from the social aspects.

> "The technical aspects of any proposal - the science, efficacy, health, environmental safety - must be assessed by an objective, scientifically independent expert review panel. ... that information should then be taken to the board level, where other considerations can be imposed. But you cannot really make adequate economic and social decisions unless you have that hard base of science and the facts on which to make those decisions. Those two functions must be clearly separated."[62]

8.84 Prof Nancy Millis, Prof David Danks and Prof Jim Pittard of GMAC were concerned that the professional expertise of GMAC and the Release Committee not be too diluted by representatives of community interest groups.[63]

8.85 Biotech Australia went even further:

> "The inclusion of individuals solely because they are very vocal or because they represent an antagonistic view (in the mistaken belief that this will result in a 'balanced committee') could result in a divided, ineffectual committee which, in turn, could lead to unnecessary restriction".[64]

Recommendation 46

8.86 The Committee recommends that the membership of GMAC consist of people chosen by the Minister for their expertise in genetic manipulation technology and/or environmental science.

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61 Sheers, M, Regulatory and Environmental Affairs Manager, Monsanto Australia Ltd: Transcript p 444

62 ibid., p 445

63 Millis, Prof N; Danks, Prof D; Pittard, Prof A J; GMAC: Transcript pp 99-101

64 Biotech Australia Pty Ltd: Submission 37 p 4

Recommendation 47

8.87 The Committee recommends that the membership of the GMO Release Authority be selected by the Minister on the following basis:

- . a chairperson
- . the chairperson of GMAC
- . two people chosen for their expertise in genetic manipulation technology
- . two people chosen for their expertise in environmental science
- . a nominee from each of the following Commonwealth Departments - Industry Technology and Commerce; Primary Industries and Energy; Arts Sport Environment and Territories; and Health Housing and Community Services
- . two people chosen for their involvement in commercial development or use of genetically modified organisms
- . two people chosen for their interest in environmental or consumer affairs issues.
- . one person chosen for knowledge of law and/or philosophy.

Recommendation 48

8.88 The Committee further recommends that the GMO Release Authority be able to propose to the Minister that their membership be temporarily supplemented by up to three additional people chosen for their expertise relevant to a particular release proposal.

B.5 Regulation of GMOs or all novel organisms?

8.89 Suggestions were made by a number of people in submissions and in oral evidence that all novel organisms should be regulated in the same way - that a distinction between novel organisms produced by genetic manipulation techniques and those produced by other methods is artificial. Similarly, organisms which are 'naturally produced' may be defined as novel organisms if introduced into an environment which has not previously been exposed to them.

8.90 Some of the comments the Committee received in favour of this approach are set out below:

> Monsanto Australia Ltd: "... Federal legislation covering 'new biota' should also include exotic species as well as other strains which while not genetically altered are new to [a] particular ecosystem or will be introduced at different population levels than would naturally occur."[65]

65 Monsanto Australia Ltd: Submission 74 p 6

Mrs Loane Skene (VLRC): "It must become mandatory for anybody proposing to release a new organism into the environment to notify somebody in advance and for compulsory environmental assessment, before an organism is released for the first time into the environment."[66]

Dr Chris Green (NSW Dept of Agriculture and Fisheries): "... this is the type of control which is probably needed to bring all organisms to be released into the environment into one umbrella grouping at the end. ... There are environmental organisms that are going to get released - ones for dealing with oil spills and that type of organism. These come under such a miscellaneous collection of legislation that environmental impact statements that might apply will either be duplicated or will not be done."[67]

Dr Merilyn Sleigh (CSIRO): "Another question which we have debated within CSIRO is whether, following the British model, it is appropriate to bring under the umbrella of an authority like the ACRE committee a much broader range of things, perhaps including biological control agents. Scientific logic certainly says that you should, but I have heard other arguments which say that would make the process too unwieldy."[68]

8.91 Bunge Australia Ltd presented a contrary view.

"There is a danger, we believe, in sweeping in with ... coverage of all novel living organisms. We believe this definition and other such definitions would be far too broad in their compass. Although the intention is clear, we believe that such definitions would legally include the current activities of farmers, fish breeders, other breeders, and horticulturalists who are currently involved, and have been for many hundreds of years, in the selective breeding of animals. ... The issues of traditional selective breeding are becoming more complex ... it is equally true for, say, livestock or improved strains of yeast for the bread baking industry or, indeed, alternative production processes for the pulp and paper manufacturing business."[69]

8.92 As Dr Sleigh's comments above indicate, the committee established in the United Kingdom to examine proposals for releases of GMOs is concerned with

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66 Skene, L, Victorian Law Reform Commission: Transcript p 1201

67 Green, Dr C, Director of Plant Pathology, NSW Department of Agriculture and Fisheries: Transcript p 1212

68 Sleigh, Dr M, Division of Molecular Engineering, CSIRO: Transcript p 1205

69 Davidge, M, Scientific and Technical Services Division, Bunge (Australia) Pty Ltd: Transcript p 462

releases of all non-indigenous organisms in the UK.[70] Similarly, amendments being drafted to the *Wildlife Conservation Act 1950* in Western Australia would result in all novel organisms being treated the same. A licence would be required for the release of any

> "... animal or class or description of animal; plant or description of plant; other lifeform or genetic material capable of being reproduced or replication in the wild; which could ... become or threaten to become injurious to naturally occurring native organisms."[71]

8.93 The Committee has not examined the production of organisms by methods other than genetic manipulation or whether there may be special dangers involved in their release. The Quarantine Service already provides a mechanism for examining the risks of importing exotic organisms. The Government should consider whether the production within Australia of organisms by means other than genetic manipulation and the release of such organisms requires special clearance procedures.

M J Lee, MP
Chairman
Report adopted by Committee 27 February 1992

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70 Poole, Prof N, Manager, Biotechnology and Regulatory Affairs, ICI Seeds and Pacific Seeds Pty Ltd: Transcript pp 406, 407

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

APPENDIX I

CONDUCT OF THE INQUIRY

On 12 June 1990, the Minister for Industry, Technology and Commerce wrote to the Committee proposing terms of reference for an inquiry into the development, use and release into the environment of genetically modified organisms. The terms of reference were amended by the Minister on 3 July 1990.

The Committee advertised the inquiry nationally in major metropolitan newspapers. In addition, Commonwealth, State and Territory government departments and several hundred individuals with an interest in the subject were written to and invited to make a submission. The Australian Biotechnology Association and the Australian Conservation Foundation provided the secretariat with address lists which greatly assisted this task. Appendix II lists those who made submissions to the inquiry. One hundred and sixty-seven submissions were received (not including supplementary submissions).

The files relating to genetic manipulation of the Australian Conservation Foundation in Melbourne and of the Law Reform Commission of Victoria were examined with the full co-operation of those bodies. The CSIRO conducted the Committee on an inspection of research facilities in the ACT where genetic manipulation work is carried out.

Ten public hearings were held in Adelaide, Brisbane, Canberra, Melbourne and Sydney. One hundred and twenty-two witnesses gave evidence. These are listed in Appendix III. Over twelve hundred pages of evidence were received at these public hearings. A transcript of all the evidence is available for inspection at the Committee Office of the House of Representatives and at the National Library of Australia.

APPENDIX II

LIST OF SUBMISSIONS

Submission No	Date	Person or Organisations
1	27/7/90	Mr Bryan Wells
2	30/7/90	Prof A J (Jim) Pittard
3	28/7/90	Ms Katherine Thirkell
3.1	21/11/90	Supplementary to Sub No 3
4	30/7/90	Dr Richard Cotton
5	6/8/90	Ms Christine Jones
6	1/8/90	Mr Geoffrey Lawrence
7	9/8/90	Prof Michael Hynes
8	16/8/90	Prof Peter Outteridge
9	18/8/90	Ms Geraldene Killmier
10	27/8/90	Dr Judith Blackshaw
11	26/8/90	Dr David Murray
12	22/8/90	Mr Ron Smith
13	24/8/90	Dr Alan Bailey and Dr Peter Mather
14	27/8/90	Dr Ian Johnsson
15	27/8/90	Dr Alfred Cheung
16	25/8/90	Ms Dorothy Davies
17	27/8/90	The Genetics Dept., The Queen Elizabeth Hospital Woodville SA (Dr Graham Webb)
18	26/8/90	P Atkins

19	27/8/90	Dr Alan Blackshaw
20	30/8/90	Prof Peter Singer
21	30/8/90	School of Medicine Flinders University SA (Mr Ross Kalucy)
22	3/9/90	Mr Steven Munro
22.1	18/2/91	Supplementary to Sub No 22
23	29/8/90	Calgene Pacific (Mr Michael Dalling)
24	31/8/90	Mr Vernon Molesworth
25	30/8/90	Dept Community Services & Health (Dr Robert Hall)
26	3/9/90	Waite Agricultural Research Institute
27	30/8/90	Dr David Straton
28	30/8/90	Ms Clare Gravenall
29	31/8/90	Mr David John Ellery
30	2/9/90	Ute Mueller
31	3/9/90	Ms Robin McCarthy
32	3/9/90	School of Biological Sciences Flinders University of SA (Dr D Catcheside)
33	3/9/90	Mr William Killmier
34	3/9/90	United Scientists for Environmental Responsibility & Protection USERP (SA) (Dr Ross Nable)
35	4/9/90	Women's Environmental Education Centre (Ms B Whiteman)
36	5/9/90	ANU Institutional Biosafety Committee (Mr Alick Dodd)

37	6/9/90	Biotech Australia P/L (Dr David Harrison)
38	6/9/90	Mr Bill Speer
39	5/9/90	University of QLD Biosafety Committee (IBC) (Mr Jim Holt)
39.1	10/9/90	Biosafety Committee Dept of Microbiology University of Queensland
40	1/8/90	Prof Ian Frazer
41	4/9/90	Mr Dominic Wilkinson
41.1	7/2/91	Supplementary to Sub No 41
42	5/9/90	Mr Duncan Hartshorne
43	5/9/90	CSIRO Division of Animal Production (Dr Oliver Mayo)
44	6/9/90	The Institute of Patent Attorneys of Australia (Mr John Slattery)
45	6/9/90	Prof Bruce Holloway
46	7/9/90	Mr David Gasteen
47	7/9/90	Mr Lee Nightingale
48	7/9/90	Ms Mandy Kirsopp
49	7/9/90	University of Adelaide (Prof Kevin Marjoribanks)
50	5/9/90	Dr Murali Nayudu
51	3/9/90	Ms Anne Benson
52	5/9/90	Mr W E (Edward) Fisher
53	6/9/90	Garvan Institute of Medical Research (Assoc Prof Donald Chisholm, Ms Julie Ferguson, Prof John Shine, Mr Colin McCaskill)

54	6/9/90	Human Genetics Society of Australia (Prof David Danks)
55	6/9/90	Monash University (Prof S Faine)
56	7/9/90	Ms Alex Hodges and Mr Ivan Laundy
57	10/9/90	Pig Research & Development Corporation
58	7/9/90	Mr Mark Callinan
59	4/9/90	Dept of Microbiolgy, Monash University (Acting Prof R Bayly)
60	7/9/90	Australian Registered Cattle Breeders' Assoc
60.1	1/11/90	Supplementary to Sub No 60
61	7/9/90	Metrotec (Dr John Smeaton, Dr Barry Lloyd, Dr Robert Seamark, Dr Julian Wells)
62	20/9/90	Animal Research Review Panel (NSW Govt) (Dr Margaret Rose)
63	5/9/90	Mr Paul Recher
64	6/9/90	Dr Geoffrey Lacey
65	7/9/90	Conservation Council of South Australia (Mr Marcus Beresford)
66	11/9/90	Development Education Network (Mr Lee O'Gorman)
67	14/9/90	Ms Paris Kostakos, Ms Karen Lacheta, Mr Craig Nobbs, Ms Gabrielle Taloni, Ms Angela Telfer
68	14/9/90	Arthur Webster P/L
69	8/9/90	Mr B Loudon
70	14/9/90	Alcoa of Aust Ltd **CONFIDENTIAL IN PART**

71	12/9/90	University of WA Prof R Parfitt)
72	14/9/90	Burns Philp & Co Ltd (Dr John Friend)
73	13/9/90	Dept of Environment and Heritage, QLD
74	17/9/90	Monsanto Australia Ltd
75	4/9/90	Australian Federation of Consumer Organizations Inc
75.1	5/10/90	Supplementary to Sub No 75
75.2	25/9/91	Supplementary to Sub No 75
76	11/9/90	The Royal College of Pathologists of Australasia
77	17/9/90	Mr S A (Arnold) Ward
78	18/9/90	Mrs Doris Metcher
79	17/9/90	Campbell Environmental Ltd WA
80	17/9/90	Chicken Meat Research & Developmental Council
81	18/9/90	Australian Agricultural & Veterinary Chemicals Council
82	18/9/90	Carlton and United Breweries Limited
83	18/9/90	Mahinda Seneviratne
84	19/9/90	Australian Council for Overseas Aid
85	20/9/90	Mrs Annie Scott
86	26/9/90	Bunge (Australia) P/L
86.1	22/11/90	Supplementary to Sub No 86
87	24/9/90	Australian National Parks and Wildlife Service
87.1	16/11/90	Supplementary to Sub No 87

88	25/9/90	Genetic Manipulation Advisory Committee (GMAC)
88.1		Supplementary to Sub No 88
88.2		Supplementary to Sub No 88
88.3	6/8/91	Supplementary to Sub No 88
89	20/9/90	APM Forests Proprietary Limited
90	3/10/90	Biotech International Limited
91	20/9/90	Dept of The Premier and Cabinet (SA)
92	5/10/90	Ms Laurelle Williams
93	3/10/90	Mr Ed Baxter
94	10/10/90	Mr G McConnell
95	20/9/90	People for Nuclear Disarmament (NSW) Inc
96	7/10/90	The Religious Society of Friends (Quakers)
97	8/10/90	Church & Society Commission Australian Council of Churches (QLD)
98	10/10/90	Mrs Patricia Naus
99	10/10/90	Mr Brian Engris and Mrs Joan Engris
100	11/10/90	Mr Frank Fisher
101	10/10/90	Cotton Research and Development Corporation
102	15/10/90	National Farmer's Federation
103	17/10/90	Australian and New Zealand Federation of Animal Societies Inc
104	11/10/90	Queensland Department of Primary Industries
105	12/10/90	Mr D Wallace

106	7/10/90	Dr David Burch, Dr Kees Hulsman, Mr Richard Hindmarsh, Prof Arthur Brownlea
106.1	7/3/91	Supplementary to Sub No 106
106.2	17/4/91	Supplementary to Sub No 106
106.3	1/5/91	Supplementary to Sub No 106
107	15/10/90	Ms Gillian Tucker
108	15/10/90	Ms Gisela Gardener
109	16/10/90	CSIRO Canberra
110	16/10/90	Ms Dianne Martin
111	17/10/90	Dr Robyn Sharp
112	18/10/90	St Vincent's Bioethics Centre (Mr Kevin Andrews, MP)
113	17/10/90	Ms Claire Sandford
114	19/10/90	Miss Helena Mills
115		University of NSW Dept of Biotechnology
116	12/10/90	NSW Department of Agriculture and Fisheries
117	24/10/90	Commonwealth Department of Community Services and Health
117.1	13/12/90	Supplementary to Sub No 117
118	24/10/90	Australian Academy of Science
119	24/10/90	Ms Bronwyn Dekker
120	19/10/90	Prof Daniel Simberloff
121	26/10/90	ICI Australia Ltd
122	1/9/90	Prof Barry Rolfe
122.1		Supplementary to Sub No 122

123	25/10/90	Dr Neil Ormerod and Rev Dr Greg Moses
124	21/10/90	Mr Dennis Murray
125	30/10/90	Blue Mountains Community Enterprises Ltd
126	31/10/90	Department of Industry Technology & Commerce
126.1	20/2/91	Supplementary to Sub No 126
126.2	26/3/91	Supplementary to Sub No 126
127	31/10/90	Patent Trade Marks and Design Office
128	26/10/90	Threatened Species Network (NSW)
129	1/11/90	Wholefoods Co-operative Limited
130	29/10/90	Australian Conservation Foundation (NSW Branch)
131	2/11/90	Mrs Lisa Earles
132	30/10/90	Australian Consumers' Association
132.1	24/4/91	Supplementary to Sub No 132
133	2/11/90	The Australian Veterinary Association Ltd
134	24/10/90	Prof Sheldon Krimsky Massachusetts USA
135	1/11/90	Social Responsibilities Commission - Anglican Diocese of Melbourne (Rev A Dargaville
136	1/11/90	Ms Robyn Buschmann
137	9/11/90	Mr Vin Heffernan MP (Victorian Parliament)
138	7/11/90	Department of The Arts, Sport, The Environment, Tourism and Territories
138.1	26/3/91	Supplementary to Sub No 138

138.2	22/5/91	Supplementary to Sub No 138
139	4/10/90	Dr Maarten Ryder
140	14/11/90	Australian Conservation Foundation
141	12/11/90	Dr Angela Lensiak
142	15/11/90	Australian Biotechnology Association
143	19/11/90	Department of Primary Industries & Energy
144	26/11/90	Mr J Thomas
145	13/11/90	Government of Western Australia
146	3/12/90	Ms Patricia Holmes
147	5/12/90	The Australian Federation for the Welfare of Animals (Inc)
148	3/12/90	Mr David Elder
149	9/12/90	W Latona
150	5/12/90	Environmental Release Committee of the Council for Responsible Genetics (Prof Philip Bereano)
151	14/12/90	Ms Anne Cossins
152	14/1/90	Galloway Cattle Society of Australia Incorporated
153	1/2/91	Centre for Molecular Biology and Biotechnology, University of Queensland
154	11/1/91	The Victorian Government
155	15/2/91	The Australian Society for Microbiology
156	4/3/91	Mr John Scott and Mrs Annie Scott
157	28/2/91	Biotechnology Industry Association Australia (Dr Elizabeth Monger)
158	17/5/91	Australian Pharmaceutical Manufacturers Association

159	3/7/91	Mrs S A Cooper
160	8/7/91	Ms Betty McKell
161	8/7/91	Ms Gazelle Wicks
162	10/7/91	A Keogh
163	22/7/91	J Allan
164	6/8/91	B Harris
165	26/8/91	Ms Elizabeth Fitzpatrick
166	2/10/91	Mrs Gloria Stirrat
167	4/12/91	University of Wollongong

APPENDIX III

LIST OF HEARINGS AND WITNESSES

Canberra, 15 November 1990

Australian Academy of Science
Prof F J Fenner, Fellow
Prof P W Gibson, Fellow

Australian Federation of Consumer Organisations
Mr S Holt, Director
Dr F E Peters, Councillor

Australian National University
Mr C D S Buller, Secretary, IBC
Dr M J Howell, Reader in Zoology

Pig Research and Development Corporation
Dr R Campbell, Director
Dr M R Taverner, Executive Director

Canberra, 16 November 1990

Australian National Parks and Wildlife Service
Mr M A Hill, Deputy Director
Mr R J Moore, Senior Wildlife Conservation Officer
Dr B J Reville, Manager, Endangered Species Unit
Dr B J Richardson, Survey Director
Dr D W Walton, Scientific Audit

Department of Community Services and Health
Dr R M Brazenor, Director Toxicology Technical Support Section
Dr R G Hall, Director, Communicable Diseases Section
Mr G M James, Assistant Secretary, Environmental Health Branch
Dr G J Maynard, Director, Food Policy Section
Dr A Proudfoot, Principal Medical Adviser, Therapeutic Goods Administration
Mr J Withell, Director, Therapeutic Goods Administration Laboratories

Department of Primary Industries and Energy
Mr G N Hooper, Chemicals Coordinator, Australian Agricultural and Veterinary Chemicals Council
Mr B Hill, Chairman, Australian Agricultural and Veterinary Chemicals Council

Genetic Manipulation Advisory Committee
Prof D M Danks, Deputy Chairman
Prof N F Millis, Chairman
Dr I M Parsonson, Member
Prof A J Pittard, Member

National Farmers' Federation
Mr G P Goucher, Director of Policy
Mr J W MacKenzie, Chairman, Research Committee

National Health & Medical Research Council
Dr W P Anderson, Chairman, Animal Experimentation Ethics Committee

Private Citizen
Prof B Rolfe
Ms P Kostakas
Ms K J Lacheta
Dr M Nayudu
Mr C K Nobbs
Ms G Talloni
Ms A Telfer

Melbourne, 21 November 1990

Australian and New Zealand Federation of Animal Societies Inc.
Ms G K Oogjes, Director
Ms R A Sullivan, Executive Member

Law Reform Commission of Victoria
Mrs L Skene, Project Manager
Mr R Wright, Executive Director

Monash University
Dr J K Davies, Biosafety Officer, Department of Microbiology
Prof P Nagley, Department of Biochemistry

Private Citizens
Dr R G Cotton
Mr F G Fisher
Prof B W Holloway
Dr G C Lacey
Mr D G McConnell
Prof P A Singer
Mrs K A Thirkell

Melbourne, 22 November, 1990

Australian Conservation Foundation
Mr R E Phelps, Genetic Engineering Campaign Officer

Bunge (Australia) Pty Ltd
Mr M R Davidge, Marketing Manager, Scientific and Technical Services Division

Calgene Pacific Pty Ltd
Dr E Cornish, Principal Research Scientist

Human Genetics Society of Australasia
Prof D M Danks, Chairman, Gene Therapy Expert Committee

ICI Australia Ltd
Dr R H Brown, Manager, Research and Technology, Crop Care
Mr R A Davies, Research Business Manager, Research Group

ICI Seeds and Pacific Seeds Pty Ltd
Prof N J Poole, Manager, Biotechnology and Regulatory Affairs

Monsanto Australia Ltd
Mrs M J Sheers, Regulatory and Environmental Affairs Manager

St Vincent's Hospital
Mr K J Andrews, Acting Director, St Vincent's Bioethics Centre

Private Citizens
Ms G E Gardener
Mr M D Niski, Representing State Member for Ivanhoe

Adelaide, 23 November, 1990

Bresatec/Metrotec
Dr B Lloyd, Managing Director, Metrotec Ltd
Dr J R Smeaton, Managing Director, Bresatec Ltd
Dr J R Wells, Consultant

Conservation Council of South Australia
Mr M R Beresford, Executive Officer

Flinders University
Dr D E Catcheside, Senior Lecturer, School of Biological Sciences

South Australian Department of Industry, Trade and Technology
Mrs E Jacka, Manager, Biotechnology Projects, Office for Special Projects

United Scientists for Environmental Responsibility and Protection, South Australia
Dr P A Davies
Dr M A Keller
Dr R O Nable
Dr P M Rogowsky

University of Adelaide
Prof J Bowie, Pro-Vice-Chancellor and Chairman of the Biohazards Committee
Mr R J Fowler, Senior Lecturer in the Department of Law
Prof A Kerr, Department of Plant Pathology, Waite Agricultural Research Institute
Dr B K May, Associate Professor of Biochemistry

Private Citizen
Dr G C Webb

Sydney, 6 February 1991

Australian Biotechnology Association
Prof P P Gray, Vice-President
Dr S D Meek

Australian Consumers Association
Dr S Chapman, Consultant
Ms J M Isles, Policy Officer

Australian Registered Cattle Breeders' Association
Dr R W Gee, President

NSW Department of Agriculture and Fisheries
Dr C Green, Director of Plant Pathology, Biological and Chemical Research Institute
Mr R Toffolon, Registrar of Pesticides

Sydney 7 February, 1991

Animal Research Review Panel
Dr M A Rose, Chairman
Dr R M Taylor, Executive Officer

Arthur Webster Pty Ltd
Dr P Lehrbach, Manager, Genetic Research

Australian Conservation Foundation
Ms K Hennessy, Sydney Branch Committee Member
Ms A F Sutton, Councillor, Sydeny Branch Committee Member

Australian Meat and Livestock Research and Development Corporation
Dr J Hackett, Consultant
Dr I D Johnsson, Program Manager

Australian Veterinary Association Ltd
Dr J R Cornwall, National Veterinary Director
Dr P E Greenwood, Secretary, Standing Committee on National Affairs

Biotech Australia Pty Ltd
Dr D E Harrison, Managing Director
Dr N S Willetts, Director, Research and Development

Burns Philp & Co Ltd
Dr R J Evans, Strain Development Manager, Food and Fermentation Division
Dr J P Friend, General Manager, Technology and Research, Food and Fermentation Division
Mr I Jenson, Divisional Microbiologist, Food and Fermentation Division

Private Citizen
Dr D R Murray

Brisbane, 8 February 1991

Australian Federation for the Welfare of Animals
Dr A W Blackshaw, Council Member,

Queensland Department of Environment and Heritage
Dr K A Lyonns, Environmental Officer

Queensland Department of Primary Industries
Mr R J Dalgliesh, Deputy Director, Pathology Branch, Animal Research Institute
Dr R G Dietzgen, Plant Pathologist
Mr R E Nieper, Director, Division of Animal Industry

University of Queensland
Prof P Outteridge, Head, Department of Farm Animal Medicine Production
Dr J M Pemberton, Member, Institutional Biosafety Committee

Private Citizens
Dr J K Blackshaw
Prof A Brownlea
Dr K Hulsman
Dr D Straton

Canberra, 22 February 1991

Commonwealth Scientific and Industrial Research Organisation
Dr E S Delfosse, Principal Research Scientist, Division of Entomology
Dr D J Llewellyn, Senior Research Scientist, Division of Plant Industry
Dr M J Sleigh, Assistant Chief, Division of Biomolecular Engineering
Dr C K Williams, Senior Research Scientist, Division of Wildlife and Ecology

Department of the Arts, Sport, the Environment, Tourism and Territories
Mr R M Ireland, Science 2
Mr N J Quinn, First Assistant Secretary, Environment Protection Division

Department of Industry, Technology and Commerce
Ms B Clarke, Assistant Secretary, Aerospace and Biological Industries Branch
Mr B J Delroy, Director, Biotechnology Section

Department of Primary Industries and Energy
Mr A Catley, Senior Assistant Director, Plant Quarantine and Inspection Branch, Australian Quarantine and Inspection Service
Mr J F Landos, Director, Quarantine Imports and Exports Division, Australian Quarantine and Inspection Service
Dr H L Lloyd, Director, Plant Variety Rights Office
Dr G D McLean, Senior Research Scientist, Bureau of Rural Resources
Dr J M Morrison, Senior Veterinary Officer, Animal Quarantine and Exports Branch, Australian Quarantine and Inspection Services
Dr M A O'Flynn, Director, Animal Welfare Unit, Livestock and Pastoral Division
Mr J Owusu, Principal Veterinary Officer, Agricultural and Veterinary Chemicals Unit
Ms A G Quinn, Director, Research and Development Policy, Corporate Policy Division

Canberra, 19 April 1991

Australian Biotechnology Association
Dr S D Meek, Chair of Subcommittee on Deliberate Release

Australian Conservation Foundation
Mr R E Phelps, Genetic Engineering Campaign Officer

Australian Consumers Association
Ms J M Isles, Policy Officer

Burns Philp & Co. Ltd
Dr J P Friend, General Manager, Technology and Research, Food and Fermentation Division

Commonwealth Scientific and Industrial Research Organisation
Dr M J Sleigh, Assistant Chief, Division of Molecular Engineering

Department of Primary Industries and Energy
Ms A G Quinn, Director, Research and Development Policy

Genetic Manipulation Advisory Committee
Prof N F Millis, Chairman

ICI Australia Ltd
Dr R H Brown, Research and Technology Manager, ICI Crop Care

Law Reform Commission of Victoria
Mrs L Skene, Project Manager, Genetic Manipulation Review

NSW Department of Agriculture and Fisheries
Dr C D Green, Director of Plant Pathology, Biological and Chemical Research Institute

University of Queensland
Associate Prof J M Pemberton, Member with Special Area of Expertise in Molecular Genetics, Institutional Biosafety Committee

Private Citizens
Dr R G Cotton
Prof B W Holloway
Dr K Hulsman

APPENDIX IV

LIST OF EXHIBITS

Exhibit No	Title/Document
1	*Biotechnology & Development*, in *BMJ*, Vol 301 21 July 1990 p 137 (attachment to Submission 4)
2	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 ANU Canberra 28 November - 2 December 1988 (attachment to Submission 6)
3	Blackshaw, Judith: *Concern about transgenic pigs being sold*, in *Pork Journal*, July 1990 p 4 (attachment to Submission 10)
4	Blackshaw, Judith: *Problems with transgenic pigs*, in *The Pig Farmer*, July 1990 (attachment to Submission 10)
5	Jacka, Eleanor: *Legislation to regulate the release of genetically manipulated organisms*, Flinders University SA 4 April 1990 (attachment to Submission 21)
6	Extract from *Quarantine Act* 1908 Community Services & Health (attachment to Submission 25)
7	Australian Quarantine & Health Service Document: *Conditions Applicable to Biological Importation*, (attachment to Submission 25)
8	Lanoy, Patrice: *Mosaic bacteria move into the market*, in *New Scientist*, 3 February 1990 p 19 (attachment to Submission 25)
9	Rayssiguier, Christiane; Thaler, David and Radman, Miroslav: *The barrier to recombination between Escherichia coli and Salmonella typhimurium is disrupted in mismatch-repair mutants*, in *Nature*, Vol 342 23 November 1989 pp 396-401 (attachment to Submission 25)
10	Straton, David: *The Genetic Engineering Debate*, in *Ecologist*, Vol 7 No 10 pp 381-388 (attachment to Submission 27)
11	Mullis, Kary B: *The Unusual Origin of the Polymerase Chain Reaction*, in *Scientific American*, April 1990 pp 36-43 (attachment to Submission 27)
12	Australian Conservation Foundation: *Revised Draft Genetic Engineering Policy*, in *RIEC*, September 1989 (attachment to Submission 27)

13 Burnet, F M: *Men or molecules? - A Tilt at Molecular Biology*, in *The Lancet*, 1 January 1966 pp 37-39 (attachment to Submission 41)

14 Mies, Maria: *Sexist and Racist Implications of New Reproductive Technologies*, in *Alternatives*, XII 1987 pp 323-342 (attachment to Submission 41)

15 Shiva, Vandana: *The Violence of Reductinist Science*, in *Alternatives*, XII 1987 pp 243-261 (attachment to Submission 41)

16 Australian Patent Office: *Patent Attorneys Abstract*, Document No AU-A-23480/88 (attachment to Submission 44)

17 Whaite, Robin and Jones, Nigel: *Biotechnological Patents in Europe*, in *The Draft Directive*, 1989 5 EIPR pp 145-157 (attachment to Submission 44)

18 Lacey, Geoff: *What Technologies Are Appropriate?*First published 1989 by Pax Christi (attachment to Submission 64)

19 Arthur Webster Pty Ltd: *A world of experience in animal health*, (attachment to Submission 68)

20 Watts, Susan: *Gene-spliced corn heralds customised crops*, in *New Scientist*, 1 September 1990 p 19 (attachment to Submission 69)

21 Baskin, Yvonne: *Getting the Bugs Out*, in *Atlantic Monthly*, June 90 (attachment to Submission 69)

22 Alcoa of Australia Ltd: *Alcoa Tree Technology Project - Technical Information*, (attachment to Submission 70)

23 Alcoa Tree Technology Project: *Trees for the Future*, (attachment to Submission 70)

24 Monsanto Australia Ltd: *Tracking Genetically Engineered Microorganisms: The Field Test*, (attachment to Submission 74)

25 Monsanto: *Of The Earth - Agriculture and the New Biology*, (attachment to Submission 74)

26 *Evaluating the Risk of Releasing Genetically Engineered Organisms*, in fortnightly supplement to *TREND* series of life science journals pp 5-9 (published by Elsevier Publications, Cambridge) Vol 2 No 14, 24 Aug 1988 (attachment to Submission 76)

27 The *Agricultural and Veterinary Chemicals Act 1988* No 91 of 1988 (attachment to Submission 81)

28 Agricultural Chemicals Advisory Committee *Terms of Reference*, Veterinary Chemicals Advisory Committee *Terms of Reference* (attachment to Submission 81)

29 *Requirements for clearance of agricultural and veterinary chemicals*, 1st edition September 1989 (DPIE) (attachment to Submission 81)

30 Hammond, J R M: *The Influences of New and Limited Impending Biotechnology Regulations on the Brewing Industry*, based on a presentation made by J R M Hammond on 23 April 1990 to the Conference on The Impact of New and Impending Regulations on UK Biotechnology (attachment to Submission 82)

31 1) Watts, Susan: *Looser rules tempt genetic engineers East*, in *New Scientist*, 20 January 1990
2) Joyce, Christopher: *US exports genetic experiments*, in *New Scientist*, 20 November 1990 (attachment to Submission 83)

32 *Biopolicy: Ideas for Public Policy and Legislation on Biotechnology*, in *Development Dialogue: The Laws of Life*, Vol 1-2 1988 Uppsala (attachment to Submission 83)

33 *Proposed Legislation - 26 May 1989*, North Carolina (attachment to Submission 91)

34 Australian Conservation Foundation: *Policy Statement No 45 - Genetic Engineering*, (attachment to Submission 93)

35 Hindmarsh, Richard: *Diminishing Biodiversity - A World Under Siege*, (attachment to Submission 93)

36 Fisher, Frank G: *What is Environmental Improvement?* (attachment to Submission 100)

37 Fisher, Frank: *A Matter of Urgency - Recognising the Social Context of the Greenhouse Effect*, in *Australian Institute of Energy News Journal*, 7 (4) 1989 pp 94-97 (attachment to Submission 100)

38 Fisher, Frank: *Technology and the Loss of Self: An Environmental Concern*, in *Environments*, Vol 20 No 2 1989 (attachment to Submission 100)

39 Rainbow Group GRAEL, European Parliament: *Deliberate release into the environment of genetically engineered organisms*, (attachment to Submission 108)

40 Katholische Landjugendbewegung Bayern (KLJB): *Auswirkungen der Gentechnologie auf die Landwirtschaft*, in *gb gruner brief*, (attachment to Submission 108)

41 Andrews, Kevin: *The Regulation of Genetic Engineering in Australia*, Master of Law Thesis, Monash University (attachment to Submission 112)

42 National Health and Medical Research Council: *Part 1: Principles for the Evaluation of Food Additives*, Ninety-first session of Council, June 1981 (attachment to Submission 117)

43 National Health and Medical Research Council: *Draft Statement on Biotechnology in the Food Supply*, November 1987 (attachment to Submission 117)

44 GMAC: *Guidelines - extract Section 1: Scope and Exemptions*, (attachment to Submission 117)

45 National Health and Medical Research Council: *Draft Format for the Application to Revise the Food Standards Code - Food Additives*, (attachment to Submission 117)

46 *Reform of Food Regulations Agreed*, Australian Health Ministers' Conference Brisbane Queensland 9-10 June 1990 - Press Release (attachment to Submission 117)

47 National Health & Medical Research Council, CSIRO, Australian Agricultural Council: *Australian code of practice for the care and use of animals for scientific purposes*, February 1990 (attachment to Submission 117)

48 Australian Department of Health: *NDF 4 Guidelines for Preparing Applications for the General Marketing or clinical Investigational Use of a Therapeutic Substance*, (attachment to Submission 117)

49 Australian Department of Health: *Appendix to NDF-4 Guidelines for Applications for Approval to Import or use Vaccines*, (attachment to Submission 117)

50 Therapeutic Goods Administration - Drug Evaluation Branch: *Guidelines for the preparation of applications for general marketing of substances produced by general manipulation for use in humans*, Canberra, March 1990 (attachment to Submission 117)

51 Department of Community Services and Health: *Guidelines for the preparation and presentation of applications for general marketing of monoclonal antibodies for use in humans*, Canberra, May 1988 (attachment to Submission 117)

52 Dekker, Bronwyn: *Research Assignment: Regulation of the Release of Genetically Manipulated Organisms in New South Wales*, (attachment to Submission 119)

53 Regal, P J: *Models of Genetically Engineered Organisms and Their Ecological Impact*, in *Recombinant DNA Technical Bulletin*, Vol 10 No 3 pp 67-95 (attachment to Submission 122)

54 Rolfe, Barry: *Final Report to the ANU IBC*, April 1990 (attachment to Submission 122)

55 Rolfe, Barry: *Planned Release of a Genetically Modified Organism*, 30 November 1988, unpublished (attachment to Submission 122)

56 Rolfe, Barry: *Background Paper to IBC, ANU re Release of Genetically Engineered Micro-organisms*, undated, unpublished (attachment to Submission 122)

57 Rolfe, Barry: *Summary of International Meeting in Wales*, April 1988 unpublished (attachment to Submission 122)

58 Rolfe, Barry: *Release of Genetically Engineered Micro-organisms Background Paper to IBC, ANU*, unpublished (attachment to Submission 122)

59 Dean-Ross, Deborah: *Release of Genetically Engineered Organisms: Hazard Assessment*, in *ASM News*, Vol 52 No 11 1986 pp 572-575 (attachment to Submission 122)

60 Fox, J L: *Emergent Scientific Principles for Deliberate Release*, in *ASM News*, Vol 54 No 7 1988 pp 355-359 (attachment to Submission 122)

61 Fox, J L: *Contemplating Suicide Genes in the Environment*, in *ASM News*, Vol 55 No 5 1989 pp 259-261 (attachment to Submission 122)

62 Fox, J L: *Test Stirs up Tempest in an N_2 Plot*, in *Bio/Technology*, Vol 8 July 1990 pp 598-599 (attachment to Submission 122)

63 Sama, Vimala: *The Release of Genetically Manipulated Organisms - A Quartet of Reports*, in *Australian Microbiologist*, May 1990 pp 92 & 93 (attachment to Submission 122)

64 Zell, R & MacKenzie, D: *Germany lays down the law on genes*, in *New Scientist*, 22 July 1989 (attachment to Submission 122)

65 Webb, B: *Dispute over monitoring*, in *Nature*, Vol 341 7 September 341 p 7 (attachment to Submission 122)

66 *Britain Awaits Verdict on Altered Organisms*, in *New Scientist*, 8 July 1989 (attachment to Submission 122)

67 Watts, S: *Cranks could undermine biotechnology*, in *New Scientist*, 29 July 1989 (attachment to Submission 122)

68 McGourty, C: *No Blanket Approval*, in *Nature*, Vol 341 21 September 1989 (attachment to Submission 122)

69 *US finalises controls on genetic engineers*, in *New Scientist*, 15 July 1989 (attachment to Submission 122)

70 MacKenzie, D: *Europe brings its members into line on genetic release*, in *New Scientist*, 30 September 1989 (attachment to Submission 122)

71 Porter, G: *Balanced Controls Urged for Engineered Organisms*, in *Advice from National Academy of Science*, USA Vol 37 No 9 October 1987 (attachment to Submission 122)

72 Watts, S: *Genes at the Bottom of the Garden*, in *New Scientist*, 15 July 1989 pp 11 & 12 (attachment to Submission 122)

73 Meek, S: *Deliberate Release Issues - Update*, in *Australian Journal of Biotechnology*, Vol 1 No 3 December 1987 (attachment to Submission 122)

74 Hindmarsh, R: *Biotechnology - Is the green movement meeting the challenge?* in *Habitat Australia*, October 1990 pp 9-12 (attachment to Submission 124)

75 Patent, Trade Marks and Designs Offices: *List of Publications/Papers on Industrial Property Protection of Biotechnological Inventions, including Transgenic Animals and Genetically Engineered Plants*, (attachment to Submission 127)

76 Phelps, Bob: *Genetic engineering - a leap into the unknown*, in *Consuming Interest*, August 1990 pp 4-8 (attachment to Submission 132)

77 Australian Consumers' Association: *Letter in response to the Victorian Law Reform Commission's Discussion Paper on Genetic Manipulation*, 28 June 1988 (attachment to Submission 132)

78 Fowler, Cary; Lachkovics, Eva; Mooney, Pat and Shand, Hope: *The Laws of Life - Another Development and the New Biotechnologies*, in *Development Dialogue*, 1988: 1-2 (attachment to Submission 132)

79 Graham, Janet: *Restoring consumer confidence in food*, in *Consumer Affairs Journal*, No 98 March/April 1989 Speech at University of Leicester on 25 April 1989 (attachment to Submission 132)

80 Thompson, Donald (MP): *Consumer benefits and biotechnology*, in *Consumer Affairs Journal*, No 98 March/April 1989 JWT Group UK - Speech addressed to The Association for Advancement of British Biotechnology (attachment to Submission 132)

81 Montanaro, Anthony and Wakefield, Denis: *Case Reports - Eosinophilia-myalgia syndrome associated with L-tryptophan use*, in *Medical Journal of Australia*, Vol 153 October 15, 1990 pp 491-493 (attachment to Submission 132)

82 Garrett, Laurie: *Drug's Genetic Engineering Probed*, in *Newsday*, August 14 1990 (attachment to Submission 132)

83 *National Consumer Council Food Charter*, (attachment to Submission 132)

84 Krimsky, Sheldon; Bergman, Kostia; Connell, Nancy; Shulman, Seth and Wilker, Nachama: *Controlling Risk in Biotech*, in *Technology Review*, July 1989 pp 62-70 (attachment to Submission 134)

85 ANU Recombinant DNA Monitoring Committee: *Guidelines for Preparation of Proposals for Planned Releases of Recombined Organisms*

86 *Resolution on biotechnology*, adopted at the 12th IOCU World Congress in Madrid 15 - 20 September 1987

87 Berkowitz, David and Maryanski, Jim: *Implications of Biotechnology on International Food Standards and Codes of Practice*, Joint FAO/WHO Food Standards Program - Codes Alimentarius Commission Eighteenth Session Geneva 3 - 12 July 1989

88 Young, Frank: *Safety First: Protecting America's Food Supply - Part Three Biotechnology: A Boon to Food Safety*, in *FDA Consumer*, 6 October 1988

89 *Regulation of Biotechnology in Australia - Proceedings of a seminar presented by the Regulatory Affairs Working Party of the Australian Biotechnology Association*, in *Australian Journal of Biotechnology*, Vol 3 No 4 October 1989 pp 303 - 316 (attachment to Submission 142)

90 Santer, Dr Vivien: *Intellectual Property Protection for Living Organisms*, (attachment to Submission 142)

91 Richards, Tessa: *Biotechnology and development*, in *British Medical Journal*, Vol 301 21 July 90 p 137

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

93 Poole, Prof Nigel: *United Kingdom System - The Advisory Groups*, and *Procedure for a Planned Release in United Kingdom*

94 Department of Health and Human Services (USA): *National Institutes of Health Guidelines for Research involving Recombinant DNA Molecules*, 7 May 1986

95 *Position Statement of the Council for Responsible Genetics*, (attachment to Submission 150)

96 Goldburg, Rebecca; Rissler, Jane; Shand, Hope and Hassebrook, Chuck: *Biotechnology's Bitter Harvest*, a report of the Biotechnology Working Group March 1990 (attachment to Submission 150)

97 *Biotechnology's Bitter Harvest*, (attachment to Submission 150)

98 Australian Biotechnology Association: *What is Biotechnology?* Nos 1 - 6

99 Australian Biotechnology Association: *The Australian Biotechnology Association*

100 NSW Department of Agriculture & Fisheries, Biological and Chemical Research Institute: *The Plant Pathology Branch Herbarium*

101 NSW Department of Agriculture & Fisheries, Horticultural Research & Advisory Station: *The Australian Inoculants Research and Control Service (AIRCS)*

102 *Biotech Australia*, in *Australian Journal of Biotechnology*, April 1990

103 Murray, David R: *Advanced Methods in Plant Breeding and Biotechnology*, CAB International, Oxford

104 Simonsen, L & Levin, B R: *Evaluating the Risk of Releasing Genetically Engineered Organisms*, in *Tree*, Vol 3 No 4; *Tibtech*, Vol 6 No 4 April 1988

105 Subcommittee on genetic manipulation of the Animal Research Review Panel and the Animal Welfare Advisory Council: *Animal Welfare Issues in Genetic Manipulation*, CONFIDENTIAL

106 Brownlea, Prof Arthur and Roiko, Anne: *Environmental Protection and Biotechnology: Response to the Discussion Paper*

107 Ministry of Agriculture, Fisheries and Food (MAFF) (UK): *New Guidelines Introduced for the Labelling of Foods Produced Using Genetic Modification*, news release dated 17 January 1991

108 *Engineering Trouble?* in *Nature*, Vol 349 3 January 1991 p 5

109 Metrotec Pty Ltd: *Submission to Senate Select Committee on Animal Welfare*, 4 August 1989

110 Garrett, Peter: *Speech to Australian Conservation Foundation on Genetic Engineering*

111 Bolkus, Senator the Hon Nick: Correspondence to Mr M Lee 7 December 1990

112 Tiedje, J; Colwell, R; Grossman, Y; Hodson, R; Lenski, R; Mack, R and Regal, P: *The Planned Introduction of Genetically Engineered Organisms: Ecological Considerations and Recommendations*, in *Ecology*, Vol 70 No 2 p 298

113 Queensland Department of Primary Industries: Correspondence attaching 2 articles, 14 February 1991

114 Delfosse, E and Cullen, J, CSIRO Division of Entomology: *Draft Report Submission to the Inquiries into Biological Control of Echium plantagineum L.*, September 1985

115 Delfosse, E, CSIRO Division of Entomology: *Submission to the Inquiries into Biological Control of Echium plantagineum L.*, February 1985

116 South Australian Country Women's Association: Correspondence to Dr Frank Peters of the Australian Federation of Consumer Organisations 27 February 1991

117 US Congress, Office of Technology Assessment: *New Developments in Biotechnology - Field Testing Engineered Organisms: Genetic and Ecological Issues*, Chapter 1 OTA-BA-350, Washington DC, US Government Printing Office, May 1988 pp 3-29

118 Skene, L: *Legal Issues in Patenting Life-Forms*, paper presented at the Conference *Ethics and Intellectual Property - Should We Create New Life Forms?* ANZ Pavilion, 19 October 1990

119 United Nations General Assembly: *Environmentally Sound Management of Biotechnology*, A/CONF.151/PC/29 31 January 1991 (attachment to Submission 138.1)

120 FAO Commission on Plant Genetic Resources: *Biotechnology and Plant Genetic Resources and Elements of a Code of Conduct for Biotechnology*, 4th Session 15-19 April 1991

121 National Wildlife Federation National Biotechnology Policy Centre: *Applications to USDA under Research Authority to Field Test Genetically Engineered Organisms (1988-1991)*, March 1991

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

123 UN General Assembly: *Environmentally Sound Management of Biotechnology*, 31 January 1991 [A/CONF. 151/PC/29].

124 *International Convention for Protection of New Varieties of Plants - final draft*, [DC/91/138] - 19 March 1991

125 *Report on the ethical and legal problems of genetic engineering*, in *Europe Environment Fortnightly*, No 317 March 21 1989 (attachment to Submission 132.1)

126 De Maria, William: *Exposing the AAT's Private Parts*, in *Legal Service Bulletin*, Vol 16 No 1 February 1991 (attachment to Submission 132.1)

127 Genetic Manipulation Advisory Committee: *Membership List as at 30 June 1991*, Facsimile message 24 July 1991

128 Department of Industry Technology and Commerce: *The history of GMAC and the grants scheme*, Facsimile message 24 July 1991

129 Martin, D, Australian Animal Health Laboratories, Division of Animal Health, CSIRO: *GMAC Guidelines for Small Scale Genetic Manipulation Work - Physical Containment Level 3*, Facsimile message 1 August 1991

APPENDIX V

REFERENCES

Books, Reports and Monographs

Andrews, K: *The regulation of genetic engineering in Australia*, Master of Law Thesis, Monash University

Anon - *Bills digest for National Food Authority Bill 1991*, Parliamentary Research Service, Department of the Parliamentary Library, Canberra, 3 June 1991

Asimov, I: *Biographical encyclopedia of science and technology*, 2nd Edition, Doubleday & Co, New York, 1982

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

Australian Quarantine and Inspection Service: *The application of risk management in agricultural quarantine import assessment: a discussion paper*, 1991

Australian Agricultural and Veterinary Chemicals Council: *Code of practice for labelling agricultural chemical products*, AGPS, Canberra, 1989

Australian Agricultural and Veterinary Chemicals Council: *code of practice for labelling veterinary chemical products*, AGPS, Canberra, 1989

Australian Agricultural and Veterinary Chemicals Council: *Annual report 1989-90*, AGPS, Canberra

Australian Academy of Science: *Biology, the common threads*, 1991, Part 2

Barker, M L: *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

Bodmer, W F: *Implications of advances in genetics for the future*, in Messel, H (edit.): *The biological manipulation of life*, Pergamon Press, 1981

CSIRO Division of Wildlife and Ecology: Information Sheet *Research into the rabbit problem*

CSIRO: *Rural sector report*, 1990

Curry, J: *The patentability of genetically engineered plants and animals in the US and Europe*, IPPL, London 1987

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

Department of Industry Technology and Commerce: *Report on first meeting of ministerial council representatives on the development of a national approach to biotechnology regulation*

Department of Primary Industries and Energy: *Annual report 1989-90*, AGPS, Canberra, 1990

Department of Science and Technology: *Genetic engineering commercial opportunities in Australia - proceedings of a symposium held in Sydney 18-20 November 1981*, AGPS, Canberra, 1982

Department of Science and Technology: *Biotechnology appropriate areas for commercial exploitation in Australia - proceedings and report of a workshop held in Canberra 22-23 November, 1982*, AGPS, Canberra, 1983

Feldmesser, J et al.: in *Agricultural chemicals of the future*, Hilton, J L, (edit.), Rowman & Allanheld, Totowa, 1985

Genetic Manipulation Advisory Committee: *Report for the period 22 August 1988 to 30 June 1989*, AGPS, Canberra, 1989

Genetic Manipulation Advisory Committee: *Guidelines for small scale genetic manipulation work*, AGPS, Canberra, December 1989

Genetic Manipulation Advisory Committee: *Report for the period 1 July 1989 to 30 June 1990*, AGPS, Canberra, 1990

Genetic Manipulation Advisory Committee: *Guidelines for large scale work with genetically manipulated organisms*, AGPS, Canberra, December 1990

McKibben, W: *The end of nature*, Random House, New York, 1989

National Health & Medical Research Council/Commonwealth Scientific and Industrial Research Council/Australian Agricultural Council: *Australian code of practice for the care and use of animals for scientific purposes*, AGPS, Canberra, 1990

National Health & Medical Research Council Working Party to Review Biotechnology in the Food Industry: *report to the eighty-first meeting of the food science and technology subcommittee*, NH&MRC, Canberra, February 1991

National Health & Medical Research Council: *Food standards code*, Department of Community Services and Health, AGPS, Canberra, 1991

National Health & Medical Research Council: *Supplement to the food standards code*, Department of Community Services and Health, AGPS, Canberra, 1991

North Carolina Biotechnology Centre, Advisory Committee on Biotechnology: *Proposed legislation - 26 May 1989*

Nossal, G J V: *Reshaping life - key issues in genetic engineering*, Melbourne University Press, 1984

Organisation for Economic Cooperation and Development: *Recombinant DNA safety considerations*, 1986

Organisation for Economic Cooperation and Development: *Draft international survey on biotechnology use and regulations*, May 1990

Recombinant DNA Monitoring Committee: *Procedures for assessment of the planned release of recombinant DNA organisms*, AGPS, Canberra, May 1987

Royal Commission on Environmental Pollution (UK): *Thirteenth report: the release of genetically engineered organisms to the environment*, July 1989

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

Senate Select Committee on Animal Welfare: *Animal experimentation*, AGPS, Canberra, 1989

Senate Select Committee *Report on agricultural and veterinary chemicals in Australia*, AGPS, Canberra, 1990

Straughan, R: *The genetic manipulation of plants, animals and microbes. The social and ethical issues for consumers: a discussion paper*, National Consumer Council, UK, 1989

Suzuki, D and Knudtson, P: *Genethics - the ethics of engineering life*, Allen and Unwin, Sydney, 1988

Sylvester, E J, Klots L C: *The gene age - genetic engineering and the next industrial revolution*, Charles Scribner's Sons, New York, 1983

Taverner, M: *Biotechnology for control of growth and product quality in meat production: implications and acceptability, notes compiled on the international symposium of the American Society of Animal Science and European Association of Animal Production, Washington DC USA December 5 - 7 1990*, Pig R&D Corporation, Canberra

Victorian Law Reform Commission: *Discussion paper no 11: genetic manipulation*, March 1988

Victorian Law Reform Commission: *Report no 26: genetic manipulation*, June 1989

Journals, Press Articles and other

Andrews, K: *Australian controls on the environmental application of biotechnology*, in *Environmental and Planning Law Journal*, Vol 5 1988

Angier, N: *Gene therapy trial shows promise, scientists say*, in *The Age*, 29 July 1991

Anon - *The Genetic engineering debate*, in *Search*, Vol 20(3) May/June 1989

Anon - *Takeover of Genentech - lessons for developing countries?* in *Biotechnology and Development Monitor*, No 3, Ministry of Foreign Affairs, The Hague/University of Amsterdam, June 1990

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

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

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

Anon - *French gene trials*, in *New Scientist*, 6 April 1991

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

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

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

Berkowitz, D and Maryanski, J: *Implications of biotechnology on international food standards and codes of practice*, in *Proc. eighteenth session joint FAO/WHO Food Standards Program, Geneva, 3-12 July 1989*, Codex Alimentarius Commission

Brown, P: *Naked DNA raises fears for researchers*, in *New Scientist*, 6 October 1990

Brown, B and Concar, D: *Where does the genome project go from here?* in *New Scientist*, 17 August 1991

Campbell, R: *Exogenous porcine somatotropin (PST): implications to the Australian pig industry and current state of development of the technology*, in *Porcine somatotropin - PST implications and strategies for its use in the Australian pig industry - proceedings of the workshop March 7-8th 1981, Canberra*, Pig Research & Development Corporation, Canberra, 1991

Charles, D: *A triple helix to cripple viruses*, in *New Scientist*, 13 April 1991

Coghlan, A: *A second chance for antibodies*, in *New Scientist*, 9 February 1991

Coghlan, A: *An explosive start to fast maturing cheeses*, in *New Scientist*, 16 March 1991

Coghlan, A: *Watery microbes fuel fresh fears over genetic release*, in *New scientist*, 29 June 1991

Coles, P: *Inquiry into Pasteur deaths*, in *Nature*, Vol 338 20 April 1989

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

Cordier, S: *Risk of cancer among laboratory workers*, in *The Lancet*, Vol 335 5 May 1990

Curtis, R: in *Proceedings of the XIII International Congress of Nutrition*, 1986

Debus, K H: *Mining with microbes*, in *Technology Review*, Vol 93(6), 1990

Department of Health (UK), Ministry of Agriculture, Fisheries & Food: *New guidelines introduced for the labelling of foods produced using genetic modification*, news release, 17 January 1991

Ellistrand, N: *Pollen as a vehicle for the escape of engineered genes?* in *Planned release of genetically engineered organisms. Trends in biotechnology/trends in ecology and evolution special publication*, Hodgson, J and Sugden, A (edits), Elsevier, Cambridge UK, 1988

European Economic Community: *European Parliament report on the ethical and legal problems of genetic engineering*, in *Europe Environment Fortnightly*, 21 March 1989

Fenwick, G et al.: *Toxicity of disease-resistant plant strains*, in *Trends in Food & Technology*, July 1990

Fox, J: *A controversial test case*, in *Bio/technology*, Vol 6 1988

Galloway, J: *Britain and the human genome*, in *New Scientist*, 28 July 1990

Garrett, L: *Drug's genetic engineering probed*, in *Newsday*, 14 August 1990

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

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

Graham, J: *Restoring consumer confidence in food*, in *Consumer Affairs Journal*, No 98, March/April 1989

Hallen, P: *Genetic engineering - miracle or destroyer?* in *Habitat Australia*, February 1990

Harlan, J R: *Evolutionary dynamics of plant domestication*, in *Proc. XII Int. Congress in Genetics, Japanese J. of Genetics*, Vol 44, Suppl.1, 1969

Hiatt, A: *Production of antibodies in transgenic plants*, in *Nature*, Vol 342, 1989

Hoar, S et al.: *Agricultural herbicide use and risk of Lymphoma and soft tissue sarcoma*, in *Journal of the American Medical Association*, Vol 256(9) 1986

Joyce C: *Microbial dustmen clean up toxic waste*, in *New Scientist*, 6 May 1983

Kingman, S: *Altered antibody could keep AIDS at bay*, in *New Scientist*, 11 February 1989

Kokjohn, T et al.: *Attachment and replication of Pseudomonas aeruginosa bacteriophages under conditions simulating aquatic environments*, in *Journal of General Microbiology*, Vol 137 1991

La Torre, J L: untitled, in Sussman, M et al. (edits): *The release of genetically-engineered micro-organisms, proceedings of the First International Conference on the Release of Genetically Engineered Microorganisms, Cardiff, UK, 1988*, Academic Press

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

Mackenzie, D: *French research centre admits cancer risk*, in *New Scientist*, 17 February 1990

Mackenzie, D: *The west pays up for third world seeds*, in *New Scientist*, 11 May 1991

Maddox J: *The great gene shears story*, in *Nature*, 7 December 1989

Marlowe, T: *Evidence of selection for the snorter dwarf gene in cattle*, in *Journal of Animal Science*, Vol 23 1964

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

Millis, N F: *Adequate guidelines are already in place*, in *Search*, Vol 20(3) May/June 1989

Newman, S: *The difficulties of patenting transgenic animals*, in *ASM News*, Vol 56(5) 1990

Raphals, P: *Does medical mystery threaten biotech?* in *Science*, Vol 250 1990

Rifkin, J: *Is nature just a form of private property?* in *The New York Times*, 26 April 1987

Roberts, L: *Genome project under way, at last*, in *Science*, Vol 243, 1989

Roberts, L: *L-Tryptophan puzzle takes new twist*, in *Science*, Vol 249 1990

Roosa, N: *The pasteur syndrome*, in *Omni*, October 1988

Slutsker, L et al.: *Eosinophilia-myalgia syndrome associated with exposure to tryptophan from a single manufacturer*, in *Journal of the American Medical Association*, Vol 264 (2) 1990

Steffan R J and Atlas R M: *DNA amplification to enhance detection of genetically engineered bacteria in environmental samples*, in *Appl & Env Microbiol*, Vol 54, 1988

Swygert, L et al.: *Eosinophilia-myalgia syndrome results of national surveillance*, in *Journal of the American Medical Association*, Vol 264 (13) 1990

Tiedje, J et al.: *The planned introduction of genetically engineered organisms: ecological considerations and recommendations*, in *Ecology*, Vol 70(2) 1989

Walgate, R: *Inquiry into lab's bone cancers*, in *Nature*, Vol 321 12 June 1986

Weinberg, R: *A molecular basis for cancer*, in *Scientific American*, Vol 250 1983

Whan, B: *Growth hormones PST and pig meat production*, in *Porcine somatotropin - PST implications and strategies for its use in the Australian pig industry - proceedings of the workshop March 7-8th 1981, Canberra*, Pig Research & Development Corporation, Canberra, 1991

Wickelgren, I: *Please pass the genes*, in *Science News*, Vol 136, 1989

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

APPENDIX VI

COMPOSITION OF GMAC SUBCOMMITTEES

Member	Expertise
1. Scientific Subcommittee	
Prof Jim Pittard	Microbiology
Dr Ashley Dunn	Molecular biology/oncogenes
Dr Wayne Gerlach	Biochemistry
Dr Peter Hudson	Microbiology
Mr David Martin	Biocontainment Engineering
Prof Kevin Marshall	Microbiology
Dr John Oakeshott	Molecular biology/entomology
Dr Ian Parsonson	Veterinary
2. Large Scale Subcommittee	
Prof Nancy Millis	Microbiology
Dr Brian Booth	Industrial Chemist
Dr Peter Hudson	Microbiology
Mr David Martin	Biocontainment Engineering
Co-opted Members	
Mr Norman Ackland	Operational fermentation facilities expert
Mr Geoffrey Connellan	Plant house expert
3. Planned Release Subcommittee	
Prof Nancy Millis	Microbiology
Prof Randall Albury	History/Philosophy of Science
Mr Eric Anderson	Environmental consultant
Dr Annabelle Bennett	Law/Biochemistry
Prof Alastair Gilmour	Environmentalist
Prof Rhonda Jones	Zoology
Prof Kevin Marshall	Microbiology
Dr Ian Parsonson	Veterinary
Dr Margaret Roper	Microbiology/ecology
Mr Phillip Toyne	Law/conservation
Mr John Whitelaw	DASETT representative/agricultural science

4. Public Liaison Subcommittee

Prof David Danks	Medicine/genetics
Prof Randall Albury	History/Philosophy of Science
Mr Eric Anderson	Environmental consultant
Dr Annabelle Bennett	Industrial Chemist
Prof Alastair Gilmour	Environmentalist
Prof Nancy Millis	Microbiology

APPENDIX VII

GMO RELEASES IN AUSTRALIA

Date[1]	Institution	Title of Release Project
18.11.88	WA Dept of Agriculture	Field trial of a live *Salmonella* vaccine to prevent death during live sheep export
(19.11.90	Extension of work)	
18.11.88	Australian National University, Canberra	Field trial of a *Rhizobium* strain marked with the transposonal Tn5 lac 2 [a genetic marker] in a controlled field release experiment.
28.2.89	Qld Dept Primary Industries	Inoculation of cattle with thymidine kinase deletion mutant infectious bovine rhinotracheitis vaccine virus.
2.3.89	Vic Dept of Agriculture	Preliminary proposal towards the release of live *Salmonella typhimurium* vaccine strain DD30 for use in sheep. (Not proceeded with.)
13.6.89	Biocare Technology	National clearance and registration of *Agrobacterium radiobacter K1026* for the control of crown gall disease.
2.5.89	CSIRO Biotechnology/ Burns Philp	Commercial evaluation of melibose utilising bakers yeast.
27.6.90	CSIRO Division of Soils	Field release of a live genetically modified strain of *Pseudomonas* for the purpose of testing a microbial tracking system.
20.12.90	Australian National University, Canberra	Controlled field release experiment of a *Rhizobium* strain containing a Sym plasmid marked into the transposon Tn 5.
20.12.90	University of Melbourne	Construction of lactic acid bacteria with improved technological properties.
17.6.91	CSIRO Division of Plant Industry	Synthetic resistance genes to potato leafroll virus.

1 Indicates the date of GMAC advice approving the release

APPENDIX VIII

CASE STUDY 1 - THE FIELD RELEASE OF A MODIFIED STRAIN OF BACTERIA FOR THE PURPOSE OF TESTING A MICROBIAL TRACKING SYSTEM.

Naturally occurring *Pseudomonas* bacteria, added as a coating on wheat roots, are able to control the fungus disease 'Take-all'. An imported strain of genetically modified *Pseudomonas* was released in October 1990 by CSIRO Division of Soils, Adelaide, to measure the distribution, survival and activity of the bacteria over a period of 15 to 18 months. This will help to predict the behaviour of the naturally occurring *Pseudomonas* when it is trialled as a biological control agent.

Date	Other bodies consulted	Researchers	Division of Soils IBC	GMAC
9 Jan 1990			IBC established	
Feb 1990	Discussions with S.A. Dept. Industry, Trade & Technology			
7 Mar 1990	Letter from S.A. Dept. of Agriculture indicating containment requirements			
4 Apr 1990	Inspection of containment equipment by S.A. Dept. of Ag. on behalf of AQIS			
Apr 1990		Release proposal submitted to IBC		
18 Apr 1990			IBC assesses proposal	
27 Apr 1990			IBC approved proposal forwarded to GMAC	
9 May 1990		Small scale proposal submitted to IBC		
24 May 1990			IBC approved proposal forwarded to GMAC	

Date	Other bodies consulted	Researchers	Division of Soils IBC	GMAC
24 May 1990	Approval of containment equipment by S.A. Dept. of Ag. on behalf of AQIS			
1-7 June 1990				Scientific Subcommittee considers both proposals
18 June 1990				Planned Release Subcommittee considers release proposal
27 June 1990				Request for more information
		Laboratory testing to collect additional data		
4 July 1990		Modified protocol sent to GMAC		
5 July 1990				Researchers advised of GMAC approval of small scale proposal under Category A(ix) & B(iv); AQIS advised of decision
23 July 1990	Cultures cleared for use by S.A. Dept. of Ag. on behalf of AQIS			

Date	Other bodies consulted	Researchers	Division of Soils IBC	GMAC
Aug/Sep 1990	Discussion with Adelaide Univ. Biohazards Committee			
10 Sep 1990		Results of laboratory tests sent to GMAC		
4 Oct 1990				Researchers advised of GMAC approval for proposed release
12 Oct 1990		Release experiment begins		
Sept 1991		Interim report due		

APPENDIX IX

CASE STUDY 2 - THE DEVELOPMENT OF A COMMERCIAL VACCINE AGAINST THE CATTLE TICK.

Cattle ticks are a major problem in the more tropical areas of Australia. Infested cattle can develop an allergic response, contract blood-born diseases and can also die from anaemia and the toxic effects of the parasite. Biotech Australia in collaboration with CSIRO Division of Tropical Animal Science have developed a vaccine using tick antigens which are made by *E. coli* genetically modified to contain the gene for the antigens. The research involved Small Scale work which eventually was scaled up and came within the Large Scale guidelines.

Date	Researchers	Biotech IBC	RDMC and GMAC
8 Aug 1983	Small scale proposals for cloning tick antigens submitted to IBC		
26 Aug 1983		IBC approval under category C1; RDMC notified	
13 Sep 1983			Proposal sent to RDMC members for comment
27 Sep 1983			Comments received - no concerns
20 May 1985	Extension of small scale work proposal submitted to IBC		
27 June 1985		IBC approves proposal; RDMC notified	
11 July 1985			Proposal sent to RDMC members for comment
15 Aug 1985			Biotech advised that C1 containment was appropriate
Early 1986	Discussion with RDMC about containment for large scale fermenters		

Date	Researchers	Biotech IBC	RDMC and GMAC
- Mar 1986	C1-LS facility proposals sent to RDMC		
24 Mar 1986			Proposals sent to Large Scale Sub-committee
23 May 1986			Comments about eight concerns sent to Biotec
19 Aug 1986	Revised containment plan sent to RDMC; facility modified		
10 Sep 1986			Biotech's response sent to Large Scale Sub-committee
29 Oct 1986			Facility approval discussed at RDMC meeting
9 Feb 1987			Further discussions by RDMC
10 July 1987			Biotech advised of concerns
19 Aug 1987	Further discussions with RDMC about containment		
- May 1988	Large scale proposal submitted to IBC		

Date	Researchers	Biotech IBC	RDMC and GMAC
31 May 1988		Discussions with researchers concerning proposal and draft Operating Manual	
- July 1988	Modifications to Draft Operating Manual (completed by September)	Large Scale proposal submitted to GMAC	Received 1 Aug 1988
9 Aug 1988			Proposal sent to GMAC members
21 Sep 1988	Facility inspection by GMAC; examination of Operating Manual		
22 Sep 1988			Inspection team reports basic compliance with C1-LS; requests four improvements
10 Oct 1988			Biotech advised of approval of facility as C1-LS, provided improvements are made; Operating Manual approved
28 Oct 1988			Biotech advised of approval of Large Scale project under C1-LS containment

APPENDIX X

GLOSSARY OF TERMS

adenine
One of the small molecular building blocks, called bases, which make up the coding units of DNA and RNA. Often abbreviated to A. In DNA, pairs with thymine(T).

adenosine diphosphate (ADP)
A molecule consisting of adenine plus a sugar plus two phosphate groups important in the energy economy of a cell. Oxidation of fuel molecules such as glucose permits ADP to take up an extra phosphate and thereby to trap energy.

adenosine triphosphate (ATP)
A molecule consisting of adenine plus a sugar plus three phosphate groups which acts as the universal currency of free energy in biological systems. Conversion of ATP to ADP releases energy which drives the work of the cell.

adjuvant
A substance which increases the efficacy of a vaccine, i.e. stimulates the immune response.

adsorption
The principle underlying chromatography. Materials form a layer on the surface of the adsorber and different materials can be separated according to the strength of their attachment to the surface.

agrochemical
Chemicals which are manufactured for use in agriculture.

AIDS
Autoimmune deficiency syndrome. A syndrome caused by the sexually transmitted human immunodeficiency virus (HIV). Similar viruses infect monkeys and cats.

alkaloid
A group of nitrogen containing-compounds present in some plants which are of great importance because of their poisonous and medicinal properties e.g. morphine, nicotine, quinine, strychnine. The chemicals are probably designed to deter plant eating animals.

allele
Alternative genes which occupy the same position on a chromosome.

allosteric effect
A protein molecule is caused to change shape through union with another molecule. As a result, a new active site is exposed.

amino acid
Building block of proteins. There are twenty naturally occurring amino acids.

amniocentesis
A medical procedure in which amniotic fliud is removed during pregnancy for diagnostic purposes.

anoestrous
Failure of an organism to go through the normal reproductive hormone cycle.

anterior pituitary
A gland situated beneath the floor of the brain which produces 6 hormones including growth hormone.

antibody
A special protein molecule made by the immune system of vertebrate animals, specifically tailored to fit other molecules, for example bacterial toxins, much as a given key fits a particular lock.

antigen
A generic term for a molecule with which an antibody reacts.

asepsis
Sterile conditions.

attenuated virus
A virus which has been damaged and so is unable multiply in its host. Attenuated viruses are used as vaccines.

autoclave
Apparatus for sterilisation by high temperature. Essentially a large pressure cooker.

autoimmune disease
A disease in which the body manufactures antibodies against some component of itself; thus a form of civil warfare in the body, one cell attacking another.

bacteria
Unicellular microorganisms containing a single very large DNA molecule per cell (the chromosome). Many species of bacteria can be grown very easily, very inexpensively, and in very large amounts in solutions consisting of a few salts and a carbon source.

bacteriophage
A virus that grows in bacteria.

bases
See adenine, guanine, cytosine, thymine, uracil.

biocide
A chemical which kills living things.

biodegradable
Broken down by living organisms. It is also a technical term denoting that a certain percentage of the chemical is broken down in a set time, e.g. for detergents to meet the Australian standard, 80% must be broken down in 21 days ('Choice' magazine, Sept. 1990).

biological containment
Use of genetically altered organisms that are unable to perform essential functions such as growth, DNA replication, transfer of DNA to other cells, infection of cells, etc., except under rigidly specified laboratory conditions. An example of biological containment would be the use, as a host organism for recombinant DNA molecules, of an *E. coli* cell that can grow only at a temperature of less than 32° C and only if both streptomycin and diaminopmelic acid, neither of which is normally found in the environment, are provided in its growth medium.

biopesticide
A genetically engineered microbe producing a naturally occurring poison which is used to control a pest.

biota
The living things in a particular region.

blastocyst
A stage in early development where the embryo consists of a small ball of cells.

botulism
A lethal food poisoning caused by the toxin of the bacterium *Clostridium botulinum*. The spores of the bacterium can be present in the soil and can contaminate food which is imperfectly preserved, especially canned food.

carcinogen
A cancer inducing chemical. (q.v. mutagen)

cDNA
Stands for copy DNA - A stretch of DNA synthesized by enzymes as a faithful copy of a particular stretch of RNA, which thus preserves the information content of that RNA.

cell
A fundamental organizational unit of all living matter. The simplest forms of life consist of just one cell, e.g. bacteria, algae or certain parasites. Higher life forms are multicellular organisms, permitting specialization of cellular function, i.e. a division of labour between cells.

cell membrane
The fatty outer skin of a cell which separates it from the next cell, from the fluid bathing cells, or from the environment.

cell membrane receptors
Protein molecules, frequently with some sugars attached, which reside in the cell membrane and possess the capacity to bind specifically some molecule which floats past, e.g. a hormone, a nutrient, or a trigger for cellular activation.

chain
Used in the context of a chain of amino acids which follow a sequence determined by the gene for that chain; many proteins consist of two or more chains linked together chemically. Thus insulin has an *a* and a *b* chain; many antibody molecules have four chains, two smaller ones called light, and two larger ones called heavy. Usually accompanied by the adjectival noun polypeptide (q.v.) meaning many amino acids.

chemical poration
The introduction of genetic material into a cell using chemicals e.g. polyethine glycol (antifreeze).

chloroplast
A membrane-enclosed subcellular organelle found in cells of plants. Chloroplasts are the site where photosynthesis occurs, they contain DNA and they are capable of replication.

chromosome
A very long double-stranded DNA molecule packed together with certain proteins which forms a sausage-like entity readily visualized under the microscope when a cell divides. The number of chromosomes per cell is a characteristic of a species; thus man has forty-six chromosomes per cell.

chymosin
An enzyme used to clot milk in cheese making. The traditional source of the enzyme is rennet obtained from the stomachs of calves. Chymosin produced from a genetically modified yeast has been approved for use in the UK.

clone
Members of a clone are genetically identical.

cloning
Causing asexual division. Frequently used as jargon in genetic engineering to describe the sequence of events by which a gene is caused to replicate a large number of times in some foreign host cell.

codon
A sequence of three bases of DNA or RNA which codes for one amino acid.

coenzyme
A large carbon containing molecule which is needed to enable an enzyme to carry out its function; the coenzyme is changed in the reaction.

cofactor
Small chemicals, usually a charged atom/s, which are required to enable an enzyme to function properly; the cofactor is not used up in the reaction.

colony
A clustered group of cells which arose from a single cell by asexual division, thus a bacterial colony may be a visible spot of 1-2 millimetres diameter consisting of millions of bacteria that are growing in a jellified medium.

commensalism
The association of organisms of different species without either receiving benefits essential or highly significant to survival.

compound
A substance consisting of two or more types of atom which are chemically joined.

conjugation
The transfer of DNA from one bacterial cell to another during bacterial mating. The DNA can be either chromosomal or plasmid DNA.

conjugative plasmid
A plasmid that can spontaneously transfer its DNA to another cell.

con-specific
A member of the same species.

cosmid
A virus-like vector used by genetic engineers that combines some of the advantages of phages and of plasmids as instruments for the cloning of genes.

covalent bonds
The type of relatively strong chemical bonds involving electron sharing that hold together most of the atoms in a molecule. The bases within one strand of a DNA molecule are linked together by covalent bonds. The two strands of a double-stranded DNA molecule are held together by the hydrogen bonds in the specific base pairs. Hydrogen bonds are weaker; they involve magnetic attraction rather than sharing of electrons.

covalently closed DNA
A DNA molecule that is circular and in which both strands are covalently continuous. Plasmids are examples of convalently closed DNA molecules.

Creutzfeldt-Jakob disease (Jakob-Creutzfeldt disease)
A genetic disease of middle life with mental disorientation, dementia, and neurological disturbances such as tremor and other involuntary movements. Death usually ensues within a year of the onset of symptoms.

cytoplasm
That portion of a cell which is not the nucleus; the site where proteins are made and where chemical energy is generated; the 'factory' portion of the cell.

cytosine
One of the four small molecular building blocks, called bases, which make up the coding units of DNA. Often abbreviated to C. In DNA, C pairs with guanine (G).

differentiation
The process whereby cells gain more specialized function. Thus, as a cell destined to turn into a red blood cell gradually builds up more and more haemoglobin, it is said to differentiate.

dioxin
A highly toxic chemical made up of chlorine, hydrogen and carbon atoms which is formed at high temperatures from a reaction between chlorine and hydrocarbons. The chemical was a contaminant of the herbicide 2,4,5-T and has been shown to be a potent mutagen and carcinogen in laboratory animals.

diploid
Having the chromosomes in pairs in the nucleus. Normal cells contain chromosomes in pairs. Thus twenty-three pairs make up the forty-six chromosomes in a normal diploid human cell. Cancer cells are frequently hyper-diploid, i.e. contain more than forty-six chromosomes. (See also haploid.)

disulphide bond
A chemical linkage between two sulphur-containing amino acids either within a single polypeptide chain or between the component chains of a multichain protein. The disulphide bonds stabilize the shape of a protein and help to keep multichain proteins as a single molecule.

DNA
Deoxyribonucleic acid. A double helical molecule consisting of a sugar-phosphate backbone and a sequence of base pairs constituting the coding units of the genetic code. Particular stretches of DNA constitute a gene, one gene being that stretch which encodes one polypeptide chain.

DNA ligases
Enzymes which catalyse the formation of the chemical bonds needed to weld pieces of DNA together. Thus, DNA ligases may join a gene from an animal cell with DNA from a phage virus, creating recombinant DNA.

DNA polymerase
An enzyme that can fill in single-stranded gaps in double-stranded DNA by inserting the proper complementary bases opposite the bases in the intact strand.

DNA replication
The process by which the two complementary strands of a DNA molecule separate and a new complementary strand for each of the separated strands is synthesized by DNA polymerase. This process gives rise to two daughter DNA molecules, each of which has a nucleotide sequence identical to that of the parental molecule.

dominant gene
A gene which will mask the activity of a recessive gene when both are present.

donor organism
The organism from which genetic material was obtained.

drenching
A procedure whereby drugs are administered to livestock by mouth.

E.coli
Escherichia coli. A harmless bacterial species which resides in the human intestine. Frequently used in genetic research, e.g. as a host cell for phages or plasmids carrying recombinant DNA.

ecology
The study of the relationships of animals and plants, especially of their communities with their living and non-living surroundings.

ecosystem
A community of organisms, interacting with one another, plus the environment in which they live and with which they interact, e.g. a wetland, a forest.

electrophoresis
A procedure in which a mixture of molecules is subjected to an electric current ensuring that each molecule moves at a rate influenced by its net electric charge; thus a useful way of analysing and separating complex mixtures of molecules, e.g. proteins.

electroporation
The introduction of genetic material into a cell via the application of a strong electrical field.

embryo transfer
A procedure whereby fertilized eggs are transferred into surrogate mothers for future development. The method is used to maximise the number of offspring produced.

endogenous
Developing or originating within an organism.

endonuclease
An enzyme capable of cutting DNA.

endoplasmic reticulum
A system of channels inside the cytoplasm of a cell for the assembly and export of protein molecules.

endotoxin
A molecule derived from the cell wall of bacteria which is highly toxic to animals.

enzyme
A protein that facilitates specific processes necessary for a cell's functioning. The enzyme is itself unchanged at the end of the process. Enzymes are produced continuously under instruction from the genes; old enzymes are eventually broken down by the cell, thus the genes ultimately control the cell's functioning.

eosinophilia myalgia syndrome
A disease associated with the use of L-tryptophan (q.v.) which reached epidemic proportions in 1989/90. Symptoms included skin rashes, muscle pain and raised levels of eosinophils, a type of white blood cell. Over 1500 cases were reported in the USA with 27 deaths. It has been alleged that the disease resulted from the genetic modification of the bacterium used to produce the L-trptophan. This has been disputed.

epithelium
A layer of cells which lines cavities or covers exposed surfaces. One surface of the layer is free. Cells of the epithelium can be involved in the secretion or absorption of chemicals.

ethology
The study of the behaviour of an animal in its normal environment.

eukaryotes
Organisms having cells containing a defined nucleus, multiple chromosomes, and a defined apparatus for mitosis. Eukaryotes can be either unicellular (yeasts, protozoa) or multicellular (animals and plants). (As opposed to prokaryotes.)

exogenous
Developing or originating from outside an organism.

exon
That portion of the gene which encodes a portion of the amino acid sequence of the protein. One gene may contain several exons. (Also see intron.)

expression vectors
Tools of the genetic engineer which permit a gene to be inserted into a cell in such a manner that, on appropriate signalling, the cell will manufacture large amounts of the protein for which that gene codes.

Factor VIII
A blood component essential for blood clotting. The component is deficient in haemophiliacs and was extracted from donated blood. Before sterilization techniques were altered, Factor VIII preparations could have contained HIV thereby transmitting AIDS to haemophiliacs.

fermenter
Apparatus, principally a large tank, use in various laboratory and industrial processes for the manufacture of products such as alcohols, acids, and cheeses by the action of yeasts, molds and bacteria.

flora
Strictly, the plants peculiar to a region, but used by microbiologists to refer in general to the local organisms, particularly bacteria or viruses.

gel electrophoresis
A procedure in which a mixture of proteins, nucleic acids or other molecules is made to penetrate into a jellified medium under the influence of a strong electric current. Molecules migrate at a rate dependent on their net electric charge and, on this basis, different molecules can be separated from one another.

gene
A segment of chromosome which determines a characteristic of a living organism. The material of genes is deoxyribonucleic acid (DNA), which contains an ordered sequence of nucleotide bases. The sequence in a specific gene may be regarded as a 'code' for a polypeptide, which is 'decoded' when the polypeptide is manufactured, or in some cases the gene may control the start or cessation of polypeptide synthesis. In higher organisms, genes consist of exons and introns (q.v.).

gene activation
A process in which a command is given which ensures that messenger RNA molecules will be made as copies of the particular gene being activated. Thus, gene activation is the first step in protein synthesis.

gene shears
A procedure for destroying messenger RNA (mRNA) produced by specific genes. Gene shears can therefore be used to prevent the action of harmful genes or defend the cell against attack by viruses. The gene shears techniques were discovered at CSIRO in 1987 and a company has been formed to exploit the discovery.

gene targeting
The process in which genes are inserted at precise sites in the host chromosome.

genetic code
The code whereby the structural information for proteins is encoded in the nucleotides of the DNA. Proteins are strings of amino acids, one amino acid out of twenty being chosen for each spot in the string. Nucleic acids are strings of nucleotides, one nucleotide out of a possible four at each spot. A sequence of three nucleotides specifies one amino acid.

genetic engineering
The technology by which genes can be isolated, transferred to other cells, replicated and activated.

genetic fingerprinting
Process by which an individual can be identified by determining their combination of various DNA sequences. The stretches of the chromosomes which are analysed vary greatly between individuals and the process has potential for great accuracy. However, it has been subject to several court cases in the USA.

genetic manipulation
Technology used to alter the genetic material of an organism, so that it produces new substances or performs new functions. The altered characteristic may or may not be inherited by the next generation.

genetic tag
A distinctive stretch of DNA which is inserted into the GMO's genetic information to enable identification.

genome
A noun used to denote the total complement of genes in a cell or individual.

genotype
The genetic constitution of an organism; its total array of genes (as contrasted with the characteristics manifested by an organism - the phenotype).

germ cell gene therapy
Introduces a new gene into the 'germ' or reproductive cells - sperm, eggs or fertilised eggs. The genetic change would then be inherited by the offspring of the treated person (as contrasted with somatic cell gene therapy).

germ-plasm
Cells in an organism containing the genes which will be conveyed to future generations.

glyphosate
The active ingredient of 'Roundup' and 'Zero'. The chemical is absorbed through the leaves and disrupts protein production in plants only. It has low toxicity to animals, does not spread through soil and is broken down by micro-organisms.

Golgi apparatus
A packaging centre for the concentration and temporary storage of protein molecules destined for export by the cell.

guanine
One of the small molecular building blocks, called bases, which make up the coding units of DNA and RNA. Often abbreviated to G. In DNA and RNA, pairs with cytosine(C).

haemoglobin
An iron-containing pigmented protein contained in the red blood cell which is responsible for carrying oxygen around the body and releasing it for the use of the cells.

haemoglobinopathies
A group of diseases resulting from an abnormality in the gene for one of the chains of haemoglobin.

haemophilia
An inheritable disease in which a protein essential for blood clotting is defective. Patients bleed too readily, particularly after injury.

haploid
Having a single set of unpaired chromosomes in each nucleus. Most cells contain pairs of chromosomes, known as a diploid set, but the cells for reproduction, the sperms and ova, contain only half this number, e.g. twenty-three chromosomes in the human, instead of forty-six in other cells. This constitutes a haploid set. The number is restored to forty-six when sperm and egg fuse.

hemizygous
A region of a chromosome of a diploid (q.v.) which is not matched by the other member of the pair of chromosomes; i.e. the genes in this region are unpaired.

HEPA filter
High Efficiency Particulate Air filter, used in containment levels C2 and higher.

heterozygous
The condition in which the two genes for a characteristic are different.

HIV
Human immunodeficiency virus - the virus which causes AIDS. Similar viruses infect monkeys and cats.

homopolymer tailing
A procedure by which a string of nucleotides, all the same, is added to the end of one strand of a DNA molecule. This string, e.g. A-A-A-A-A will readily stick to another DNA molecule tailed with the complementary nucleotides, e.g. T-T-T-T-T.

homozgous
A condition in which both genes for a particular character are the same.

hormone
A class of chemical messenger molecules, travelling in the blood stream, synthesized by cells in an endocrine gland and capable of influencing growth and metabolism within other, perhaps distant, cells which possess receptors for that hormone.

host organism
The organism into which the genetic material was placed.

Huntingdon's disease
A genetic disease caused by a dominant gene (q.v.). The disease, which results in progressive loss of mental capacity and physical coordination in late middle age, can be identified before the onset of symptoms using a gene probe.

hybrid
Organism resulting from parents that are genetically distinct e.g. from different species or well-marked varieties within a species. A hybrid may be fertile or sterile.

hybridoma
A cell which results from the fusing a normal cell with a cancer cell; the hybridoma is able to continuously divide continuously.

hydrocarbon
An organic compound containing only hydrogen and carbon atoms.

hyperplasia
Increase in the amount of tissue by an increase in the number of cells which individually retain their usual size (contrasts with hypertrophy).

hypertrophy
Increase in the size of a tissue or organ via an increase in individual cell size without an increase in cell number (contrasts with hyperplasy).

immunobiological
A biological substance used to create immunity to disease.

immunoglobulins
Molecules found in the plasma and tissues of vertebrates that act as antibodies.

insulin
A hormone made by *B* cells in the pancreas necessary for the proper utilization of glucose within the body.

interferon
A generic term used to describe three groups of molecules. These molecules are synthesized by cells as a result of virus infection and temporarily interfere with the growth of other viruses in that or nearby cells.

intron
Stretch of DNA occurring within a gene which, however, does not code for amino acids of the relevant protein. When a gene is activated, the RNA molecules made as copies of the gene faithfully reflect both introns and exons(q.v.), but before this RNA travels to the cytoplasm, the sequences corresponding to introns are cut out and the (shorter) RNA corresponding only to copies of exons is joined up to constitute the final messenger RNA template.

in utero
Refers to development inside the uterus.

in vitro
Refers to biological processes made to occur outside an organism (usually in glass).

in vivo
Refers to biological processes which occur inside a living organism.

lac operon
A group of genes and control elements responsible for the proper utilization of lactose by bacterial cells. Frequently used by genetic engineers as a switching device for gene activation.

lesion
Any structural change in a bodily part resulting from injury or disease.

ligase
An enzyme that catalyses the covalent bonding of two segments of an interrupted strand of double-stranded DNA.

lipase
An enzyme capable of catalysing the digestion of fats.

lipid
A technical term for describing fatty molecules in biology.

liquid chromatography
A process used to separate components of a liquid mixture. The mixture is allowed to pass slowly through adsorbent (q.v.) material and the various components become adsorbed in different layers.

locus
The position on a chromosome which is occupied by a particular gene.

lymphoma
Tumours arising from cells of the lymphatic system and primarily affecting the lymph nodes, e.g. Hodgkin's disease.

lysosomes
Small pouches within the cytoplasm of cells containing enzymes capable of digesting particles or molecules that enter the cell.

major histocompatibility complex
A group of genes which determine the tissue type of an individual, i.e. compatibility with another for organ transplantation. Also involved in the regulation of immune responses.

mastitis
An infection of the mammary gland, common in cows.

meiosis
A special type of cell division which creates the reproductive cells, the sperm and the ova. During the process, not only is the number of chromosomes halved, e.g. in the human from forty-six to twenty-three, but also the paternal and maternal genes become recombined in new ways. As this happens differently in each meiotic division, no two sperms or no two ova in any individual are exactly the same. (Contrast with mitosis)

messenger RNA (mRNA)
A copy of the DNA which moves from nucleus to cytoplasm and serves as the immediate coding entity which is decoded as proteins are made.

metabolism
The chemical processes that occur within organisms. Metabolism is controlled through the actions of enzymes (q.v.) which are produced under instructions from the genes.

micro-injection
Technique by which genetic material is physically injected into the nucleus of a cell.

micro-nutrients
Substances which are only required in minute amounts.

micro-organism
A living entity too small to be seen by the unaided eye. Also called microbes.

microtubule
Fibre-like structures within the cytoplasm which are involved in the movement of materials and organelles around the cell.

mites
Animals related to spiders and ticks, having eight legs. Mites are often serious pests and many have become resistant to pesticides.

mitochondria
Subcellular particles within the cytoplasm which generate chemical energy for use by the cell.

mitosis
The non-sexual division of cells whereby each daughter cell receives the full diploid number of chromosomes. (Contrast with meiosis.)

mobile genetic element
Portion of the genome which, unlike most DNA, does not occupy a fixed position but can jump from spot to spot on a chromosome or even move between chromosomes.

model
A computer model, which is an attempt to represent a real-life situation to enable predictions to be made without having to undertake costly and time-consuming experiments.

molecule
A grouping of atoms which together make a stable substance.

monoclonal antibody
An antibody made by the progeny of a single cell, thus extremely pure, precise and homogeneous.

monoculture
The common agricultural system in which only one type of plant is grown in an area.

morphology
The form and structure of an organism.

mosaic
Refers to an individual organism which is made up of genetically different cells.

multivalent vaccines
Vaccines which are engineered so as to confer immunity to several diseases. The immunity stimulating chemicals from several disease organisms are incorporated into the virus which is used for the vaccine.

mutagen
An agent which causes mutations, or changes, in the sequence of bases in the genetic material of an organism. May be chemical or physical (eg ionising radiation). (q.v. carcinogen)

mutant
An organism with a mutation in it.

mutation
A change in the genetic material of an organism. Mutations can be base-pair changes, deletions, additions, or inversions of a series of base pairs. Mutations can be deleterious, neutral, or advantageous, depending on their nature and on the environment in which the organism must survive.

nematode
Roundworms. Widespread, numerous, and usually microscopic animals often causing serious diseases of both animals and plants.

niche
An ecological term referring to the way of life of the organism e.g. soil dwelling predator.

Niemann-Pick disease
A rare genetic disorder in which a defect in a gene inside the lysosome causes accumulation of lipid inside the cell. Somewhat related to Tay-Sachs disease (q.v.).

nitrogen fixation
A process occurring in legumes and some other plants in which gaseous nitrogen is converted to nitrogen salts which can then be used by the plant to form proteins etc.. The process is made possible by bacteria which live in nodules formed by the roots of the plant.

nonconjugative plasmid
A plasmid that cannot transfer its DNA to another cell. Many nonconjugative plasmids can, however, be 'mobilized' to transfer their DNA in the presence of a conjugative plasmid in the same cell.

nucleic acids
Two types of polymer molecules,DNA and RNA(q.v.), which act as the repositories of genetic information. They consist of a backbone of alternating sugar and phosphate portions, with a coding unit or base attached to each sugar.

nucleotides
The building blocks from which nucleic acids are made, i.e. a sugar with an attached coding unit (i.e. a base) and a phosphate group.

nucleus
The control centre of the cell, where the DNA resides, separated from the 'factory' portion of the cell, the cytoplasm, by a double membrane.

oncogene
A gene or genes which, when inappropriately activated, can be involved in the production of cancer.

organelles
Small subcellular particulate structures within the cytoplasm of a cell, recognizable in the electron microscope and frequently separable from other organelles or the fluid, structureless part of the cell by biophysical techniques. Many organelles possess specific functions known in detail.

organic compound
A compound based on carbon; other types of atom may be present but at least some carbon atoms must be connected.

organo-metallic compounds
Organic compounds containing metal atoms. Often these compounds are more toxic than the metal because they are more easily absorbed by cells.

osteochondrosis
Refers to bone and cartilage tissue.

palindromic sequences
Stretches of DNA the sequence of bases in which read identically backwards or forwards.

pathogen
In microbiology, a virus or bacterium that causes disease.

PCB
Polychlorinated biphenyl. A fat soluble toxic pollutant which is stable and can accumulate through food chains. It may lower immunity and has been implicated in the recent deaths of marine mammals in the North Sea.

peptide synthesis
The process by which amino acids are joined together to form short or long chains.

pesticide treadmill
The cyclical process in which the application of a pesticide reults in the evolution of resistance, necessitating the use of higher concentrations or a new pesticide. Eventually, if new pesticides cannot be developed fast enough, the pest wins the battle.

pH
The acidity of a solution. The scale runs from 0 to 14 with 7 being neutral. Below 7 is acid while above is alkaline; the acidity increases or decreases 10 times for each unit of pH.

phage
Abbreviation of bacteriophage virus, a virus capable of infecting and destroying bacteria. Frequently used as a vector (q.v) by genetic engineers.

phenotype
The total array of observable characteristics or an organism; its morphological and physiological properties. In a given environment, a given genotype will always determine the same phenotype. Any change in the phenotype in that given environment implies a change in the genotype - a mutation.

phosphorylation
The metabolic process whereby a phosphate group is added to a molecule; a chemical method of increasing its energy prior to subsequent reactions.

photoperiod
Relates to the length of light and dark an organism experiences - behaviour and many processes within organisms are affected by daylength or nightlength.

physical containment
Equipment or practices that put a physical barrier of some sort between the experimenter and part or all of his/her experiment. Examples of physical containment are the use of glove boxes and laminar air flow safety cabinets, the avoidance of mouth-pipetting, the autoclaving of contaminated material, the maintenance of a laboratory under negative air pressure with respect to surrounding laboratories, the wearing of laboratory coats and gloves.

physiology
The processes which occur within an organism.

plant tissue culture
A process which enables plants to be reproduced in test tubes using a variety of plant hormones.

plaque
A clear area, e.g. where a phage population has destroyed bacteria growing on a jellified medium.

plasmid
A circular piece of DNA capable of self-replication within a cell independently of nuclear DNA. Frequently used as a vector (q.v.) in genetic engineering.

pleiotropic
When a gene affects more than one characteristic in a phenotype (q.v.).

polymer
A molecule made up of a number of smaller subunits.

polymerase chain reaction
A technique which enables DNA fragments to be multiplied in the test tube. It allows measurable quantities of DNA to be obtained for subsequent use from amounts which normally would be undetectable.

polypeptide
A stretch of two or more amino acids joined by peptide bonds constituting a protein or one chain (q.v.) of a multichain protein.

polyribosome
A collection of ribosomes (q.v.) attached to a messenger RNA molecule engaged in aiding the synthesis of proteins according to the coded instructions in the RNA.

polysaccharide
A large molecule made up of many sugar units. E.g. starch.

porcine somatotropin (PST)
A hormone which stimulates growth in the pig. It is a protein which can be broken down by the digestive system and has to be given by injection or some sort of slow release implant. It affects growth in cells and influences metabolic pathways, channelling nutrients towards the production of lean tissue rather than fat.

primary transcript
That molecule of RNA first synthesized as a faithful copy of a whole gene when a gene is activated. Portions of the primary transcipt (the introns) are cut out before the messenger RNA moves to the cytoplasm.

probe
A stretch of DNA or RNA labelled with a radioactive isotope, capable of binding to, and thus 'finding' a stretch of DNA with a complementary sequence.

projectile transfer
Technique by which genetic material is fired into the nucleus of a cell on a projectile.

prokaryotes
Simple unicellular organisms such as bacteria and blue-green algae. Prokaryotes have their genetic material in the form of simple filaments of DNA and lack a defined nucleus and nuclear membrane.

promoter sequence
The sequence of genes which act as a switch and turn on another set of genes.

pro-nucleus
The nucleus of either sperm or egg before their fusion during fertilization; pro-nuclei are haploid (q.v.).

protein
Complex, often very large Molecules composed of amino acids, which perform most of the cell's work. Includes enzymes, hormones, antibodies, carriers for other molecules, receptors and structural molecules. Protein molecules are made up of folded chains of polypeptides.

protein kinase
An enzyme which catalyses the addition of a phosphate group to certain amino acids of proteins.

protein synthesis
The process by which the amino acids are joined together to form proteins. Almost synonymous with peptide synthesis, except that the latter usually refers to shorter stretches of amino acids.

protoplasts
Cells of bacteria or plants from which the cell wall has been removed.

pseudorabies (false rabies)
A disease usually of cattle and pigs caused by the DNA containing herpesvirus. The infection which affects the nervous system is not transmissable to humans. Infected animals are not aggressive.

rabies
A disease, usually of foxes, wolves, bats and domestic animals, which is caused by an RNA virus. In wild animals it is characterised by a loss of fear, unpredictable rages, and excess saliva production. The disease can be transmitted to humans where it causes general malaise followed by hyperexcitability, hydrophobia, coma and death.

range
An area or volume of the environment in which a particular organism can be found. (Compare with 'territory'.)

rDNA
Shorthand for recombinant DNA; genetic information which has been created or rearranged prior to experimentation.

recessive gene
A gene which will masked by the activity of a dominant gene when both are present.

recombinant DNA
DNA molecules of different origin that have been joined together by biochemical techniques to make a single molecule, usually circular and usually capable of some specific biological function, especially *self-replication* in an appropriate cell.

redundancy of function
Describes the situation in which several species perform similarly in the same ecological role.

restriction endonucleases
Enzymes which cut the DNA double helix only where a particular sequence of base pairs is present.

retrovirus
A virus which uses RNA as the genetic material but possesses the enzyme reverse transcriptase (q.v.) and which can thus cause a DNA copy of itself or some part of itself to be made inside the cell.

reverse transcriptase
An enzyme capable of using RNA as a template and creating a DNA copy of the relevant sequence.

ribosomes
Small, particulate entities within the cytoplasm which attach to messenger RNA and help to translate that message into a particular amino acid sequence. Essential for protein synthesis in the cell.

RNA
Ribonucleic acid. A single-stranded molecule consisting of sugar, phosphate and a string of bases. Different sorts of RNA have different functions. Messenger RNA is the immediate template for protein synthesis.

sarcoma
Cancer deriving from cells which perform a support or packing function in the body (connective tissue).

sequencing
The process of determining the sequence of nucleotides (in DNA or RNA) or amino acids (in proteins).

solanine
A toxic alkaloid present in a group of plants which includes the potato and tomato.

solutes
The substances that are dissolved in a solvent to form a solution.

somaclonal variation
During the process of producing clones (q.v.) occasional variation occurs due to mutation.

somatic cell gene therapy
Will introduce a new normal gene into the patient's body or 'somatic' cells. It would treat only that patient; the change would not be passed onto the patient's children. (Constrast with germ cell gene therapy.)

somatotropin
Growth hormone. Bovine somatotropin (BST) is used to increase milk production. Work is proceeding in using the hormone to decrease the fat content of meat in pigs and sheep.

sticky ends
Short single-stranded sequences of DNA capable of binding to short, complementary stretches on other DNA molecules.

substrate
The target for an enzyme's action.

Tay-Sachs disease
An inherited disease, occurring predominately in Ashkenazi Jews, due to a genetic defect in an enzyme, hexosaminidase A, which leads to abnormal accumulation of certain fats in nerve cells causing severe mental retardation and death.

territory
An area or volume of the environment which is defended by a particular organism. Territories are often associated with breeding behaviour. (Compare with 'range'.)

tetanus
Also called 'lockjaw'. A disease caused by the toxins of the bacterium *Clostridium tetani*. Spores of the bacteria can be present in the soil and can gain access to the body via cuts. Symptoms include sustained muscular spasm, contraction and convulsion.

thymine
One of the small molecular building blocks called bases, which make up the coding units of DNA and RNA. Often abbreviated to T. In DNA, pairs with adenine (A).

tissue plasminogen activator
An enzyme used to dissolve blood clots. The chemical has been produced by biotechnology.

tissue typing
The process by which scientists determine the genes of a person which are important for organ transplantation.

toxin
A poison.

TPA
Tissue plasminogen activator - a chemical produced via genetic engineering which is used to dissolve blood clots. It is an alternative treatment to the use of streptokinase which is derived from a bacterium.

transcription
The process whereby the DNA double helix unwinds and an RNA copy of a gene is synthesized complementary to one of the strands.

transduction
The transfer of genetic information from one bacterium to another through the agency of a bacteriophage. Bacterial genes become incorporated into the phage particles which, after release from the dead host cell, act as vectors in transporting this genetic material into other bacterial cells.

transfection
Insertion of DNA into a cell without a vector and integration of that DNA with the cell's own genes. Generally an inefficient process but occurs sufficiently frequently that, if transfected cells can be selectively grown, genetic engineering can be achieved.

transfer RNA (tRNA)
An abbreviation of amino acid transfer RNA. Each particular transfer RNA molecule can ferry a particular amino acid to the right spot on the ribosome, thus helping in protein synthesis.

transformation
When applied to bacteria, this term means acquisition by a bacterium of new genes following infection of that bacterium by DNA carrying these genes. When applied to animal cells, this terms means conversion of the cell from a normal, noncancerous cell to an abnormal, cancerous cell capable of causing a tumour when injected into an animal. Transformation in animal cells can be 'spontaneous' or can be caused by certain oncogenic animal viruses or by carcinogens.

transgenic animals
Are produced by genetic manipulation techniques. Fertilised eggs are injected with foreign genes, such as those that promote growth, modifying the animal's genetic makeup. This new genetic code is then passed on to the offspring.

translation
The process by which the coded message in messenger RNA is read, resulting in the formation of a corresponding protein.

transposons
Mobile stretches of DNA which can move around within the genome instead of (like most DNA) residing in one place in the one chromosome.

triazines
A group of herbicides based on a six member ring structure containing three nitrogen atoms. Applied to the soil, the chemical inhibits photosynthesis. One type is a fungicide.

tryptophan
An amino acid which was taken to alleviate insomnia and premenstrual tension. It was associated with a disease, eosinophilia myalgia syndrome (q.v.).

uracil
A base unique to RNA informationally equivalent to thymine in DNA. Abbreviated to U.

vaccine
A substance which confers protection against a pathogen. The vaccine is sufficiently similar to the pathogen to evoke an immune response which is effective against the pathogen, but the vaccine does not itself cause an acute form of the disease.

vacuole
A sack-like subcellular entity in a cell which looks relatively translucent in the electron microscope. Frequently involved in transporting food into the cell or some product out of the cell.

vector
A tool of the genetic engineer used to transport recombinant DNA into a host cell and to permit its extensive replication there independently of the replication of the cell's own DNA; a generic term covering phages, plasmids, cosmids and other types of mobile DNA.

viroid
A class of viruses that occurs in plants and animals as a naked strand of RNA, which is infectious but lacks the genetic information to specify a protein coat.

virulent
Extremely infectious.

virus
The smallest and simplest form of life. Micro-organisms which are obligatory parasites, capable of multiplying only inside living cells.

APPENDIX XI

DISSENTING REPORT

Three Members of the Committee would have preferred the following alternative recommendations.

1. **Recommendation 2**

   The Committee did **not** investigate somatic cell gene therapy. It should therefore **not** make any recommendations as to how it should be regulated.

2. **Recommendation 47**

   GMO Release Authority
   Because of the importance of releasing genetically modified organisms into the environment, each release should be subject to GMAC recommendations.

   The release should then be considered by a Joint Parliamentary Committee of Members and Senators and if recommended by that Committee for release, the matter should be subject to debate in the Parliament and the release authorised by Parliament.

FRANK FORD, MP

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