The Parliament of the Commonwealth of Australia

Genetic Manipulation:
The Threat or the Glory?

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

February 1992

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The choice of title of this report was influenced by the title of the selection of writings by Sir Peter Medawar, OM: *The Threat and the Glory—Reflections on Science and Scientists* edited by David Pyke, Oxford University Press, 1991.

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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

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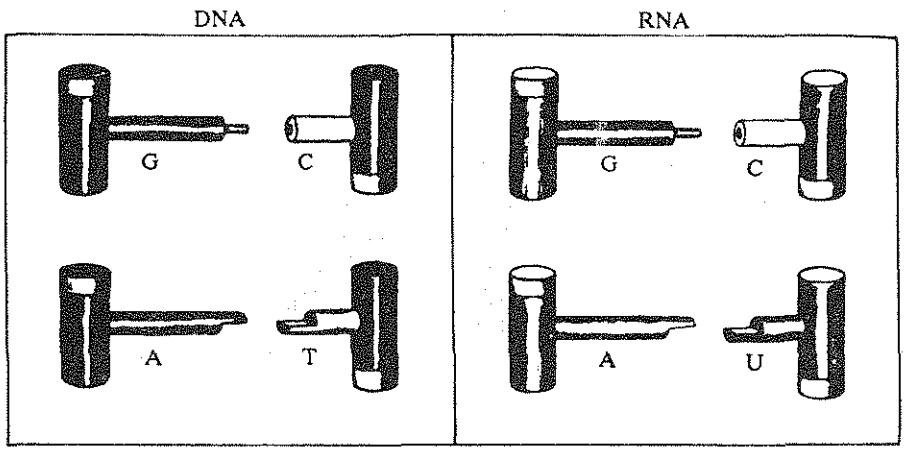
6 The sex chromosomes in a male mammal are not identical - one being an 'X' and the other a 'Y'.

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]

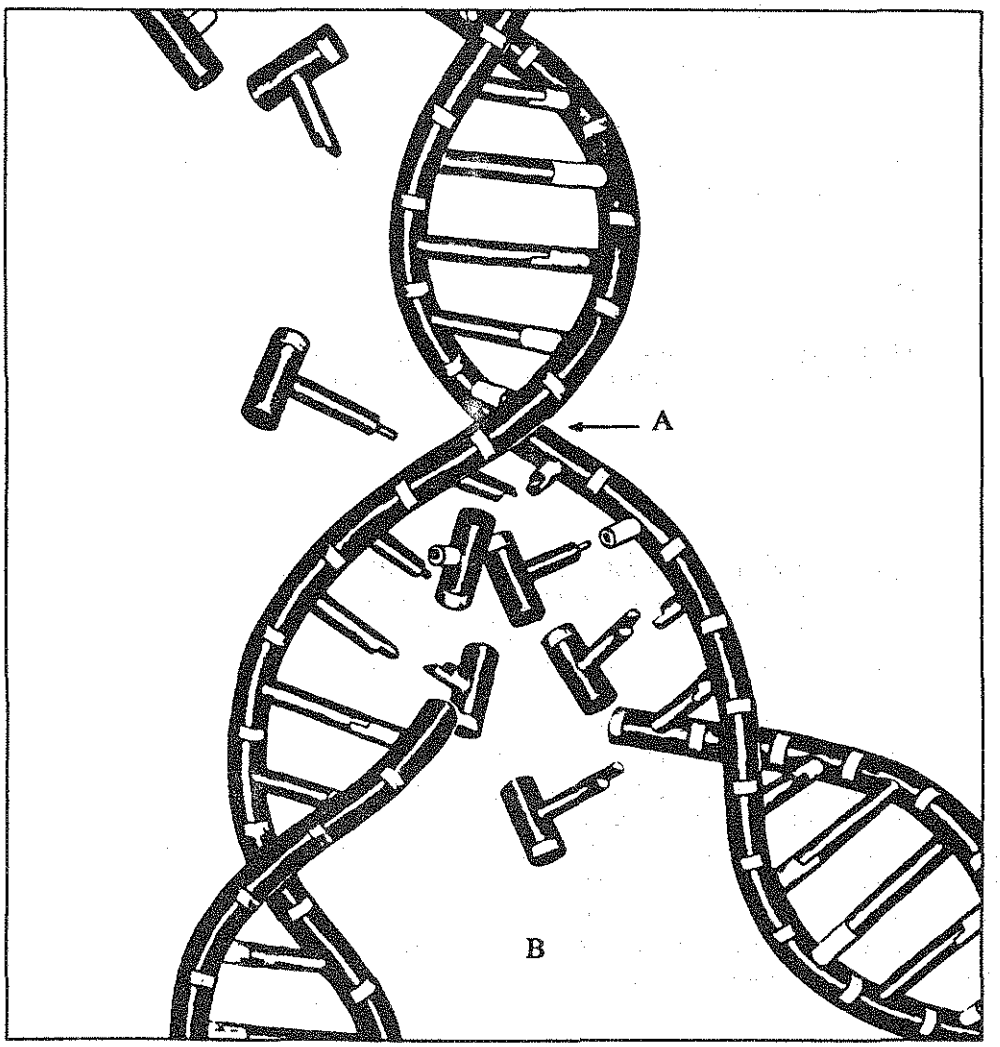
Fig. 1.1 The Types of Nucleotide



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.

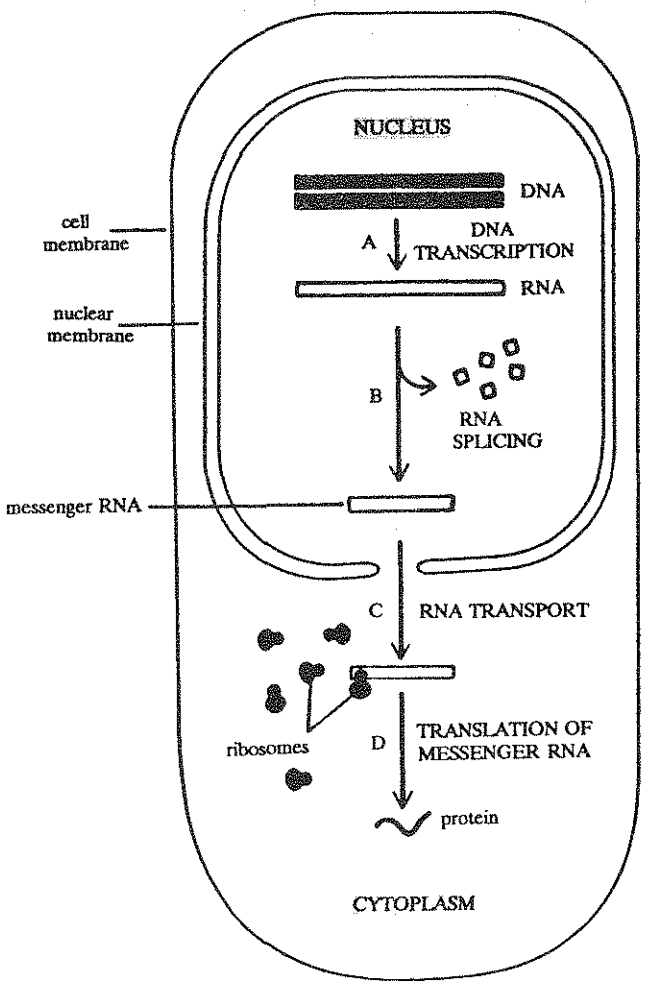
10 Nossal, G: op. cit., p 10

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.

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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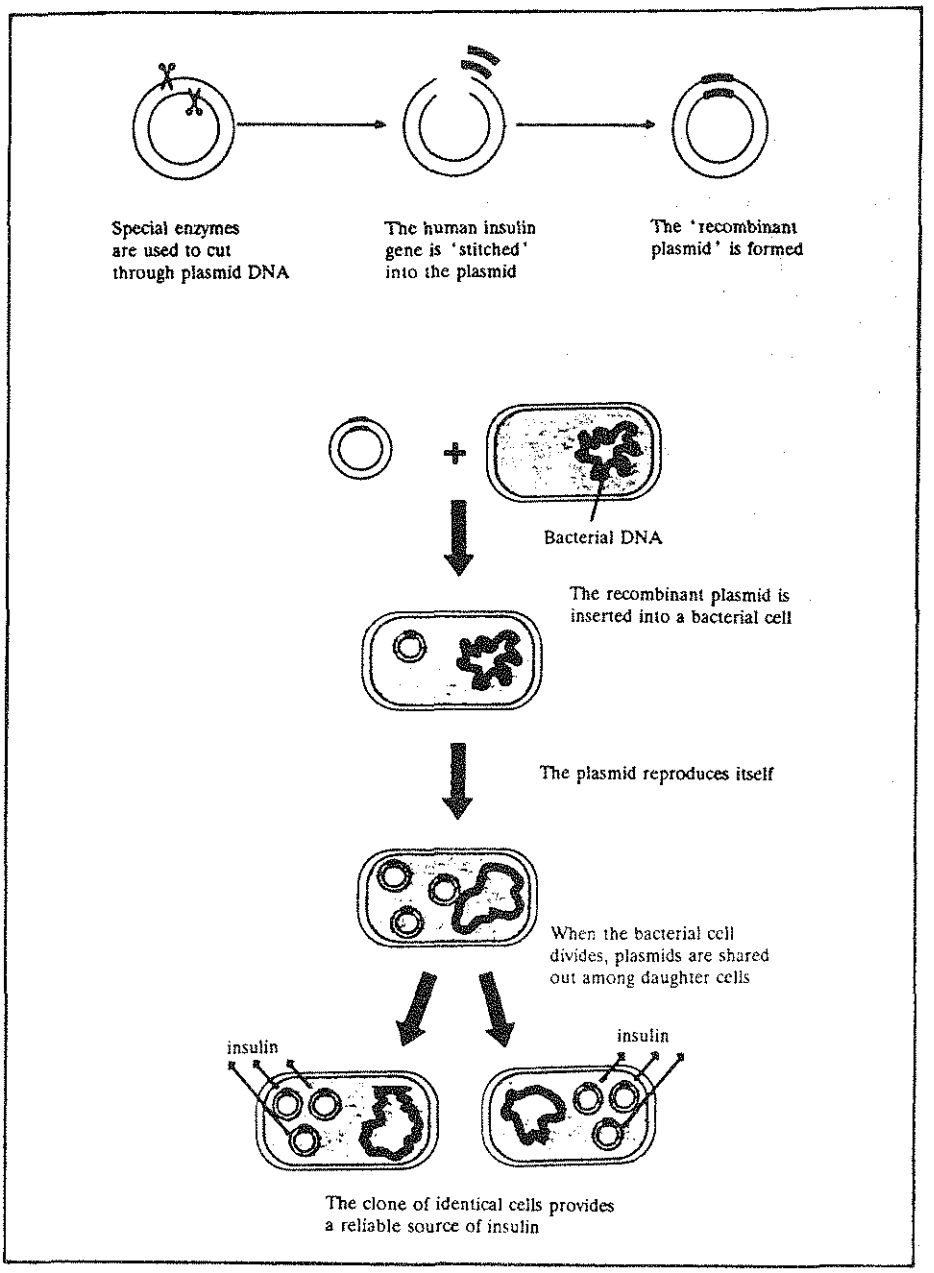
18 ibid., p 37

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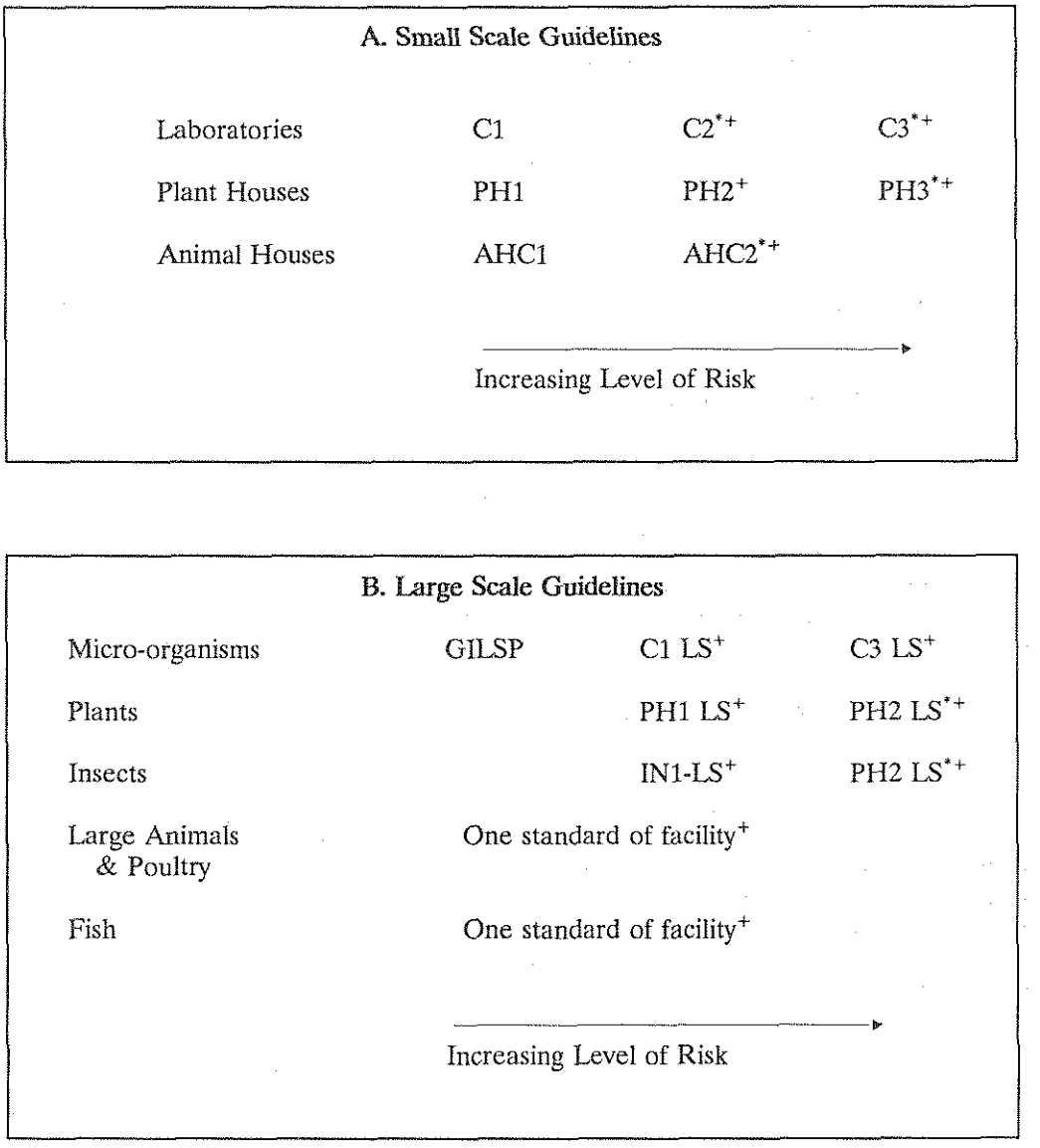
12 NH&MRC/CSIRO/AAC: *Australian code of practice*: Exhibit 47

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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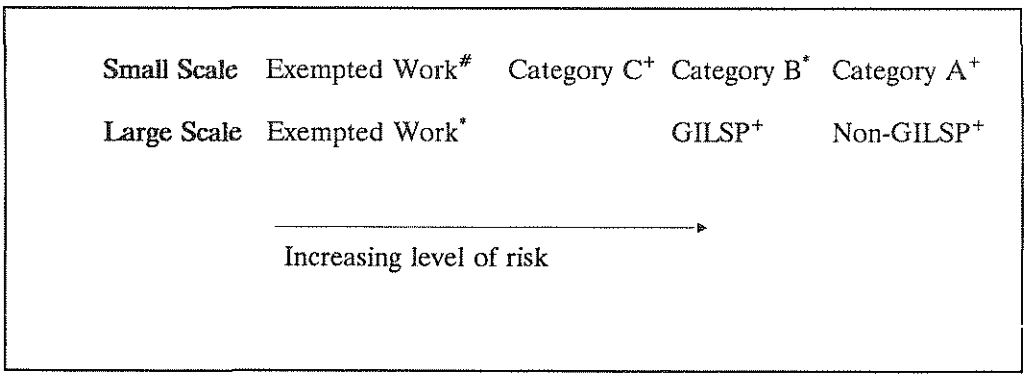
45 RDMC: *Planned release guidelines*, Section 4.8

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 <u>not</u> 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