

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

A Report to the Recombinant DNA Monitoring
Committee and the Commonwealth Department of
Science and Technology

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REGULATION OF RECOMBINANT DNA RESEARCH AND APPLICATIONS**

**A REPORT TO THE RECOMBINANT DNA
MONITORING COMMITTEE AND THE
COMMONWEALTH DEPARTMENT OF SCIENCE AND TECHNOLOGY**

BY

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FOREWORD

BACKGROUND

Biotechnology is now a rapidly developing area of technology. New products and processes have been made possible by recent scientific advances especially in the area of genetic manipulation. As with all new technologies it is necessary to be alert for new safety problems. The Commonwealth Government established the Recombinant DNA Monitoring Committee in 1981 as a means to monitor the safety of the new technology.

The Committee has no legislative base and has been instructed to operate a voluntary monitoring system while hazard assessment proceeds. A Commonwealth/State network of official contacts has been established to assist liaison with State agencies.

The Committee's terms of reference call for it to establish guidelines for the conduct of recombinant DNA work. These guidelines are to cover laboratory work (whether research or more routine), industrial/commercial processes, field and clinical trials and purposeful releases into agriculture and the environment generally.

By setting up a voluntary system which spans the responsibility of many Commonwealth and State agencies the Government has been able to act quickly to put in place for the community a set of safety guidelines and a monitoring system which if adhered to should ensure the safety of workers, the general public and the environment in this narrow but new area of technology.

The Department of Science and Technology in association with the Recombinant DNA Monitoring Committee has commissioned this consultancy study primarily to gain a much firmer understanding of the body of Australian law which may impinge upon the use of the recombinant DNA technique.

SPECIFIC PURPOSES OF THE CONSULTANCY

A Coordination of the Guidelines with Existing Regulations

The Committee's guidelines span a very wide range of activities. This range includes occupational and public health, product safety (food, drugs), agricultural practices, environment protection, transport of dangerous goods, importing and exporting.

It is highly desirable that the guidelines be framed in terms consistent with existing legislation. It is, of course, essential that the guidelines not be in conflict with any legislation. To date the Committee has attempted to identify possible conflicts by circulating drafts to State governments through the liaison network and through the knowledge of its own members.

The purpose of this part of the consultancy was to identify and briefly describe the major Commonwealth and State laws which regulate the activities the Committee must monitor or its guidelines must cover, and identify the agencies responsible for the administration of these laws.

B Alternative Mechanisms to Perform this Monitoring Function

The Committee's terms of reference require it to report by October 1986 on the need to continue monitoring. This was included in the terms of reference in recognition of the fact that few, if any, safety problems directly related to recombinant DNA had been, in 1981, identified. Thus a re-evaluation after five years operation of the need to continue to pay special attention to this area was seen as prudent.

Without in any way pre-empting the outcome of the Committee's assessment, or the Government's consideration of its report, it is recognised that if a decision is made to continue monitoring then options other than continuing to use a stand-alone committee may warrant consideration.

The purpose of this part of the consultancy was to identify possible options for having the monitoring function performed in whole or in part by existing agencies as an additional aspect of the statutory tasks they are already required to perform.

One part of the task was to identify those aspects of the Committee's tasks which are poorly regulated or unevenly treated in different States.

For administrative convenience governments are likely to be attracted to options which require little or no amendment of legislation. Irrespective of this the consultant was asked to consider otherwise attractive options which may involve some changes to legislation. The consultant was also invited to consider whether viable options exist for the introduction of specific legislation to cover this work as a whole. In evaluating this latter option there is a need to take account of the often substantial cost involved in establishing and operating a new inspectorate or a reviewing authority. It should also be recognised that while resolution of compensation claims is an important issue the main aim of this monitoring and hence any special legislation would be to minimise the prospect of any damage being done in the first place.

C The Capacity of Existing Laws to Control Recombinant DNA Work

To date the voluntary monitoring system has been successful in obtaining compliance with the guidelines. In the light of these circumstances it is assessed as very unlikely that governments will need to use the force of law to control individuals or organisations performing this work.

However, since the consultant was required to review most relevant legislation for the first two elements of this consultancy the opportunity was taken to request a list of laws which could, if required, be immediately used to control an organisation which refused to follow the guidelines and was doing work which the Committee considered had some hazard associated with it.

While the threat of punishment may be sufficient to cause an organisation to follow the guidelines, it was considered preferable that laws be identified which allowed for immediate intervention by government to cease the work.

Department of Science and
Technology

PREFACE

The threefold purpose of the Report is set out in Part 1, Section 1.1. Broadly, the Report identifies legislation in nine Australian jurisdictions - the Commonwealth, six States and two Territories - which is of relevance, or of possible relevance, to recombinant DNA research and technological applications in Australia.

Unavoidably, given this primary task, it has not been possible in the Report to analyse fully every relevant statute. Indeed, it may be that some relevant statutes have been overlooked.

Common law regulation of recombinant DNA work has been mentioned in the Report, but is not the subject of detailed discussion.

The deliberately narrow focus of the Report has also meant that the wider ethical, philosophical and social implications of recombinant DNA work have not been addressed.

Finally, I would like to record my thanks to Richard Harding AM for his conscientious research assistance. Without his help, the Report could not have been prepared in the time available.

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June 1984

PART 1: AN INTRODUCTION TO THE LEGAL REGULATION OF RECOMBINANT DNA IN AUSTRALIA

1.1 THE OBJECT OF THE REPORT

This Report has three broad objectives:

1. the identification and description of major Commonwealth, State and Territory laws having relevance to the monitoring and regulation of recombinant DNA work in Australia;
2. the identification of the various administrative structures available in Australia to monitor or regulate recombinant DNA work, being structures alternative to the Recombinant DNA Monitoring Committee which currently operates under the aegis of the Commonwealth Department of Science and Technology; and
3. an assessment of the capacity of existing Australian laws effectively to monitor and regulate recombinant DNA work.

1.2 WHAT IS DNA?

Many biologists consider the explanation of the structure of DNA by Watson and Crick in 1953, to be probably the single-most important discovery in biology.¹ Biology, of course, is the branch of knowledge that deals with living organisms and life processes; DNA (or Deoxyribonucleic acid) is at the root of these processes, comprising the genetic material of all cells and many viruses.²

As it has been further explained, in not too technical a way,

"DNA is a double helix, containing two strands wound around each other. The crucial parts of the structure are the bases C (cytosine), G (guanine), A (adenine) and T (thymine) in the centre and they constitute the genetic program. The sequence of these four bases, essentially the letters of the genetic alphabet, spells out all the genetic information."³

The genetic information is made up of a series of units (or "sentences") which are called "genes". In simple terms, the "secret of life" is in the replication of DNA. In the usual living processes, an organism passes on its genetic information to the next generation of that organism. Thus life goes on, and each succeeding generation of an organism carries with it the genetic information and design of its predecessor. Of course, an exchange of genetic information might also occur in the natural crossing of organisms of the same, or very closely related, species.

1.3 GENETIC ENGINEERING

This is an expression suggestive of an ability in biologists to engineer a change in the genetic features of organisms which would not occur naturally. As the Australian Academy of Science has explained, ever since humans tamed dogs or horses, and became agriculturalists, selective breeding - or "genetic engineering" -

has been practiced to produce animals and plants of a desired kind.⁴

The expression has, however, been used in various contexts, especially in relation to human reproductive techniques designed to produce embryos of a predetermined sex.⁵

It is, though, since the development of a scientific technique which enables the deliberate recombination of DNA molecules - recombinant DNA work - that the expression has assumed a connotation in the realms of science fiction quite different from its proper denotation.

1.4 THE RECOMBINANT DNA TECHNIQUE

Whereas genetic information might be exchanged in the natural crossing of organisms, as noted above, the recombinant DNA technique allows an exchange to be engineered by scientific methods. Thus, genes not natural to a particular organism might be introduced into it, through its DNA molecule, and subsequently be expressed as a new gene in the organism when it is reproduced.

This technique has been described more technically in the following terms:

"Recombinant DNA techniques permit DNA from a donor species to be excised by a special enzyme (an endonuclease) and joined by a ligating enzyme to the DNA of a vector whose DNA has been cut by the same endonuclease. The resultant hybrid, or recombinant DNA (rec DNA) molecule can then be introduced into an appropriate host organism, and under the right conditions, the recombinant molecule is replicated along with the host DNA and the introduced genes are expressed. In this way the host can acquire novel properties which it could not have acquired by conventional breeding methods."⁶

It is, of course, the uses to which the recombinant DNA technique might be put which today spark the human imagination. Commercial and public research enterprises involved in the "biotechnology" industry - in which recombinant DNA work is relevant - envisage important potential uses in the pharmaceuticals, chemical, energy and agricultural industries. But, as Dr Herman Lewis has noted,

"(i)t has been said that the application of this technology is limited only by the limits of our imagination. The technique permits the isolation of genes not normally accessible to genetic manipulation. These could include specialized properties of humans, elephants, eucalyptus trees, kangaroos, koala bears, electric eels, organisms that live under the pressures at the depth of the seas, in high temperatures of hot springs, or the low temperatures in the ice at the poles of our planet".⁷

Particular uses and potential applications of recombinant DNA technology are discussed further later in this Part of the Report.

1.5 THE RECOMBINANT DNA CONTROVERSY

Controversy with respect to recombinant DNA work appears to have its starting point in about 1973. The controversy, its nature and history, makes fascinating reading; here, the significant aspects of the controversy will merely be raised as the details are fully described elsewhere.⁸

Between 1971 and 1973, in the United States, researchers at different research institutions began to develop prototype recombinant DNA techniques. At Stanford in California, for example, Paul Berg was experimenting with tumor viruses. When another cancer researcher, Robert Pollack, came to hear of this recombinant work with the tumor virus he "had a fit".⁹ As Stanley Cohen, also a researcher at Stanford who helped develop the recombinant technique, later put it: we became "concerned that manipulation of certain genes could give rise to novel organisms whose infectious properties and ecological effects could not be predicted."¹⁰

In the late part of 1973 and into 1974, a chain of events ultimately resulted in a moratorium on recombinant DNA research. In September 1973, a letter generated by the Gordon Research Conference, signed by Singer and Sill, was published in Science.¹¹ This letter called for further study into the hazards to laboratory workers and the public.

In July 1974, the "Berg" letter was published in Science,¹² and in its British counterpart, Nature. This letter carried the recommendations of a committee of a small group of scientists which was asked to formulate the (US) National Academy of Sciences' response to the Singer and Sill letter. Essentially, the Berg committee proposed a moratorium on recombinant DNA research until potential hazards could be better evaluated.

Three things might here be observed: first, that the raising of the controversy was at the instance of researchers of the recombinant DNA technique; secondly, that one of the primary initial fears of the research was hazard to those engaged in it in laboratories; and, thirdly, that fears for broad ecological hazard were also voiced.

→ From the point of publication of the Berg letter in particular, the recombinant DNA controversy really escalated, in the sense that the media, politicians and the public became substantially embroiled in it: no longer was it merely an issue for discussion at research conferences. Some expressed the view that quiescent tumor cells might be activated by the recombinant technique;¹³ others argued that pathogenic or toxic proteins might be created.¹⁴ The fear clearly was that the health of laboratory workers and the general public would be put at risk by recombinant DNA research. At another level, critics of the research feared its ultimate use by terrorists or in biological warfare.

But it was probably the "Brave New World" assertions that commanded much public attention. As one commentator has put it:

"(I)t is conceivable that governments will develop an interest in using genetic engineering as a means of ordering society, and in this context the brave new world is distant but daunting".¹⁵ Or as another testified before a subcommittee of the U.S. Congress:

"(L)earning geneticists and molecular biologists have officially gone on record as favouring the kind of genetic alteration of human life that Hitler envisioned and that Huxley warned of."¹⁶

➤ Aside from human genetic manipulation for such horrendous purposes, chimerical humanoids (Frankenstein's monsters) or animals are sometimes suggested in the literature of this era as possible deleterious products of recombinant DNA work;¹⁷ not to mention the stereotype of novel genetic crosses, the "quacking orange".¹⁸

The pure science-fiction of some of these allegations tends to disguise the serious philosophical, ethical and social implications to which such research nonetheless gives rise. To some, recombination of DNA is akin to "playing god".¹⁹ Professor Robert Sinsheimer, an ardent early critic of the research technique, asked, for example, "Shall we take into our hands our own future evolution?"²⁰

Many of these implications remain with us today, especially in the area of research with humans. In other areas of research, however, such implications are not so obvious.

1.6 THE HISTORY AND DEVELOPMENT OF RECOMBINANT DNA REGULATION IN THE UNITED STATES

As a result of scientific concerns, and following an international conference held at the Asilomar Conference Centre, Pacific Grove, California, in February 1975, the U.S. National Institutes of Health (a Federal regulatory agency) in 1976 promulgated "guidelines" for research on recombinant DNA molecules.²¹

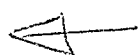
As Dr Edward Korwek has pointed out, the initial approach to Federal regulation in the U.S. was based "almost entirely on the assumption that a unique risk exist(ed) with R-DNA research."²² The purpose of the guidelines was stated explicitly to be the "protection of the laboratory worker, the general public, and the environment from infection by possibly hazardous agents that may result from (R-DNA) research."²³

Regulation itself was by means of both biological and physical containment. Biological containment is aimed at the disablement of organisms used in recombinant DNA work so that, should any escape of materials occur, they should be incapable of surviving outside the laboratory. Thus the risk of environmental disruption is reduced.

Physical containment is intended to secure safe laboratory or work-place practices so that laboratory workers, the general public and the natural environment are not brought into contact

with recombinant materials, thus again reducing or minimizing health and environmental hazards.

In the case of certain research - for example, the formation of recombinant DNA molecules derived from pathogenic organisms or from genes that are toxic to vertebrates - the NIH Guidelines were absolutely prohibitive. 

In the intervening years, the result of extensive experimentation and risk assessment is that most scientists no longer assume the existence of "unique risks" in recombinant DNA work, and the initial assumption and approach of the NIH Guidelines have now been altered. In 1981, as a result of acceptance of the view that the organism E. Coli - the one most frequently used in recombinant DNA research and technology - should be exempted from regulation under the Guidelines, it has been estimated that approximately ninety percent of recombinant DNA work is now exempt from the Guidelines.²⁴ Indeed, it has been forecast that 

"(The) general trend toward deregulation of R-DNA experiments is likely to continue, with the eventual elimination of the Guidelines as mandatory regulations, because none of the thousands of R-DNA clones produced over the past several years have caused any harm."

What perhaps is noteworthy about the U.S. experience, is that the regulation to date has been concerned with the "safety" aspects of recombinant DNA work - the safety of the worker, the public and the environment - rather than the ethical, philosophical or social implications. As the "unique risk" assumption has gradually reduced in intensity, recombinant work has begun to be monitored as but another area of science and technology having broad environmental implications. In fact, it is the technology - the applied science - that has today become the focus of regulation. 

The issue thus now arises whether, on the one hand, we require special regulatory structures to monitor and control all aspects of recombinant work or whether, on the other hand, existing regulatory structures in such areas as occupational health and safety, public health and environmental protection, are capable of integrating recombinant DNA monitoring and control with their existing responsibilities and duties.

1.7 THE HISTORY AND DEVELOPMENT OF RECOMBINANT DNA REGULATION IN THE UNITED KINGDOM

Although recombinant DNA research and technology are not activities exclusive to the US, it is clear that much significant work has been carried out in the US in the past decade or more. Nonetheless, important work is carried out also in the UK, Western Europe and Japan, and many countries in these regions have endeavoured to regulate recombinant DNA work to some extent. In this section we will briefly account for the history and development of regulation in the UK.

The background to regulation in the UK is usefully described elsewhere.²⁶ Briefly, the UK story parallels that of the US. As

noted above, in 1974 the "Berg" letter was published simultaneously in the US and the UK. Prior to it, however, a report of the British Association for the Advancement of Science²⁷ had discussed the implications of advances in genetics and microbiology. Then, after two deaths from an accidental release of smallpox virus from a London laboratory in 1973, a Committee of Inquiry reported to Parliament.²⁸ In 1975, a further working party, under the chairmanship of Sir George Godper, reported on the use of dangerous pathogens in laboratories.²⁹

Following the publication of the "Berg" letter, another working party, chaired by Lord Ashby, reported on the potential benefits and potential hazards of "experimental manipulation of the genetic composition of micro-organisms." The report of this working party recommended that research be allowed to continue, but that steps be taken towards the physical and biological containment of risks.³⁰ It was, however, left to a further working party, that of Sir Robert Williams, to draft a code of practice and make recommendations for the establishment of an advisory service for laboratories involved in recombinant DNA research.³¹

Following this report, in late 1976, a Genetic Manipulation Advisory Group (GMAG) was established which, on a purely voluntary basis, advised on research proposals from U.K. institutions. In 1978, the Health and Safety (Genetic Manipulation) Regulations were promulgated under the Health and Safety at Work Act 1974 (U.K.). These regulations were aimed at securing the safety of laboratory workers. As Cripps has noted, they did not extend to the protection of plant or animal life.³²

1.8 THE HISTORY AND DEVELOPMENT OF RECOMBINANT DNA REGULATION IN AUSTRALIA

In 1975, following the world-wide moratorium on recombinant DNA work, the Australian Academy of Science established the Academy of Science Committee on Recombinant DNA Molecules (ASCORD) and, soon after, published a set of guidelines governing such research.

In formulating appropriate guidelines, the Academy of Science took account of both the U.S. and the U.K. experience pertaining to regulation. In the event, the guidelines produced for Australian purposes were considered

1. to place greater reliance than in the U.S. on physical containment requirements, preferring instead the U.K. approach;
2. to place greater reliance than in the UK on biological containment requirements; and
3. to introduce flexibility into the containment levels approach by providing for each research proposal to be separately considered by ASCORD.³³

In 1980, the Australian Academy of Science recommended the establishment by the Federal government of a "Surveillance Committee" to supervise all work with recombinant DNA in Australia.³⁴ In 1981, the government duly responded to this recommendation by establishing a Recombinant DNA Monitoring Committee (together with its Scientific Sub-Committee) for the purpose of providing advice to the Commonwealth Minister for Science and Technology on the "continuing assessment of the hazards associated with the production and/or application of material incorporating recombinant DNA molecules unlikely to occur in nature."³⁵ The monitoring committee continues to operate.

The ASCORD guidelines were replaced by guidelines of the Recombinant DNA Monitoring Committee. Current guidelines issued by the Committee relate to both small scale and large scale recombinant work. Guidelines to deal with the deliberate release of recombinant organisms into the environment, are currently being drafted by the committee (see section 3.2 for further details).

The Guidelines are purely administrative in character and do not, of themselves, have any legal force or effect. They may, however, be incorporated in contracts of employment between researchers and employers, or in funding grants from government or other bodies. In this way effective legal constraints may in practice be imposed on research in Australia.

Private or commercial research and technology which does not depend on outside or public funding is, therefore, legally immune from the imposition of such controls and, theoretically, might not have to comply with the Guidelines. Good commercial practice in Australia should ensure that the possibility of non-compliance remains "theoretical".

Apart from these administrative measures, existing Australian laws, some of the Commonwealth, but mainly of the Australian States and Territories, are capable of having some application to recombinant work where it has implications for occupational health and safety, public health, primary industry practices and environment protection. The law, to the extent that it is relevant, was not, of course, specially designed to deal with the possible hazards associated with recombinant work.

1.9 AN INTRODUCTION TO RECOMBINANT DNA RESEARCH IN AUSTRALIA

A decade ago, the recombinant DNA technique was first being developed and perfected. The mere existence of the technique, though imperfect, gave immediate rise to fears for occupational and public health and safety as well as for the safety of ecological systems. Additionally, and perhaps most extravagantly, the ethical, philosophical and social implications of "playing God" confronted and confounded scientists and non-scientists.

A decade later, today, the environmental safety fears of recombinant work have been somewhat allayed, although the other

set of implications remain unanswered. Experience with the recombinant technique may well provide the explanation for this, for it has been used to develop research into, and applications in, areas of traditional concern and inquiry for society and scientists - the provision of scarce drugs and other pharmaceuticals; the improvement of plant breeding; the enhanced recovery of oil and minerals. Whilst the technique has been, and is, used for "good", the implications and fears of its use for "evil" remain far below the surface of society's and the scientist's consciousness.

Revealed by survey

In Australia there is currently being carried on a broad range of research involving the recombinant DNA technique.³⁶ Under the current guidelines of the Recombinant DNA Monitoring Committee, Institutional Biosafety Committees play a key role in the approval and supervision of research work in public research institutions such as universities, and in private commercial laboratories.³⁷ The committee performs an overall monitoring function in relation to such research.

1.10 AN INTRODUCTION TO POTENTIAL RECOMBINANT DNA APPLICATIONS

The recombinant DNA technique may be applied outside the research context in basically two important ways. First, the technique may be used to replicate (or clone), an organism so that a valuable, non-living, substance in it, or product of the process, will exist in useful commercial quantities. Thus, the recombinant technique may potentially be of great use in the manufacture of pharmaceuticals, medicines, chemicals and food, as explained in a little more detail below.

Secondly, the technique may be used to produce novel organisms, that is, living things which did not previously exist in nature, for socially useful purposes. Used in this way, the technique may be useful in producing modified strains of plants or animals, or special organisms capable of enhancing oil and mineral recovery, improving agricultural practices or acting as a cleansing agent in some cases of pollution. It would also enable the production of live vaccines in the pharmaceutical and medical industries for use in the treatment of animals and plants, and humans.

Pharmaceutical and medical applications of the recombinant technique might enable the production of important hormones (insulin and growth hormones, eg), immunoproteins (eg, vaccines for viral hepatitis, herpes, interferon), enzymes (for the treatment of blood disorders) and other proteins, as well as non-protein pharmaceuticals (eg, many antibiotics) more cheaply and plentifully than is presently possible.

A number of major chemicals are currently produced by a fermentation process using micro-organisms and may be more easily and economically produced by recombinant means. These would include such end products of normal metabolism as alcohols and solvents, primary metabolites of biosynthesis such as amino acids and nucleotides, secondary metabolites such as antibiotics, pigments and surfactants, and transformations such as steroids

and hydrocarbons. These products have a wide range of uses in the manufacture of fertilizers, plastics and pesticides.

Similarly, in the food industry, the fermentation processes which are currently used in baking, brewing and winemaking might be replaced with the recombinant technique. The technique might also be used either to transform edible biomass (animal or plant material) into food for human consumption or animal feed.

Leaving aside the production of live vaccines for medical purposes, the recombinant DNA technique when used for any of the purposes just discussed, produces, or is used as an aid in the production of, a non-living thing. However, it might also be used to produce a novel organism.

In primary industry, there is the prospect of using recombinant means to engineer new strains of crops having disease, pest and drought resistant qualities; or a new plant strain that returns increased amounts of nitrogen to the soil ("nitrogen fixing" plants). New organisms might also be created to serve agricultural needs, for example, the "bug" designed in the United States to cause the formation of frost on crops at lower temperatures than at present, thus reducing the frost damage potential of many important crops. In animal production, recombinant work has significance not only for improved vaccines, as noted, but also in animal breeding.

In the mining and other physical environmental areas, micro-organisms might be used, for example, in the mineral leaching process by better isolating valuable minerals from a solution of mixed substances; and also for the purpose of minerals recovery from waste dumps or waste products.

Micro-organisms designed to "eat" other substances might equally be used to recover oil from wells, in the clean-up of oil spills on water, and to degrade and de-toxify sewage and industrial toxic solid and liquid wastes.

These various applications of the recombinant DNA technique fall within the scope of the Recombinant DNA Monitoring Committee's monitoring functions.

1.11 FACTORS LEADING TO THE APPLICATION OF RECOMBINANT DNA TECHNIQUE

The widespread application of the recombinant DNA technique will depend upon a number of factors. First, it is necessary to appreciate that for many years means alternative to that of the recombinant technique, many already utilizing micro-organisms, have been available and used to produce pharmaceuticals, chemicals, foods, to recover minerals and oil, and to clean-up pollution. Selective animal and plant breeding is, of course, an activity humans have pursued for hundreds of years. The promise of recombinant technology is that it may enable the easier performance of these tasks, and the production of higher quality and safer products as well as in the case of some products, a higher volume of them than is possible by alternative technologies.

Whether the recombinant technique will be preferred to other technologies will depend on a careful balancing of these perceived advantages with concerns for the industrial safety of the technology, the environmental hazard it presents and its financial cost to industry.

1.12 RECOMBINANT DNA APPLICATIONS IN AUSTRALIA

Clearly not all potential applications will be carried on in Australia. In a 1981 review report of the CSIRO it was noted³⁸ that

"Australia cannot hope to carry out the necessary research to realise the potential in all these fields. There is however, world-ranking research in progress in fields of high relevance to biotechnological development and it would be provident to concentrate resources for their support and extension and to encourage maximum communication and collaboration between those working in these areas. Further, there are special Australian needs and opportunities in biotechnology which are unlikely to be studied and developed elsewhere."

Having identified six principal areas appropriate to Australia,³⁹ the review report clearly foresaw Australia developing the following recombinant technologies

- . Gene expression
- . Gene transfer systems
- . Diagnostic probes
- . Antibodies for diagnostic purposes
- . Vaccines against infectious diseases and parasites of animals.
- . Proteins important in animal husbandry
- . Ethanol production
- . Ligno-cellulosics from agriculture and forestry
- . Starch from cereals and cassava
- . The bioconversion of certain wastes into useful products
- . Mineral recovery.

Whether Australia will develop recombinant technology in these ways only time will tell.⁴⁰ In the primary industry field, however, the CSIRO clearly are advancing their researches; wider ranging industrial applications may also appear in the not too far distant future.⁴¹

1.13 THE HAZARDS OF RECOMBINANT DNA WORK

The hazards of recombinant work may arise basically in two ways. First, in the course of research or in the application of the technique, there might occur an accidental release of substances into the work place and the broader environment. Secondly, as a result of successful research or its application, there might occur a deliberate release of a novel organism into the broader environment.

Should an accidental release of recombinant substances occur there might be a health and safety risk to those in the workplace, often a laboratory, as well as the risk of pollution should the substance escape from the workplace. Because recombinant work involves living organisms, and sometimes pathogenic ones, a broad environmental risk is heightened.

In the case of deliberate release of a novel organism, the broad environmental effects of its release may not easily be predicted. A novel organism may have both a direct impact on the environment and an indirect one. (For example, assume a micro-organism were specially designed to clean up oil spillages at sea. It may be that the novel organism is effective in "eating-up" the oil, but should the organism survive in the marine environment after the clean-up, what will its impact be on the pre-existing delicate marine ecology? It is possible, of course, that the novel organism by surviving will displace some naturally occurring organism and so disrupt the environmental balance. Every time the deliberate release of a novel, or recombinant, organism is proposed, its environmental impact in its host environment, and on the broader environment, must be contemplated in terms similar to those in this example. ←

1.14 REGULATION: ADMINISTRATIVE SURVEILLANCE OR LEGAL CONTROL?

A recurring theme in the recombinant DNA controversy is the extent to which scientific research should be the subject of regulation. Regulation, in this context, means any form of outside guidance or control, whether of learned institutes or of government.

If a form of regulation is deemed appropriate another question must be answered: should regulation be of a voluntary kind or compulsory?

These questions seem to arise whenever human activities, scientific or otherwise, carry with them any serious risk of human or environmental hazard or have serious ethical, philosophical or social implications. At the outset of the 1970s, recombinant DNA work, of course, was deemed to carry such risks and involve such implications; hence the justification for some outside intervention in, some regulation of, the research and technology.

As we have seen, at least in the United States, the trend has been towards deregulation of recombinant work. After exemptions, it seems that today only about ten per cent of such work in the US is directly regulated by the NIH Guidelines. Yet this observation, if left to stand alone, fails to note the legal developments which are occurring in the US simultaneously with deregulation. As research is applied, as technology prospers and the biotechnology industry becomes a reality, regulation, in a legal sense, appears to be increasing. Indeed, Dr Korwek, writing with reference to United States developments, predicted some three years ago (1981):

"If the trend towards relaxation of the Guidelines continued to the point of their being eliminated as mandatory regulations, governmental agencies are likely to become more visible in regulating R-DNA activities. OSHA (The Occupational Safety and Health Administration) presently is evaluating and developing a regulatory policy on R-DNA because of its concern with the protection of workers from existing or potential hazards that might be peculiar to the biotechnology."⁴²

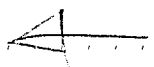
Consequently, it should be carefully noted that there is today considerable discussion in the US concerning the capability of traditional and existing legal means to control, if necessary, hazardous recombinant work. Occupational safety and health legislation, public health legislation, laws relating to toxic and hazardous substances and agricultural practices, and, particularly, the law relating to environmental risk assessment, are increasingly referred to in this context. Some of these laws are capable, without amendment, of applying to recombinant DNA work. Others may only require fine-tuning to have application.

It is important to observe, therefore, that whatever the force of the movement away from single-purpose recombinant DNA monitoring or regulatory bodies, there is, or is developing, a movement (perhaps with an equal and opposite force) to subsume substantive legal regulation of recombinant work under existing safety, health and environmental legal regimes. On the other hand, as the large number of exemptions to the NIH Guidelines perhaps exemplify, the substance of regulation has, over the decade, been reduced, even though the potential for legal regulation may today be greater.

In Australia, since 1975, compliance with guidelines respecting recombinant work has been voluntary, supervised at first by a committee of the Academy of Science, and later by the Recombinant DNA Monitoring Committee within the Commonwealth Department of Science and Technology. Four main reasons have been advanced in support of the Australian voluntary approach:

1. That compliance with guidelines in many other countries is voluntary;
2. That in a relatively small research community in Australia 'peer pressure' is an important factor in the screening and monitoring of safe recombinant DNA work;
3. That most research work is carried out under grants from the Australian Research Grants Scheme (ARGS) and from the National Health and Medical Research Council (NH&MRC) which are made subject to compliance with the guidelines; and
4. That biosafety committees overseeing recombinant work in Australia have a firm, if not legal, basis having been established by the research institutions themselves.⁴³

Without pressing this issue to resolution, it may be suggested that as Australian research expands from public to

private institutions, as the research is increasingly applied and, indeed, if overseas experience suggests the need for greater legal regulation, then the initial Australian approach to the voluntary/compulsory, surveillance/ control, issue may need rethinking. 

1.15 COMMONWEALTH-STATE POWERS AND RESPONSIBILITIES

Since the federation of the Australian States in 1901, and the formation of a national political entity - the Commonwealth of Australia - the extent of the powers and responsibilities of each level of government has been the subject of continual discussion, not to say tension. As novel problems confront the Australian community, the question often arises whether the Commonwealth, or a State, government has power to deal with the matter. Whether the Commonwealth or a State has power with respect to recombinant DNA work in Australia is not an issue lending itself to definitive resolution, although a number of propositions can be stated with relative certainty in the course of discussion.

First, it is clear that, apart from certain powers which are exclusive to it, the Commonwealth Parliament only has power to make laws with respect to those matters enumerated in s.51 of the Commonwealth Constitution. Unless a Commonwealth power is appropriate, in some aspect, to the regulation of recombinant DNA work, then its regulation is a matter exclusively within the legislative competence of each State.

If the Commonwealth does have power to deal with the matter in some respect under s.51, its power to do so is concurrent with that of the States. In the event of conflict between a Commonwealth and a State law, s.109 of the Constitution provides for the Commonwealth law to prevail to the extent of any inconsistency between the laws.

In the light of these principles it is clear that the Commonwealth has exclusive powers to control all aspects of recombinant DNA work in the area of the Seat of Government (under s.52) and in Commonwealth Territories (under s.122).

Since a measure of self-government was granted to the Northern Territory in 1978, the Commonwealth today no longer retains a primary responsibility to make all laws in this jurisdiction, although it may disallow laws made by the Northern Territory Legislative Assembly.⁴⁴

So far as its national powers under s.51 of the Constitution are concerned, the potential is great for the enactment of valid Commonwealth law relating to various aspects of recombinant work. The potential arises from the power of the Commonwealth parliament under s51, to make laws with respect to many matters which may affect the viability of recombinant work, including

- . quarantine;
- . trade and commerce with other countries and between the States;
- . bounties on production;

- . foreign corporations, and trading and financial corporations formed within the limits of the Commonwealth;
- . sickness benefits;
- . copyright;
- . defence;
- . external affairs.

Part 4 of the Report discusses some of these powers in a little more detail. Additionally, it should be noted that the Commonwealth might also legislate with respect to matters referred to it by a State. This power, clearly, would provide the vehicle for national legislation on the broad topic of DNA.

Aside from these express legislative powers, it has also been suggested by the High Court of Australia that the Commonwealth is possessed of a "national implied power". Most High Court Justices agree that "there is to be deduced from the existence and character of the Commonwealth as a national government and from the presence of ss51(xxxix) and 61 a capacity to engage in enterprises and activities peculiarly adapted to the government of a nation and which cannot otherwise be carried on for the benefit of the nation."⁴⁵ It seems to be accepted that this power would enable the Commonwealth to establish research bodies (such as the CSIRO) and to expend moneys on inquiries, investigation and advocacy in relation to matters affecting public health.⁴⁶

The national implied power might possibly support a Commonwealth law dealing with such an important matter as recombinant DNA research and technology control or, at least, a power to involve itself in research and financial support in the area. As Commonwealth funding may be significant, Commonwealth control of the purse strings may be a powerful means of indirect control of recombinant work. Of course, the existing powers of the Commonwealth with respect to project funding under s96 of the Constitution already enable it to achieve much indirect control of projects through conditional, or tied, grants.

All this is not to say that the Commonwealth will, or should, exercise its undoubted powers of regulation over various aspects of recombinant work. Whether such powers are used will doubtless depend on the means politically considered the best for achievement of a satisfactory uniform approach to the regulation of recombinant DNA work in Australia, should regulation be considered necessary.

1.16 THE STRUCTURE OF THE REPORT

With this background, the Part 2 of the Report will proceed to identify the law in Australia relating to the accidental release of recombinant DNA substances into the environment. Worker and public health and safety considerations, as well as broader environmental concerns, will provide the focus of this part of the Report.

Part 3 of the Report will examine the problems posed by the deliberate release of recombinant organisms into the environment, and the legal controls which may be relevant to such acts.

Finally, in Part 4, the Report will seek to analyse the comprehensiveness and effectiveness of existing laws and administrative structures to monitor or control recombinant work in Australia, and comment on the means available, should it be considered necessary, to improve the existing administrative and legal regimes.

PART 2: ACCIDENTAL RELEASE

2.1 INTRODUCTION

This Part of the Report seeks to identify laws relevant to the release of substances accidentally from the recombinant DNA process. As discussed in Part 1, recombinant work at either the research stage or during application of the recombinant technique, may result in an accidental release of substances into the workplace or by way of overflow into the environment. Some of the substances released may have implications for the health and safety of workers and the public, and for the environment in an ecological sense.

Such controls as do exist in Australia may be considered to operate at two levels. First, there are those controls which seek to prevent or minimize the likelihood of an accidental release, or enable preventive action to be taken should it occur. Thus we shall examine the Guidelines of the Recombinant DNA Monitoring Committee attached to the Commonwealth Department of Science and Technology; laws designed to secure safe and healthy workplaces for those in research and industrial occupations; and laws enabling the control of the spread of disease to humans, plants and animals in the event of an accidental release.

Secondly, there are laws which, without seeking to impose a control regime in the sense just described, create explicit sanctions for certain proscribed acts or activities. Thus we shall examine, in the main, laws proscribing pollution. Of course, the preventive controls, if they have been exercised, may also proscribe conduct. To the extent, therefore, that the first level of controls do create sanctions they will also be mentioned.

A number of things will become obvious in the course of discussion of these various controls. First, that save for the Monitoring Committee's administrative guidelines, such controls as may here be relevant are so only incidentally, for they were not specially designed to deal with the accidental release of substances from recombinant work. This is not something to be marvelled at, however, for it is in the nature of the subject areas of concern that legislation should be broad and enabling so that government can take action in respect of necessarily unforeseen events.

Secondly, a matter of comment arising out of the first point, there is no particular rhyme or symmetry to some of the laws we shall examine in this Part. Laws operating at the second level, creating sanctions, especially, may be found in the most obscure parts of the statute books in each Australian jurisdiction.

Thirdly, the pattern of such controls that are discussed here is by no means consistent from one jurisdiction to the next. In most of the areas we shall consider, it is to State and Territory law that we must turn. The law in each jurisdiction is by no means the same, and it is not always to be discovered in the same place, or necessarily administered by corresponding government agencies.

To the extent that it is possible to do so, the aim of this Part of the Report is as follows:

1. To identify, on a jurisdictional basis, the administrative or legal controls designed to prevent an accidental release of substances from recombinant work, and the relevant control agencies;
2. To set out any statutory sanctions relevant to the accidental release of substances from recombinant work.

The common law, which also imposes liability for loss or damage sustained from unauthorised activities, will be referred to in a later section of this Part, and discussed in a little more detail in Part 3.

2.2 OCCUPATIONAL SAFETY AND HEALTH

It is apparent that in carrying out recombinant DNA research or technology, the safety and health of workers may be placed in hazard. Laboratory workers who in the course of their employment may deal with dangerous substances or materials and factory workers engaged in large-scale recombinant work, are examples of workers placed in hazard. How great the hazard, how real the risk, is not an issue at this point. Rather, the potential of hazard is the stimulant to this section of the Report which identifies the major pieces of legislation designed to protect the health of such workers and impose sanctions on those who breach legal standards.

2.2.1 Prevention: Introduction

The law relating to occupational health and safety in Australia is today at a watershed, reflecting important international developments of the last decade or so. The "old" approach in this area has been characterised as that

"which lays down in some detail minimum standards to be applied in specified industrial environments, or in specified industries, or in relation to specified industrial devices or processes."⁴⁷

By contrast, the "new" approach

"prescribes a broad and overriding duty on employers to provide a safe working environment, with the addition of detailed regulations demonstrating how that duty is to be fulfilled in particular industries."⁴⁸

Accordingly, whether recombinant DNA work is affected, or might be affected, by such legislation depends very much on the approach of the relevant legislation.

Safety and health at work issues are predominantly under State control pursuant to current Constitutional arrangements.⁴⁹ The Commonwealth does, however, have exclusive power to regulate the work activities of its own employees, those in Commonwealth

Territories,⁵⁰ as well as the power, concurrent with the States, to make laws with respect to "conciliation and arbitration for the prevention and settlement of industrial disputes that extend beyond the limits of any one State."⁵¹ This last-mentioned power means that interstate industrial disputes can be the subject of a federal law; thus the issues of worker's safety and health throughout Australia might indirectly be made the subject of a Commonwealth law.

It is also appropriate to note the concurrent legislative power of the Commonwealth with respect to trading and financial corporations and in the field of external affairs. As the Tasmanian Dam case so well illustrates, the Commonwealth may deal with many matters not obviously within Commonwealth competence. In the context of the present discussion, there would appear no reason why occupational safety laws might not be enacted by the Commonwealth in the course of controlling the activities of trading and financial corporations throughout Australia. It might also be possible for the Commonwealth to legislate to implement an international agreement dealing with occupational safety and thus effect national control in this area of concern.⁵² As pointed out in Part 1 of the Report, however, political and public policy choices may well militate against the Commonwealth exercising its legislative options in this area of concern.

Indeed, such a simple statement of the potential Constitutional position belies the fact that many significant safety and health issues pertaining to intra-State industrial disputation presently remain outside Commonwealth jurisdiction. As a result, the States have, over many years, built up a considerable array of legislation in this area. Legislation in Queensland and Western Australia, together with the Northern Territory and the Australian Capital Territory, typifies the "old" approach to regulation in this area. In South Australia, Tasmania, Victoria and New South Wales, legislation is considered to be adopting the "new" approach.⁵³ What this means in the context of worker's health and safety issues arising out of recombinant DNA work becomes clearer in the following discussion.

2.2.2 New South Wales

Under the "old" approach to these issues it is fair to say that the occupational safety and health hazards of recombinant DNA work cannot easily be comprehensively monitored or regulated.

Take for example the Factories Shops and Industries Act, 1962 (NSW). Whilst this Act applies to many industrial situations it does not apply to all of them. The Act is fundamentally directed to health and safety issues in factories. A "factory" is defined in s4 of the Act in the following terms:

"Factory" means-

(a) any building or place other than a farm or rural holding used exclusively for agricultural, horticultural or pastoral purposes in which -

(i) four or more persons are engaged directly or indirectly in a manufacturing process; or

(ii) fewer than four persons are engaged in a manufacturing process and which the Governor has pursuant to this Act declared to be a factory; or

(iii) one or more persons are engaged directly or indirectly in -

(a) a manufacturing process involving the use, handling, or processing of lead, any alloy of lead, or any compound of lead, or any substance or thing containing lead, any alloy of lead, or any compound of lead; or

(b) spray painting; or

(iv) mechanical power is used in or in aid of -

(a) a manufacturing process, or

(b) any of the following processes carried out for trade or sale or gain or as ancillary to any business, that is to say, the sorting or packing of goods or articles, the filling of bottles or other containers, the freezing, chilling or storing in cold storage of goods or articles, or the generation of water power or any other power; or

(v) electricity is generated or mechanically transformed."

A workplace will, therefore, only be a factory for the purpose of the Act where it involves

"any handicraft or process in or incidental to the making, assembling, altering, repairing, renovating, preparing, ornamenting, finishing, cleaning, washing, breaking up, or adapting of any goods or any articles or any part of an article for trade or sale or gain, or as ancillary to any business, and includes any handicraft or process declared by the Governor, pursuant to this Act, to be a manufacturing process."

This definition in s4(a) is interesting for it demands of a "manufacturing process" the following elements:

- . the engagement of four or more persons;
- . making or preparing of "goods" or "articles"; and
- . manufacture for "trade or sale or gain".

The last element indicates that the Act is not concerned with regulation of activities in public institutions which do not make goods or articles for "trade, sale or gain". One suggested example of this is that bakeries ("bakehouses" in the Act) attached to, say, a public hospital quite possibly are not within the s4(a) definition if bread is made only for hospital purposes and not for a wider market for sale or gain.⁵⁴

The restrictive definition of "manufacturing process" would also limit the power of the Governor under the s4(a)(ii) of the definition, to declare a place a "factory" for the purpose of the Act. For only a place at which a "manufacturing process" as defined is carried on may be affected by such a declaration.

As a result, it is possible to draw the conclusion that this "old" type legislation is likely to be of little relevance to much recombinant DNA work as it will not, at least when conducted at a public institution, be classifiable as a "manufacturing process". Large-scale recombinant work carried out by industrial bodies for commercial purposes may, however, be the subject of regulation under the "factory" and incidental definitions.

In 1983, New South Wales moved to adopt the "new" style approach with the enactment of the Occupational Health and Safety Act, 1983. This Act complements and does not replace existing "old" style legislation, such as the Factories, Shops and Industries Act, 1962. As the Act explains one of its objects is

"to provide the means whereby the associated occupational health and safety legislation may be progressively replaced by comprehensive provisions made by or under this Act."⁵⁵

A substantive duty is cast upon employers by s15(1) in the simplest terms:

"Every employer shall ensure the health, safety and welfare at work of all his employees."

A similar duty is expressed in s16(1) in respect of self-employed persons.

Regulations may be made under s45 for the general purpose of carrying into effect the objects of the Act, and may regulate specific places or activities or apply generally throughout the jurisdiction. The important objects of the Act, which would support far-reaching regulations, are set out in s5(1) as follows:

- "(a) to secure the health, safety and welfare of persons at work;
- (b) to protect persons at a place of work (other than persons at work) against risks to health or safety arising out of the activities of persons at work;
- (c) to promote an occupational environment for persons at work which is adapted to their physiological and psychological needs; and

- (d) to provide the means whereby the associated occupational health and safety legislation may be progressively replaced by comprehensive provisions made by or under this Act."

It is clear, therefore, that recombinant DNA work, whether research or technology, might be regulated under this Act. The legal position might be summarized in the following way:

- recombinant work, whether research or technology, is capable of being classified as "work" under the Act;
- Employers are to ensure the health and safety of persons engaged in such work whether as employees or self-employed persons at a place of work;
- regulations under the Act may be made affecting research or industrial places of work.

The substantive duty cast on employers to ensure worker safety and health appears to be quite strict. It does not impose the duty in terms of "reasonable" precautions. Indeed, s15(2) provides that the duty is breached if an employer fails to do such things as:

- "(a) to provide or maintain plant and systems of work that are safe and without risks to health;
- (b) to make arrangements for ensuring safety and absence of risks to health in connection with the use, handling, storage or transport of plant and substances

... ."

By reason of s53, however, this apparently strict standard is ameliorated, so that it is a defence in proceedings for breach of ss15 or 16, for an employer to prove that

- "(a) it was not reasonably practicable for him to comply with the provisions of the Act ...;
- (b) the commission of the offence was due to causes over which he had no control and against the happening of which it was impractical for him to make provision."

But even with this amelioration, it is clear that in a prosecution the onus is on the employer to prove that he had taken "reasonably practicable" steps to ensure worker safety health, in contrast to the position under the other "new" style Acts discussed below.

Section 48(1) provides that proceedings for an offence under the Act cannot be commenced without Ministerial consent, as is also the case in Victoria.

Furthermore, the right to institute civil proceedings of the kind discussed above (for an injunction to prevent breach of the Act) is taken away by s22(a), at least in respect of the substantive duties imposed by ss15 and 16.

2.2.3 Queensland

The Factories and Shops Act 1960 (Qld) takes the old style approach. By s5 of this Act, a "factory" means:

"(i) every building, premises, or other place whatsoever in which-

(a) two or more persons, including the occupier, are engaged in a manufacturing process; or

(b) steam, water, mechanical, or any other power is used in or in aid of a manufacturing process or in packing goods for transport; or

(c) electricity is generated or transformed for the supply of heat, light, or power; or

(ii) every bakehouse, cafe, or other place whatsoever where food or drink for human consumption is prepared or manufactured for sale or trade or gain; or

(iii) every laundry in which two or more persons, including the occupier, are engaged or employed, or in which mechanical power is used, and in which laundry work is performed for hire or reward or gain otherwise, or which is carried on as ancillary to another business; or

(iv) every boat-building yard, ship-building yard, dock, dockyard, ship-repairing yard, or other place in which any ship or boat is constructed, reconstructed, repaired, fitted, refitted, or finished, or broken up; or

(v) every shearing shed, woolscour, or boiling down works."

This definition is in many respects similar to that of the New South Wales Factories, Shops and Industries Act. An essential element of the first part of it is the need for a "manufacturing process" to be carried on at a place for it to be a "factory". A "manufacturing process" is defined in s5(1) to mean

"Any handicraft or process in or incidental to the making, assembling, altering, repairing, renovating preparing, ornamenting, finishing, cleaning, washing, or adapting of any goods or of any other articles or of any part thereof for trade or sale or gain or as ancillary to any business;"

Thus, for the reasons advanced during the discussion of the similar NSW Act, research and other recombinant DNA work carried on in public institutions, at least not for economic gain, remain unaffected by the legislation. It may be possible, however, to

control recombinant DNA research or technology carried on in a traditional industrial setting.

Noticeably, the Queensland Act does not allow the Governor to declare any other places to be a factory either in a broad sense or in the limited sense of the NSW Act.

Interestingly, though, the Director-General of Health and Medical Services in Queensland is broadly empowered under the Health Act 1937-81, s.61(3) to make regulations as he deems necessary "to secure the health and well-being of persons in industry generally or in any particular industry", including "The prevention, notification, and for treatment of prescribed industrial diseases". "Industry" is not defined in terms by the Act, but if it is given a broad meaning, clearly it might include research into as well as applications of the recombinant technique conducted by commercial enterprises. Non-profit enterprise by research bodies may not be affected, however, by such regulation if it were made applicable to them.

An issue which we cannot resolve but may raise, in the light of these conclusions, is whether industry - commissioned research carried on in public or private research institutions is liable to regulation under such legislation. Indeed, as the relationship or division between science and technology is increasingly difficult to describe with clarity, so is the answer to this different issue. In other contexts, the High Court of Australia has been able to determine whether what appear to be a governmental corporation is also a trading or financial corporation.⁵⁶ There appears no reason why universities, for example, despite the non-profit declarations of their charters, might not also be held to be involved in "manufacturing processes" in the relevant factories Acts sense.⁵⁷ It may be argued, of course, that pure research activities do not involve the production of "goods" or "articles" and so are not within the "manufacturing process" definition of these old style Acts in any event.

2.2.4 Western Australia

Also adopting the old approach, the Factories and Shops Act 1963 (WA) applies to factories. In s5(1) of the Act "factory" is generally defined to mean:

"any premises in or on which four or more persons including the occupier are employed or engaged, directly or indirectly, in a handicraft, or in making, preparing, altering, repairing, ornamenting, finishing, cleaning, sorting or adapting articles for trade or for sale or for purposes of gain

It may readily be appreciated that a crucial element of a factory is, once again, the existence of a "manufacturing process", which expression is in terms extremely similar to that in the New South Wales and Queensland Acts.

Thus, the Western Australian Act, although it does go on to enumerate other places which are to be treated as factories

whether or not they meet the general definition (none of which affect recombinant DNA work), has the same limited potential for application to recombinant work carried out by commercial enterprise. The conclusions drawn from the operation of the Queensland Act are broadly relevant to the Western Australian Act.

2.2.5 South Australia

The Industrial Safety, Health and Welfare Act, 1972 (SA) provides our first example of the operation and potential of the "new" style legislation. First, by s29(b), a substantive obligation is imposed on employers:

"Every employer in any industry, every occupier of industrial premises and every constructor in relation to any construction work shall-

...

(b) take all reasonable precautions to ensure the health and safety of workers employed or engaged in that industry or in or on those premises or on or in connection with that work."

This obligation has a very wide scope for, unlike the old Factories Acts approach, the terms "industry" and "industrial premises" are defined in s7(1) of the Act to include all "activities" and all "places" declared by the Governor as such under s23(10).

It is immediately apparent that under this approach to occupational safety and health issues, regulation is not restricted by narrow definitions of "factory" and "manufacturing process", which hinder the wide application of the old style Acts. In relation to recombinant DNA work, therefore, whether it be research or technology, a declaration by the Governor that a place - for example, a research laboratory - or an activity - for example, the recombination or manipulation of molecules (very generally) - might very simply be brought within the scope of the Act and the substantive obligation in s29(b) cast on employers.

The substantive duty, it should also be noted, is owed not merely to "employed persons" but to all workers. This follows from the definition of "worker" in s7(1) in the following terms:

"'worker' in relation to an industry, industrial premises or construction work includes any person employed or engaged for regard in that industry, industrial premises or construction work, whether or not the person is so employed or engaged under a contract of employment and whether or not the relationship of master and servant exists between that person and any other person

Not only does the Act impose this substantive duty, which may be considered as an "umbrella" over the entire system of employer responsibility, but it also authorises by s39(1) the making of regulations both in respect to general and specific safety and

health matters. Regulations are explicitly authorised by s39(2) in respect of "industry" and "industrial premises". The Schedule to the Act attempts to list some specific matters which might be regulated, including

- "1. The prevention or reduction of work injuries and the action to be taken on the occurrence of any injury

...

3. Certificates of competency for persons engaged in prescribed work.

...

12. The handling and storage of materials.

...

15. Safety supervisors."

In relation to recombinant DNA work, therefore, the new approach of the Act may be summarized in this way:

- . recombinant DNA work, whether research or technology, may potentially be declared an "industry" for the purposes of the Act;
- . places where recombinant work, whether research or technology, is carried on may be declared "industrial premises" for the purpose of the Act;
- . a substantive duty is cast on employers of workers in an industry, and occupiers of industrial premises, to take all reasonable precautions to ensure the safety and health of workers employed therein;
- . specific regulation of recombinant work, or places at which it is carried out, is possible under the Act.

The substantive duty approach to the occupational safety and health issue is most interesting and has important ramifications in every industry and on every industrial premises. It suggests that an employer might be prosecuted for an offence against the Act in any case where a person believes reasonable precautions have not been taken to ensure worker safety and health. The section may even be sufficient to support an application by a "specially interested" person for an injunction to restrain the apparent breach of the Act by an employer.⁵⁸

As there is nothing in the Act to the contrary, such citizen or worker actions are possible and provide an interesting potential source of enforcement of the Act additional to that of the inspectorate established by other parts of the Act.

The s29(b) standard itself is, however, suitably loose to make the likelihood of success of any such action small, except in cases where safety or health precautions are blatantly avoided

in an obvious case or where established precautions are for no good reason dispensed with to suit the convenience of the employer.

The obligation to take all "reasonable precautions" has, quite fairly, been equated with the obligation to do what is "reasonably practicable" to ensure worker safety and health.⁵⁹ The High Court of Australia has accepted that this standard takes account of such factors as the nature, cost and practical consequences of precautions likely to eliminate or reduce hazard to workers; that is, that the standard involves a weighing of all the advantages and disadvantages of the adoption of safety precautions.⁶⁰ This issue is one of some greater complexity than is immediately apparent and is usefully discussed elsewhere.⁶¹

It is clear, however, that the prosecutor of an alleged offence to the Act (or in civil proceedings) must prove that the employer has not taken reasonable precautions. In New South Wales as noted earlier, the onus of proof in criminal cases has been reversed with the effect that the employer must show that the precautions he has taken are reasonable in the circumstances.⁶²

2.2.6 Tasmania

Tasmania followed South Australia's adoption of the "new" approach with its Industrial Safety, Health and Welfare Act 1977 (Tas). It indeed conforms closely to the pattern and substance of the South Australian Act.

Unlike the latter, however, the Tasmanian Act differs in respect of some material definitions affecting the scope of the Act. Whereas the South Australian Act defines "industry" and "industrial premises" by reference to activities and places so declared by the Governor, the Tasmanian Act attempts a substantive definition.

First, however, it should be noted that s32 of the Act requires that

"Every occupier of a work place and every person carrying on an industry shall take reasonable precautions to ensure the health and safety of persons employed or engaged at that work place or in that industry."

"Industry" is then defined in s3(1) to mean

"any industry, trade, business, undertaking, profession, calling, function, process, or work in which persons are employed or engaged, and includes the use of machinery in an educational or training establishment"

In a slightly circular way, "work place" is defined in s3(1) to mean

"any premises or place in which persons are employed or engaged in industry."

It is apparent that the ultimately undefined terms "industry" and, in particular, "work" - appearing in the "Industry" definition - are crucial to the potentially wide application of the Act.

It is to be further observed, that it is only industry or work "in which persons are employed or engaged" that are included within the definition. This may be considered to require an element of contract in the performance of work by any person, and exclude voluntary work.⁶³ This may suggest that such work should be for financial gain.

A "work place", it is suggested, might be considered not as, say, the entire industrial premises involved in the production of goods, but component parts or units within the larger premises. Such a view better accords with the "industry" definition which clearly contemplates an individual "process", for example, being the subject of the substantive employer's s32 duty.

As under the South Australian Act, regulations may be made under a general power (s49(1),(2)) and in respect of specific matters set out in Schedule 2 of the Act (s49(3)). Regulations may also be applied to specific industries or work place, or generally (s49(4)). Schedule 2 lists matters, similar to those set out in the Schedule to the South Australian Act, which might be made the subject of regulation.

It is possible to summarize the potential application of this Act to safety and health issues arising out of recombinant DNA work as follows:

- Unlike the South Australian Act, the Tasmanian Act might not readily apply to recombinant research work. However, as persons involved in recombinant work, even at a research level in public or private (non-profit) institutions may be said to be "employed or engaged" in "work", there is no logical reason why all such work should not be considered within the scope of the act.
- Thus, occupiers of work places (employers or owners), and those carrying on industry, are obliged to take "reasonable precautions" to ensure the safety and health of workers therein.
- Specific regulation of recombinant work might, as a result, also be possible.

So far as the substantive duty in s32 is concerned, the discussion above on the equivalent duty in the South Australian Act is here relevant.

As under the South Australian Act, there appears nothing in the Act to prevent any member of the public, including a worker, to prosecute a breach of the Act, or (in the case of such a person with standing to sue) to initiate civil proceedings for an injunction to prevent the breach of the Act.

In criminal proceedings for breach of the Act, the onus appears to remain with a prosecutor to prove the commission of the alleged offence; in other words, in the case of s32, that the employer failed to take "reasonable precautions" for the safety and health of workers.

Worthy of note also is s29(a) of the Act which requires the occupier of a workplace to prepare a statement of the policy to be adopted in the workplace to ensure the health and safety of workers. This procedure may enable a full testing of safety measures proposed in respect of recombinant work.

2.2.7 Victoria

Under the Industrial Safety, Health and Welfare Act 1981 (Vic) the new style legislation continues its onward Australian march. A substantive duty is first cast, in s11(1), in the following simple terms:

"The occupier of a workplace shall ensure, so far as is reasonably practicable, the safety, health and welfare of persons employed or engaged in or on that workplace."

By s11(2) an attempt is made to particularize some matters of concern, for example

"(b) arrangements for ensuring so far as is reasonably practicable, safety and absence of risk to health in connexion with the use, handling, storage and transport of articles and substances"

A "workplace" is defined in s3 to mean

"any building, structure site or place where work is or is normally performed by any person for his or his employers monetary compensation, gain or reward."

The "workplace" definition includes any place where a person works for his own gain as well as a place where a person works for his employer's gain. Unless one can argue, for example, that a university researcher does not conduct his research for "monetary compensation, gain or reward", the definition appears capable of having application to public institutions as well as private enterprise. A university researcher is employed; his contract of employment will generally require satisfactory performance according to proper directions, and obliges the university to remunerate him for his "work". This conclusion could be avoided only by narrowly construing the definition to relate to a place where a person produces some saleable item. This does not seem a warranted view of the Act.

Of course, it does not follow that one would conclude that the university is engaged in work for monetary compensation, gain or reward in these circumstances.

By s33, the Governor in Council is authorised to make regulations for the general "safety, health and welfare" of persons engaged in workplaces, as well as particular matters of concern which mirror those prescribed in the schedules of the

South Australian and Tasmanian Acts referred to above. This includes the power to prescribe standards by reference to documents issued by other authorities or bodies.

In relation to recombinant DNA work, we might summarize the potential scope of the Act as follows:

- . Recombinant research and technology employed in commercial or industrial circumstances would appear to be "work" carried on at a "workplace".
- . Research carried on in public or private institutions may potentially be affected by the Act.
- . Where the Act does apply, it imposes on an occupier the duty to take "reasonably practicable" steps to ensure the health and safety of workers employed or engaged in the work.

Institutional research work carried out for industry may, or may not, be within the contemplation of the Act. Where it is carried out under a contract for service it would appear not be work performed for an "employer", but only a "principal". Other research arrangements between an institution and industry, though, might fall within the workplace definition.

In other respects, the Victorian substantive obligation is similar in weight to that imposed by the South Australian and Tasmanian Acts.⁶⁴

In the matter of enforcement of the duty, and other provisions of the legislation, however, the Victorian Act, by s27, restricts proceedings for an offence against the Act to cases authorized by the Minister responsible for the Administration of the Act. This section does not appear to restrict the right of a sufficiently interested person to bring a civil action for an injunction to prevent breach of the Act.

Also worthy of mention, is the Act's requirement for "policy statements". It is provided in s11(3), that

"every occupier of a workplace to prepare and as often as may be appropriate revise written statement of his general policy with respect to the safety and health of persons employed in or on the workplace and the organization and arrangements for the time being in force for carrying out that policy ..."

This duty has the potential to emphasize the responsibility of employers to foster safe and healthy work systems.

2.2.8 Northern Territory and the Australian Capital Territory

Neither the Northern Territory nor the Australian Capital Territory have any comprehensive legislation of the old or the new style. The Northern Territory, however, does have a Construction Safety Act 1975 (NT) and the Australian Capital

Territory the Machinery Ordinance 1949 (ACT). These laws do not impinge on recombinant DNA work.

2.2.9 Commonwealth

As indicated in the Introduction to this section of the Report, the Commonwealth has not to date exercised all legislative powers potentially available to it in the broad field of occupational health and safety.

Prior to 1983, the Commonwealth's involvement had largely been limited to the conduct of its own employees. In 1974, The Code of General principles on Occupational Safety and Health in Australian Government Employment were issued. The permanent head of a Department or the chief functional officer of a Commonwealth agency are responsible under the Code for ensuring that the provisions of the Code are applied.⁶⁵ Amongst other things, the Code lays down measures for cases where "harmful chemical and physical agents are used and produced".⁶⁶ Furthermore, a statement of safety policy and responsibilities must be issued.⁶⁷

In cases of Commonwealth involvement in recombinant work, therefore, the Code at least requires the responsible branch of government to focus on health and safety issues. The Code is, however, purely administrative in character, having no legal basis. A breach of the Code does not amount to a breach of law which can be remedied by a court.

So far as the overall substance of the code is concerned, it should be noted that recommendations of the Commonwealth Director-General of Health underpin the effective operation of the Act. The Director-General has determined that National Health and Medical Research Council (NH&MRC) occupational health guides are to be treated as his recommendations for the purposes of the Code. None of these guides appear currently to deal directly with the occupational hazards of recombinant DNA work, although clearly such a guide could be integrated with the Code. There do exist currently, of course, the guidelines of Recombinant DNA Monitoring Committee attached to the Department of Science and Technology in respect of both small scale and large scale recombinant work.

The history of these guidelines was referred to in Part 1 of the Report. Both sets of guidelines depend, for their effective operation, upon the establishment within an institution of an Institutional Biosafety Committee (IBC). The broad role of an IBC is to approve all recombinant DNA work proposals within the institution prior to the commencement of any work.

The guidelines spell out measures designed to secure both physical and biological containment of recombinant work, although biological containment is especially encouraged. Different types of recombinant work are controlled strictly or very strictly according to their nature.

The small-scale guidelines relate to "the production of material incorporating recombinant DNA molecules unlikely to

occur in nature". Exempt from these guidelines are experiments where the donor species is also the host species, or is a species known to exchange genetic information normally with the host species.

The large-scale guidelines apply to work within contained facilities where the processes involve the use of organisms or cells which contain foreign DNA inserted by the recombinant DNA technique and the volume of culture, medium or tissue is larger than 10 litres. Thus two categories of work fall outside the scope of these guidelines: self-cloned organisms and isolated recombinant DNA molecules.

In the case of large-scale work only, additional to the IBC there must also be appointed a Biological Safety Officer whose general function it is to give advice on biosafety issues on a day to day basis.

As discussed in Part 1 of the Report, these Guidelines are purely administrative in character, and do not have a separate legal status as, for example, do Regulations made with the authority of an Act of Parliament. When incorporated into a contract of employment, or made part of the conditions upon which research or development funds are made available to a person or institution, however, breach of the Guidelines may have legal ramifications leading either to termination of a person's employment or withdrawal of research funds.

It should be noted that although these are the only set of explicit rules affecting recombinant work at the Commonwealth level (indeed throughout Australia), they do not operate in a vacuum. There exist various codes affecting the use of dangerous and therapeutic substances which also impinge on recombinant work. For example, large-scale recombinant work involving pathogenic substances would need to meet the Code of Good Manufacturing Practice for Therapeutic Goods issued by the National Biological Standards Laboratory of the Commonwealth Department of Health. The latter, whilst also administrative in character and having no separate legal status, clearly has an important function in practice. Good laboratory containment practices employed in research work are also here relevant.

The likelihood of increased Commonwealth involvement in the broad issue of occupational health and safety has increased since the election of the Hawke Government and the establishment of the Interim National Occupational Health and Safety Commission (INOHSC). The Commission, which is without regulatory power in the area, has the function of attempting to overcome the complex jurisdictional problems in the area and to assist in the formulation of national standards capable of implementation in the States and Territories. Related to the establishment of INOHSC is the Government's proposal to set up a National Occupational Health and Safety Office (NOHSO) to implement the Commission's policies in the federal sphere, an Environmental Contaminants Authority (ECA), to licence new chemicals at the national level, and a National Institute of Environmental and Occupational Health (NIEOH), to provide hazard information and perform related activities.

Federally initiated steps of this kind may in time ensure comprehensive national or uniform legislation. In the short term, especially in relation to recombinant DNA safety and health concerns, the INOHSC would appear to be capable of acting as a monitoring and standard-formulating agency responsible for activating the relevant State and Territory legislation. In this regard, it is interesting to note that in the United States the federal Occupational Safety and Health Administration (OSHA) has also been suggested as a potential regulator of recombinant DNA work.⁶⁸

2.2.10 Administration of State Legislation

In every State, whether it has old or new style legislation, an inspectorate is established to enforce the provisions of the Act. Essentially, its task is to ensure compliance with existing laws and regulations and, where appropriate, prosecute breaches of the law. An inspectorate usually includes a Chief Inspector and other subordinate inspectors.

Old style Acts are ultimately administered by the State Minister responsible for matters of labour and industry through the Secretary of the relevant Department.⁶⁹

Under the new style Acts, whilst the relevant State Minister remains ultimately responsible for the administration of the legislation, a separate safety, health and welfare body is usually established to advise the Minister on matters arising under the Act. In South Australia, there is an Industrial Safety, Health and Welfare Board set up to administer the Act "subject to the general control and direction of the Minister."⁷⁰ In Tasmania a board with the same title exists.⁷¹ In Victoria, the body is the Industrial Safety, Health and Welfare Advisory Council.⁷² In New South Wales, the Occupational Council of New South Wales is the equivalent body.⁷³

Queensland, although it has an old style Act, has nevertheless introduced a Factories and Shops Health, Welfare and Safety Board.⁷⁴

In broad terms, these bodies have the function of investigating and reporting to the Minister on all matters relating to the effective administration of the legislation and also with respect to special health and safety problems.⁷⁵ It would appear that all bodies, except that in South Australia, may carry out its functions of its own motion. In South Australia the Board may only operate at the instance of the Minister.⁷⁶

If it is desired to formulate special policies concerning the health and safety of workers in recombinant work, therefore, there is ample scope either for Ministerial or Departmental investigation of the issues under the old Acts, if they are capable of applying to such work. The Boards and Councils set up under the new Acts also allow an investigation to be carried out, possibly with greater ease given the greater independence of these bodies from Ministerial direction.

2.2.11 Powers of the Inspectorate

Under all health and safety Acts, inspectors are empowered to enter, inspect and examine workplaces to which the Acts apply to ensure compliance with provisions of the Acts or Regulations designed to secure safe and health work systems. If special rules applicable to recombinant DNA work were created, it would be possible for inspectors throughout the States to monitor and enforce compliance with a relevant legal rule.⁷⁷

Another important power in the inspectorate is that which may lead to a notice of closure of premises or specific activities to which an Act applies where the safety and health rules are being contravened or the system of work is hazardous to the health or safety of workers.⁷⁸

2.2.12 Enforcement of Legislation by Workers

Apart from the possibility of individual workers initiating criminal proceedings for breach of the Acts, or civil proceedings for an injunction to prevent breach of the Act, as noted above, the new style Acts often establish means for workers to be represented on bodies directly concerned at industry level with the administration of the Act, or for a worker's representative to take immediate action to prevent hazardous activities.

By s31 of the Industrial Safety, Health and Welfare Act 1972 (SA), where ten or more workers are employed at industrial premises they can elect a "workers' safety representative". However, neither the Act nor the Regulations provide the representative with the power to do more than consult with an employer over work practices.

The provision of the Industrial Safety, Health and Welfare Act 1977 (Tas), s34 is similar to the South Australian provision. The Tasmanian Regulations, however, go further: they enable the representative to bring hazards to the notice of employers, and to inspect the workplace during normal hours.⁷⁹

In Victoria, the Industrial Safety, Health and Welfare Act 1981 (Vic) goes even further by providing for the election of representatives and, if the representatives request it, the appointment of a safety committee.⁸⁰ But, as in Tasmania, only consultation is required between the employer and the representatives on health and safety issues. A safety committee may, however, keep under review measures taken to ensure health and safety.

By contrast, under the Occupational Health and Safety Act, 1983 (NSW), only committees are provided - not representatives. A committee's function is to monitor health and safety practices, like the Victorian counterpart, although it is also empowered to request an inspector to resolve intractable issues between an employee and an employer.⁸¹

2.2.13 Commonwealth Administrative Functions

As noted above, the Interim National Occupational Health and Safety Commission (INOHSC) has been established by the Commonwealth Government to assist in the formulation and implementation of national policies in this area. Whilst the Commission has no doubt a very important function, it should carefully be noted that it is legally powerless to implement its policies at the State level, and instead must rely on uniform State action to achieve its goals.

2.2.14 Sanctions

The old style legislation discussed in this section has been designed to enable government to lay down safe and healthy work practices where appropriate. Only to the extent that Regulations have been made, is it possible to identify sanctions imposed by the legislation for certain types of misconduct. As no regulation of recombinant work is obvious under these laws at present, it is not possible to identify specific sanctions.

The new style legislation, however, imposes a substantive duty on the occupier of a workplace to ensure it is safe. It is, therefore possible to identify a sanction of a sort under these Acts. If it can be proved that recombinant DNA work is not being conducted in a safe way then the sanction might be imposed. Compliance with the relevant guidelines of the Recombinant DNA Monitoring Committee would probably be accepted by a court as evidence of a safe system of work.

The following is a summary of the relevant substantive duty sections and the penalties for which an occupier may be liable in case of non-compliance.

South Australia: Industrial Safety, Health and Welfare Act, 1972, s29(b). Penalty \$500.

Tasmania: Industrial Safety, Health and Welfare Act 1977, s33. Penalty \$500.

Victoria: Industrial Safety, Health and Welfare Act 1981, s11(1). Penalty \$2,000.

New South Wales: Occupational Health and Safety Act, 1983, s15(1). Penalty \$50,000 in the case of a corporation; \$5,000 in any other case.

2.3 PUBLIC HEALTH

2.3.1 Introduction

It is often difficult to draw distinctions between issues of occupational health, public health and environment protection. Where distinctions are drawn, it is often for convenience sake. This section, in this slightly arbitrary sense, will identify, again on a jurisdictional basis, legislation designed to prevent the occurrence of situations harmful or potentially harmful to members of the public outside the workplace. Examples include

legislation which affects the use of dangerous substances or goods, and legislation concerned with the spread of infectious disease to humans. An accidental release of a recombinant DNA substance may be capable, if not biologically disabled upon escape, of creating hazard for humans. Other environmental controls will be discussed in the next section. Sanctions imposed for the creation of hazard to the public will also be listed in this section.

2.3.2 Infectious diseases

In the event of an outbreak of infectious disease, urgent government action would be necessary to identify the hazard, isolate it and remove it. Legislation in the States and Territories, commonly public health legislation, is designed in roughly similar ways to combat any threat of the spread of infectious disease. The common pattern of the legislation is to enable the declaration of quarantine areas and the empowering of public health officials to isolate and remove the source of hazard. Often, the legislation imposes an obligation on members of the public to notify an outbreak of disease.

The Commonwealth also has legislation enabling it to take quarantine steps in such cases. Indeed, under the Constitution, the Commonwealth Parliament is able to make laws with respect to "quarantine", a power which it has not yet utilized to its fullest extent. Rather, the approach to control of infectious disease assumes the effectiveness of complementary Commonwealth and State/Territory legislation.

2.3.3 New South Wales

Under the Public Health Act, 1902 (NSW), the Governor may declare any disease to be an "infectious disease".⁸²

Should any case of small-pox, plague, or cholera, or infectious disease appear, the Government may initiate preventive action by declaring any area to be an "infected area".⁸³

Once an area is so declared the Health Commission of New South Wales is empowered to "take such steps and give such orders and directions as in its opinion are necessary to segregate or isolate the inhabitants of or the persons ... within such area ... and to disinfect any home or premises therein ...".⁸⁴

By these means official action may be taken to isolate and contain any outbreak or escape of infectious disease whether the same should originate from recombinant DNA work or any other work or source.

Under s102, regulations may be made with respect to the prevention and control of infectious diseases.

2.3.4 Victoria

The Health Act 1958, s3(a) defines "infectious disease" fairly narrowly, however s3(b) permits the Government to

proclaim⁸⁵ any disease to be an infectious disease.

Local councils are empowered to deal with infectious diseases in the first instance.⁸⁶ It is however the Health Commission of Victoria which has ultimate responsibility for dealing with an outbreak. Under s122 of the Act, the Commission is authorised to take all necessary steps for dealing with an outbreak and to exercise all the powers of a council. Under s123, the Minister may require the use of land and buildings, subject to appropriate recompense.

In cases of emergency, as adjudged by the Minister, the Commission may be authorized by the Minister under s133 to act broadly to prevent the spread of disease, including to declare people to be quarantined, and places or things to be isolated.

The Government is also empowered under s140 to make Regulations for or with respect to the whole matter of infectious disease control prior to any outbreak of disease.

2.3.5 South Australia

The Health Act 1935, s4(a) refers to a list of infectious diseases in the Second Schedule of the Act. Under s4(b), however, the Government may proclaim any disease to be an infectious disease.⁸⁷

Control of the spread of infectious disease is in the first place in the hands of local boards of health, but at a higher level by the Central Board of Health.

In serious cases, the Government, under ss140 and 141, may authorize the Central Board to isolate houses or premises in order to prevent the spread of a disease.

Regulations may also be made under s147(1)(a)-(c) to deal with infectious diseases.

2.3.6 Queensland

The Health Act 1937-81, Div III deals with "communicable diseases". A number of such diseases are listed in s32, however the government on the recommendation of the Director-General of Health and Medical Services may declare any other disease to be a communicable disease.

Local authorities have the primary responsibility to control infectious diseases subject to the direction and control of the Government or Director-General.⁸⁸

The Director-General is however empowered under s33 to make all such Regulations as he thinks necessary to prevent the outbreak or occurrence of any disease and to suppress a disease. This power would appear to authorise regulations concerning isolation, quarantine, and seizure of persons and things. Unlike the powers of relevant authorities in other jurisdictions, however, the Director-General must first make regulations to such

effect. The Act does not directly empower the Director-General to take such actions.

2.3.7 Tasmania

The Government may cause any disease to be declared an "infectious disease" under s13(1) of the Public Health Act 1962.

As in other States, local authorities have the primary responsibility to control of the spread of an infectious disease, although the Minister is in a position to direct an authority to exercise its powers.⁸⁹

In an emergency or other appropriate situation, the Minister is directly empowered to do such things as declare land or buildings insanitary, cause the destruction of property, isolate parts of the State, and control the movement of persons or things within the State.⁹⁰

Under s14 of the Act, regulations may be made by the Governor with respect to the control of infectious disease, for example, prescribing the isolation, for the public welfare of any part of the State.⁹¹

2.3.8 Western Australia

The Health Act 1911, s248 permits the Government to cause any infectious disease to be declared a "dangerous infectious disease". Infectious diseases are defined in s3(1) of the Act and include a disease declared to be an "infectious disease". Different powers are granted to different officials to deal with infectious diseases and dangerous infectious diseases.

As in other States, local authorities have the primary responsibility to prevent the spread of infectious diseases.⁹²

The Commissioner of Public Health is, however, if authorised by the Minister, able to exercise the authority of local councils to deal with dangerous infectious diseases.⁹³ Under s251, land may be declared by the Commissioner to be insanitary, property destroyed, persons and places quarantined, and the movement of persons and things within the State controlled.

There exists under Part XIV of the Act a broad power to make regulations for carrying into effect the provisions of the Act. Such regulations might also aid the control of the spread of infectious disease.

2.3.9 Northern Territory

The approach of the Public Health Act to most public health matters in the Territory is to authorise the making of regulations to effect the desired controls. The Act does not, like similar Acts in the States, directly empower government to take action in respect of infectious disease.

The Act, by s10(a), allows regulations to deal with "the prevention of disease" generally, as well as, in s10(e), "the

designation of diseases and measures for the control of diseases". Under the regulation making power, extensive control of the spread of infectious diseases may be effected, although existing Regulations do not appear to relate specifically to infectious diseases.

2.3.10 Australian Capital Territory

As in the Northern Territory, the Public Health Ordinance 1928, s12, enables regulations to be made respecting the prevention of disease generally. Existing regulations do not appear to deal with the matter comprehensively, and no official is directly empowered by the Ordinance to control diseases, infectious or otherwise except by first making regulations.

2.3.11 Commonwealth

The Commonwealth has broad constitutional power to deal with the import and export of things into and from Australia under s51(i) of the Constitution, and so might effect control, inter alia, over things considered to be dangerous or hazardous to the public or the environment generally. Where an outbreak of, say, infectious disease occurs within Australia, however, other controls are necessary. Under s51(ix), the Commonwealth has a broad power to make laws with respect to "quarantine", which power has been exercised to some extent with the enactment of the Quarantine Act 1908.

The Act operates alongside relevant State quarantine legislation. In cases of emergency, however, the Commonwealth Government may cause a proclamation to be issued suspending, in effect, the operation of State legislation,⁹⁴ thus enabling national action to deal with the emergency.

The term "quarantine" as used in the Act has a special meaning:⁹⁵

"Quarantine has relation to measures for the inspection, exclusion, detention, observation, segregation, isolation, protection, treatment, sanitary regulation, and disinfection of vessels, installations, persons, goods, things, animals or plants, and having as their object the prevention or introduction or spread of diseases or pests affecting man, animals, or plants."

The Act is, however, largely intended to deal with the introduction into Australia of "quarantinable disease" by vessels, and by the importation of goods, plants and animals. Extensive controls are exerciseable under the Act in respect of vessels, persons and things entering Australia, but little has traditionally been said about the outbreak of disease from within Australia. In many cases, therefore, State and Territory legislation must be co-ordinated to achieve control in such cases.

The significant exception to the general thrust of the Act is the broad quarantine power in s2B of the Act. It first provides that:

"Where the Governor-General is satisfied that an epidemic caused by a quarantinable disease or danger of such an epidemic exists in a part of the Commonwealth, the Governor-General may ... declare the existence in that part of the Commonwealth of that epidemic or of the danger of that epidemic."

What follows from such a declaration is that the Commonwealth Minister is broadly empowered to "give such directions and take such action as he thinks necessary to control and eradicate the epidemic, or to remove the danger of the epidemic, by quarantine measures or measures incidental to quarantine."⁹⁶

These powers would clearly enable the Commonwealth to achieve national action in the event it is required. It is dependent on there being

- . an epidemic or danger of one,
- . caused by a "quarantinable disease".

A "quarantinable disease" is defined in s5(1) to include any disease declared by the Governor-General to be a "quarantinable disease". Government action may be necessary to declare certain diseases to be "quarantinable diseases" before action may be taken.

Although the powers are broad, a court would have jurisdiction to entertain an application for review of the legality of any executive action taken by the Commonwealth.⁹⁷ A court might be prepared to review the determination that an epidemic or danger of one existed. Equally it might be prepared to rule whether particular measures, for example, the seizure and destruction of property, would be authorised under s2B(2). (Under the Constitution s31(xxxi) property could only be taken or destroyed if compensation were given by the Commonwealth to the property owner.) The powers are, however, so broadly cast, that a court would be cautious in substituting its view of what is an epidemic and what is an appropriate step for dealing with it, for that of the Commonwealth Government.⁹⁸

Other provisions of the Act which enable quarantine measures over domestic disease outbreaks include s18(1)(b), which makes "every person infected with a quarantineable disease", and s18(2)(b), which makes "all goods infected with a quarantinable disease" ("goods" includes animals and plants: s5(1)), the subject of quarantine.

As a result, it would appear that the Act authorizes the apprehension of persons subject of quarantine.⁹⁹ Directions may also be given to persons the subject of quarantine or to persons in possession of goods the subject of quarantine.¹⁰⁰

The Commonwealth may also prohibit the removal of plants and animals and goods within the Commonwealth from one part of it to another.¹⁰¹

2.3.12 Sanctions

Legislation in this area is concerned with the prevention and control of the spread of infectious disease. No provision directly imposes a sanction upon a person for allowing the escape of an infectious disease. Rather, the legislation is designed to deal with disease once it has escaped. There are sanctions imposed for failure to comply with lawfully prescribed control requirements,¹⁰² of course, but these are remote to our inquiry. They only apply once the control scheme has been brought into operation. The release of infectious disease may also result in liability at common law. This is an issue discussed in a later section of this Part, and in Part 3 of the Report.

2.3.13 Dangerous Goods and Substances

The public may be protected from accidental harm from hazardous goods or substances by the initial control of the manufacture, use, sale, possession, or importation into Australia or a State or Territory, of the dangerous goods or substance.

The purpose of this section of the Report is to highlight laws which enable such control. In relation to recombinant DNA work, such controls may initially prohibit the importation of necessary substances crucial to the carrying on of the work, restrict or prevent the use or sale of certain substances in research or manufacturing processes, and regulate the use, sale or possession of products of recombinant work.

Specific dangerous goods legislation will be examined on a jurisdictional basis. Special "therapeutic" goods legislation, which exists in some jurisdictions, will also be discussed. Finally, reference will be made to various controls affecting research or manufacturing processes, or their products.

In New South Wales, the Dangerous Goods Act, 1975 (NSW), s4 enables "any substance or article" to be prescribed as "dangerous goods" for the purpose of the Act.

It is an offence under s9 of the Act to keep dangerous goods upon a premises except under licence issued by the Chief Inspector or Dangerous Goods. The penalty for an individual is \$1,000, for a corporation, \$5,000.

In this way, substances or articles used in recombinant DNA work may be regulated to prevent their use.

The Noxious Microbes Act, 1900 (NSW) s5, specifically makes it an offence to keep or distribute "noxious" or infectious microbes, unless licenced.

In South Australia, the Dangerous Substances Act, 1979 (SA), s2 enables any substance to be declared a "dangerous substance. Under s14, it is an offence to keep a dangerous substance without licence. The Act provides a \$1,000 penalty for this offence.

In Victoria, the Drugs, Poisons and Controlled Substances Act 1981 (Vic) (not operative as at 31 December 1983) enable broad

control of the use and manufacture of a wide range of dangerous substances. "Poisons and controlled substances" are listed in the Schedules to the Act, and under s12, may be added to. The Act creates a number of offences relating to the manufacture, sale and use of such substances.

The Tasmanian Dangerous Goods Act 1976 (Tas) s2, enables any substance to be declared dangerous. It is an offence under s8 for a person to keep a dangerous substance. The penalty prescribed by the Act is \$500. The Act also provides for the control of the manufacture of a dangerous substance.

Under the Northern Territory Dangerous Goods Act 1980 (NT), s5, any substance may be declared a dangerous substance. It is an offence under s16 to keep such a substance. The prescribed penalty is \$5,000. The Act, which was not operative as at the 1 July 1983, also enables control of the manufacture of a dangerous substance.

Public health legislation also enables the control of dangerous goods. Under the Public Health Act, 1902 (NSW), the Governor may declare any substance to be a "dangerous substance".¹⁰³ Similar powers exist in most of the other jurisdictions,¹⁰⁴ although not specifically in the Northern Territory.

Control over dangerous substances is achieved through the grant of power to make extensive regulations, including regulations

- (b) prohibiting or regulating the use of a dangerous substance;
- (e) controlling the storage, handling and conveyance of a dangerous substance;
- (f) establishing procedures to be followed in the event of escape or spillage of a dangerous substance;¹⁰⁵

A similar regulation power exists in Victoria, South Australia, Tasmania and the Australian Capital Territory.¹⁰⁶

Where a dangerous substance has been regulated, an officer of the Health Commission of New South Wales may enter premises at any reasonable time¹⁰⁷ to ensure compliance with the regulations,¹⁰⁸ and inspect examine and test materials for this purpose.¹⁰⁹ Similar powers may be found in three of the four other jurisdictions which have specific dangerous goods or substances legislation.¹¹⁰

Under the New South Wales Poisons Act, 1966 (NSW) Poisons Regulations 1982 deal with poisonous substances. Other jurisdictions have similar legislation.¹¹¹

Food, drugs, agricultural chemicals and pesticides legislation in various jurisdictions also enable control over particular substances considered hazardous.

The Commonwealth under import regulations may also control the entry into Australia of all manner of dangerous goods and substances. For example, the Therapeutic Goods Act 1966 (Cth), allows the government to deal with a dangerous substance, or its use, which causes, or is likely to cause, a serious outbreak of disease in humans or animals, by

- . prohibiting importation into Australia or the substance; or
- . declaring appropriate quarantine measures.¹¹²

Additional to these laws in some jurisdictions is specific legislation dealing with "therapeutic" substances. The Commonwealth, New South Wales and Tasmania each have such Acts. Queensland and Western Australia deal specifically with therapeutic goods under their health legislation.¹¹³

The scheme of the State Acts is to allow Government to declare goods to be "therapeutic". Such goods include therapeutic substances and devices.

The State Acts make it an offence for a person to manufacture for sale¹¹⁴ or sell¹¹⁵ a therapeutic substance unless licensed so to do.

Under the Therapeutic Goods and Cosmetics Act, 1972 (NSW) a therapeutic substance is generally defined to include a substance used to

- . prevent, diagnose, cure or alleviate a disease in man or animal;
- . influence, inhibit or modify a physiological process in man or animal;
- . test the susceptibility of man or animal to a disease or ailment; or
- . destroy or inhibit micro-organisms that may be harmful to man or animal.¹¹⁶

Where recombinant DNA technology has as its aim the manufacture for sale of substances having such uses, it may effectively be controlled under the Act.

It may be considered doubtful, however, whether the scope of this control includes recombinant DNA research work, for usually such work would not involve manufacture "for sale" - or "sale" - of any goods, even if it could be argued that research work does involve the "manufacture" of a substance.¹¹⁷ Research in industry, however, may possibly be within the scope of the Act if a broad view of "manufacture for sale" is taken. The view may be taken that research in such circumstances would be for the ultimate or indirect purpose of manufacture of substances for sale. If, however, the Act is intended to deal only with the manufacture of goods, in the immediate sense, then industry research may also be beyond the reach of each Act.

Under these Acts there exists wide powers of search and seizure¹¹⁸ and analysis¹¹⁹ of goods seized which may afford evidence of breach of the Act.

The Commonwealth Act does not create a licensing system. Whereas the State legislation is not seriously limited in the methods it might employ to regulate therapeutic goods, the Commonwealth is. Nonetheless, the Therapeutic Goods Act 1966 (Cth) does effect a broad range of controls with respect to therapeutic goods, apparently justified under a number of heads of Constitutional power.¹²⁰

First, "therapeutic goods" is defined in a manner similar to the State Acts. The main difference is that the accompanying definition in the Act of "therapeutic use"¹²¹ does not include the

- . destruction or inhibition of micro-organisms that may be harmful to man or animal

factor, which is common to NSW and Tasmania Acts, but not the Queensland and Western Australian legislation.

The Commonwealth Minister may in respect of such goods, determine standards¹²² and lay down requirements concerning labelling and packaging.¹²³ In consequence of these rules, the Act prohibits the importation into Australia of goods for therapeutic use that do not conform to the standards or other requirements.¹²⁴ Similarly, the Act forbids interstate trade and commerce in therapeutic goods¹²⁵ and the supply of pharmaceutical goods for therapeutic use¹²⁶ unless the standards and other requirements are met. Nor may such goods be supplied to the Commonwealth or the Northern Territory, or to any Commonwealth or Territory authority, unless they conform to the standards and other requirements.¹²⁷

These provisions appear capable of controlling the use of substances important in recombinant DNA research and industry, unaffected as they are by the licensing scheme in respect of commercial manufacturing which prevails under the State Acts. Hence, a research institution desiring to import into Australia certain substances for recombinant work may find its actions subject to Commonwealth scrutiny and control.

2.3.14 Manufacturing and Related Processes

Various State, Territory and Commonwealth laws and administrative practices can affect the process by which manufacturing and other processes, including research is carried out, especially in areas where hazardous or dangerous substances are used in the process. Legislation concerned with occupational health and safety, already discussed in this part, can substantially affect such processes. As just noted, processes for the manufacture of "therapeutic" goods are directly controlled by licensing procedures in four Australian jurisdictions, and, in the Commonwealth, are affected by use standards. Moreover, the general controls over the use or sale

of dangerous goods, foods, drugs and other articles in most jurisdictions can have ramifications for manufacturing industry in Australia, as well as for the importers into Australia of such goods.

What, perhaps, is not fully appreciated is the array of administrative, that is, non-legal, procedures or guidelines that affect processes of industry and research in Australia. Many professional, governmental and joint professional industry/governmental organizations produce informal rules which are voluntarily complied with by researchers and industry to ensure the safe performance of their activities. Many of the determinations, standards or procedures produced by these organizations are directly or indirectly incorporated in Australian legislation at all levels of government. In other respects, the rules are incorporated in conditions of research grants. The National Health and Medical Research Council (NH&MRC), the National Biological Standards Laboratory (NBSL) and the Standards Association of Australia (SAA) are examples of such bodies.

Recombinant DNA work may be affected by some of these rules, for example, those affecting safe laboratory practices and manufacturing processes involving biological processes. Additionally, as we have seen, the guidelines of the Recombinant DNA Monitoring Committee of the Commonwealth Department of Science and Technology directly affects small and large recombinant DNA work.

In some jurisdictions the manufacture of dangerous substances may be directly controlled by legislation. The Dangerous Goods Act 1976 (Tas), s7, makes it an offence to manufacture duly proclaimed "dangerous goods" without a licence. The prescribed penalty is \$1,000.

In Victoria, the Drugs, Poisons and Controlled Substances Act 1981 (not proclaimed at 31 December 1983), Division 8, also requires the manufacture of certain scheduled substances to be licensed. The Act, by s55, enables the use of controlled substances to be prohibited in certain circumstances.

The Northern Territory Dangerous Goods Act 1980 (not in operation as at 1 July 1983), s15, makes it an offence to manufacture "dangerous goods" without a licence. The prescribed penalty is \$5,000. The Act, by s14, also requires all persons to take proper care in the use, of dangerous substances.

In South Australia, the Dangerous Substances Act, 1979, s12, requires all persons to take proper care in the use of a dangerous substance.

In New South Wales, the Noxious Microbes Act, 1900, s5 makes it an offence, inter alia, to rear or propagate any "noxious" or "infectious" microbes unless licenced so to do. The penalty prescribed by s13 is 2 years imprisonment or \$200.

In all jurisdictions, legislation enables the regulation of food and beverage purity standards. Usually, a power to make

regulations is to be found in the public health legislation. In Queensland, however, the Food Act, 1981 permits such control. In the Northern Territory, the Food and Drugs Act 1936-1979 and the Food Standards Act 1979 are both relevant.

Apart from these controls one should note the special provision of the Therapeutic Goods Act 1966 (Cth) which empowers the Commonwealth Director-General of Health both to obtain information from a "manufacturing corporation" concerning the procedures it employs in the manufacture of a "biological product",¹²⁸ and to determine the procedure to be carried out in the production of a biological product.¹²⁹ A "biological product" is defined in s23A(1) as follows:

"biological product" means goods for therapeutic use that are, are produced from, or the production of which involved the use of, organisms or the tissue or body fluids of organisms, and includes vaccines and toxoids, but does not include antibiotics or products derived from plants, other than antibiotics or such products that are used as antigens or happens".

Whilst these Commonwealth powers may not relate to every process in which the recombinant technique is used, in that not all products of the technique are "biological", the power certainly might be used in respect of some organisms directly produced by recombinant means.

Finally, it might generally be noted that under most dangerous goods and health legislation, and the Commonwealth Therapeutics Goods Act 1966, broad labelling, packaging and transporting regulations might be imposed in respect of hazardous goods or substances.

2.4 ENVIRONMENT PROTECTION

2.4.1 Introduction

The accidental release of recombinant DNA substances into the environment may be hazardous to organisms other than humans. It may pose a risk to disease to animals and plants; and it may cause a deterioration in the quality of the physical environment, especially land, water and air.

In this section, laws designed to prevent or control the spread of disease to plants and animals are identified, as well as laws dealing with environmental quality control. In respect of the latter, the main purpose of this section will be to indicate legislative sanctions for waste discharge or pollution offences. A more detailed discussion of environmental quality controls will be provided in Part 3 of the Report dealing with the deliberate release of recombinant organisms into the environment.

2.4.2 Plant diseases

Each of the Australian States and Territories has long had legislation designed to prevent the introduction into the

jurisdiction of diseases and pests likely to affect plants or fruit, as well as to enable the eradication of them should they occur. The Commonwealth also has legislation which enables the quarantining of diseased plants.

2.4.3 States and Territories

The broad scheme of the relevant legislation is to define the "diseases" or "pests", or both, the spread of which it seeks to control. Usually, even where an Act provides a specific or general definition of these terms, it also empowers the Government to cause a disease to be declared for the purpose of control.¹³⁰

The substantial measure created by the Act for controlling diseases and pests likely to be harmful to plants is the power to prohibit the bringing into the State of anything likely to introduce a disease or pest.¹³¹

Ancillary to this means of control are powers to

- . establish quarantine areas
- . require persons to employ quarantine or disease or pest eradication measures
- . effect the seizure of certain plants, fruit and other things
- . destroy infected plants¹³².

Inspectors may be appointed with the usual powers of entry and seizure necessary to enforce the legislation.¹³³

2.4.4 Commonwealth

As noted in the earlier section of this Part dealing with public health, the Quarantine Act, 1908 (Cth) may allow broad control to be exercised over "quarantinable disease" which infects not only humans and animals, but also plants.

The Act would in an emergency permit broad Ministerial quarantine directives and measures incidental thereto, aimed at the isolation and eradication of disease, including the vegetation infested with it.¹³⁴

Plants made the subject of the Commonwealth Act might be generally quarantined and their movement from one part of the Commonwealth to another part, duly regulated.¹³⁵

2.4.5 Animal Diseases

The States and Territories have long had legislation to prevent the spread of disease or pests to animals. The legislation is similar, and follows closely the scheme of, the various plant disease Acts.

Additional to any definition of disease in the Acts, Government may cause any disease, being a disease in stock, to be declared a disease for the purpose of the legislation.¹³⁶

The Acts usually require notice of diseased stock to be given to officials,¹³⁷ and authorize the Minister or an official to declare any land to be a quarantine area on account of the presence of any disease.¹³⁸

Government may also control the importation of stock, animal products, and other things which might infect or contaminate stock with disease.¹³⁹

As in the case of plant disease control, inspectors appointed under the Acts have extensive powers to stop enter and search vehicles and destroy stock in certain circumstances.¹⁴⁰

There exists also an extensive power to make regulations dealing with these diseased stock.¹⁴¹

In New South Wales, the Cattle Slaughtering and Diseased Animals and Meat Act, 1902 also makes some provision for the destruction of diseased animals both within and outside slaughterhouses.¹⁴²

Apiary legislation in most jurisdictions allows control to be exercised over diseased bees.

In the Commonwealth, the Quarantine Act 1908, discussed in the preceding sections, applies to animals in the same way as it does to humans and plants.

2.4.6 Environmental Quality Controls: Introduction

In most jurisdictions there are laws controlling the discharge of matter to the environment. The ultimate aim of these laws is to prevent or minimize the pollution of the atmosphere, water and the soil. The majority of jurisdictions have specific Acts dealing with each type of pollution. A few jurisdictions have enacted a comprehensive statute to deal with all types of pollution. In practice, however, each form of pollution is the subject of discrete control by an environment protection agency.

2.4.7 Waste Discharge to Soil: Introduction

In one sense, the control of soil pollution is the least satisfactory form of pollution control in Australia. Whilst Victoria and Tasmania have comprehensive pollution control Acts which deal with air, water and soil pollution in a similar way, in most other jurisdictions only air and water pollution are the subject of comprehensive control. In these latter jurisdictions soil pollution control is achieved by the operation of various Acts.

2.4.8 New South Wales

In New South Wales, the Waste Disposal Act, 1970 (NSW) sets up an authority to deal with waste disposal in the metropolitan region. It empowers the authority to establish depots, licence carriers of waste, and regulate the nature of wastes which may be left at depots.¹⁴³ As a "depot" has a broad meaning including any premises to which waste has been transported for storage or disposal,¹⁴⁴ these provisions effect a universal waste management control system, at least in the metropolitan area.¹⁴⁵ Clearly, though, they do not affect the treatment, storage or disposal of wastes on-site at the premises where they are generated. Nor do they create a specific soil pollution offence.

2.4.9 South Australia

In South Australia, the management of waste disposal is effected through the South Australian Waste Management Commission Act, 1979. A broad licensing system operates in respect of the use of premises for waste storage or treatment¹⁴⁶ and the collection and transportation of wastes.¹⁴⁷ It is an offence for a person to do such things without a licence. There is also a broad power to make regulations dealing with wastes.¹⁴⁸

The Act does not, however, specifically make it an offence for a person to pollute soil. In this context, health¹⁴⁹ and local government legislation¹⁵⁰ may be relevant.

2.4.10 Western Australia

In Western Australia, local authorities are empowered by the Health Act 1911 to operate waste management depots and generally to control waste management.¹⁵¹ Soil pollution may possibly be an offence under this Act, for it proscribes any "deposit which is offensive or injurious to public health."¹⁵²

Regulations made under the Local Government Act 1960 may also be relevant to waste discharge to soil.¹⁵³

2.4.11 Queensland

The position in Queensland is basically similar to that in Western Australia. Local authorities are empowered to collect and dispose of refuse under the Health Act 1937-81.¹⁵⁴ It is also a statutory nuisance under the Act to cause a "deposit which is nuisance or injurious or prejudicial to health".¹⁵⁵ Regulations made under this Act may also be relevant.¹⁵⁶

2.4.12 Tasmania

The Environment Protection Act 1973 makes it an offence to cause soil pollution.¹⁵⁷ It is a defence, however, to show that prescribed waste emissions standards have been complied with or, if no standards are applicable, that the best practicable means have been used to prevent pollution.¹⁵⁸

The Act also requires "Scheduled premises"¹⁵⁹ to be licensed. Thus, the discharge of any wastes to soil from such unlicensed premises would be an offence.¹⁶⁰

2.4.13 Victoria

In Victoria, a comprehensive pollution control Act makes it unlawful to discharge any wastes to the environment, including to the soil.¹⁶¹ The unauthorised discharge of wastes, even accidentally, is proscribed by the Act. Under the Act it is also an offence to pollute the soil.¹⁶²

Except in certain cases,¹⁶³ the pollution of soil from an accidental release or recombinant material would constitute an offence under the Act.

Existing health and local government legislation creating statutory nuisance offences may also create soil pollution offences.

2.4.14 Northern Territory

In the Northern Territory, the Public Health Act, whilst not dealing specifically with soil pollution, enables Regulations to be made dealing with wastes and refuse.¹⁶⁴

2.4.15 Australian Capital Territory

In the Australian Capital Territory a variety of laws control soil pollution. It is an offence under the Protection of Lands Ordinance 1937, for example, for a person to deposit on unleased Commonwealth land "any substance, material or thing" without permission.¹⁶⁵

Waste management is achieved through the Garbage Regulations, made under the Building and Services Ordinance 1924, and require garbage to be kept for collection.¹⁶⁶

Otherwise, soil pollution is not specifically controlled in the Territory.¹⁶⁷

2.4.16 Water Pollution: Introduction

Water quality control is effected by each of the States and Territories. The Commonwealth does not exercise broad controls over water quality.

In most jurisdictions there exists a broad system of control over the discharge of matter to water. In some jurisdictions no wastes may be discharged to water without a licence. In others, only certain premises, or certain waters, are the subject of a licensing scheme. In all jurisdictions a sanction is created for water pollution.

Set out in this section are the sanctions created by State and Territory legislation for in respect of unlicensed discharge or water pollution. The broad water quality control systems in each jurisdiction designed to prevent the occurrence of water

pollution are examined in Part 3 of the Report dealing with the deliberate release of recombinant organisms.

2.4.17 New South Wales

Clean Waters Act, 1970, s16: water pollution offence. Penalty: \$40,000 for a corporation, with a daily penalty of \$20,000; for any other person \$20,000, with a daily penalty of \$10,000.

2.4.18 Victoria

Environment Protection Act, 1970:

1. s20(1) prohibits discharge of any wastes without licence. Penalty: 10 penalty units (s67).
2. s38 requires waste discharges to water to be in accordance with State Environment Protection Policy (SEPP), if any. Penalty: 10 penalty units (s67).
3. s39 prohibits water pollution. Penalty: 100 penalty units, with a daily penalty of 40 penalty units.

2.4.19 Queensland

Clean Waters Act 1971:

1. s23(1) makes it an offence for the occupier of premises to discharge wastes to waters without licence. Penalty: \$10,000, with a daily penalty of \$1,000 (s48).
2. s31, imposes a duty on the occupier of premises to prevent water pollution. Penalty: \$10,000, with a daily penalty of \$1,000 (s48).

2.4.20 South Australia

Water Resources Act, 1976, s61 prohibits the discharge of any wastes to water without permit. Pollution, per se, is not referred to in the Act. Penalty: \$10,000.

2.4.21 Tasmania

Environment Protection Act, 1973:

1. s23 makes it an offence to operate "scheduled premises" without licence. Penalty: a daily penalty of \$1,000 (s48).
2. s15(1)(b) prohibits water pollution. Penalty: \$5,000, with a daily penalty of \$1,000 (s47).

2.4.22 Western Australia

1. Rights in Water and Irrigation Act, 1914, s10 creates a water pollution offence. Penalty: \$200 (s72). See

also s27A.

2. Waterways Conservation Act, 1976, s48(3) generally prohibits water pollution (of waters affected by the Act). Penalty: \$5,000, with a daily penalty of \$100.

2.4.23 Northern Territory

Control of Waters Act, s10 prohibits water pollution. Penalty: \$1,000 (s17).

2.4.24 Australian Capital Territory

Lakes Ordinance 1976, s33 prohibits pollution of lakes. Penalty: \$200.

A Proposed Draft Water Pollution Ordinance 1983 (ACT), if enacted, will prohibit waste discharges to classified waters without a licence. At the time of submission of this Report, the draft Ordinance had not been enacted.

Additional to the specially designed water quality control laws, public health, local government or water management legislation often create specific or statutory nuisance offences for water pollution or instances of it.¹⁶⁸

It may also be an offence under State and Territory sewerage legislation or regulations to discharge wastes into the sewerage system.¹⁶⁹ The broad controls which exist in each jurisdiction over sewage disposal would enable the proscription of the discharge of recombinant materials in this way, should it be considered appropriate.

2.4.25 Air Pollution: Introduction

As in the case of water quality control, it is the States and Territories, and not the Commonwealth, which currently exercises control over air quality.

In most jurisdictions there exists a broad system of control over the discharge of matter to air. As with water quality control, in some jurisdictions no matter may be discharged to air without a licence. In others, only certain premises are the subject to a licensing scheme. Surprisingly, and by contrast to the water quality legislation, not all air quality legislation imposes a sanction in respect of air pollution.

The control systems are more fully examined in Part 3 of the Report dealing with the deliberate release of recombinant organisms. In this section, the sanctions created by State and Territory laws in respect of unauthorized waste discharge to air, and air pollution, will be identified.

2.4.26 New South WalesClean Air Act, 1961:

Under this Act, there is no separate offence for air pollution. Instead there are a number of relevant control provisions.

1. s10, requires the operator of "scheduled premises" to be licenced. Penalty: for a corporation, \$40,000, with a daily penalty of \$20,000; for any other person, \$20,000, with a daily penalty of \$10,000.
2. s15 requires the operator of "scheduled premises" to comply with relevant emission standards, or otherwise use the best practicable means available to minimize pollution. Penalty: as in 1.
3. s19 requires the operators of all other premises to comply with relevant emission standards, or otherwise use the best practicable means available to minimize pollution. Penalty: as in 1.

2.4.27 VictoriaEnvironment Protection Act, 1920

1. s20(1) prohibits the discharge of any wastes without licence. Penalty: 10 penalty units (s67).
2. s40 requires waste discharges to the air to be in accordance with State Environment Protection Policy (SEPP), if any. Penalty: as in 1.
3. s41 prohibits air pollution. Penalty: 100 penalty units, with a daily penalty of 40 penalty units (s43).

2.4.28 QueenslandClean Air Act 1963-1978

This Act does not specifically make it an offence to pollute air. Instead, a number of its provisions are designed to control pollution.

1. s18 requires "scheduled premises" to be licensed. Penalty: \$10,000, with a daily penalty of \$1,000 (s46(3A)).
2. ss26 and 31 require all premises in Queensland to comply with prescribed emission standards, or otherwise to use the best practicable means available to minimize pollution. Penalty: as in 1.

2.4.29 South Australia

There is no specific air pollution offence under the relevant legislation. The Health Act 1935-75 rather authorizes the making of regulations to control air pollution. Offences may be created

thereunder for failure to comply with the air quality control system.

2.4.30 Tasmania

Environment Protection Act, 1973

1. s23 makes it an offence to operate "scheduled premises" without a licence. Penalty: a daily penalty of \$1,000 (s48).
2. s15(1) prohibits air pollution. Penalty \$5,000, with a daily penalty of \$1,000 (s47).

2.4.31 Western Australia

Clean Air Act 1974-81

1. s23 requires all "scheduled premises" to be licensed. Penalty: \$10,000, with a daily penalty of \$1,000 (s52).
2. ss33, 38, 39 require all premises to comply with prescribed emission standards, or otherwise to use the best practicable means available to minimize pollution. Penalty: as in 1.

2.4.32 Northern Territory

Public Health Act, s10(1) may enable air pollution to be controlled by regulation, as in South Australia, and, thus, offences may be created by regulation. To a small extent only, the Public Health (General Sanitation, Mosquito Prevention, Rat Exclusion and Prevention) Regulations may be relevant to air quality control.

2.4.33 Australian Capital Territory

At present, there is no general law dealing specifically with air pollution. Odours arising from premises may constitute an offence under the Public Health (General Sanitation) Regulations, Reg 8.

A Proposed Draft Air Pollution Ordinance 1983 (ACT) will provide a more comprehensive approach to air pollution in the Territory when enacted. At the time of the submission of this Report it had not been enacted.

Additional to clean air legislation, public health and local government legislation often create statutory nuisance offences which may be relevant in the case of air pollution.¹⁷⁰

2.4.34 Flora and fauna

Waste discharges likely to cause harm by transmission of disease to plants or animals have already been discussed. Discharges to water likely to affect marine and aquatic life are affected by water pollution controls. Through the air and soil pollution control systems, other harms likely to be suffered by plants and animals are capable of control.

An accidental release of recombinant DNA materials directly causing harm to plants and animals might also offend provisions of the general criminal law, prevention of cruelty to animals legislation, and various wildlife (both plants and animals) protection Acts. These laws are not discussed in this Report. They will usually be only of secondary, or even tertiary, relevance to an accidental release of recombinant DNA materials.

2.4.35 Common Law Liability: Preventive Law

Quite apart from the various statutory regimes or provisions designed to secure occupational and general public health and safety, as well as to protect the physical environment from disruption, it is important to note that traditional common law remedies (trespass and nuisance in particular), may have some utility in the case of an accidental discharge of recombinant DNA materials into the environment.

The tort of trespass occurs whenever a person intentionally permits or causes interference with another's person or property.¹⁷¹

The tort of nuisance¹⁷² may be divided into two categories: private and public. Private nuisance occurs when a person substantially interferes with the use and enjoyment of another's land. Public nuisance occurs when a person substantially interferes with the enjoyment of a public right, or with the use and enjoyment of the land of a number of persons.

Should the accidental release of recombinant materials so interfere with another's person, property or the exercise of a public right (eg to be in a public park, or to use a road or a footpath), a court in its discretion¹⁷³ might grant an injunction at the instance of a person so affected¹⁷⁴ to restrain the breach of the law.

Should loss or damages ensue, an affected person may not only seek the grant of an injunction, but also apply for financial compensation (damages) for the sustained loss. Liability for damages, involving other common law rules, is considered further in Part 3 of the Report.

PART 3: DELIBERATE RELEASE

3.1 INTRODUCTION

In Part 1 of this Report, several important applications of the recombinant DNA technique were identified. Apart from a continued use of the recombinant technique in research laboratories, it might be employed on a larger scale in industry to produce, for example, pharmaceuticals. Many of these beneficial uses of the technique produce non-living substances, like pharmaceuticals, which do not pose new hazards to society or the environment. To the extent that they may be chemically or otherwise hazardous, existing controls over their manufacture and the subsequent usage, should prove adequate. In other words, the products are not to be treated any differently from all other dangerous or hazardous substances or goods. Part 2 of the Report outlined the existing legal controls over such processes and products.

Increasingly, however, recombinant DNA technology may produce recombinant organisms for special beneficial purposes. In Part 1 of the Report, some of these living products were identified: new varieties of plants or breeds of animals; live vaccines for veterinary or human uses; specially designed micro-organisms for use in pollution abatement and in mineral and oil recovery. Of course, an underlying potential use of the recombinant technique is in the human reproductive and genetic processes.

Part 2 of the Report identified those laws which, firstly, seem capable, in a primary or secondary way, of penalising persons in respect of accidental release of materials from the recombinant DNA process and, secondly, enable preventive (or clean-up) action to be taken in the event of their accidental release.

This Part of the Report deals with those laws which may directly or indirectly penalise and regulate the deliberate release of a recombinant organism into the environment. A number of the laws examined in Part 2 may be relevant here, especially those dealing with the manufacturing of dangerous substances or goods, as well as those concerned with the preservation of environmental quality. But other laws may also be relevant to the control of a deliberate release program, including environmental impact assessment procedures, environmental quality control laws, and legislation regulating agricultural and primary industry practices.

It is not possible to be definitive in carrying out this task, for the full array of existing laws appropriate to deal with a deliberate release program will usually only become evident when the deliberate release program is particularized. Hence, those laws of general relevance, first, to environment protection and, secondly, to human protection are discussed in this section.

It will be observed in this Part of the Report, that the Commonwealth does not exercise sole, or even umbrella, control over deliberate release programs. As a result, it is necessary

to identify relevant laws in each of the States and Territories, as well as the Commonwealth. To achieve this, important areas of possible control will be discussed on a jurisdictional basis.

3.2 The Administrative Proposals of the Recombinant DNA Monitoring Committee appointed by the Commonwealth Minister of Science and Technology

During 1984 the Recombinant DNA Monitoring Committee began preparation of guidelines for the deliberate release of organisms modified by the recombinant DNA technique. An early draft of these guidelines was given to the author so that he might gain an understanding of the Committee's approach or at least its initial approach to the subject. Quite clearly, the comments and analysis in this sub-section must be viewed in the light of the fact that the Committee is yet to determine its final approach. Inquiries regarding the current stage of the development of these guidelines should be referred to the Secretary of the Committee. The draft guidelines are designed to ensure that proposed releases are adequately examined and reviewed to minimize the possibility of genetically manipulated organism causing harm to agriculture and the environment in general.

Under the draft, an institutional biosafety committee (IBC), initially undertakes review of a deliberate release proposal. The proposal is then referred to the Monitoring Committee which must proceed to advise the IBC whether it (the IBC) should approve or reject the proposal.

Before the Monitoring Committee will advise approval of a proposal it must be "demonstrated", by a person or institution (co-extensive with the IBC) seeking to release an organism, that the organism is "most unlikely to have any harmful affect on the environment (including agriculture)." The effect of this procedure is to require the person or institution proposing release to establish its safety rather than require the monitoring committee to establish hazard.

To assist it in its deliberations, the person seeking release must provide the Monitoring Committee with information concerning the purpose of the project, of which the deliberate release is part, and the environmental aspects of the release. The provision of such information by the person seeking release is akin to the preparation by a proponent of works of an environmental impact statement under environmental impact assessment law, a matter dealt with further below.

The information provided to the Monitoring Committee is designed to enable a reasonable assessment of the direct impact of a released organism, as well as its likely survival rate and, hence, likelihood to have an indirect ecological impact.

A number of points should be made concerning the draft. First, it is not an instrument having the force of law. It does not have, for example, the status of an Act of Parliament, nor is it passed by authority of an Act of Parliament as, for example, is delegated legislation such as Regulations, Rules, Orders and

By-Laws. Consequently, any breach of the procedures laid down by the draft Interim Statement is not per se a breach of the law.

If the procedures have any legal effect it can only be because government or other institutions in granting research and development funds, or employers in contracts of employment, demand, thus making it a contractual term enforceable by normal civil litigation, that the Committee's procedures be followed.

Secondly, whilst such legal grant and employment constraints exist by virtue of the concern of a relatively small group of interested researchers, institutions and government, one cannot envisage major difficulty with procedural compliance. However, it may be suggested that in the event of expansion of industrial or agricultural application of the recombinant technique, these purely administrative procedures will lose any element of legal enforceability and carry with them nothing but moral suasion.

At this early stage the Monitoring Committee's draft provides no opportunity either for public comment on the information provided to the Committee, or for members of the public to make representations to the Committee as to the advice it should render an IBC concerning a proposed deliberate release. Given the potential for considerable public unease in some cases of deliberate release, the brevity of the proposed procedures may warrant review.

Finally, it is interesting to note that the draft does not take away from IBCs the responsibility to approve or reject deliberate release proposals. The Monitoring Committee merely advises an IBC of its view of a proposal. Of course, nor does the Monitoring Committee have any legal power to require its approval to a deliberate release programme. In any event, a two-stage decision-making process may be considered safer than a one-stage process. Whether, given the potential impact of a deliberate release program, sole responsibility for the approval of it should lie with a government authority rather than a (necessarily) localised IBC remains an open issue.

3.3 ENVIRONMENTAL IMPACT ASSESSMENT (EIA) LAW

3.3.1 Introduction

It is possible that Commonwealth and State law may require an assessment of the environmental impact likely to flow from a deliberate release into the environment of a recombinant organism. It should be noted at the outset, however, that not all jurisdictions have EIA laws, as distinct from administrative procedures, and that where laws do exist, they are often attended by enforcement difficulties.

3.3.2 Commonwealth

The Environment Protection (Impact of Proposals) Act 1974 (Cth) was enacted with the lofty object of ensuring "to the greatest extent that is practicable, that matters affecting the environment to a significant extent are fully examined and taken into account in and in relation to-

- (a) the formulation of proposals;
- (b) the carrying out of works and other projects;
- (c) the negotiation, operation and enforcement of agreements and arrangements (including agreements and arrangements with, or with the authorities of, the States);
- (d) The making of, or the participation in the making of, decisions and recommendations; and
- (e) the incurring of expenditure, by or on behalf of, the Australian government and authorities of Australia, either alone or in association with any other government, authority, body or person.¹⁷⁷

To achieve this "object", the Act provides for the formulation and approval of "Administrative Procedures" in respect of the preparation and use by government decision-makers of environmental impact statements (EIS).¹⁷⁸ It is also possible for environmental assessment to be effected by a public environmental inquiry.¹⁷⁹

Whether the Act, and its Administrative Procedures, are capable of requiring environmental assessment in any case, as distinct from facilitating assessment where government or a decision-maker may think it a prudent step, is dependent on a number of further issues:

1. What obligation, if any, is imposed by the Act for the conduct of EIA?
2. If there is an obligation, upon whom is it imposed?
3. Is the obligation enforceable by court order?

It is accepted by most legal commentators that s5 of the Act is merely an objects provision and does not impose an enforceable obligation on Commonwealth decision-makers to have regard to environmental factors in decision-making.¹⁸⁰ Nor does section 6 in terms do so, although the Administrative Procedures it authorizes, and to which we shall soon turn, may well have such an effect. Section 8 appears to be the provision of the Act most relevant in our search as it provides that a Minister shall:

'give all such directions and do all such things as, consistently with any relevant laws as affected by regulations under this Act, can be given or done by him -

- (a) for ensuring that procedures for the time being approved under this Act are given effect to in and in connexion with matters dealt with by the Department administered by him and that any authority of Australia in relation to which he has ministerial responsibilities observes, and assists in giving effect to, those procedures; and

- (b) for ensuring that any final environmental impact statement formulated in accordance with those in accordance with those procedures, are taken into account, in matters to which they relate, in the Department administered by him and by any authority of Australia in respect of which he has ministerial responsibilities.'

Section 8 does not, however, explicitly require the preparation of an EIS in prescribed circumstances.¹⁸¹ Instead it merely imposes on the responsible Minister, not the instant decision-maker, the obligation to ensure that the Administrative Procedures are complied with, and that, where an EIS has been prepared, it is considered. To the extent that there is a duty cast upon a Minister it is subject to the "practicability" and "feasibility" qualifications. To date, no legal action has been successfully concluded in reliance on s8; indeed there are few examples of litigation instituted in reliance on s8.¹⁸² To say the least, s8 imposes an obligation of uncertain content and weight.

The Administrative Procedures are pivotal to the effective operation of the Act. There are two difficulties with these Procedures, however, one being whether they are themselves enforceable, the second being whether they contain clear obligations in any event. As to the second point, nowhere in the Procedures is it explained in what circumstances the Procedures commence to operate, or who initiates them.¹⁸³ It appears that an "Action Minister", that is a Minister to whom a decision-maker is ultimately responsible, may initiate the EIA process, but clearly is under no legal obligation so to do. Equally, there is no clear initiation obligation or right on or in the Commonwealth Department of Environment. Nor is there anything in the Procedures specifying the circumstances in which the Procedures are to be initiated - foreexample, where a government decision is likely to have a significant environmental impact. Thus one is lead to the conclusion that the Act does not create any clear procedural obligations in respect of which a court could find that a prescribed code for behaviour has been violated.

As to the first point, it is highly arguable that the Administrative Procedures do not themselves create legal obligations, having merely an administrative effect. Consequently, whatever procedural or substantive code of behaviour is prescribed by them, they cannot be equated with "law". In a sense, they may have no higher legal status than any other set of departmental (administrative) directions. There is, however, room for different views and no court has finally determined this issue.¹⁸⁴ To the extent that s8 requires the Minister to ensure compliance with the Administrative Procedures, this deficiency may be overcome. It may mean, however, that obligations apparently cast by the Procedures themselves on persons other than the Minister, may not be directly enforceable. To put the issue simply, to prove such a person may have breached the Procedures is not to say that the Minister has, by virtue of s8, failed to do all he can to ensure compliance with the Procedures.

Whatever obligations the Act, or the Procedures, may create, may be effectively undone, so far as enforcement of the Act is concerned, by the restrictive common law standing rules limiting the circumstances in which a member of the public may initiate legal proceedings based on a breach, or threatened breach, of the Act. In the leading case Australian Conservation Foundation v Commonwealth,¹⁸⁵ the High Court established the principle that such proceedings may only be initiated by a member of the public with a "special interest" in the subject matter of the proceedings over and above that enjoyed by other members of the public. An "intellectual or emotional" interest is not of itself sufficient.¹⁸⁶ This ruling will make it extremely difficult for the Act to be enforced without the fiat of the Commonwealth Attorney-General.¹⁸⁷

It may, nevertheless, be possible for members of the public to enforce the Act by an action based on s10 of the Act, an overlooked but important provision. It places the Minister for Environment under a duty to respond to a request from any member of the public for information concerning 'what action, if any, has been taken, or is proposed, for ensuring consideration' of a matter referred to in section 5.

By writing to the Minister asking what action has been taken on a particular matter a person may either prompt the Minister into action or receive a reply that no action is contemplated. No action may be contemplated either because it is the Minister's opinion that section 5 does not apply to the action or simply because, regardless of its environmental impact, the Minister is not interested in the matter. If the latter is the case, a person might gain political capital even though no court action might be possible. If the former, then it is quite open to argue that a court could review the Minister's decision that the action was not within section 5. This follows because section 10 does not leave to the Minister's discretion the issue of whether a matter is caught by section 5; it simply requires the Minister to respond to a request for information where a section 5 action presently exists. Thus, whether or not an action is within section 5 may be a question of law capable of being determined by a court at the instance of the person who has requested information of the Minister. On the other hand, section 10 might possibly be narrowly construed to allow requests only in respect of matters which the Minister has already determined to be within section 5. Such a narrow construction, however, does not accord with the ordinary meaning of the words in section 10.

The thrust, or spirit, of the Act, if not its precise requirement, is to subject to environmental assessment all government decision-making having the potential to affect the environment. If a significant impact is likely to occur then an EIS should be prepared so that a proposal is rigorously examined. As "environment" is defined in broad terms under the Act,¹⁸⁸ there can be little doubt that the deliberate release of an organism into the environment is capable of being caught by the Act. If a government decision is to be made, or the funding of a proposal is to be approved, in respect of a project in which the deliberate release of a recombinant organism will occur, then there is no reason in principle why environmental assessment

should not occur. Indeed, the Commonwealth Minister for Science and Technology, as the Minister ultimately responsible for the decisions of the Recombinant DNA Monitoring Committee, may be considered subject to s8 of the Act in relation to the Committee's decisions both in respect of decisions on specific projects and in the formulation of guidelines.

The conduct of an EIS, should it be required under the Administrative Procedures, raises some interesting issues. In the United States, a considerable body of law has been built in this area over a decade and a half. As it has been succinctly stated, the National Environmental Policy Act of 1969 (US), "requires agencies to fully consider and disclose to the public environmental impacts and uncertainties, to speculate on all but highly remote consequences, and to divulge competing scientific views."¹⁸⁹ Indeed, an EIS in some cases may have to comply with the "worst case" rule, that is, an analysis of the environmental effects of a low probability/high risk action associated with the project and of the probability of the action.¹⁹⁰

There has been no such legal or administrative development of EIA law under the Commonwealth Act, although it may be argued that there is no reason why the thorough US approach could not be justified under the Administrative Procedures. Procedure 4.1, for example, specifies that an EIS should to the extent appropriate in the circumstances of the case -

To the extent appropriate in the circumstances of the case, an environmental impact statement shall -

- (a) state the objectives of the proposed action;
- (b) contain a description of the proposed action;
- (c) analyse the need for the proposed action;
- (d) indicate the consequences of not taking the proposed action;
- (e) examine any feasible and prudent alternative to the proposed action;
- (f) include information and technical data adequate to permit a careful assessment of the impact on the environment of the proposed action;
- (g) describe the environment that is likely to be affected by the proposed action and by any feasible and prudent alternative to the proposed action;
- (h) assess the potential impact of the environment of the proposed action and of any feasible and prudent alternative to the proposed action, including, in particular, the primary, secondary, short-term, long-term, adverse and beneficial effects on the environment of the proposed action and of any feasible and prudent alternative to the proposed action;

- (i) outline the reasons for the choice of the proposed action;
- (j) describe, and assess the effectiveness of, any safeguards or standards for the protection of the environment intended to be adopted or applied in respect of the proposed action; and
- (k) cite any sources of information relied upon in, and outline any consultations during, the preparation of the environment impact statement.

It is quite open to argue, especially under Procedure 4.1(h), that a rigorous analysis of the potential impact of deliberate release, its cumulative effect, and indeed a "worst case" analysis, are all within the contemplation of the Procedures and the Act.

3.3.3 The States and Territories

Where there is Commonwealth action, the Commonwealth EIA law may have application. Thus significant Commonwealth activity, albeit within the boundary of a State and Territory may be the subject of an EIS. Where there is no such involvement, State or Territory law governs the situation. In New South Wales, Victoria, South Australia and the Northern Territory, there exists a legislative basis for EIA. In other States, EIA is purely an administrative matter covered by government guidelines having no legal force or effect. The ACT does not have discrete EIA legislation, although the Commonwealth EIA legislation will often have application to local decision-making. The Commonwealth legislation may also apply to Northern Territory decision-makers.

3.3.4 New South Wales

New South Wales has the most legally exacting EIA law in Australia, including the Commonwealth. The Environmental Planning and Assessment Act, 1979(NSW) Part V, potentially applies to a wide range of activities likely to impact upon the environment. First, it should be noted that the scope of this law is not as all-embracing as the Commonwealth Act. The "activities" to which it applies includes only physical activities, and to recommendations, proposals or expenditure relating to physical activities, which government plans to carry out or for which government approval is necessary.¹⁹¹ By contrast, the Commonwealth Act in s5 focusses broadly on decisions which affect the environment. Thus in New South Wales a government decision to fund a scientific research project concerned with the production of nitrogen-fixing plants through recombinant DNA means might not be an "activity" under Part V of the Act, whereas under the Commonwealth Act a funding proposal of that type clearly might affect the environment, albeit in the longer term. However, under either Act, a decision by government, or an activity funded or approved by government, to release deliberately into the environment a recombinant organism clearly might be the subject of EIA procedures.

Where, under the New South Wales Act, there exists a relevant "activity", then two important requirements command attention:

1. s111 demands that the relevant government agency "consider and examine to the fullest extent possible" the environmental impact of the activity;
2. s112(1) demands that, if there is likely to be a significant environmental impact, the government agency examine and consider an EIS, prepared in accordance with prescribed regulations, before approving or carrying out the activity.

At least three things flow from this law. Firstly, the failure of a government decision maker to consider to the fullest extent possible the environmental impact of an activity, regardless of the significance of the impact, may lead to an injunction restraining the activity from being carried on. Secondly, the failure to prepare an EIS where an activity may have a significant environmental impact, may similarly lead to the grant of a restraining injunction.¹⁹² Thirdly, the failure to prepare an EIS in accordance with the regulations may also lead to an injunction restraining the activity.¹⁹³

As yet, the NSW Act has not been fully tested by legal probes. There is uncertainty as to how rigidly the courts will interpret the requirement to prepare an EIS in accordance with the regulations. So far a "substantial compliance" test has been developed on the basis that one cannot expect an EIS to comply with a standard of absolute perfection. There are however strong grounds for arguing that the thorough approach used in the United States in this area, is both appropriate and relevant.¹⁹⁴ This may lead for example to the adoption of "worst case" analysis in cases involving the deliberate release of a recombinant organism.

3.3.5 Victoria

In Victoria, the Environment Effects Act 1978 lays down guidelines for the environmental assessment of "public works" having environmental significance.¹⁹⁵ The Act has only secondary application to private works.¹⁹⁶

Whilst the Act was apparently intended to provide legislative recognition for pre-existing administrative procedures, it has in fact imposed certain obligations on those directly involved in works likely to impact upon the environment. First, the proponent of public works, that is, the person to carry them out, must decide whether the works will have a significant effect on the environment. If they will, an Environment Effects Statement (EES) must be prepared.¹⁹⁷ If the proponent is in doubt, then he should prepare a Preliminary Environment Report (PER).¹⁹⁸ The Minister for Conservation may also call for the environmental assessment of public works even though a PER or EES has not been lodged with him.¹⁹⁹ The Minister for Conservation may finally determine whether a public work will have a significant effect on the environment,²⁰⁰ although the Governor in Council is able to override the Minister's decision.²⁰¹

"Public works" is defined to mean "works undertaken or proposed to be undertaken by or on behalf of the Crown or for public statutory bodies but does not include works undertaken by or on behalf of municipalities."²⁰² Whether or not the deliberate release of a recombinant organism would be within the Act's primary scope, therefore, will depend on exactly who is responsible for the release project or activity. As the Act is primarily concerned with works which the government itself carries out, works carried out by others with government approval or funding are not directly affected by it.

The Act has only secondary application to works other than public works by enabling government decision makers to request environmental assessment of private works they have been requested to approve.²⁰³ Alternatively, the Minister ultimately responsible for such decisions may require the decision maker to seek assessment.²⁰⁴ But these provisions only have effect where a law requires a person to approve an activity.

In some cases involving deliberate release of a recombinant organism, therefore, where government approval of one sort or another may be required, a decision maker or his Minister may ensure environmental assessment of the activity occurs. However, it should be noted that there is no primary obligation requiring assessment.

It should also be noted that our entire discussion on the Victorian Act is dependent on an activity involving the deliberate release of a recombinant organism being "works", the expression around which the Act revolves. Even s8(1) which uses the expression "decision" seems to require a decision in respect of a "works".²⁰⁵ The Act does not, however, define "works". The Guidelines issued under the Act refer to major kinds of physical activity - engineering works, industrial complexes - which impact upon the environment, but there is no reason why a project involving deliberate release of a recombinant organism should not similarly be included under a wide definition of the expression, especially if it is taken to mean the "doing of something".²⁰⁶

Where environmental assessment does occur, the Minister for Conservation is formally involved in the process due to the Act's requirement that he prepare, "as soon as reasonably practicable in the circumstances of the case", an Assessment of the works. Pending the Minister's Assessment, works cannot be carried on.²⁰⁷

The Guidelines to the Act specify in some detail the content of a PER and EES which may lead to the Minister's final Assessment. There is ample indication in them that these documents should address all likely "physical, biological, social and environmental" effects, and so can deal with the environmental implications of works involving deliberate release.

Finally, it should be observed that the Act does not provide the public with any formal rights to participate in the EIA process. Such rights as they do have are entirely discretionary.²⁰⁸ Indeed, the Act's obvious aim is that the

Minister for Conservation should have all necessary power to see that EIA occurs where it is necessary. Thus the public have not been afforded enforcement rights. Nonetheless, a number of important obligations have been imposed by the Act requiring the preparation of a PER, or a EES, the preparation of an Assessment, and the prohibition of works pending an assessment. In certain cases, a specially interested member of the public may have the right to enforce these obligations or prevent their breach.²⁰⁹

3.3.6 Western Australia

In Western Australia no law positively requires environmental assessment of projects likely significantly to affect the environment. However, a Procedures Bulletin of the Department of Conservation and Environment directs proponents of major works to refer the proposal to the Department. If a full assessment of the project is deemed warranted by the Department, it refers the proposal to the Environment Protection Authority (EPA) which conducts an Environmental Review and Management Programme (ERMP), similar to an EIS.

Given the power of the EPA(WA) to direct persons to take action specified by the EPA in respect of pollution,²¹⁰ the administrative EIA process is likely to be followed in practice, despite the absence of a more formal legal basis.²¹¹

Thus, the general power of any Minister to refer any "proposed development, project ... or other thing" which may have a detrimental effect on the environment to the EPA so that it may furnish advice in respect of it,²¹² lawfully enables government to initiate an EIA of any matter, including one involving the deliberate release of a recombinant organism into the environment. Nonetheless, it should be noted that there is no primary prohibition on deliberate release subject to the consideration of an EIS, as arguably might be the case in New South Wales.

3.3.7 Tasmania

An administrative EIA procedure has been established under Guidelines and Procedures for Environmental Impact Studies issued by the Tasmanian Department of the Environment. As is the case in Western Australia, these guidelines are to some extent linked to other environmental legislation.

Where a licence is sought under the Environment Protection Act 1973 (Tas), to establish and operate "scheduled premises", the Director of Environmental Control is, under the Guidelines, able to determine the need for an EIS. Scheduled premises cover many forms of private development, although, as currently drafted, they do not include deliberate release activities.

In relation to public development, the Guidelines suggest that the decision-making authority should determine the need for an EIS. In cases involving deliberate release by a government body, therefore, an administrative, but not legal, responsibility lies with that body to prepare itself an EIS in relation to the activity.

3.3.8 Queensland

By virtue of s29(2) of the State Development and Public Works Organization Act 1971-78 (Qld), all government departments, authorities and local bodies are obliged to take into account the environmental effects of development in their decision making, and "in doing so have due regard to such policies or administrative arrangements as may be approved from time to time by the Minister."

Under s29(1) of the Act, the Co-Ordinator General has the broad function to ensure that "proper account is taken of environmental effects" of development by government decision makers.

Administrative EIA procedures are set out in a 1979 booklet published by the Co-Ordinator General's Department. They suggest that EIA will only be required by the Co-Ordinator General where "relatively complex environmental issues" are raised by a project.²¹³ It may be argued that where an EIS is prepared it must be considered under s29(2).²¹⁴

Public works, under the guidelines, may also be the subject of EIA. Public bodies are encouraged to make an early preliminary assessment of likely environmental impacts.

In Queensland, EIA may also occur where land use planning consent is required from a local government authority. Local authorities may under s32A of the Local Government Act of 1936, resolve to require an EIS in respect of applications for consent coming before it.²¹⁵

As in Western Australia and Tasmania, EIA of a deliberate release mechanism may be achieved by administrative action. Except for some cases under local government law, it is not a legal requirement. Unless private activity is subject to some other government approval process it is unlikely to be environmentally assessed.

3.3.9 South Australia

By virtue of s49(1) of the Planning Act, 1982 (SA) the Minister for Planning may require the preparation of an EIS where a person proposes to undertake "a development or project ... of major social, economic or environmental importance."

Where a planning authority must consent to a "development" in respect of which an EIS has been prepared, it must "have regard" to the EIS.²¹⁶

It appears, however, that the EIS may be required whether or not consent to the development or project is required by law. Thus the Minister might call for EIA of a proposed deliberate release project whether or not it could lawfully be carried on without consent. This is in contrast to the position of private activity under Queensland law.

As "development" is defined under the Act to include any "act or activity in relation to land declared by regulation to constitute development" a simple administrative step could include a deliberate release project within the scope of s49. It may be, in any event, that a proposed deliberate release is a s49 "project". This expression is not defined in the Act and could be given a meaning sufficiently broad to include a deliberate release or program.

3.3.10 Northern Territory

The Environmental Assessment Act 1982 (NT) bears a great similarity to the Commonwealth Act. It facilitates EIA, but does not require it to be carried out in any given circumstance. It enables Regulations to be passed authorizing environmental factors to be taken into account by decision-makers; the preparation of an EIS; or the conduct of an environmental inquiry.

As the Northern Territory remains constitutionally subordinate to the Commonwealth, the Environment Protection (Impact of Proposals) Act 1974 (Cth), may also impinge on decisions made by Northern Territory officials.

3.3.11 Australian Capital Territory

Although the Australian Capital Territory does not have discrete EIA procedure prescribed by a local Ordinance, it should be noted that the Environmental Protection (Impact of Proposals) Act 1974 (Cth) may run in the Territory. The Act and its procedures have a potentially wide application,²¹⁷ and may apply not only to decisions made under Commonwealth Acts, but also under Territory Ordinances.

3.4 RELEASE TO WATER

3.4.1 Introduction

The discussion in Part 2 of the Report dealing with pollution control laws in each jurisdiction forms the basis of this section.

Recombinant organisms, as we have seen, may potentially be used to clean up oil spills or other contamination of water. Equally the waste from recombinant work may be discharged to water, whether or not through sewerage or drainage systems. This section focusses on laws capable of controlling such activities.

3.4.2 Victoria

In each of the States, water quality control laws are capable of dealing with the deliberate release. Under the Victorian Environment Protection Act 1970, for example, all discharges of "waste" to the "environment" are prohibited without licence. As "waste" is very broadly defined to include any substance which causes "alteration" to the environment, whether or not beneficial, the potential for immediate control of deliberate release of recombinant materials is obvious. Clearly,

recombinant wastes discharged to water would need to be licensed by reason of the change which would occur in the chemical constituency of water.

Whether the same can be said of a deliberate release of recombinant organism is, however, problematical. Would, in an oil spill clean-up operation, the organism alter the chemical constituency of water? The answer probably is "No". "Matter" does not become "waste" unless an "alteration" to the environment occurs. It might be contended, of course, that the physical or chemical constituency of water is changed or altered in such circumstances by the addition of a novel organism.

"Environment" is defined in s4(1) to include water, atmosphere, soil, vegetation, climate, sound, odour, aesthetics, and the "biological factors of plants and animals". Unless one can say that the recombinant organism "alters" these things upon release, it may not be within the scope of the prohibition on waste discharges without licence.

The Act's prohibition of the "pollution" of water, on the other hand, may effectively bring about control. Section 39 of the Act prohibits the pollution of water so as to make it, inter alia, hazardous for living things. Clearly the release of recombinant wastes might cause pollution. So might a deliberately released novel organism. Its presence in a marine environment might pose a threat to aquatic and marine life, or to the life of animals which use the water.

3.4.3 South Australia

The broad prohibition of the discharge of waste into water without a licence under section 61 of the Water Resources Act, 1976 (SA) is similar to that contained in the Victorian Act. However, the "waste" definition in the South Australian Act may enable control over a broader range of activities.

"Waste" is defined in s5(1) to include

"any matter or thing ... which if added to water may cause any interference with the physical, chemical or biological properties of water which may render it less fit for any purpose for which it may be used by man, animal, fish, plant or other organism and includes any ... materials used or produced in or by any manufacturing processes, mining or quarrying, agriculture ...".

It is open to contend that whether the recombinant materials are wastes from a manufacturing process etc, or a novel organism, the definition is applicable to them. The addition to a water supply of such an organism would appear to interfere with the "physical" or "biological" properties of water and clearly might render it useless to other organisms as a source of sustenance, or as a natural habitat (in the event that the novel organism displaces existing ones from that part of the environment). As a result the Act may be considered to have the widest scope of all water quality control laws in Australia.

3.4.4 New South Wales

It is an offence under s16(1) of the Clean Waters Act, 1970 (NSW) to pollute water, although a person does not commit an offence if he holds a licence in respect of the waste discharge.²¹⁸ This provision enables pollutants to be discharged with a licence. If a waste discharge does not cause pollution, there is no licensing procedure or prohibition in respect of it. Thus the New South Wales position may be contrasted with the basic position in Victoria and South Australia.

Pollution occurs under the Act when any "matter" is placed "in or on water ... so that the physical, chemical or biological conditions of the water is changed".²¹⁹ Consequently, as in Victoria and South Australia there is little difficulty in concluding that the discharge of recombinant waste materials to water, from a manufacturing process, for example, might be pollution, and might not be performed except with a licence. If a recombinant organism is discharged to water, it may also be open to argue that it has changed the "physical" or "biological" condition of water, if not the chemical condition, and so is pollution.

Apart from its licensing power under the Act, the State Pollution Control Commission in New South Wales has the power under Regulation 21 of the Clean Water Regulations to issue directions to occupiers of land to employ control equipment and to "undertake such measures as will ... control or prevent the discharge or likely discharge of ... pollutants." Obviously, in practice, this power is an important potential means of control of recombinant DNA releases.²²⁰

3.4.5 Queensland

The Clean Waters Act 1971-1979 (Qld) imposes a broad licensing procedure in respect of waste discharges to water. By s23 of the Act, "the occupier of any premises from which wastes are discharged" to water commits an offence if he does not hold a licence in respect of the activity.

The definition of "wastes" in s8 includes a solid, gas or liquid "capable of causing water pollution". The term specifically includes "materials used in or produced in manufacturing, mining, agriculture and other trade processes". This part of the definition seems to avoid, in most cases, having to prove that a material is likely to cause "pollution". Where it is necessary to do so, that is, where the materials do not originate from the identified processes, it is necessary, according to the s8 definition of "water pollution", to show a

"change in the properties of any waters such as to cause or be likely to cause a nuisance or render such water harmful ... to public health, safety or welfare or to domestic, commercial ... uses ... or to livestock, wild animals, birds, fish or other aquatic life."

The licensing provisions apply to every occupier of premises. "Premises" are defined very broadly in s8 to include, finally,

"any place". Thus, the Act is capable of applying to recombinant releases of all types. If a novel organism can be treated as a "solid, gas or liquid" then, under the first limb of the "wastes" definition, its release may also require to be licensed.

Discharges to water by persons other than the occupiers of premises do not appear to be controlled by the Act. The general provision prohibiting water pollution - s13 - also applies only to the "occupier of premises".

The Minister responsible for the Act is broadly empowered to seek a Supreme Court injunction to restrain any waste discharge which is likely to create water pollution.²²¹

Finally, all occupiers of premises must ensure that their premises are not used so as to cause water pollution. The Water Quality Council can issue directions as to appropriate procedures to be followed to avoid the incidence of water pollution.²²² Failure to comply with these obligations or directions is an offence.²²³

3.4.6 Tasmania

Under the Environment Protection Act 1973 (Tas), s23, no person may operate "scheduled premises" unless he is licensed so to do.²²⁴ Scheduled premises are those set out in Schedule 1 to the Act and include major industrial processes, for example, chemical works. The Minister responsible for the administration of the Act is, however, empowered to declare premises to be scheduled premises.²²⁵

Apart from this broad control mechanism, the Act prohibits the discharge by an occupier of land of a "pollutant" into water sources.²²⁶ Section 17 more generally prohibits the discharge of pollutants into water, from any location.

A "pollutant" may be prescribed; alternatively, it is any substance which causes "pollution".²²⁷ "Pollution" is further defined by the Act to be any "contamination or alteration" of any part of the environment so as to affect beneficial uses adversely, or to cause a condition detrimental to humans, animals, plants, microbes, or property.²²⁸

It would seem clear that recombinant materials as waste products of a manufacturing process, or novel organisms intended to perform specific tasks in the environment, might potentially cause pollution as defined in the Act.

3.4.7 Western Australia

Although the Rights in Water and Irrigation Act, 1914 (WA) makes it an offence to pollute water,²²⁹ it is the Waterways Conservation Act, 1976 (WA) which enables broad control to be effected by a government authority over important waters in Western Australia. Section 48 of this Act prohibits the discharge of polluting matter to water or land where it will be likely to lead to "the impairment of the physical, chemical or

biological condition" of those waters.²³⁰ The discharge of industrial and manufacturing wastes is specifically prohibited by the Act.²³¹

It is a defence to such an offence, however, for a person to hold a "disposal licence". Such a licence is issued under s47. In the exercise of the licensing powers, the Waterways Commission must have regard, inter alia, to whether any substance discharged to land or water is likely

"(iv) to be injurious to marine or animal or human life; or

(v) to deplete excessively the oxygen content of water."

Under both the Rights in Water and Irrigation Act, 1914²³² and the Waterways Conservation Act, 1976,²³³ government has power to restrain activities likely to lead to water pollution.

The Waterways Conservation Act would appear to have the potential to control both recombinant waste materials from manufacturing processes, as well as the release of novel organisms to water (or land) if it is likely to lead to water quality impairment. The only reservation pertains to control of the release of novel organisms. It may be possible to argue that the Act is concerned only with non-living matter. However, as noted earlier, "matter" should be given a broad construction and includes both non-living and living things. Thus "matter" is simply the substance of any living or non-living thing.

3.4.8 Northern Territory

Whilst the Control of Waters Act prohibits pollution of water,²³⁴ the Act does not appear to establish a broad licensing system over waste discharges to water similar to those operating in the States. It does, however, allow for the prescription of waste discharge standards.²³⁵

To control the discharge of recombinant DNA waste products, it would seem necessary either to prescribe standards or pass special control regulations under the Act or under the Public Health Act.²³⁶ Of course, it remains open to argue that any deliberate release of recombinant materials amounts to pollution under s10 of the Act, although to prove such a case it is necessary to establish that the thing discharged was "noisome".

It would also seem open to the government to institute proceedings under the Act to restrain any activity likely to interfere with water quality. This would follow, it may be contended, from the vesting of "property in, and the right to the use and flow and to the control of water" in the Crown.²³⁷ Thus any activity likely to interfere with this right might be the subject of injunctive proceedings.

3.4.9 Australian Capital Territory

Water quality control in the Australian Capital Territory is not easily effected under current law. Pollution of the

Territory lakes is absolutely prohibited;²³⁸ and water supplies are similarly protected.²³⁹

A draft Water Pollution Ordinance is currently being considered for the Territory. Its provisions would prohibit the discharge of wastes into waters unless in conformity with established standards. A licence would issue in respect of authorised discharges.²⁴⁰ The proposed Ordinance would depend heavily on the control of waste discharges through the sewerage system.

As in other jurisdictions, only to the extent that recombinant wastes or organisms constitute a source of detriment to water quality may some control be exerted.

3.5 RELEASE TO AIR

3.5.1 Introduction

It is possible that novel organisms might affect air quality in the course of a deliberate release program, for example, aerial spraying to control plant, insect or animal pests. In such cases, the deliberate release may possibly be controlled by air quality control (pollution) legislation, or in some jurisdictions by aerial spraying legislation.

3.5.2 Air quality control: States and Territories

Air quality control is usually considered to be within the province of the State and Territory legislatures, and not a matter for Commonwealth legislative action.

In most jurisdictions air quality control is achieved under clean air legislation which is primarily designed to deal with pollution from stationary sources, such as factory premises, although it may also apply to mobile sources such as motor vehicles. The activity of aerial spraying has not usually been perceived as a pollution problem and, hence, has not been the subject of specific clean air controls.

Thus, in New South Wales, Queensland, Tasmania and Western Australia, aerial spraying would not easily be controlled. The clean air legislation in these three jurisdictions depends largely on air emissions from premises, which includes land. Licences are usually required in respect of emissions from scheduled premises.²⁴¹

In Victoria, however, the position may be different, for as noted in the discussion above concerning deliberate release to water, the Environment Protection Act 1970 (Vic) requires all "waste" discharges to the "environment" to be licenced. If aerial spraying causes an "alteration" to the atmosphere, as surely it must, then a licence may arguably be required for such an activity.

In South Australia, regulations under the Health Act 1935-1975 (SA) may enable regulations to be passed dealing specifically with aerial spraying. This may also be possible in the Northern Territory under the Public Health Act. The Australian Capital Territory is effectively without legislation in this area.²⁴² When a draft clean air ordinance is ultimately passed for the Territory, it will apply only to premises.

3.5.3 Aerial Spraying

Aerial spraying is, however, directly controlled in some jurisdictions. In New South Wales, the Aerial Spraying Act, 1969 prohibits spraying except by a pilot who holds a prescribed certificate, and unless a security has been lodged with the appropriate authority to cover liability in the case of damage to property arising out of spraying. The Aerial Spraying Control Act 1966 (Vic) and the Aerial Spraying Control Act 1966 (WA) are to similar effect. Regulations made under these Acts may prohibit absolutely the use of certain agricultural chemicals in aerial spraying.

In other jurisdictions, dangerous goods and substances legislation and/or agricultural chemical legislation may also enable an indirect control over aerial spraying by prohibiting the use of certain substances.

3.6 RELEASE TO SOIL

The basic controls over soil pollution are outlined in Part 2 of the Report. In summary, there appear to be few controls over soil pollution. The Victorian Environment Protection Act 1970, by reason of its broad prohibition of the discharge of "waste" to the "environment", discussed more fully above in the section concerning deliberate discharge to water, may enable direct control to be achieved in Victoria, at least, in cases where a recombinant organism is discharged to soil.

It is difficult, however, to imagine that the Act was ever intended to prohibit the planting of crops. In this case, deliberate release programs involving the planting of recombinant plants may also be considered beyond the scope of the Act.

Novel organisms used for agricultural purposes, for example, as pesticides, would be controllable by agricultural chemicals legislation and dangerous goods or substances legislation in most jurisdictions.

Town and country planning controls (or environmental planning controls) may also enable a measure of control to be exerted over a deliberate release program by prohibiting, or making subject to planning approval, the use of land for such a purpose. Each of the States and Territories has land use planning legislation 242A. The Commonwealth does not, except in the Australian Capital Territory and certain other Commonwealth places, exercise direct control over land uses.

It should be noted, however, that planning controls do not always bind government or governmental agencies either in point of law or in their administrative design. Furthermore, State and Territory legislation is usually considered constitutionally incompetent to regulate the land use activities of the Commonwealth Government or its agencies, wherever such uses may occur.

As a result, planning controls may be considered to have their greatest potential scope in respect of deliberate release land-uses conducted by private, non-governmental, bodies.

3.7 PLANTS AND ANIMALS

3.7.1 Introduction

Controls over plants and animals may be relevant to the deliberate release of a recombinant organism in at least three ways. First, they may serve to control the initial use of the recombinant DNA technique in the production or breeding of plants and animals.

Secondly, if plants or animals produced by recombinant means subsequently are considered harmful to other plants, animals or humans, then controls over pest plants and animals may potentially eradicate them.

Thirdly, where a plant or animal is considered a pest, biological eradication measures, perhaps utilizing a recombinant organism, might be adopted to eradicate the pest.

3.7.2 Recombinant Plants and Animals considered as Pests

State and Territory legislation enables plants to be, or to be declared as, a pest and liable to destruction. Commonwealth law may also be relevant to certain dangerous plants. In the main, such laws do not directly apply to the deliberate release of a recombinant plants, and only have significance once the organism has been released and control is desired. It may be possible, however, to declare a plant to be a pest in advance of its reproduction and wider use in agriculture.

3.7.3 New South Wales

The Plant Diseases Act, 1924, s3(1) authorizes the Governor to declare anything to be a pest. A pest is also generally defined in this subsection to mean any organism of the animal kingdom, other than the vertebrata, which feeds upon or is injurious to plants. It would appear that in declaring anything to be a pest the Governor is not limited by the general definition.

The Act contains broad powers to control and eradicate pests. Under s6, quarantine areas may be established. Owners or occupiers of land may be required, under s14, to take steps to prevent the spread of a pest. Under s5A(1)(a), the Minister may require the owner or occupier of land "to do or permit" such acts, and to take such measures, as are specified in a Ministerial Order.

3.7.4 Victoria

The Vermin and Noxious Weeds Act 1958 enables the Governor in Council to declare any plant to be a "noxious weed".²⁴³

In general, it is the duty of the Minister of Lands to take "reasonable action" to destroy and suppress noxious weeds on Crown Land.²⁴⁴ This duty may be extended to private land.²⁴⁵

The Act otherwise creates a Vermin and Noxious Weeds Destruction Board and empowers Inspectors to seize and destroy noxious weeds.²⁴⁶ Offences relating to the keeping or trading in noxious weeds are also created by the Act.²⁴⁷

The Act merely enables destruction of plants perceived to be pests or "noxious". The Act does not in direct terms impose any liability on persons engaged in agricultural research or industrial activities pertaining to plants other than noxious weeds.

Even if a plant is declared noxious under the Act, it is possible for a person to gain the approval of the Board to grow noxious weeds "for research or other purposes",²⁴⁸ and not be liable to criminal prosecution.

3.7.5 South Australia

The Pest Plants Act, 1975 (SA) enables strict control to be effected over plants which have been declared pests. Control, though, depends upon government action. The Governor may, upon the recommendation of the Pest Plants Commission, declare any plant to be a "pest plant".²⁴⁹

Pest plants may be classified in one of three ways:²⁵⁰

1. as a "primary pest plant", in which case it ought to be destroyed;
2. as an "agricultural pest plant", which is detrimental to primary industry;
3. a "community pest plant", which is detrimental to the community or the environment.

The Act creates a notification²⁵¹ and destruction²⁵² system as well as specific offences designed to prohibit trade in pest plants.²⁵³

Interestingly, the Commission might control the transportation or movement of "any animals, plants or soil" for the purpose of preventing the spread of a pest plant.²⁵⁴

Under the Act, therefore, in relation to any perceived risk arising out of recombinant organisms used in primary industry, direct control over a specific plant might be achieved by proclaiming it a "pest" and bringing into play the full range of eradication measures contained in the Act.

3.7.6 Queensland

The Diseases in Plants Act, 1929, s5(v) empowers the Governor in Council to declare any plant, insect or fungus to be a pest, but only in "any fruit district". Fruit districts may be declared under s5(iii).

Whilst the Act is clearly concerned with the protection of orchards, it may have a broader application. Under s8, no pest may be introduced into Queensland. Pests may be seized on the order of the Minister or an inspector under s9. Indeed, under s10, inspectors have wide powers of entry, search and seizure in respect of pests. Under s15, quarantine areas can be established inside or outside a fruit district, for wide ranging quarantine purposes.²⁵⁵ Ultimately, pests may be eradicated by inspectors, or by land owners.²⁵⁶

Notice of pests must also be given within 24 hours to the Agricultural Department by the occupier of any land or premises.²⁵⁷

3.7.7 Tasmania

The Noxious Weeds Act, 1964, s4, enables the Governor to declare a plant to be a noxious, secondary, or prohibited weed.

Inspectors appointed under the Act are responsible for its administration, although municipal councils may also be required to assist in its administration.²⁵⁸

The Act contains wide powers of control over noxious and other weeds. Owners and occupiers of land are required, by s13, to take measures to eradicate such weeds. Inspectors may issue a notice to a land owner or occupier, under s14, requiring eradication measures to be adopted. Such a notice may be reviewed by a magistrate if its recipient appeals under s15.

Certain areas of land may be declared "infested areas" under s19. Regulations may then be made concerning noxious and other weeds in that area.

Under ss24 and 25, an Inspector has wide powers of entry, search and seizure in respect of noxious and secondary weeds.

3.7.8 Western Australia

The Agricultural and Related Resources Protection Act, 1976, Pt IX deals with pest plants. Responsibility for pest plant control lies with local councils.

First, a pest plant means, by virtue of s109, a plant that is prescribed as such by a council's by-laws (made under s110). A council's by-laws may also require the owner or occupier of private land to eradicate pest plants. In case of non-compliance, council may itself effect the eradication of the pest plant.

Other types of plants, "declared plants", are controlled by a Government department on public lands by virtue of s39, and by municipal councils on land within their control, by virtue of s42. The occupier of private lands must notify the Agriculture Protection Board forthwith upon finding a declared plant on his land.

3.7.9 Northern Territory

The Noxious Weeds Act, s5 authorises the Minister to declare a plant to be a Class A noxious weed, a Class B noxious weed, or a Class C noxious weed. Class A weeds are those requiring eradication. Class B weeds are those the spread or growing of which requires control. Class C weeds are those whose introduction into the Territory requires control.

The Minister or an inspector may, under s7, require a person being the owner or occupier of land to take appropriate eradication or control measures in respect of a noxious weed.

3.7.10 Australian Capital Territory

The Noxious Weeds Ordinance 1921, s4 authorises the Minister to declare any plant to be a noxious weed. Owners of land are,

by s5, required to eradicate noxious weeds on their land. In the event of non-compliance, the Minister or a person authorized by him, may, under s6, enter and eradicate the weed.

3.7.11 Commonwealth

The Quarantine Act 1908 discussed in Part 2, Section 2.4.4, is also relevant here.

3.7.12 Recombinant Animals Considered as Pests: Introduction

State, Territory and Commonwealth laws may enable control of animals considered dangerous to the public or, particularly, to agriculture.

3.7.13 New South Wales

The Pastures Protection Act, 1934, Pt VI deals with noxious animals. The Governor may, under s79(2), declare any animal or bird to be a noxious animal.

Occupiers of land are placed under a duty, by s81, to destroy noxious animals. The Pastures Protection Board in a given district may also order the destruction of noxious animals under s82.

Permission may, however, be granted under s83 to the keeping of a noxious animal. The Act does not specify upon what criteria permission will be granted.

3.7.14 Victoria

The Vermin and Noxious Weeds Act 1958 discussed above in relation to pest plants is relevant also to the control of pest animals. The Governor in Council may declare any animal or bird to be "vermin" under s3(2). Similar powers and duties apply in the control of vermin as were outlined in the earlier section.

3.7.15 Western Australia

The Agricultural and Related Resources Protection Act, 1976, s35 enables animals to be declared. Depending on the degree of danger posed by a particular animal, it might be prohibited absolutely or controlled in a less prohibitive manner.²⁵⁹

Controls over declared animals are the same for declared plants which were discussed in the earlier section dealing with pest plants.

3.7.16 South Australia

The Vertebrates Pests Act, 1975, s6(1) authorises the Governor to declare vertebrate animals to be vertebrate pests.

An officer authorized for the purpose by the Vertebrate Pest Control Authority has, under s26, wide powers of entry search and seizure in respect of such pests.

Local councils assist in the administration of the Act.²⁶⁰

3.7.17 Tasmania

The Vermin Destruction Act 1950, s4(2) authorises the Governor to declare any bird or animal to be vermin.

By s8, a duty is cast upon every occupier of land to destroy all vermin on his land. A similar duty is cast by s10 on a government official with respect to Crown lands. The Agriculture Department may also by notice under s12, require an occupier of land to destroy vermin. An appeal board is specially constituted under the Act to deal with appeals against the issuance of any such notice.²⁶¹

3.7.18 Queensland

The Diseases in Plants Act. 1929, discussed in the preceeding section, enables insects to be declared "noxious". More generally, the Stock Routes and Rural Lands Act of 1944 to 1951, enables animals to be declared noxious. It seems that a declaration may not be made unless the animal has been declared non-protected or prohibited under the Fauna Conservation Act, 1974-79, s26.

3.7.19 Northern Territory

The Territory Parks and Wildlife Conservation Act, Part IV, enables animals to be declared pests, controlled and eradicated.

3.7.20 Australian Capital Territory

The Rabbit Destruction Ordinance 1919, allows the Minister to declare any animal or bird to be a "noxious animal".

The Minister may, under s33, issue a notice requiring owners or occupiers of land to destroy noxious animals. Section 34 provides that in case of non-compliance with such a notice, the Minister or a person authorized by him may enter land and carry out the eradication measures.

3.7.21 Biological Controls of Pest Plants and Pest Animals

Typically, the pest plant and pest control legislation examined in the preceding sections required land occupiers and, ultimately, a government body or official to take measures to "suppress", "destroy", or "eradicate" pests. It is unusual, however, for these Acts to particularise appropriate control measures, although regulations made under the Acts often do.²⁶² It seems that physical culling eradication measures, the poisoning of pests or other, perhaps, biological means of control, might all be appropriate eradication measures. The latter is of interest in this context as live organisms may prove a successful and efficient means of destroying many traditional pests to agriculture.

Of concern always, however, is the liability which may attach should harm result to some person or his property, including

land, from the use of such biological control measures. Whilst the Acts examined relieve an authorized officer of some liability in respect of his official actions, this may not be so in all cases. Indeed, in a 1938 District Court decision in New South Wales,²⁶³ a land occupier was held to be liable under the common law negligence and nuisance rules for the death of travelling cattle from grasshopper poison. The land occupier claimed he had sprayed the poison on grass in compliance with his duty under the Noxious Insects Act, 1934 (NSW) "continually to suppress and destroy" noxious insects. The court found, however, that the spraying method adopted by the occupier did not comply with that laid down in the Regulations to the Act and, so, a defence to the action based on statutory authorisation failed.

The decision clearly rested on the fact that poisoning procedures were laid down in Regulations made under the Act, which, if they had been complied with, would not have resulted in the death of the cattle. Nonetheless, the case illustrates the apparent deficiency of such pest control laws. One cannot always be certain that a particular eradication measure will not cause harm to a person, or his property. The Acts do not, even where regulations may sanction the use of a particular measure, put beyond doubt the legal immunity of official action. Even where some legal immunity is granted by a statute, it will only be in respect of the "reasonable exercise" of the statutory powers.²⁶⁴ Thus a proposal to eradicate Paterson's Curse (*Echium*) by biological means was recently restrained by injunction in a civil action.

To authorize the use of biological control measures, it has been proposed that complementary Commonwealth, State and Territory legislation should be enacted especially for the purpose.

In June 1984, the Biological Control Bill 1984, was introduced into the Commonwealth Parliament. Whilst the Bill, when enacted, will have application only in the Australian Capital Territory, it is intended that "mirror" legislation will be produced in the States and the Northern Territory. As a result, comprehensive uniform legislation on this topic will exist in Australia.

The broad purpose of the Act is to enable pest control by biological means to be carried on free from any legal liability. The impetus for the legislation was provided by the civil litigation in South Australia, referred to above, in which two beekeepers and two graziers were successful in obtaining a Supreme court injunction to prevent the eradication of Paterson's Curse by biological means.²⁶⁵

The scheme of the legislation, when in place, will be to enable certain pests, whether animals, insects or plants, to be the subject of eradication measures. These are referred to in the Bill as "target organisms". Once such an organism has been targeted, the biological means by which eradication should occur may be identified. The organism ultimately selected as the biological means of control is referred to in the Bill as the "agent organism".

The legislation will require applications to be made for an organism to be declared a target organism or an agent organism. In the first instance, the application is to be made to a Commonwealth Biological Control Authority which then refers it to the Australian Agricultural Council for consideration. Where it is proposed that an organism be targeted or made a control agent, the proposal must be publicly advertised and public comment on the proposal considered by the Authority. The Authority (not the Council) will ultimately decide whether the organism should be made a target or an agent. Sections 20 and 29, respectively, of the Commonwealth Bill set out certain matters to be considered by the Authority in dealing with the application, including

- (a) in the case of a proposed target organism, whether it will cause significant harm to a person or environment; and
- (b) in the case of a proposed agent organism, whether the release of the organism would cause significant harm to a person or the environment.

It is possible for these elaborate approval procedures to be avoided, under the proposed s30, where an emergency exists, and for organisms to be made a target or an agent for the purposes of the legislation.

The ultimate purpose of the legislation is to make impossible any legal action to prevent the biological control of pests. Section 36(1) of the Commonwealth Bill thus provides:

"No action or other proceeding shall be instuted or continued in any court-

- (a) to prevent the release of agent organisms in accordance with section 35;
- (b) to recover damages in respect of any loss incurred, or any damage suffered, in a Territory by reason of the release of agent organisms in accordance with that section; or
- (c) to recover damages in respect of any loss incurred, or any damage suffered, in a State by reason of the release of agent organisms in accordance with that section."

This effectively rejects the availability of injunctive relief of the sort obtained by the South Australian beekeepers and graziers. The Act instead provides for the objections of such persons to be dealt with in an administrative way according to their merits, rather than in a technical legal way where the merits of the case may not always be fully considered.

It should be carefully noted, however, that approval to use biological control means may be conditional. The legal immunity afforded by the proposed s36 will only apply if the conditions of approval have been met. Indeed, the proposed s35 provides that

organisms shall not be released otherwise than in accordance with such conditions.

The Biological Control Bill, when enacted, will apply to the use of naturally occurring organisms as well as any produced by recombinant DNA techniques for control purposes. Either type is equally an "organism" for the purposes of the Act.

The Bill, it may also be noted, suggests a legislative model for the broad control of all deliberately released recombinant organisms (whether or not the Authority and the Council would be the appropriate approval agencies in all deliberate release cases).

Finally, it is proposed in the Bill by s5(1) that existing Commonwealth law continues to apply, and that the Bill is meant to be in substitution for any other law. This is of interest for it may possibly mean that environmental impact assessment procedures under the Environment Protection (Impact of Proposals) Act 1974 (Cth) add EIS obligations to the Bill's own, rather exhaustive, publicity provisions. In this regard, it might be noted that the EIA obligations under the Impact of Proposals Act only exist to the extent that they are consistent with any other law. It may well be concluded in this context, that the EIA obligations are inconsistent with the broadly similar functions of the Authority and the Council under the proposed legislation. If this argument were to be accepted, the Impact of Proposals Act would not, therefore, have application to decisions under the biological control legislation in the Commonwealth sphere.²⁶⁶

3.7.22 Animal Breeding Controls: General

Legislative controls over the breeding of animals in Australia appear to be minimal. Primarily it is the States and Territories which are responsible for regulating breeding. The Commonwealth may, particularly through its importation controls, affect some control over the activity. Throughout history, including European Australian history, the breeding of stock has been considered an important community objective.

The common pattern of Australian legislation with respect to animals has been, first, to ensure that stock is protected from pest plants and animals;²⁶⁷ secondly, to protect certain classes of native animals from destruction; and, thirdly, to regulate stock and related industries for commercial reasons. The first type of legislation has already been discussed in this Report. The other two are not directly relevant to our discussion. The only additional type of common regulation in Australia has been in respect of the artificial insemination of stock. Apart from these legislative controls, animal breeding techniques do not appear to be directly controlled by legislation. Institutional research standards may, of course, secure satisfactory practices in the course of most research in Australia. A person's failure to comply with such standards may result in the termination of employment or the cancellation of research funding for a given breeding program.

The scheme of legislation dealing with the artificial insemination of stock is to prohibit without licence both the collection and storage of the semen of stock, and the operation of artificial insemination of any stock. Such controls clearly may have application to artificial animal breeding programs involving recombinant DNA work.

Whether these laws will apply to all animal breeding programs may, however, depend on such legally technical matters as the scope of the definition of "stock" in an Act (does it include all animals) and whether or not breeding programs carried on for or on behalf of government is affected by legislation (usually the "Crown" is only bound by an Act if there are express words to that effect).

3.7.23 Artificial breeding

Legislation in the most jurisdictions first makes it an offence for any person to keep, store or pack the semen of any species of stock for sale without license.²⁶⁸ South Australia deals with the matter in a slightly different way.²⁶⁹ The Australian Capital Territory does not have any relevant legislation.

It is also an offence for any person other than a veterinary surgeon (or person with prescribed qualifications) or owner of the stock, to perform the operation of artificial insemination of the stock.²⁷⁰

Regulations may be made to deal generally with artificial breeding.²⁷¹

The definition provided in most Acts is broad enough to include all birds and animals, at least upon the Governor's proclamation to that effect.²⁷²

The Acts are administered by the relevant departments of primary industry in each jurisdiction.²⁷²

Most Acts do not bind the Crown. The consequence of this may be to exclude from control the breeding activities carried out by government departments or authorities. In most cases, departments and authorities would be considered as the "alter ego" of the Crown and entitled to claim the immunity of the Crown from legislation unless expressly included within its scope.

Indeed in a number of States, there have been established a specialist Board with the precise functions of providing artificial breeding services to the community, and to conduct experiments for the purpose of improving breeding techniques.²⁷⁴ There is no indication in the legislation that these Boards are themselves subject to regulation.

It should further be noted that the Commonwealth, whilst not directly involved in the legislative control of research or technology in the area of animal breeding, is involved to the extent that, with the advice of various industry councils or committees, it may expend moneys on research in such areas as

animal production.²⁷⁵ The Acts do not, however, enable direct control over research, although the Commonwealth's power to enter into research agreements on such terms and conditions as it thinks fit, would enable effective control to be realised over a deliberate release research program.

3.7.24 Plant Production Control

Unlike animal breeding, which is directly controlled by legislation so far as it involves the artificial insemination of stock, plant production is not controlled directly in any obvious way by legislation.

Earlier sections of the Report described legislation dealing with pest plants and diseased plants. This legislation may indirectly enable control to be effected over plant breeding, although it would be a cumbersome means of so doing.

Possibly, so far as planting programs are concerned, the soil pollution legislation briefly discussed in this Part and in Part 2 of the Report, may be argued to have some relevance and impose a measure of control.

Apart from the possible application of such laws, plant breeding is an activity of research encouraged in Australia by all levels of government and industry, and may generally be considered to be unregulated in a legislative sense. The most important possible legislative control would be the application to a deliberate release program of the environmental assessment laws in the various jurisdictions. These laws, as discussed earlier in this part, are not uniform throughout Australia.

In the States, the various Departments of Agriculture are often involved in plant breeding programs. At the Commonwealth level, it is principally the Commonwealth Scientific and Industrial Research Organisation (CSIRO) which is involved in this type of research.²⁷⁶

Various Commonwealth Acts also encourage and facilitate research, through funding, into various forms of plant production.²⁷⁷ Research agreements made by the Commonwealth under such legislation may effectively regulate programs involving the deliberate release of a recombinant organism.

The only legislation dealing specifically with plants in the States and Territory, apart from pest plants and diseased plants, is that pertaining to agricultural seeds. Such legislation deals primarily with the labelling and description of agricultural seeds and does not directly affect their production. Nonetheless, it would appear possible to regulate the sale and distribution of recombinant plants seeds, if not their production, under the general power of regulation contained in these Acts.²⁷⁸

3.8 RECOMBINANT DNA AND HUMANS

Probably the area of single-most concern to the community is the potential use of the recombinant DNA technique in relation to

humans. The potential uses of the technique in the area of medical science range from the non-controversial production of many types of pharmaceuticals intended for human use, to manipulation of human genes themselves, either, perhaps in an acceptable way, to treat genetic deficiencies in humans or, at an alarming extreme, to engineer the human reproductive process so as to produce a human of predetermined characteristics.

It goes without saying that the ethical, philosophical and social dimensions of recombinant DNA work on humans are enormous. It is also fair to say that thus far little serious community debate has focussed on these issues. Clearly, there is need for informed community discussion of them.

One reason why debate has not occurred thus far in Australian society, may be due to the extremely cautious developments which have occurred generally in the recombinant field. It is easy to raise alarm by pointing to animal and plant production experiments and asking why humans should not be next. The answer probably is that things do not happen quite in that way. Animal and plant production is an area of experimentation with which humans have long been concerned; recombinant DNA work may assist in the production of better breeds of animals and species of plants. In the course of human history, however, the occasions upon which human breeding experimentation has occurred are, thankfully, few; where they have occurred the entire world society has considered them outrageously deviant.

It might reasonably be concluded, therefore, that medical science and those involved in it are not hastening toward the genetic manipulation of humans for ill-considered experimental purposes. Nonetheless, there will be a day when the recombinant DNA technique may offer humans the potential, for the first time, to treat some human genetic deficiencies. The response our society should make - either to accept the benefits of medical science or to reject them in consequence of the fear of where it may all lead the human race - is something for consideration now, rather than later.

The law, in this context, may presently be considered quite unequal to the task. That is not, however, an entirely remarkable thing. The basic store of law in Australian society is the common, or judge-made, law which has evolved, first in England, latterly indigenously, to deal with (often) novel circumstances. As yet, common lawyers have not had the opportunity to construct new rules or modify old ones to deal with the complex new issues medical science is in the course of raising.

Equally, statute law, the law of Parliament, has not yet been enacted. No doubt it will respond when the issues develop sufficiently for a wise response to be made on behalf of the community.

There are analagous areas of medical science which prove this legal course to be most likely. Once the possibility of tissue transplants in humans became a reality, a legal response to them

became necessary. Today most jurisdictions in Australia have legislation dealing with the matter.

The common law rules that are applicable to medical science generally are also applicable to recombinant DNA work involving humans. To interfere with a person, without his or her consent, is at common law, a trespass. To detain unlawfully a person against his or her will is, at common law, false imprisonment. To treat a person for an ailment without due care and skill, amounts to negligence. In each of these cases the judicial remedy is prevention of the offending activity, if at all possible, by way of injunction, or an award of damages (financial compensation) if it is too late for prevention.

If recombinant DNA medical technology were to be lawfully applied to a person, that is, with his or her knowing consent, then the common law may well have no rule to deal with the matter. The basic dilemma confronting society is: Should there be a rule?

It should immediately be added that should such medical technology be applied in a research institution, hospital, or other circumstances contrary to the contractual rules established by any such body with one of its researchers/medical scientists, then contractual remedies would be available leading to the cancellation of the persons employment. Equally, should the offending activity be in breach of the terms of a research or other grant, the grant might immediately be terminated. The reality of medical research is such that these remedies are likely to be effective in practice.

Statute law may impinge, to some extent, on medical research in this area, at least where the body of a deceased or living person is used for medical or research purposes. Most jurisdictions have legislation dealing with anatomy and tissue grafting (or transplantations). In relation to anatomy, the scheme of the relevant legislation is to make it an offence for any person to keep a body in his possession for anatomical examination at any place other than a prescribed place, such as a school of anatomy.²⁷⁹ Nor may any person examine a person anatomically unless he is the holder of a licence for the purpose, or authorised to do so by the holder of a licence.²⁸⁰ Schools of anatomy must be licenced.²⁸¹ A body may only be given to a school of anatomy, in certain circumstances, in accordance with the wishes of the deceased or by the person in possession of the body.²⁸²

Similarly, substances (usually tissues) may only be extracted from the body of a deceased person for transplantation for therapeutic purposes in a living person if the deceased has consented to such action prior to his or her death, or by permission, in certain circumstances, of the person in lawful possession of the body.²⁸³

In all jurisdictions, except Tasmania, the legislation referred to in the last footnote applies also to the taking of tissues from living persons.

In some jurisdictions (for example, Tasmania, South Australia and the Northern Territory) there is also specific legislation controlling the sale of blood.

3.9 BIOLOGICAL WARFARE

Concern has long been expressed that the recombinant DNA technique might be used to produce biological weapons for modern warfare. The Crimes (Biological Weapons) Act 1976 (Cth), which implements the Convention for the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, by s8 makes unlawful the production of "microbial or other biological agents of types or in quantities that have no justification for prophylactic, protective or other peaceful purposes".

3.10 COMMON LAW LIABILITY

3.10.1 Introduction

It is, in one sense, erroneous to suggest that in Australia recombinant DNA research and technology is unregulated, or largely unregulated, by law. In the absence of statutory intervention in recombinant activities, common law liability rules operate. These rules may be seen either as the foundation law upon which the edifice of statutory law is constructed, or as the law which fills the vacuum created by an incomplete body of statutory law.

Common law rules have been referred to in this Report already in various contexts. In Part 2, dealing with accidental release, it was observed that common law rules pertaining to nuisance and trespass in particular, may well enable a court to issue an injunction to prevent harm flowing from the release or threatened release of recombinant DNA materials. In part 3, the possibility of such action was also observed in relation to a deliberate or proposed deliberate release, of a recombinant organism. The Commonwealth Biological Control Bill 1984, of course, has its origins in the injunctive relief obtained at common law in South Australia, to prevent the use of biological controls in the eradication of Paterson's Curse.

Additional to injunctive relief in the event of a breach of a common law rule is the possible award of damages (financial compensation) for loss or damage occasioned by a deliberate - or, indeed, accidental - release of recombinant materials. Various causes of action are potentially available in this regard. They include actions in trespass, nuisance, negligence and Rylands v. Fletcher. They may be of use to compensate a plaintiff for personal injury in the workplace or outside it, as well as property loss, for example, damage to crops or livestock.

These causes of action and their potential application to novel circumstances, is a complex area of the law. It is intended here, merely to outline their nature, and not to discuss them in detail.^{283A}

3.10.2 Negligence

Where a person suffers personal or property loss as a result of another's negligent conduct, damages may be awarded in respect of the loss. The negligence action is, however, comprised of three necessary elements: the defendant must owe the plaintiff a "duty of care"; the defendant must have breached the duty of care; and the breach must have been both the cause of the loss and have been "reasonably foreseeable".

An accidental release of recombinant DNA materials may conceivably occur and cause harm to those in the workplace and beyond it. Conceivably, a deliberate release program may also result in the occasion of harm to some person or his property. Proof of the elements of the action will determine if a negligence action lies. Whether or not a particular type of loss was foreseeable may well depend on the nature of the recombinant work the subject of an action. Work with infectious diseases may be considered more likely to cause injury in case of accident than other types of work.

Assuming that those involved in recombinant DNA work have a duty to be careful in their work so that the public, or particular persons, are not harmed, it remains always to determine whether that duty has been breached. In this regard, a defendant's non-compliance with the Recombinant DNA Monitoring Committee's Guidelines for small and large-scale recombinant work, and in relation to deliberate release programs, may suggest a breach of duty. If, however, a court is not prepared to hold the standard of care exactly equivalent, in all cases, to the Guidelines, then they will not be a precise measure of the required standard. It may be argued and accepted, for example, that the guidelines are unnecessarily strict, and that their breach is not in all cases to be equated with negligence.

3.10.3 Public Nuisance

Liability for nuisance may arise in public nuisance or private nuisance. Public nuisance arises where a person commits an unlawful act which endangers the lives, safety, health, property or comfort of the public, or obstructs them in the exercise of their rights. Where a person suffers "particular" or "special" damage as a result of a public nuisance, damages may be awarded.

Obviously, the escape of a substance or thing which puts at risk the well-being of the public, or interferes with the exercise of a public right, as might conceivably, or arguably, occur with the accidental or deliberate release of a recombinant DNA substance or thing, might attract this rule.

The requirement of proving "particular" damage may not be easy. For example, whether or not a farmer whose stock may have been affected by a recombinant substance could prove "particular" damage when all farmers in the area have been similarly affected, may prove a difficulty; although one might conclude that as long as a class of persons are particularly affected the test is satisfied.

Once an action in public nuisance is proved, liability for damage follows, unless the accident can be shown to be "inevitable", or the acts of the defendant were authorised by statute. The latter defence will only be available where the precise acts complained of were authorised. It is not enough to show, for example, that research is authorised generally, but that a particular recombinant DNA deliberate release program was authorised by the statute.²⁸⁴

3.10.4 Private Nuisance

Private nuisance occurs where the plaintiff's land is actually damaged, or its use and enjoyment is substantially disturbed. Where land, or things upon it, are damaged, damages may be awarded against a defendant, in favour of a plaintiff land owner or occupier.

The cause of action is thus limited to those instances where a person who suffers loss to land, is also the owner or lawful occupier of that land.

As in other cases, it is a defence to the action to establish statutory authorisation.

3.10.5 Trespass

Trespass to land occurs in the case of unauthorised intentional entry or interference to land. The owner or occupier of land may recover damages for any loss sustained by the trespass.

It is a defence to a trespass action to show that the interference was involuntary or was authorised by statute.

3.10.6 Rylands v. Fletcher

Unlike an action in negligence, the rule in Rylands v. Fletcher²⁸⁵ tends towards the strict liability of those held to infringe it. The rule has been expressed in the following terms:

"... a person who for his own purposes brings on his land and collects and keeps there anything likely to do mischief if it escapes, must keep it at his peril, and if he does not do so, is prima facie answerable for all the damage which is the natural consequence of the escape."²⁸⁶

There is a qualification to the wide application of the rule, however: the use of the land from which the thing escapes must be "non-natural".

In Australia, the High Court decision in Benning v. Wong²⁸⁷ has given some expression to the rule, although it is often considered the decision has added to its uncertainty of application.

Clearly, there are a number of elements to the Rylands v. Fletcher cause of action:

- . as noted, the use of the land must be "non-natural";
- . the thing brought on the land must have, it seems, "mischievous possibilities"²⁸⁸ or be a "dangerous thing or substance";²⁸⁹
- . it also appears that a person can only be liable for an escape of the thing from land over which he has lawful control.

Consequently, the escape of recombinant DNA materials, accidentally or deliberately, if they may in themselves be considered dangerous, may result in the owner of the land from which the escape occurred, being held strictly liable for any subsequent loss occasioned by the escape. Potentially, any persons on public land affected by an escape of a dangerous substance or thing, or the owner of land so affected should be able to claim under the rule for any loss suffered by them.

The rule does not apply however

- . unless the escape occurs from the defendant's land;
- . where a person suffers loss on the defendant's premises;
or
- . where the activity is carried on with statutory authority.²⁹⁰

Because recombinant DNA activities can take so many different shapes and forms, and an escape might not only be deliberate but accidental, it is not with any certainty that one could predict the outcome of the application of the rule in Rylands v. Fletcher in this area.

**PART 4: THE ADEQUACY OF RECOMBINANT DNA REGULATION IN AUSTRALIA:
SUMMARY AND ANALYSIS**

4.1 SUMMARY

This Part of the Report is intended to provide a summary of the existing means of regulation and administration of recombinant DNA work, as well as a preliminary analysis of the adequacy of regulation in Australia.

It is crucially important first to note the federal structure of Australian government. The division of legislative power between the Commonwealth of Australia and the States and Territories has, in the past, resulted in the assumption, by the States and latterly the Territories, of primary responsibility for the regulation and administration of many areas in which recombinant DNA work has importance, or important potential effects. This is not to say that the national government - the Commonwealth - is powerless in these areas, for clearly it is not.

Historically, it has been the Australian States, and not the Commonwealth, which has legislated in the majority of subject areas of discussion in this Report. In Part 1 of the Report, it was observed that various heads of Commonwealth power under the Constitution could justify an increased legislative role by the Commonwealth in the regulation of recombinant DNA work. As the landmark decision of the High Court of Australia in Tasmania v. Commonwealth²⁹¹ illustrates, Commonwealth power is potent indeed in the control of corporations²⁹² and with respect to the implementation of international agreements under the external affairs power.²⁹³ Thus Commonwealth law might directly affect corporate activity in Australia for the purpose of the regulation of recombinant DNA work. The power appears to have been expressly relied upon in the enactment of the Therapeutic Goods Act 1966 (Cth), s23D.²⁹⁴ The external affairs power might enable the Commonwealth to implement an international agreement, if there were one, dealing with recombinant DNA activities and their regulation. Specific international agreements, for example, the existing International Labor Organisation Convention 155, might also be ratified and implemented to provide the Commonwealth with wide ranging power with respect to occupational health and safety.

Presently, as the Therapeutic Goods Act 1966 (Cth) perhaps best illustrates, the Commonwealth has exercised its power over importation of goods,²⁹⁵ interstate trade and commerce,²⁹⁶ and the immigration²⁹⁷ to reduce the threat of dangerous substances, disease and pests in Australia. To some small extent this Act may also rely upon the quarantine power.²⁹⁸ The latter power has only been used sparingly by the Commonwealth to date.

The quarantine power has been used mainly to support the Quarantine Act 1908 (Cth). The Act, discussed in Part 2 of the Report, historically has dealt with point of entry problems, leaving internal quarantine measures to the States. However, amendments to the Act in more recent times have broadly empowered the government to impose quarantine measures domestically in

Australia to deal with certain epidemics.²⁹⁹ The executive powers created by the Act may not, however, represent the limit of possible power. The power to make a law "with respect to Quarantine" may enable the Commonwealth to go further. The extent of the power depends on the proper construction of "Quarantine". The definition in s4 of the present Act is probably a good guide to the interpretation of the term

"Quarantine has relation to measures for the inspection exclusion, detention, observation, segregation, isolation, protection, treatment, sanitary regulation and disinfection of vessels, persons, goods, things, animals or plants, and having as their object the prevention of the introduction or spread of diseases or pests affecting man, animals or plants."

Given also the power of the Commonwealth parliament to make a law with respect to "matters incidental" to quarantine,³⁰⁰ it may be argued that the Commonwealth could directly legislate to control a range of research projects and technological applications of the recombinant DNA technique where it can reasonably be established that such projects or applications carry with them the risk of the spread of disease.³⁰¹ Such a law would seem to have as its object the prevention of the introduction or spread of disease or pests. Clearly, the Commonwealth may validly enact a quarantine law which anticipates a disease or pest risk; it is not limited to control after the event of disease or pest transmission. Similarly, it is not limited only to control of exotic diseases or pests (those from outside Australia), but may also deal with indigenous disease or pests.

It is important, nonetheless, to recognize the historical political developments of the Australian federal system which have produced existing legal controls. A primary task of this Report has been to identify existing laws as they apply, or potentially may apply, to recombinant work.

The second important matter to note is the historical developments in recombinant DNA work in Australia and elsewhere. A little more than a decade ago the recombinant DNA technique first became available to molecular biologists. Since then it has been further refined and used in various areas of scientific research. More recently it has been used in a wide range of practical applications. The significance of these developments generally, as well as for the structure and content of this Report, is that today it is necessary to ascertain those legal controls which have application to human activities which may lead, on the one hand, to an accidental discharge of materials used in recombinant DNA work, and those, on the other hand, which have application to a deliberate release of a novel organism, that is, an organism not found in nature, and constructed by the recombinant DNA technique.

The difference between these two circumstances is that in much research or its technological applications, it is not intended that any recombinant organism should escape the confined place in which it has artificially been created. If this should

happen, it is an accident. Whereas, the second circumstance necessarily involves the use of a novel organism for perceived human benefit. In both cases, however, it can be argued that humans, animals and other natural organisms, and the physical environmental systems, will be put at risk if recombinant material or a recombinant thing is released into the environment. But whilst the end concern may be similar, the means of controlling recombinant activities necessarily differs from those in which accidental release occurs and those involving a deliberate release of a novel organism.

Thus, in Part 2 of the Report, those laws pertaining to the health and safety of persons inside and outside research laboratories and industrial workplaces were discussed, together with laws capable of protecting plants and animals as well as air, water and soil. In the sphere of human safety these laws included industrial health and safety legislation, public health legislation designed to grapple with an outbreak of infectious disease, dangerous goods and substances legislation, as well as laws intended to control manufacturing processes and the nature of products themselves. In all of these areas, State and Territory laws provide the basis of control. In a number of areas, however, for example, industrial health and safety, the use of therapeutic goods or substances, and quarantine, increasing Commonwealth - State/Territory consultation and implementation mechanisms are helping to overcome provincial approaches to complex problems. Nonetheless, agreed national strategies are usually implemented by provincial statutes.

Specifically, in the area of industrial health and safety, State and Territory laws are not uniform. Old style legislation, such as Factories Acts, in a number of States and Territories appear largely incapable of regulating all workplace practices in research and industry, especially in public institutions. The potential of effective control in all workplaces under new style legislation in other States, however, has been noted, and is an important potential means of control of accidental release of materials from recombinant work.

Existing public health legislation in respect of the prevention of the spread of infectious disease in the event of an accidental release of recombinant materials is probably sufficient to deal with such an outbreak, although in some jurisdictions local authorities or health boards carry the initial burden of control. If it is considered that urgent quarantine action may be required at State or Territory levels of government, then it may be that these laws require review in the light of likely modern-day sources of hazard. Commonwealth legislation in this area may, however, effectively fill any gaps in provincial legislation. The powers of the Commonwealth under the Quarantine Act 1908 ss2B and 12A, are possibly little known, but have a potentially wide scope. Indeed, as noted above, the width of the power of the Commonwealth Parliament with respect to the matter of quarantine is one of interesting conjecture.

Traditional powers in the States and Territories to deal with the spread of disease to plants and animals appear quite adequate. In the main these are exerciseable by State and

Territory departments of agriculture. The Commonwealth quarantine powers are also capable of exercise in this area.

Generally, it might be observed that few laws in these areas currently prescribe sanctions or penalties in circumstances relevant to an accidental release of recombinant material. To the extent that sanctions do exist, they are usually to be found in environmental quality (pollution) legislation which sometimes, but not always, creates offences in respect of air pollution, water pollution or soil pollution. Whether or not a given release amounts to pollution will depend on the facts of each case. Some common law remedies, especially in nuisance, may otherwise enable the control - usually the prevention - of activities likely to cause human or property damage.

Part 3 of the Report shifted the focus from legal control of accidental release of recombinant DNA material to legal control of deliberate release of novel organisms. At present, it would seem that it is mainly experimental research projects that squarely pose the problems associated with a deliberate release program. Technological applications of the recombinant technique in a broad-based industrial sense, appear to be some years away from realisation.

In Australia, much of the experimental research aimed at the production of novel organisms is in the primary industry field, especially plant breeding. At present, no law deals specifically with the release of novel organisms. Nonetheless, legislation broadly relevant to many areas likely to be affected by a deliberate release program does exist in most jurisdictions. Although plant breeding appears to be the subject of minimal legislative control, animal breeding, especially by means of artificial insemination, is the subject of legislation in every jurisdiction except the Australian Capital Territory (and the Commonwealth).

The other important potential control of a deliberate release program is the environmental impact assessment (EIA) legislation in each jurisdiction. In most jurisdictions, New South Wales being the notable exception, EIA law is not automatically triggered by a deliberate release program. Instead, an environmental impact statement (EIS) or inquiry will usually only be furnished or held at government behest. In New South Wales, by contrast, Part V of the Environmental Planning and Assessment Act, 1979 (NSW), requires an EIS to be prepared and examined in many cases where a decision to be made by a government body will significantly affect the environment.

Apart from these laws, there is also the possibility that environmental quality legislation might impose some measure of control over a deliberate release program. Under the Victorian Environment Protection Act 1970 (Vic), for example, any discharge of matter to the environment which causes an "alteration" to the environment, technically should be licensed under the Act. If "pollution", as defined in the Act, will result from the discharge, then a licence cannot be granted. Due to the startlingly broad statutory definitions of such pivotal terms as "waste", "environment" and "pollution", compliance with this Act

may be necessary in Victoria before a deliberate release program can lawfully be commenced.³⁰²

The approach of the Act is, however, the exception rather than the rule in Australian environmental quality law. Air, water and soil pollution legislation in most jurisdictions does not appear capable of ready application to control the deliberate release of novel organisms.

In these circumstances, the common law liability rules concerning negligent conduct, the keeping on land of dangerous things, and nuisance are of particular significance. The knowledge that a deliberate release program might either be prevented by the application of common law rules or carry with it the obligation to compensate financially any person who suffers personal or property loss as a consequence of the program, may well inhibit the formulation of a proposal to initiate a deliberate release program. In this context, the passage of the Biological Control Act 1984 (Cth) is of signal importance, for it illustrates that specific statutory authorisation of novel technological programs may be necessary to overcome the possible strictures of the common law.

4.2 ANALYSIS

The lessons learned from the legislative review in Parts 2 and 3 of the Report are, therefore, various. First, the obvious lesson, that no legislation in Australia has been enacted specifically to deal with the release, accidental or deliberate, of recombinant DNA substances. Secondly, as a result, those laws which may be considered applicable to recombinant work are typically to be found in State and Territory legislation designed to deal with matters of worker safety, public health, animal and plant health and environment protection. Thirdly, that these laws were mostly enacted at a time when the risks associated with recombinant DNA work, such as they may be, were not within the contemplation of those drafting the legislation. Fourthly, that the gradual growth of concern, apparent in Australia at all levels of government, for matters of national concern to be dealt with by national strategies, both highlights a current fragmentation of controls between Commonwealth and State or Territory authorities, as well as a need to consider further the appropriateness of a national strategy to regulate or monitor recombinant DNA work. The national monitoring functions which have been exercised by the Recombinant DNA Monitoring Committee attached to the Commonwealth Department of Science and Technology since 1981, lend support to this observation.

There is another lesson, however, which must be borne in mind when reflecting upon, in particular, the adequacy of existing laws. It is the realisation that it is not always necessary or appropriate to enact new laws to respond to allegedly new problems. Some problems may not be new at all, but merely old ones in a new guise. For example, a number of existing occupational health and safety laws may currently enable the control of the risks associated with an accidental release of a recombinant DNA substance in a research or industrial workplace. Equally, controls over the manufacturing process and dangerous

goods and substances at both State/Territory and Commonwealth levels may currently be utilized to control indirectly all manner of industrial and research processes utilizing the recombinant DNA technique. It may be, however, that State and Territory laws designed to prevent the spread of disease, especially in relation to humans, require general review in the light of possible accident risks associated with research, and with the chemical and pharmaceutical industries, including those where recombinant DNA substances may accidentally be released.

Deliberate release programs, in a similar way, may be considered as but another area of environmental concern capable of being dealt with by existing environmental impact assessment laws and procedures and other environmental controls. Or it may be that the placement of novel organisms in the environment is an activity so unprecedented in the nation's experience that new laws or procedures are needed to cope with its hazardous potential. On the one hand, scientific developments in the recombinant DNA area have been sufficiently conservative and cautious to date, that special legal controls over scientific research or technology may be considered unwarranted. On the other hand, the degree of public unease at the release of novel organisms may be so great as to suggest the sensible legal regulation of deliberate release programs. Should legal control be imposed it might not only dissipate public fear but also consolidate the steady and worthwhile directions of research involving the recombinant DNA technique. If history provides any lessons for policy-makers, the uncontrolled introduction of exotic organisms (consider some of those introduced since European inhabitation of Australia: rabbits, starlings, Paterson's Curse) has not been to Australia's lasting benefit. Furthermore, recent history shows that the availability of common law actions to prevent the use of novel processes (for example, the biological control of pests) may roughly be compared with the insertion of a large spanner in what are generally considered socially useful works.

Taken overall, the review of legislation in Part 2 of the Report tends to the conclusion that existing laws are adequate, or can be made so, to protect properly workers, the public and the environment from harms which might arise from an accidental release of a recombinant substance.

By contrast, the review of legislation in Part 3 suggests that existing environmental impact assessment laws do not have automatic application to such programs, and that most environmental quality laws are not designed to deal with such discharges. Whilst some animal and plant legislation may enable limited control over production, they are not designed to ensure a full assessment of all the risks involved with a deliberate release program before it proceeds.

If it is accepted that existing law is deficient in this area, the possibilities for improvement are basically three. First, to tighten existing environmental impact assessment laws so that all activities likely to significantly affect the environment are properly assessed. Secondly, to issue special administrative directions under existing administrative style

environmental impact assessment laws, requiring assessment of all deliberate release programs.³⁰³ Thirdly, to enact special legislation requiring all proposals for the release of recombinant organisms to be environmentally assessed. The guidelines proposed in the draft Interim Statement of the Recombinant DNA Monitoring Committee tentatively adopt, in an administrative manner, the third approach.

If legal, rather than merely administrative, environmental risk procedures were adopted, it would not be imperative that a new regulatory agency be also established. As discussed in the next section, an existing administrative body might have its functions suitably enlarged to deal additionally with the environmental assessment of a deliberate release program.

4.3 ADMINISTRATIVE COMPLEXITIES

These tentative conclusions do not have any regard to administrative complexities, especially in a federal system of government. For one thing, such matters as occupational health and safety and environment protection are not accorded the same level of priority in all jurisdictions. It would seem also, that in an area as technically complex as research and technological processes involving the recombinant DNA technique, it would be unwise to expect the Commonwealth, six States and two Territories to establish common standards and monitoring and review procedures. Instead, as the developments in such areas as occupational health and safety and environmental contaminants most recently demonstrate, joint Commonwealth - State/Territory government initiatives are not only achievable but most likely to secure satisfactory national strategies in areas of common concern. The same degree of common purpose is also evidenced by the proposed uniform legislative action to facilitate biological measures in the eradication of pests throughout Australia.

It is yet another issue to determine, even in a unitary governmental system, an appropriate administrative structure for the control of recombinant DNA work. As noted in Part 1 of the Report, the United States experience was first to regulate, fairly vigorously, most recombinant work under the National Institutes of Health (NIH) guidelines. Subsequently, over a number of years, recombinant work exempted from the guidelines grew to such an extent that in 1980, only about 10 per cent of such work was affected by them. As a result of this phenomenon, it has been suggested that traditional government agency regulation of recombinant work will necessarily grow.³⁰⁴ A trend towards utilization of traditional means of environmental control has also been suggested in the United States, especially in relation to deliberate release programs.³⁰⁵

From these tentative conclusions, and suggested United States trends, it might be suggested that, as far as possible, existing Australian laws and administrative structures should be utilized to effect legal control over recombinant DNA work.³⁰⁶ It seems appropriate, nonetheless, to establish a national consultative body (or bodies) with the function of supervising or monitoring developments in the area generally, and able to encourage policy formulation and implementation through other relevant national

consultative bodies, or directly through existing Commonwealth, State or Territory legislation. As presently structured, the Recombinant DNA Monitoring Committee appointed by the Commonwealth Minister of Science and Technology lacks the status of such a national consultative body. However, it might conceivably form the basis of such a body. Alternatively, existing consultative or advisory bodies in special areas of concern might have added to their functions, a recombinant DNA monitoring and/or policy formulation function.

In this way, for example, risks associated with an accidental release of a recombinant DNA substance in the workplace might become the concern of the Interim National Occupational Health and Safety Commission (INOHSC), and risks to agriculture might become the concern of the Australian Agricultural Council (AAC). Environmental impact assessment of a more general kind might possibly become the concern of the Department of Home Affairs and Environment or the Australian Environment Council (AEC). This list of suggested bodies is not in any way intended to be definitive, but merely indicative of a possible approach to the formulation and administration of national policies relative to the risks possibly associated with recombinant DNA work.

Perhaps the most effective administrative approach, and one which would have the virtue of recognising historical Australian administrative developments in this area, would be the retention in the short term of the existing Recombinant DNA Monitoring Committee with its existing functions, followed by a conscious program whereby its functions would progressively be transferred to other specialist consultative bodies. In such circumstances, a body such as the Recombinant DNA Monitoring Committee might continue to function as an umbrella organization with a monitoring and overview role; its main functions including individual scrutiny and casework functions, however, would be exercisable by the specialist agencies. Any such proposal would only be viable, and should only be considered, where it could be demonstrated that a specialist body has the technical competence and guaranteed manpower and financial resources to perform a designated recombinant DNA function.

4.4 TWO FINAL COMMENTS

Two final points need to be made concerning the various matters raised in this Report. First, the focus of the Report has, narrowly and deliberately, been that of the legal regulation of the science and technology of the recombinant DNA technique. Ultimately, debate concerning the law and policy context of recombinant DNA work must occur in the broader context of the regulation of science and technology in general and genetic manipulation in particular. That is an issue not addressed in this Report.³⁰⁷

Secondly, whilst the application of laws to recombinant DNA work involving humans has been raised in the Report, it has, again deliberately, only been attempted in a preliminary way. Ever since the public became aware of the recombinant DNA technique, the fear of some in the community has been that it may eventually allow humans 'to play God'. Specifically, their

concern is that the human reproductive process might be engineered genetically to produce humans with predetermined characteristics. The issues raised by this concern may ultimately be proved to have been unfounded. They are, however, issues of a fundamental ethical, philosophical and social kind which the Australian community simply cannot avoid. They, too, are issues not finally addressed in this Report.³⁰⁸

FOOTNOTES

- 1 See, eg, Kemp, "What is Recombinant DNA?" in Genetic Engineering: Commercial Opportunities in Australia AGPS, (1982) at p8.
- 2 See, The Australian Academy of Science, Recombinant DNA: An Australian perspective Canberra, 1980, Glossary of terms at p.125.
- 3 Kemp, supra note 1.
- 4 Recombinant DNA: An Australian Perspective supra note 2, p.1.
- 5 Ibid.
- 6 Recombinant DNA Monitoring Committee, Report for the Period October 1981 to October 1982, Canberra, A.G.P.S., 1983, p.1.
- 7 Lewis "Development of Recombinant DNA Technology: The U.S. Experience" in Genetic Engineering, supra note 1, p16 at p20.
- 8 See, eg, Swazey, Sorenson and Wong, "Risks and Benefits, Rights and Responsibilities: A History of the Recombinant DNA Research Controversy" (1978) 51 So Cal L Rev 1019. See also John Lear, Recombinant DNA - The Untold Story (1978).
- 9 Id, at p1021, where full quotation is set out.
- 10 Id, at p1022, where full quotation is set out.
- 11 See (1973) 181 Science 114.
- 12 (1974) 185 Science 303.
- 13 See RF Beers and EG Bassett, Recombinant Molecules (1977) p472.
- 14 See DA Jackson and SP Stich, The Recombinant DNA Debate (1979) p161.
- 15 YM Cripps, Controlling Technology (1980) p17.
- 16 Hearing before the Subcommittee on Health and Scientific Research of the Committee on Human Resources, United States Senate, Ninety-Fifth Congress, First Session on s1217 (1977) p219.
- 17 Korwek, "OSHA Regulation of Industrial Applications of Recombinant DNA Technology" (1981) 50 Cincinnati L Rev 284 at 284.
- 18 Comment, "Recombinant DNA and Technology Assessment" (1977) 11 Georgia L Rev 785 at 793.
- 19 See J Goodfield, Playing God (1977).

- 20 Sinsheimer, "Troubled Dawn for Genetic Engineering" (1975) 168 New Scientist 148, at p150.
- 21 (1976) 41 Fed Reg 27,902.
- 22 Korwek, supra note 17, at p287. For a discussion of the legal nature of the NIH guidelines, see: Korwek "The NIH Guidelines for Recombinant DNA Research and the Authority of FDA to Require Compliance with the Guidelines (1981) 21 Jurimetrics J 264.
- 23 NIH Guidelines for Research Involving Recombinant DNA Molecules, (1977) 1 NIH Environmental Impact Statement 44; quoted in Korwek, ibid.
- 24 Korwek, supra note 17, p288.
- 25 Ibid.
- 26 Cripps, "A Legal Perspective on the Control of the Technology of Genetic Engineering" (1981) 44 Modern L Rev 369 at pp372-377.
- 27 Publication 7412, September 1974; referred to in Cripps, id., p372, fn 16.
- 28 Report of the Committee of Inquiry into the Smallpox Outbreak in London in March and April 1973, Cmnd 5626 (1974); referred to in Cripps, id, p372, fn 17.
- 29 Report of the Working Party on the Laboratory Use of Dangerous Pathogens, Cmnd 6054 (1975).
- 30 Report of the Working Party on the Experimental Manipulation of the Genetic Composition of Micro-organisms, Cmnd 5880 (1975), p.15.
- 31 Report of the Working Party on the Practice of Genetic Manipulation, Cmnd 660 (1976).
- 32 Cripps, supra note 26, p376.
- 33 See Recombinant DNA: An Australian Perspective, supra note 2; Ch 8, esp at pp68, 69.
- 34 Id., p xii, rec 1.
- 35 See "Terms of Reference" of the Committee set out in Appendix A to the Report of the Recombinant DNA Monitoring Committee for the period October 1981 to October 1982.
- 36 A list of research projects may be found in the Recombinant DNA Monitoring Committee Report for the period October 1982 to June 1983, (1984) Appendix D.
- 37 See "Guidelines for Small-Scale Work with Recombinant DNA" Recombinant DNA Monitoring Committee Department of Science and Technology, Canberra 1983.

- 38 CSIRO, Biotechnology Research and Development (1981) p51.
- 39 1. Genetic manipulation and cell fusion; 2. Products derived by genetic manipulation, cell fusion and tissue culture; 3. Process technology; 4. Substances for fermentation; 5. Waste treatment; 6. Mineral processing. A seventh, lower priority area, identified was that of tertiary oil recovery.
- 40 See broad ranging discussion of the commercial opportunities in Genetic Engineering, supra note 1, Session 4.
- 41 Gentech Ltd, eg, was listed as a public company on the 10 May 1984. (Its first production was reported to be a genital herpes test kit.)
- 42 Korwek, supra note 17, p291.
- 43 Recombinant DNA: An Australian Perspective, supra note 2, pp70, 71.
- 44 See Northern Territory (Self-Government) Act 1978 (Cth) s9.
- 45 Victoria v Commonwealth (1975) 134 CLR 338 at p362, per Mason J. Seemingly endorsed by Gibbs CJ in Tasmania v Commonwealth (1983) 46 ALR 625 at p675.
- 46 Ibid.

PART 2: ACCIDENTAL RELEASE

- 47 Adrian Merritt, Guidebook to Australian Occupational Health and Safety Laws (1983) p117.
- 48 Ibid. The thrust for the "new" approach may be attributed to US and UK developments. See, eg, the Occupational Safety and Health Act 1970 (US) and the Health and Safety at Work Act 1974 (UK). In Australia, it would appear that the 1972 Robens Report (U.K.) has been of particular influence in the formulation of Australian "new" approach. See Adrian Merritt, supra note 1, Ch 6, et seq.
- 49 See, CCH, Australian Industrial Safety, Health and Welfare, Vol 1, paragraph 5-115 - 5-125.
- 50 Although as to the N.T., see supra note 44, and accompanying text.
- 51 Constitution, s51(xxxv).
- 52 In the light of the Tasmanian Dam case, it should be noted, the way would appear to be open for the Commonwealth to implement, eg, an International Labour Organization (I.L.O.) agreement on the subject of worker health and safety, pursuant to the power of the Commonwealth Parliament under s51(xxviii) of the Constitution, to make laws with respect to "external affairs".

53. Adrian Merritt, *supra* note 47, p117.
54. Adrian Merritt, *supra* note 47, p123.
55. s5(1).
56. See, eg, Tasmania v Commonwealth where the Court held that the Hydro-Electric Commission of Tasmania was of the latter character.
57. This comment is also relevant to the old style legislation in other jurisdictions.
58. See, eg, action of a similar nature taken in Onus v Alcoa of Australia Ltd (1981) 55 ALJR 632. As to who is "specially interested" and so has standing to bring such a suit, and Australian Conservation Foundation v Commonwealth (1980) 54 ALJR 176.
59. Adrian Merritt, *supra* note 1, p286.
60. See, eg, Nelson v John Lysaght (Aust) Ltd (1975) 49 ALJR 68 at p74, per Gibbs J (now Gibbs CJ).
61. See Adrian Merritt, *supra* note 47, Ch 2.
62. In this regard, the NSW provision appears exceptional.
63. Adrian Merritt, *supra* Note 47, p345.
64. s5(1)(d).
65. Code, Section 2.1.
66. Code, Section 9.
67. Code, Section 3.
68. See, eg, Korwek "OSHA Regulation of Industrial Applications of Recombinant DNA Technology" (1981) 50 Cincinnati L Rev 284. In the United Kingdom, the Health and Safety at Work Act 1974 has already been used to deal with workplace safety practices relating to recombinant DNA work (see Health and Safety (Genetic Manipulation) Regulations). See discussion in Cripps, "Legal Perspective on the Control of the Technology of Genetic Engineering" (1981) 44 Modern L Rev 369.
69. See, eg, Factories and Shops Act, 1960 (Qld), s9; Factories and Shops Act, 1963 (WA) s11. A Factories Welfare Board is set up under s44.
70. Industrial Safety, Health and Welfare Act, 1972 (SA), s8.
71. Industrial Safety, Health and Welfare Act, 1972 (Tas.), s.16.

- 72 Industrial Safety, Health and Welfare Act, 1981 (Vic.), s5.
- 73 Occupational Health and Safety Act, 1983 (NSW), s8.
- 74 Factories and Shops Act 1960 (Qld), s39.
- 75 Industrial Safety, Health and Welfare Act, 1972 (S.A.), s16;
Industrial Safety, Health and Welfare Act, 1977 (Tas.), s18;
Industrial Safety, Health and Welfare Act, 1981 (Vic.), s6;
Occupational Health and Safety Act, 1983 (N.S.W.), s10;
Factories and Shops Act, 1960 (Qld), s41.
Factories and Shops Act, 1963 (WA), s46.
- 76 Industrial Safety, Health and Welfare Act, 1972 (S.A.), s16(1).
- 77 NSW: Factories, Shops and Industries Act, 1962 (NSW), s73.
 Qld: Factories and Shops Act 1960 (Qld), ss11-13.
 SA: Industrial Safety, Health and Welfare Act, 1972 (SA), s19.
 WA: Factories and Shops Act 19.63 (WA), s16.
 Tas: Industrial Safety, Health and Welfare Act, 1977 (Tas), ss11, 12.
 Vic: Industrial Safety, Health and Welfare Act, 1981 (Vic), s22.
- 78 NSW: Factories, Shops and Industries Act, 1962 (NSW), s12.
 Qld: Factories and Shops Act 1960 (Qld), s89. SA: ibid, s20. WA: Factories and Shops act 1963 (WA), s29(2). Tas: ibid, s13. Vic: ibid, s18.
- 79 Industrial Safety, Health and Welfare (Employers Safety Representatives) Regulations 1982 (Tas), Reg 7.
- 80 s12.
- 81 s24.
- 82 s28.
- 83 s30A(1).
- 84 s30A(2).
- 85 s389(1) contains the proclamation power.
- 86 See generally Pt VI of the Act.
- 87 s5 contains the proclamation power.
- 88 See s.34A, especially s.34A(1)(a).
- 89 ss8, 16.
- 90 s17.
- 91 s14, esp s.14(1)(e).
- 92 s249.

- 93 s251.
- 94 s2A.
- 95 s4.
- 96 s2B(2). It is an offence under s2B(3) to fail to comply with such a direction or to hinder such action. S86E provides a penalty. S12A also authorizes certain actions to prevent a "quarantinable disease" in an emergency.
- 97 Whether a person would have standing to maintain such an action would be a difficult issue. The Attorney-General of a State or Territory might, and so might a person whose property or financial interests were affected by government action.
- 98 Although, admittedly, as Professor Douglas Whalan has noted, the courts would look at the powers closely given their width: see Douglas J Whalan, "The Legal Implications of an Exotic Disease Invasion into Australia", paper presented to 1984 ANZAAS conference, Canberra, May 1984.
- 99 s31(1)(b).
- 100 s70D.
- 101 s13(1)(g).
- 102 See eg Quarantine Act, 1908 (Cth) s2B(3).
- 103 s71A.
- 104 Vic: The Health Act 1958 (Vic) does not specifically create such a power. Instead it defines a "dangerous substance" and "substance" in a broad way in s.106, and defines "dangerous" in a similarly broad way in s.3.
SA: Health Act, 1935 (SA) s.148(1) (in 3) enables "dangerous substances" and "dangerous processes" to be declared under s5a(1).
Qld: Health Act 1937-1981, s110 and s5 definitions of "article" and "drug".
Tas: Public Health Act 1962 (Tas), s.142(6). Though this relates strictly to "dangerous occupations", note s142(7) which may allow a measure of control.
WA: Health Act, 1911 (WA) does not deal with all substances, but does allow "drugs", "food" and "therapeutic substances" to be controlled: see Pt VIII. See also s235A whereby food as drugs may be declared "dangerous".
ACT: Public Health Ordinance 1928 (ACT), s.12 enables regulations to be made for the "maintenance of health". This may support control of use of dangerous substances and processes.
- 105 s71C(1).
- 106 Vic: Health Act 1958 (Vic), s108.
SA: Health Act, 1935 (SA), s147(1) (n 3)-(n 6).

Tas: Public Health Act 1962 (Tas), s142(6), (7).

Qld: Health Act 1937-1981 (Qld) s110 enables the Director-General of Health and Medical Services to prohibit the use of an article or drug.

WA: Health Act, 1911 (WA), s240 enables broad regulation of dangerous things.

ACT: Public Health Ordinance 1928 (ACT), s12.

107 Except residential premises, which he may only do with the consent of the occupier: s.71D(3).

108 s71D(2).

109 s71D(6).

110 Vic: Health Act 1958 (Vic), ss400, 401.

SA: Health Act, 1935 (SA), s50 sets out the limits of the power to inspect where the Act otherwise creates an inspection power.

Tas: Public Health Act 1962 (Tas), ss116, 117.

ACT: Regulations made under the Public Health Ordinance 1928 might prescribe these powers.

111 Vic: Poisons Act 1962 (Vic) and Poisons Regulations 1963, Nos 1, 2 and 3; SR 158, 186, 187/1963.

Tas: Poisons Act 1971 (Tas) and General Regulations 1975 as amended.

WA: Poisons Act 1964 (WA) and Poisons Act Regulations 1965

NT: Poisons Act 1924 (NT); Poisons and Dangerous Drugs 1983 (NT)

ACT: Poisons and Narcotics Drugs Ordinance 1978 (ACT), and Poisons Regulations.

112 s29. "Substance" does not appear to be specially defined in the Act and so a broad, natural meaning should be accorded the term.

113 Cth: Therapeutic Goods Act 1966 (Cth).

NSW: Therapeutic Goods and Cosmetics Act, 1972 (NSW).

Tas: Therapeutic Goods and Cosmetics Act 1976 (Tas), (not yet proclaimed as at 30.11.83).

Qld: Health Act 1937-81 (Qld), s110. Definition of "drug" in s5 includes therapeutic goods as defined in the Commonwealth Act.

WA: Health Act, 1911 (WA), Pt VIII, Division 3B.

114 NSW: s12

Tas: s4.

Qld: See Therapeutic goods and Other Drugs Regulations.

WA: Health Act, 1911 s241F.

115 NSW: s13

Tas: s5.

116 NSW, s4(1) definition of "therapeutic use".

Tas, s2(1) definition of "therapeutic use".

Qld: Health Act, s5 definition of "drug" includes the therapeutic goods definition in the Commonwealth Act, discussed further below.

WA: Health Act, s3(1) definition of "Therapeutic use" is similar to NSW definition but does not have the fourth component. Thus it is also similar to that in the Commonwealth Act.

117 Fisher "The Use of DNA and the Law in Australia" (1982) 56 ALJ 6 at p13 suggests otherwise. But Fisher fails to note that it is "manufacture for sale" that is prohibited by s12 and not "manufacture" simpliciter. However, in relation to the Commonwealth Act, his definition is accurate.

118 NSW: ss29-38

Tas: ss23-30.

Qld: see Therapeutic Goods and Other Drugs Regulations; Health Act, s15.

WA: Health Act, 1911 s349.

119 NSW: ss39 and 40

Tas: ss9-12, 31-40.

Qld: Health Act, *ibid.*

WA: Health Act, 1911, s13.

120 Note s9 of the Act which suggests the supporting powers over importation of goods, trade and commerce between the States, pharmaceutical benefits and Territories; see also DE Fisher, *supra*, note 117, p12.

121 s5(1).

122 s11.

123 s15.

124 s19(1).

125 s20. This may be considered regulation in the light of s92 of the Constitution which says that interstate trade and commerce should be "absolutely free". Regulation motivated by health considerations should not offend this constitutional freedom.

126 s21.

127 s22.

128 s23D.

129 s23F.

130 NSW: Plant Diseases Act, 1924 s3(1). The power to issue the Proclamation is contained in s4(1).

SA: A number of Acts are relevant: Fruit, and Plant Protection Act, 1968 s3. Phylloxera Act, 1936-75, deals specifically with phylloxera disease affecting vineyards

allowing quarantine measures and other powers broadly similar to those specified in the following text.

- Tas: Plant Diseases Act 1930-1966, s4.
 Vic: Vegetation and Vine Diseases Act 1958, ss3(1), 5.
 Qld: Diseases in Plants Act, 1929-72, ss5, 4; Diseases in Timber Act, 1975, ss4, 3.
 WA: Plant Diseases Act, 1914-1981, ss4, 5
 NT: Plant Disease Control Act 1979, ss6, 8. The Vine Fruit and Vegetable Protection Act, 1885 (SA) also appears to remain in force in the Territory.
 ACT: Plant Diseases Ordinance 1934, s5(1).
- 131 NSW: Plant Diseases Act, 1924, s4.
 SA: Fruit and Plant Protection Act, 1968 ss4, 5.
 Tas: Plant Diseases Act 1930-1966, s4.
 Vic: Vegetation and Vine Diseases Act 1958, ss5, 4.
 Qld: Diseases in Plants Act, 1929-72, s5.
 WA: Plant Diseases Act, 1914-1981, s5.
 NT: Plant Disease Control Act 1979, s8.
 ACT: Plant Diseases Ordinance 1934, s6.
- 132 NSW: Plant Diseases Act, 1924, ss5, 6; 5A, 8, 14, 15; 9; 17.
 Tas: Plant Diseases Act 1930-1966, ss8, 6.
 SA: Fruit and Plant Protection Act, 1968 ss6, 7, 9, 12.
 Vic: Vegetation and Vine Diseases Act 1958, ss5(5), 6-12.
 Qld: Diseases in Plants Act, 1929-72, ss15, 11, 9, 17; Diseases in Timber Act, 1975, ss4, 6.
 WA: Plant Diseases Act, 1914-1981, ss.6, 12, 18, 23, 17, 19, 22.
 NT: Plant Disease Control Act 1979, ss10, 11, 13, 18, 19.
 ACT: Plant Diseases Ordinance 1934, s6, 7(a), 7(d).
- 133 NSW: Plant Diseases Act, 1924, ss11, 13-18A.
 SA: Fruit and Plant Protection Act, 1968 ss10, 13.
 Tas: Plant Diseases Act 1930-1966, ss5, 6.
 Vic: Vegetation and Vine Diseases Act 1958, ss3A, 3B, 16A, 17.
 Qld: Diseases in Plants Act, 1929-72, s6, 10; Diseases in Timber Act, 1975, ss6, which sets out powers of a "forest officer" appointed under the Forestry Act, 1959.
 WA: Plant Diseases Act, 1914-1981, ss7, 6A, 13.
 NT: Plant Disease Control Act 1979, ss7, 14.
 ACT: Plant Diseases Ordinance 1934, ss6(g), 7.
- 136 NSW: Stock Diseases Act, 1923, s.4. Note also the broad definition of "disease" in s.3.
 SA: Stock Diseases Act, 1934-75 ss5(1), 6(1)(aa).
 Qld: Stock Act 1915-81, s3, Exotic Diseases in Animals Act, 1981 s5.
 Vic: Stock Diseases Act, 1968, ss3, 4(1)(3)(a).
 Tas: The Stock Act, 1932, s3.
 WA: Disease is broadly defined in s6 and not subject to Proclamation, but note also "exotic disease" which may be proclaimed under ss6, 7(1), and "enzootic disease" definition in s6.

NT: Stock Diseases 1954, s5 broadly defines "disease", and does not leave its determination to Proclamation.
ACT: Stock Diseases Ordinance 1933, ss3, 4. See also Livestock Diseases Act 1978 (Cth) which enables control over diseased animals in the ACT.

137 Requirement to give notice:

NSW: s9; Vic: s11; SA: s19; Qld: Exotic Diseases in Animals Act 1981, s8; Tas: s10; WA: This may be done by regulation: for "enzootic diseases" see s10, for "exotic diseases" see s13; NT: ss35, 36; ACT: s7.

138 Quarantine power:

NSW: s10. Note also s10A which enables special quarantine areas to be declared in cases of emergency. Vic: s6(1)(b), a power of an inspector; SA: s6(d),(e); Qld: Stock Act ss12A, 13; Exotic Diseases Act, s9; Tas: s9; W.A.: This is done by regulation: for "enzootic diseases" see s10; for "exotic diseases" see s13; NT: s12; note also "restricted areas, s22A; ACT: power is respecting "infected areas", see s10.

139 Power to Control Stock Movement:

NSW: ss12A, 17A; Vic: s4(3)(c); SA: ss6(a)(b), 28, 20; Qld: Stock Act, ss9, 12; Tas: s6; WA: s16; also achieved by regulation: for "enzootic diseases" see s10, for "exotic diseases" see s13; NT: ss23, 24; ACT: prohibition and entry may only be achieved by regulation: s12(a).

140 Inspectorate:

NSW: s11B; Vic: ss5, 6, 6A, 9 (destruction), 20; SA: ss9-17; Qld: Stock Act, ss4, 14, 16, 26C(10), Exotic Diseases in Animals Act, ss12, 19-22; Tas: ss4, 5, 11 (destruction); WA: s8 and regulation-making powers in ss10(2)(k) and 13(3)(b), (c); NT: ss7-11, 15, 22B, 42; ACT: ss5, 6, 9, 8 (destruction).

141 Regulation-making power:

NSW: s23; SA: ss8, 8a; Qld: Stock Act, s31, Exotic Diseases in Animals Act, s47; Vic: s52; Tas: s62, V; WA: ss10 & 13 respectively concerning "enzootic" and "exotic" diseases, and generally s15; NT: s48; ACT: s12.

142 ss33-44.

143 ss17, 18, 22, 23.

144 s5.

145 See Schedule to Act describing this area, and s6(1) which would seem to allow any area in the State to be included within it.

146 s23.

147 ss24, 25.

148 s49.

- 149 Eg, potentially, Health Act, 1935-75 (SA) Part VI dealing with "insanitary conditions".
- 150 Eg Local Government Act, 1934-75 (SA), ss536a (\$100 penalty); 783 (\$200 penalty) at least in respect of private dwellings and public places.
- 151 See Part IV, Division 5, ss112-123.
- 152 s182(3).
- 153 Local Government Act (Depot of Refuse and Litter Infringement) Regulations 1973.
- 154 ss95-99A.
- 155 s77(4). A notice to abate such a nuisance may be issued and an offence may be committed (daily penalty of \$10) if it is contravened: see s79.
- 156 See Refuse Management Regulations 1977.
- 157 ss15(1)(c), 47. A penalty of \$5,000 and a daily penalty of \$500 is prescribed by s47(1).
- 158 See: ss15(1), (4) and (5).
- 159 "Scheduled Premises" are described in Schedule I to the Act, and include major commercial and industrial premises.
- 160 See: ss23, 48. A daily penalty of \$1,000 is prescribed by s48.
- 161 Environment Protection Act 1970, s20(1).
- 162 s45, Penalty: 100 penalty units, with a daily penalty of 40 penalty units.
- 163 See Window v Phosphate Co-operative Co of Australia [1983] 2 VR 287.
- 164 s10(j). See: Public Health (Night-Soil, Garbage, Cesspits, Wells and Water) Regulations 1960-1982; Public Health (General Sanitation, Mosquito Prevention, Rat Extermination and Prevention) Regulations 1960-1982.
- 165 s7 (Penalty of \$40).
- 166 Regs 3, 12.
- 167 See generally, ML Barker Conservation Law in the A.C.T. (1983) pp96-99.
- 168 NSW: See eg, Public Health Act, 1902, s64(k) (\$200 penalty: s106); Water Act, 1912, s21A (\$2,500 penalty).
SA: Health Act, 1935-75, s99 (\$100 penalty).
Qld: Health Act 1937-81, s77(2) (\$500 penalty: s175).

- Tas: The Environment Protection Act discussed above appears to be the principal source of such pollution control.
- Vic: Health Act 1958, ss40, 43(c)(i). Water supply may be protected in some cases: s80; Water Act 1958, ss244-46; Groundwater Act 1969, s77.
- WA: Health Act, 1911. s129 (\$200 penalty or 6 months imprisonment).
- NT: Public Health Act, s10(1) allows regulations to be made to deal with a nuisance, but does not deal specifically with water pollution.
- ACT: Public Health Ordinance, 1928 and Public Health (General Sanitation) Regulations, regs 19, 20.

169 Sewerage control is effected in various jurisdictions under the health or local government Acts, or by special sewerage legislation.

170 Vic: Health Act 1958, s40 (general offence to create a nuisance).

SA: Local Government Act, 1934-75, s540a (\$10 penalty).

ACT: Odours arising from premises may constitute an offence under the Public Health (General Sanitation) Regulations, Reg 8. air pollution otherwise is not subject to penalties. See ML Barker, Conservation Law in the ACT (1983) pp92-95.

NT: Public Health Act, s10(1) may enable air pollution to be controlled. It has not as yet been so used, except insofar as offences created by the Public Health (General Sanitation, Mosquito Prevention, Rat Exclusion and Prevention) Regulations are relevant.

171 See H Luntz, AD Hambly & R Hayes, Torts: Cases and Commentary (1980).

172 See RA Buckley, The Law of Nuisance (1981).

173 Exercise of the discretion may depend upon the seriousness of the case and likely repetition of the nuisance.

174 In the case of public nuisance, it would seem that a member of the public could only bring the action if he had a "special interest" in the proceedings. See Australian Conservation Foundation v Commonwealth (1980) 54 ALJR 176. The Attorney-General would be in a position in any event to bring the action. In the case of private nuisance, the occupier of affected land would have standing to sue.

PART 3: DELIBERATE RELEASE

177 s5(1).

178 s6.

179 s12.

180 RJ Fowler Environmental Impact Assessment, Planning and Pollution Measures In Australia (1982) (hereafter EIA Law), p27.

181 Cf Environmental Planning and Assessment Act, 1979 (NSW), s112, discussed below.

182 See, eg, Australian Conservation Foundation v Commonwealth (1980) 54 ALJR 176; and Tasmanian Wilderness Society v Fraser (1982) 56 ALJR 763.

183 See RJ Fowler, EIA Law, supra note 180, pp21-2.

184 But see Fowler "The Prospects of Judicial Review in Relation to the Federal Environmental Impact Statement Legislation" (1977) 11 MULR 1.

185 (1980) 54 ALJR 176.

186 Ibid, per Gibbs J at p181.

187 The standing difficulty may be overcome if the Attorney-General brings an action himself, or authorizes the proceedings in the public interest. It may also be that foreshadowed legislative amendments to the Act will alter the standing ruling.

188 s4.

189 McChesney and Adler, "Biotechnology Released from the Lab: The Environmental Framework" (1983) 13 Env Law Reporter (US) 10366 at p10371, footnotes deleted.

190 Ibid, p10372. The rule appears to have recently been relaxed: see Yost "Don't but Worst Case Analysis" (1983) 13 Env Law Reporter (US) 10394.

191 See s110 definition of "activity" which requires decisions to be tied to a "development, work or project".

192 See Kivi v Forestry Commission of NSW (1983) 47 LGRA 38.

193 See Prineas v Forestry Commission of NSW (1983) 49 LGRA 408.

194 See Farrier, "Environmental Assessment in New South Wales" (1984) 1 Env and Planning LJ 151, for a brief discussion of the EIS content issue.

195 s3(1).

196 s8.

197 s4(1)(b).

198 s4(1)(a).

199 s6(1).

200 s3(2).

201 s3(3).

202 s2.

203 s8(1).

204 s8(2).

205 s8(2) suggests this. See also RJ Fowler, EIA Law supra, note 180, p38.

206 See definition of "works" in Oxford English Dictionary.

207 ss6(2), 8(2). For an assessment of the effectiveness of the Act in securing comprehensive control over major works, see Morris, Barker & Hooper, Planning & Environment Service (Vic), (1984) Ch 17.

208 See Morris, Barker & Hooper, *ibid*.

209 See Morris, Barker & Hooper, *ibid*, for a full discussion.

210 Environmental Protection Act, 1971 (WA), s76(2).

211 See RJ Fowler EIA Law, supra note 205, pp67-8.

212 Environmental Protection Act, 1971 (WA), s57(1).

213 RJ Fowler, EIA Law, supra note 105, p76.

214 *Ibid* p80.

215 *Ibid* p81.

216 s49(7).

217 See ML Barker, Conservation Law in the ACT (1983), Ch 7.

218 s16(6).

219 s16(1).

220 For an account of its general use to date, see RJ Fowler, EIA Law, supra note 105, p154-5.

221 s34(1).

222 s34(3).

223 s49. General offence section \$400 penalty and daily penalty of \$40.

224 Note s48 penalty: daily penalty of \$1,000.

225 s22A(2).

226 ss15(1)(b); but note the "best practicable means" defence in case of emissions: s15(5)(a).

227 s2(3).

228 s2(2). A "microbe" is further defined, in case it is otherwise held not to be either animal or plant, a point not taken in other Acts.

229 s10.

230 s48(3)(a).

231 s48(3)(b).

232 s11.

233 ss49, 50.

234 s10; note also s10A(1).

235 s10A(2)-(4).

236 Control of Waters Act, s10A(1); Public Health Act, s10(1).

237 Control of Waters Act, s3.

238 Lakes Ordinance 1976 (ACT), s33 (\$200 penalty).

239 Public Health (General Sanitation) Regulations (ACT), Regs 19, 20.

240 See generally; ML Barker; Conservation Law in the ACT (1983) pp91-2.

241 See, Part 2 "Air Pollution" for an outline of the relevant legislation.

242 See Part 2, "Air Pollution" discussion.

242A NSW: Environmental Planning and Assessment Act, 1979
 Qld: Local Government Act 1936; City of Brisbane Town Planning Act
 SA: Planning Act 1982
 Tas: Local Government Act 1962
 Vic: Town and Country Planning Act 1961
 WA: Town Planning and Development Act, 1928
 NT: Planning Act
 ACT: National Capital Development Commission Act 1957
 (Cth); Leases Ordinance (ACT)

243 s14; see also definition of "noxious weed" in s3(1).

244 s6(1).

245 s6(4).

246 s13.

247 s16.

248 s16(3).

249 s35(1).

250 s35(2).

251 ss36, 43.

252 ss43, 29.

253 Division IV.

254 s47.

255 s15(2).

256 See ss11, 12, 17.

257 s16.

258 ss8, 9.

259 See s36.

260 See Division III.

261 See s17.

262 See, eg, Agriculture and Related Resources Protection Act, 1976 (WA) s105(1)(a).

263 Buffier v Warrah Shire Council (1938) 56 WN(NSW) 9.

264 See, eg, Agriculture and Related Resources Protection Act, 1976 (WA) s100.

265 See Second Reading Speech of Mr J Kerin on Biological Control Bill 1984 (Cth).

266 See similar reasoning in Canberra Labor Club Inc v Minister for the Capital Territory unreported decision of Federal Court of Australia (Davies J), discussed in ML Barker, Conservation Law in the ACT (1983) Ch 7.

267 See discussion in Part 2, "Animal Diseases", Section 2.4.5.

268 NSW: Stock (Artificial Insemination) Act, 1948, s3.

Vic: Stock (Artificial Breeding) Act 1962, ss3, 6.
Qld: Artificial Breeding of Stock Act, 1974, ss13, 22. This Act is the most comprehensive of its kind in Australia.
Tas: Artificial Breeding Act 1964, s15(1)(a)(ii), (c).
WA: Artificial Breeding of Stock Act, 1965, s5.
NT: Stock (Artificial Breeding) Act 1979, s4.

269 SA: Artificial Breeding Act, 1961-1974, does not follow this model precisely. Instead, it allows, under s26(ba) for regulations to be made to prohibit or regulate (ie, license) "the collection or use of semen". Thus, offences may be created by regulation.

270 NSW: s8.

Vic: s10. In Victoria, additionally, it is not an offence for a person acting under authority of the owner to perform the operation. This Act also makes it clear that an owner who performs or causes the operation must not only be using his stock, but also semen collected from his stock. The NSW and other Acts are not as clear on this point.

Qld: s18. The Act, s6, exempts veterinary surgeons or stock owners from this prohibition.

Tas: s15(1)(a)9ii), (b), (2).

WA: s10.

NT: ss4(1)(c), 12.

271 NSW: s11.

Vic: s13.

Qld: s52, and Schedule.

Tas: s24.

WA: s13.

NT: s17.

272 NSW: s2(1).

Vic: s2.

Qld: s7(1). Only "animals" may be affected by the proclamation power. Although birds are not specially mentioned, they are, of course, animals.

Tas: s(2) says "stock" has the same meaning as in the Stock Act 1932. That Act, s3, enables any animal to be declared to stock by the Governor.

WA: s4.

NT: s3.

273 See generally, the Appendix to the Report.

Qld: Director of Animal Industry in the Department of Primary Industry has primary responsibilities including licensing, subject to the Minister for Primary Industry.

Tas: The Artificial Breeding Board, set up by the Act, has responsibility for licensing under the Act.

WA: Department of Agriculture. Licences issued by the Minister.

SA: Department of Agriculture, and Artificial Breeding Board.

NT: Chief Inspector under the Stock Diseases Act has primary administrative responsibilities including most approval powers. Approval matters may be appealed to the Minister.

- 274 Tas: Artificial Breeding Act 1964, ss4, 5.
 WA: Artificial Breeding Board Act, 1965, s10. See also the Animal Resources Authority Act 1981, which provides for the Authority to breed "laboratory animals".
 SA: Artificial Breeding Act, 1961-1974, ss4, 24.
- 275 See, eg, Australian Meat and Livestock Corporation Act 1977 (Cth) ss7(a), 8(3)(b); Australian Science and Technology Council Act 1978 (Cth), ss5, 7; not yet proclaimed. Chicken Meat Research Act 1969 (Cth); Dairying Research Act 1972 (Cth); Fishing Industry Research Act 1969 (Cth); Meat Research Act 1960 (Cth); Pig Industry Research Act 1971 (Cth); Science and Industry Research Act 1949-1982 (Cth).
- 276 See CSIRO Biotechnology Research and Development (1981).
- 277 See, eg, Australian Dried Fruits Corporation Act 1978 (Cth); Barley Research Act 1980 (Cth); Cotton Research Act 1982 (Cth); Dried Fruits Research Act 1971 (Cth); Honey Research Act 1980 (Cth); Wheat Research Act 1957 (Cth); Wine Research Act 1955-1980 (Cth).
- 278 NSW: Agricultural Seeds Act, 1921, s15.
 Vic: Seeds Act 1982, s28.
 SA: Agricultural Seeds Act, 1938-1975, s26.
 Tas: Seeds Act 1950, s14(1).
 Qld: Agricultural Standards Act 1952-1981, s00.
 WA: Seeds Act 1981, s26(1).
 NT: Seeds Act 1976, s38; not yet in operation.
 ACT: No such legislation appears to be operative in this jurisdiction.
- 279 NSW: Anatomy Act, 1977, s14(1).
 Qld: Transplantation and Anatomy Act 1979-81, Pt V.
 SA: Anatomy Act, 1884-1954; Transplantation of Human Tissue Act, 1974; both to be repealed by the Transplantation and Anatomy Act, 1983 (not yet proclaimed), Pt III.
 Tas: Anatomy Act 1964, s14.
 Vic: Human Tissues Act 1982, Pts IV and VI.
 WA: Anatomy Act, 1930, s22.
 NT: Anatomy Act of 1884 (SA) applies in the NT.
 ACT: Transplantation and Anatomy Ordinance 1978, Pt III.
- 280 NSW: Anatomy Act, 1977, s14(2).
 Qld: Transplantation and Anatomy Act 1979-81, Pt V.
 SA: Transplantation and Anatomy Act, 1983 (when proclaimed), Pt III.
 Tas: Anatomy Act 1964, s12.
 Vic: Human Tissues Act 1982, Pts IV and VI.
 WA: Anatomy Act, 1930, s22.
 NT: Anatomy Act of 1884 (SA) applies in the NT.
 ACT: Transplantation and Anatomy Ordinance 1978, Pt III.
- 281 NSW: Anatomy Act, 1977, s7.
 Qld: Transplantation and Anatomy Act 1979-81, Pt VI.
 SA: Transplantation and Anatomy Act, 1983 (when proclaimed), Pt VI.
 Tas: Anatomy Act 1964, s5.

- Vic: Human Tissues Act 1982, Pts VII.
 WA: Anatomy Act, 1930, s4.
 NT: Anatomy Act of 1884 (SA) applies in the NT.
 ACT: Transplantation and Anatomy Ordinance 1978, Pt VI.
- 282 NSW: Anatomy Act, 1977, s8.
 Qld: Transplantation and Anatomy Act 1979-81, Pt V.
 SA: Transplantation and Anatomy Act, 1983 (when proclaimed), Pt III.
 Tas: Anatomy Act 1964, s13.
 Vic: Human Tissues Act 1982, Pts IV and VI.
 WA: Anatomy Act, 1930, s9.
 NT: Anatomy Act of 1884 (SA) applies in the NT.
 ACT: Transplantation and Anatomy Ordinance 1978, Pt III.
- 283 NSW: Tissue Grafting and Processing Act, 1955, ss5, 2. To be repealed by the Human Tissue Act, 1983 (not yet proclaimed).
 Qld: Transplantation and Anatomy Act 1979-81
 SA: Transplantation of Human Tissue Act, 1974; to be repealed by the Transplantation and Anatomy Act, 1983 (not yet proclaimed), Pt III.
 Tas: Anatomy Act 1964, s10.
 Vic: Human Tissues Act 1982.
 WA: Human Tissue and Transplants Act, 1982.
 NT: Human Tissue Transplant Act, 1979.
 ACT: Transplantation and Anatomy Ordinance 1978.
- 283A For a further discussion of common law liability, see: Cripps "Avenues of Compensation for Genetic Engineering Accidents" (1980) NZ U Law Rev 150; University of Melbourne, University Assembly Report on Genetic Engineering (c1978); and Select Bibliography attached to this Report.
- 284 See, eg, Allen v Gulf Oil Refining Ltd [1981] AC 1001, at p1013 per Lord Wilberforce.
- 285 (1866) LR 1 Ex 265.
- 286 Ibid, 279-80, per Blackburn J.
- 287 (1969) 122 CLR 249.
- 288 Ibid, 249, per Windeyer J.
- 289 Ibid, 255, per Barwick CJ.
- 290 There is, however, dispute as to the extent of this defence to the rule. See H Luntz, AD Hambly and R Hayes, Torts: Cases and Commentary (1980) pp992-95.
- 291 (1983) 46 ALR 625.
- 292 Constitution s51(xx).
- 293 Ibid, s51(xxix). YM Cripps Controlling Technology (1980) Ch 5 usefully discusses the relevance of international law to recombinant DNA work, including the possibilities of

international agreements which may lead to the regulation of such work.

294 Discussed in Part 2, "Dangerous Goods and Substances", Section 2.3.13.

295 Constitution, s51(i).

296 Ibid, s51(xxvii).

297 Ibid, s51(i).

298 Ibid, s51(ix).

299 See Quarantine Act 1908 (Cth), ss2B, 12A, discussed in Part 2 of the Report, Section 2.3.11.

300 Constitution, s51(xxxix).

301 For a discussion of the possible breadth of the quarantine power, see: J Quick and RR Garrahan The Annotated Constitution of the Australian Commonwealth (1901) pp566-568. Any such regulation would be subject to s92 of the Constitution which guarantees freedom of interstate trade and commerce.

302 The Act may not, however, apply to Commonwealth agencies. A State Act will not bind the Commonwealth Crown, unless the Commonwealth submits itself to State regulation.

303 This option may also require amendment of some laws to ensure that government has power to call for assessment of a deliberate release program whether it be publicly or privately sponsored.

304 See Korwek, "OSHA Regulation of Industrial Applications of Recombinant DNA Technology" (1981) 50 Cincinnati L Rev 284.

305 See McChesney and Adler, "Biotechnology Released From the Lab: The Environmental Regulation Framework" (1983) 13 Env Law Reporter (US) 10366, at pp10379-80.

306 There are, of course, those who would argue for the enactment of a discrete Genetic Engineering Act designed to regulate all facets of recombinant work and other means of genetic manipulation. See, eg, YM Cripps, Controlling Technology (1980) esp at pp80-123. Note also that there was once introduced into the United States Congress a Bill to establish a "National Recombinant DNA Safety Regulation Commission": see Chalfant, Hartmann, Blakeboro "Recombinant DNA: A Case Study in Regulation of Scientific Research" (1979) 8 Ecology L Q 55, at 127.

307 For a general discussion of these important issues, see: Favre and McKinnon "The New Prometheus: Will Scientific Inquiry be Bound by the Chains of Government Regulation?" (1981) 19 Duquesne L Rev 651; Chalfant, Hartmann, Blakeboro, supra note 306; Symposium on Biotechnology and the Law in

(1978) 51 Southern Calif L Rev; and Select Bibliography
attached to this Report.

APPENDIX

Summary of

(a) Commonwealth, State and Territory Government Ministerial Portfolios, Departments or Bodies;

(b) Legislation

having possible relevance to the regulation of recombinant DNA work in Australia.

The information in this Appendix is provided by reference to five main subject areas: Primary Industry; Public Health; Occupational Health and Safety; Environment Protection; and Technology.

In each subject area, the broad administrative structure in each jurisdiction is described, where possible, by identifying the Ministry, Departments, Divisions, and relevant statutory authorities. This information has been set out in some detail, and includes some Divisions or authorities whose functions may not be directly relevant to the matters raised in the body of the Report. It is hoped that by doing so, the reader may gain a better overview of existing administrative structures and relationships.

Legislation administered by each Ministry, so far as it is or may be considered relevant, to recombinant DNA work in Australia, is also set out by reference to subject areas. No attempt has been made, however, to list every piece of legislation administered by each Ministry described.

Note: An asterisk * has been placed beside each Statute which is mentioned specifically or generally in the body of the Report.

PRIMARY INDUSTRY

COMMONWEALTH

Ministry	Departments etc.	Legislation administered
Minister for Primary Industry	Department of Primary Industry - Meat and Wool Division - Dairy and Intensive Livestock Division - Field Crops Division - Forestry and Horticultural Crops Division - Fisheries Division - Export Inspection Service - Bureau of Animal Health Australian Agricultural Council - Standing Committee on Agriculture: Sub-Committees - -Animal Health Committee -Plant Health Committee -Co-ordinatig Committee on Agricultural Chemicals -Vertebrate Pests Committee -Consultative Committee on Exotic Insect Pests, Weeds and Plant Diseases -Consultative Committee of Animal Diseases Australian Fisheries Council Fishing Industry Research Committee Australian Forestry Council	Barley Research Act 1980* Chicken Meat Research Act 1969* Cotton Research Act 1982* Dairy Produce Act 1924 Dairying Industry Act 1962 Dairying Research Act 1972* Dried Fruits Research Act 1971* Export Control Act 1982 Fisheries Act 1952 Fishing Industry Research Act 1969* Honey Research Act 1980* Livestock Diseases Act 1978 Meat Research Act 1960* Pig Industry Research Act 1971* Stock Diseases Ordinance* Wheat Research Act 1957* Wine Research Act 1955* Wool Industry Act 1972*

NEW SOUTH WALES

Ministry	Departments etc.	Legislation administered
Minister for Agriculture and Fisheries	Department of Agriculture - Division of Animal Health -Animal Quarantine Service - Division of Animal Production - Division of Research and Advisory Services - Division of Plant Industries - Export and Import Branch - Biological and Chemical Research Institute - Pesticides and Environmental Studies Branch -Pesticides Registration Section Pasture Protection Boards Soil Conservation Service of New South Wales	Agricultural Seeds Act, 1921* Apiaries Act, 1916* Cattle Slaughtering and Diseased Animals and Meat Act, 1902* Dried Fruits Act, 1939 Fertilizers Act, 1934 Meat Industry Act, 1978 Institute of Rural Studies Act, 1973 Noxious Insects Act, 1934* Pastures Protection Act, 1934* Pesticides Act, 1978* Plant Diseases Act, 1934* Soil Conservation Act, 1938 Stock (Artificial Insemination) Act, 1948* Stock Diseases Act, 1923* Stock Foods and Medicines Act, 1940
Minister for Natural Resources	Forestry Commission of New South Wales - Wood Technology and Forest Research Division	Forestry Act, 1916

QUEENSLAND

Ministry	Departments etc.	Legislation administered
Minister for Primary Industries	Primary Industries Department ('Directorates':) Division of Plant Industry Division of Animal Industry Divisin of Dairying and Fisheries Research Stations Agriculture Horticulture Veterinary Public Health Plant Pathology Soil Conservation Services ('Inspectorates':) Plant Quarantine Animal Quarantine Council of Agriculture Veterinary Surgeons' Board	Agricultural Chemicals Distribution Control Act 1966-1978 Agricultural Standards Act 1952-1981* Apiaries Act 1982* Artificial Breeding of Stock Act 1979* Dairy Produce Act 1978-1979 Diseases in Plants Act 1929-1972* Exotic Diseases in Animals Act 1981-82* Fisheries Act 1976-1982 Fruit and Vegetables Act 1947-1972 Soil Conservation Act 1965-1982 Stock Act 1915-1981*
Minister for Lands, Forestry and Police		Diseases in Timber Act 1975* Forestry Act 1959-1982

VICTORIA

Ministry	Departments etc.	Legislation administered
Minister of Agriculture	Agriculture Department - Division of Veterinary Field Services - Division of Veterinary Public Health - Division of Veterinary Laboratory Services - Division of Plant Industries - Division of Plant Research - State Chemistry Laboratory - Scientific and Information Services Branch Stock Medicines Board Veterinary Board of Victoria Hamilton Pastoral Institute Advisory Committee Rain-Making Advisory Committee Victorian Crops Research Institute Advisory Council	Aerial Spraying Control Act 1966* Agricultural Chemicals Act 1958* Fertilizers Act 1974 Fruit and Vegetables Act 1958 Rain-Making Control Act 1967 Seeds Act 1971* Stock (Artificial Breeding) Act 1972* Stock Diseases Act 1968* Stock Foods Act 1958 Stock Medicines Act 1958 Vegetation and Vine Diseases Act 1958* Veterinary Research Institute Act 1972
Premier	Agricultural and Domestic Chemicals Review Committee	
Minister for Conservation, Forests and Lands	Department of Conservation, Forests and Lands - Fisheries and Wildlife Division - Soil Conservation Authority - Vermin and Noxious Weeds Destruction Board - Forests Commission	Fisheries Act 1968 Forests Act 1958 Soil Conservation and Land Utilisation Act 1958 Vermin and Noxious Weeds Act 1958* Wildflowers and Native Plants Protection Act 1958*

SOUTH AUSTRALIA

Ministry	Departments etc.	Legislation administered
Minister of Agriculture	Department of Agriculture - Animal Health Division - Land Use and Protection Division - Plant Industry Division Pests Plants Commission Vertebrate Pests Control Authority	Apiaries Act, 1931-1974 Artificial Breeding Act, 1961-1974* Fruit and Plant Protection Act, 1968-1976* Noxious Insects Act, 1934-1974* Pest Plants Act, 1975* Seeds Act, 1979* Soil Conservation Act, 1939-1978 Stock Diseases Act, 1934-1976* Stock Foods Act, 1941-1972 Stock Medicines Act, 1934-1973 Vertebrate Pests Act, 1975-1977*
Minister of Forests	Woods and Forests Department	Forestry Act, 1950-1981

WESTERN AUSTRALIA

Ministry	Departments etc.	Legislation administered
Premier and Cabinet, Treasurer, Minister Co-Ordinating Economic and Social Development, and Minister for Forests, Tourism, and Women's Interests	Forests Department	Forests Act 1918

TASMANIA

Ministry	Departments etc.	Legislation administered
Minister for Industry and Small Business	Inland Fisheries Commission	Fisheries Act, 1959
Minister for Inland Fisheries		
Minister for Health	Department of Health Services	Pesticides Act 1968*
Minister for Community Welfare and the Elderly		
Minister for Ethnic Affairs		
Minister for Primary Industry	Department of Agriculture	Apiaries Act 1978* Fruit and Vegetables Act 1953
Minister for Forests	Fertilizers Board	Noxious Insects Act 1951*
Minister for Sea Fisheries	Stock Medicines Board	Plant Diseases Act 1930* Seeds Act 1950*
Minister for Water Resources	Veterinary Board	Stock Act 1932* Stock Medicines and Fertilizers Act 1950
	Weeds Consultative Committee	Noxious Weeds Act 1964*
	Forestry Commission	Forestry Acts 1920, 1954 and 1977

NORTHERN TERRITORY

Ministry	Departments etc.	Legislation administered
Minister for Primary Production and Conservation	Department of Primary Production - Division of Agriculture and Stock - Animal Industry Branch - Plant Industry Branch - Research Services - Branch - Quarantine - Fisheries Division Agricultural Development and Marketing Authority Conservation Commission - Soil Conservation Advisory Council	Plant Diseases Control Act* Seeds Act* Stock (Artificial Breeding) Act* Stock Diseases Act* Stock Foods Act Forestry Act Soil Conservation and Land Utilization Act

AUSTRALIAN CAPITAL TERRITORY

Ministry	Departments etc.	Legislation administered
Minister for Territories and Local Government (Commonwealth)	Department of Territories and Local Government - Conservation and Agriculture - Lands Divisions - Forests Division - Conservation of Wildlife	Apiaries Ordinance 1928* Leases Ordinances (various) Nature Nature Conservation Ordinance 1980* Soil Conservation Ordinance 1960 Protection of Lands Ordinance* Plant Diseases Ordinance 1934* Stock Ordinance 1934*

PUBLIC HEALTH

COMMONWEALTH

Ministry	Departments etc.	Legislation administered
Minister for Health	Department of Health - National Biological Standards laboratory - Australian Dental Standards laboratory - National Health and Medical Research Council Division - Public Health Division - Quarantine Division - Therapeutics Division Capital Territory Health Commission Registration Boards of the Australian Capital Territory Commonwealth Serum Laboratories Commission Australian Drug Evaluation Committee - Anti-Cancer Sub-committee - Endocrinology Sub-committee - National Drug Information Advisory Sub-committee - Vaccines Sub-committee Ministerial Committee on Drug Strategy National Health Technology Advisory Panel National Health and Medical Research Council National Therapeutic Goods Committee Therapeutic Goods Advisory Committee - Therapeutic Goods Standards Committee	Commonwealth Serum Laboratories Act 1961* Medical Research Endowment Act 1937 Narcotic Drugs Act 1967 (part only) Quarantine Act 1908* Therapeutic Goods Act 1966*

NEW SOUTH WALES

Ministry	Departments etc.	Legislation administered
Minister for Health	Health Commission of New South Wales - Institute of Clinical Pathology and Medical Research - Central Cancer Registry - Pharmaceutical Services Branch New South Wales State Cancer Council	Anatomy Act, 1977* Noxious Microbes Act, 1900* Pathology Laboratories Accreditation Act, 1981* Poisons Act, 1966* Public Health Act, 1902* Pure Food Act, 1908* Therapeutic Goods and Cosmetics Act, 1972*

VICTORIA

Ministry	Departments etc.	Legislation administered
Minister of Health	Health Commission - Hospitals Division - Public Health Division Anit-Cancer Council of Victoria Cancer Institute Board Dental Board of Victoria Medical Board of Victoria Pharmacy Board of Victoria Food Standards Committee Poisons Advisory Committee Proprietary Medicine Advisory Committee	Health Act 1958* Health Commission Act 1977 Human Tissue Act 1982* Industrial Safety Health and Welfare Act 1981* Medical Act 1958 Poisons Act 1962*

QUEENSLAND

Ministry	Departments etc.	Legislation administered
Minister for Health	Health Department - Laboratory of Microbiology and Pathology - Division of Environmental and Occupational health - Queensland Institute of Medical Research - Medical and Other Professional Registration Boards	Drug Standards Adopting Act 1976 Food Act 1981* Health Act 1937-1981* Transplantation and Anatomy Act 1979* Queensland Institute of Medical Research Act 1944-1981

SOUTH AUSTRALIA

Ministry	Departments etc.	Legislation administered
Minister of Health	South Australian Health Commission - Communicable Disease Control Unit, Epidemiology Branch - Health Promotion Services - Health Surveying Branch - Occupational Health Branch - Pharmaceutical Branch Institute of Medical and Veterinary Science	Food and Drugs Act 1908-1972* Health Act 1935-1975* Narcotic and Psychotropic Drugs Act, 1934-1974

WESTERN AUSTRALIA

Ministry	Departments etc.	Legislation administered
Minister for Health	Hospital and Allied Services Public Health Department	Anatomy Act 1930* Animal Resources Authority Act 1981* Clean Air Act 1964* Health Act 1911* Human Tissue and Transplant Act 1982* Pharmacy Act 1964 Poisons Act 1964*

TASMANIA

Ministry	Departments etc.	Legislation administered
Minister for Health	Dental Board of Tasmania	Anatomy Act 1964*
Minister for Community Welfare and the Elderly	Dental Health Services Advisory Committee	Local Government Act 1982* Pesticides Act 1968
Minister for Ethnic Affairs	Department of Health Services Medical Council of Tasmania Pharmacy Board of Tasmania Poisons Advisory Committee	Public Health Act 1962* Quarantine Act 1881* Sale of Blood Act 1964* Therapeutic Goods and Cosmetics Act 1976* Medical Act 1959 Pharmacy Act 1908 Poisons Act 1971*

NORTHERN TERRITORY

Ministry	Departments etc.	Legislation administered
Minister for Health and Housing	Department of Health - Environmental Health Division - Planning and Development Division - Health Professions Registration Boards of the Northern Territory	Containers for Hazardous Substances Act Dangerous Drugs Act* Food and Drugs Act* Food Standards Act* Human Tissue Transplant Act* Notifiable Diseases Act Pharmacy Act Poisons Act* Prohibited Drugs Act* Public Health Act*

AUSTRALIAN CAPITAL TERRITORY

Ministry	Departments etc.	Legislation administered
Minister for Health (Commonwealth)	Capital Territory Health Commission	Health Commission Ordinance 1975 Public Health Ordinance 1928* Poisons and Dangerous Drugs Ordinance 1933* Poisons and Narcotics Drugs Ordinance 1978

ENVIRONMENT

COMMONWEALTH

Ministry	Departments etc.	Legislation administered
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Minister for Home Affairs and Environment	Department of Home Affairs and Environment - Environment Divisionm -Bureau of Flora and Fauna Australian Environment Council Australian National Parks and Wildlife Service Council of Nature Conservation Ministries	Environment Protection (Impact of Proposals) Act 1974* National Parks and Wildlife Conservation Act 1975
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Minister for Resources and Energy	Australian Water Resources Council	
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NEW SOUTH WALES

Ministry	Departments etc.	Legislation administered
Minister for Planning and Environment	Department of Environment and Planning Heritage Council of New South Wales State Pollution Control Commission - Air and Motor Vehicles Division - Water, Wastes and Noise Division National Parks and Wildlife Service Metropolitan Waste Disposal Authority	Clean Air Act, 1961* Clean Waters Act, 1970* National Parks and Wildlife Act, 1974 State Pollution Control Commission Act, 1970* Waste Disposal Act, 1970* Environmental Planning and Assessment Act, 1979*
Minister for Natural Resources	Metropolitan Water Sewerage and Drainage Board Hunter District Water Board Water Resources Commission	Conservation Authority of New South Wales Act, 1949 Hunter District Water, Sewerage and Drainage Act, 1938* Metropolitan Water, Sewerage and Drainage Act, 1924* Water Act, 1912* Water Resources Commission Act, 1976

VICTORIA

Ministry	Departments etc.	Legislation administered
Minister for Planning and Environment	Ministry for Planning and Environment - Environment Protection Authority -Advisory Committee on Licensing Waste Discharges to Water -Industrial Waste Advisory Committee -Waste Recycling Advisory Committee -Pollution and Waste Management Advisory Panel - Environment Protection Council -Solid Waste and Pollution Committee -Waste Licensing and Enforcement Committee -Water Quality Committee - Land Conservation Council	Environment Effects Act 1978* Environment Protection Act 1970* Land Conservation Act 1970 Town and Country Planning Act 1961
Minister of Water Supply	Ministry of Water Resources and Water Supply - Water Resources Council - Melbourne and Metropolitan Board of Works - State Rivers and Water Supply Commission	Sewerage Districts Act 1958 Melbourne and Metropolitan Board of Works Act 1958 Drainage of land Act 1975 Victorian Water and Sewerage Authorities Association Act 1981 Water Act 1958 Water Resources Act 1975
Minister for Conservation, Forests and Lands	Department of Conservation, Forests and Lands - National Parks Service - Fisheries and Wildlife Division	National Parks Act 1975 Wildlife Act 1975

QUEENSLAND

Ministry	Departments etc.	Legislation administered
The Premier	Co-Ordinator General's Dept (Environment Assessment)	
Minister for Local Government, Main Roads and Racing	Brisbane and Area Water Board	Brisbane and Area Water Board Act 1979-1981 Clean Waters Act 1971-1982* Sewerage and Water Supply Act 1949-1982*
Minister for Environment, Valuation and Administrative Services	Department of Mapping and Surveying - Division of Air Pollution Control	Clean Air Act 1963-1981*
Minister for Tourism, National Parks, Sport and the Arts	Department of the Arts, National Parks and Sport - Queensland National Parks and Wildlife Service	Fauna Conservation Act 1974-1979* National Parks and Wildlife Act 1975-1982 Native Plants Protection Act of 1930
Minister for Water Resources and Maritime Services	Queensland Water Resources Commission	Water Act 1926-1981 Water Resources Administration Act 1978-1981

SOUTH AUSTRALIA

Ministry	Departments etc.	Legislation administered
Deputy Premier Minister of Mines and Energy	Department of Mines and Energy	Water Resources Act, 1976*
Minister of Environment and Planning	Department of Environment and Planning - National Parks and Wildlife Service - Pollution Management Division	Environmental Protection Council Act, 1972-1980 Health Act 1935-1975* National Parks and Wildlife Act, 1972-1974 Planning Act, 1982*
Minister of Water Resources	Engineering and Water Supply Department - Consumer Services Branch - Revenue Branch	Sewerage Act, 1929-1975* Water Resources Act, 1976*
Minister of Local Government	Department of Local Government South Australian Waste Management Commission	Local Government Act 1934-1975* South Australian Waste Management Commission Act, 1979*

WESTERN AUSTRALIA

Ministry	Departments etc.	Legislation administered
Minister for the Environment, Multicultural and Ethnic Affairs, and the Arts	Department of Conservation and Environment Environmental Protection Authority National Parks Authority Waterways Commission	Environmental Protection Act 1971* National Parks Authority Act 1976 Waterways Conservation Act 1976*
Minister for Agriculture, Fisheries and Wildlife, and Minister Assisting the Minister for Forests	Department of Fisheries and Wildlife	Wildlife Conservation Act 1950
Minister for Water Resources, and Parliamentary and Electoral Reform and Leader of the House	Metropolitan Water Authority	Country Areas Water Supply Act 1947 Country Towns Sewerage Act 1948* Metropolitan Water Supply, Sewerage and Drainage Act 1909* Water Supply, Sewerage and Drainage Act 1912* Western Australian Water Resources Council Act 1982

TASMANIA

Ministry	Departments etc.	Legislation administered
Minister for Tourism	Department of the Environment	Environment Protection Act 1973*
Minister for National parks and Recreational Lands	National Parks and Wildlife Service	National Parks and Wildlife Act 1970
Minister for Environment		
Minister for Licensing		
Minister for Primary Industry	Metropolitan Water Board	Metropolitan Water Act 1961
Minister for Forests	Rivers and Water Supply Commission	Southern Regional Water Act 1960
Minister for Sea Fisheries		Rivers Pollution Act 1881*
Minister for Water Resources		Sewers and Drains Act 1954
		Water Act 1957

NORTHERN TERRITORY

Ministry	Departments etc.	Legislation administered
Chief Minister	Conservation Commission of the Northern Territory	Environmental Assessment Act 1982

AUSTRALIAN CAPITAL TERRITORY

Ministry	Departments etc.	Legislation administered
Minister for Home Affairs and Environment (Commonwealth)	Department of Home Affairs and Environment	Environment Protection (Impact of Proposals) Act 1974 (Cth)*
Minister for Territories and Local Government	Department of Territories - Pollution Division	Lakes Ordinance 1976*

OCCUPATIONAL HEALTH AND SAFETY

COMMONWEALTH

Ministry	Departments etc.	Legislation administered
Minister for Employment and Industrial Relations	Australian Copnciliation and Arbitration Commission National labour Consultative Council Interim National Occupational Health and Safety Commission	Conciliation and Arbitration Act 1904* National Labour Consultative Council Act 1977
Minister for Industrial Relations	Department of Industrial Relations - Division of Industrial Relations - Division of Inspection Services - Mines Inspection Division Occupational Health, Safety and Rehabilitation Council of New South Wales	Coal Mines Regulation Act, 1912 Dangerous Goods Act, 1975* Factories, Shops and Industries Act, 1962* Industrial Arbitration Act, 1940 Mines Inspection Act, 1901 Occupational health and Safety Act, 1983*

VICTORIA

Ministry	Departments etc.	Legislation administered
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Minister for Employment and Training	Occupational Health and Safety Commission	
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Minister of Labour and Industry	Department of Labour and Industry - Division of Inspection Services - Division of Technical Services Industrial Safety Health and Welfare Advisory Council	Industrial Safety Health and Welfare Act 1981*
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Minister for Minerals and Energy	Department of Minerals and Energy - Hazardous Materials Division	Groundwater Act 1969
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QUEENSLAND

Ministry	Departments etc.	Legislation administered
Minister for Employment and Industrial Affairs	Department of Employment and Industrial Affairs - Division of Occupational Safety - Industrial Inspectorate Workers' Compensation Board of Queensland	Factories and Shops Act 1960-1982*

SOUTH AUSTRALIA

Ministry	Departments etc.	Legislation administered
Minister of Industrial Affairs	Department of Industrial Affairs and Employment	Dangerous Substances Act, 1979* Industrial Safety Health and Welfare Act, 1972-1983*

WESTERN AUSTRALIA

Ministry	Departments etc.	Legislation administered
Minister for Industrial Relations and Administrative Services, and Leader of the Government in the Legislative Council	Department of Industrial Affairs Western Australian Government Industrial Relations Service Workers Assistance Commission	Factories and Shops Act 1963*
Minister for Minerals and Energy, and Minister Assisting the Minister Co-Ordinating Economic and Social Development	Department of Mines Western Australian Mining and Petroleum Research Institute	Explosives and Dangerous Goods Act 1961* Mining and Petroleum Research Act 1981

TASMANIA

Ministry	Departments etc.	Legislation administered
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Minister for Mines	Department of Mines	Dangerous Goods Act 1976*
Minister for Transport		
Minister for Administrative Services		

Minister for Industry and Small Business	Consumer Affairs Council	Sale of Hazardous Goods Act 1977*
Minister for Inland Fisheries		

Deputy Premier	Attorney-General's	Industrial Safety, Health and Welfare Act, 1977*
Attorney-General	Department	
Minister for Education	Department of Labour and Industry	
Minister for Industrial Relations	Industrial Advisory Council	
Minister for Police and Emergency Services	Industrial Boards Industrial Safety Health and Welfare Rural Industries Safety Advisory Committee	

NORTHERN TERRITORY

Ministry	Departments etc.	Legislation administered
	Department of Mines and Energy	Dangerous Goods Act*
	- Mines Division	Inspection of Machinery Act *
	-Inspection and Safety	
	-Occupational Hygiene	
	-Environment	
	Protection	
	- Industrial Safety	
	Divison	
	-Machinery Safety	
	-Dangerous Goods	
	-Industrial Safety	
	Co-Ordinator	

AUSTRALIAN CAPITAL TERRITORY

Ministry	Departments etc.	Legislation administered
Minister for Territories and Local Government (Commonwealth)		

TECHNOLOGY

COMMONWEALTH

Ministry	Departments etc.	Legislation administered
Prime Minister	Australian Science and Technology Council - Technological Change Committee	Australian Science and Technology Council Act 1978*
Minister for Science and Technology	Department of Science and Technology - Industrial research and Development Branch - Technology Development Division -National Materials Handling Bureau -Technical Information Unit - Patent Trade Marks and Designs Office Commonwealth Scientific and Industrial Research Organization - Institute of Animal and Food Sciences -Division of Animal Health -Division of Animal Production -Project for Animal Research and Development -Division of Fisheries Research -Division of food Research -Division of Tropical Animal Science -Molecular and Cellular Biology Unit -Wheat Research Unit - Institute of Biological Resources -Division of Entomology -Division of forest Research	Australian Insstitute of Marine Science Act 1972 Industrial Research and Development Incentives Act 1976 Science and Industry Research Act 1949*

COMMONWEALTH (cont)

Ministry	Departments etc.	Legislation administered
	-Division of Horticultural Research	
	-Division of Plant Industry	
	-Division of Soils	
	-Division of Tropical Crops and Pastures	
	-Division of Water and Land Resources	
	-Division of Wildlife and Rangelands Research	
	- Institute of Industrial Technology	
	-Division of Applied Organic Chemistry	
	-Division of Chemical and Wood Technology	
	-Division of Protein Chemistry	
	- Laboratory for Rural Research	
	- Marine Laboratories	
	- Advisory Council	
	Australian Industrial Research and Development Incentives Board	
	Australian Industrial Research and Development Advisory Committee	
	Australian Industrial Research and Development Technical Standing Committee	
	Australian Institute of Marine Science	
	Australian Marine Sciences and Technologies Advisory Committee	
	National Standards Commission	
	Recombinant DNA Monitoring Committee	
	- Scientific Sub-committee	

NEW SOUTH WALES

Ministry	Departments etc.	Legislation administered
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Minister for Technology	New South Wales Science and Technology Council Technology Research Unit	
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VICTORIA

Ministry	Departments etc.	Legislation administered
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Minister for Employment and Training	Victorian Technology Advisory Committee	
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QUEENSLAND

Ministry	Departments etc.	Legislation administered
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Minister for Industry, Small Business and Technology	Queensland Science and Technology Council	
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SOUTH AUSTRALIA

Ministry	Departments etc.	Legislation administered
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Minister for Industrial Affairs	Department of Industrial Affairs and Employment - Technology Change Office	
	Department of Trade and Industry, Economic Technological Developments	

WESTERN AUSTRALIA

Ministry	Departments etc.	Legislation administered
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Deputy Premier and Minister for Industrial Development, Technology and Defence Liaison	Department of Industrial Development Technology Directorate	
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