CHAPTER EIGHT

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CHAPTER EIGHT

THE WAY AHEAD

A. Requirement for Legislation

8.1 There are three main reasons why legislative action might be needed as a result of the development of genetic manipulation techniques. Firstly, to ensure that there are adequate controls to protect the environment from the accidental or intentional release of genetically modified organisms. Secondly, to fill in any apparent gaps in existing legislation governing the clearance and registration of products which may now contain, or be produced by, genetically modified organisms. Thirdly, if it is considered that adherence to the existing voluntary guidelines concerning contained genetic manipulation work should be made mandatory, any new legislation must clarify the administrative framework.

A.1 Accidental or deliberate releases

8.2 Chapter 5 in this report dealt with the environmental issues relevant to the inquiry in some detail. Existing Commonwealth and State legislation which might be applicable to the environmental impact of releases of GMOs was outlined. A number of recommendations were made for measures to help reduce the risks.

8.3 One possible eventuality is the accidental release of GMOs from commercial or research premises. Recommendations 36 to 39 and recommendation 45 in this report concerning the regulation of contained work with GMOs, should help to minimise the chance of accidental release and to minimise any dangers if release does occur.

8.4 Reference was made in chapter 5 to various State Acts concerning air and water quality, waste management, or sewerage, or health matters which might be applicable to escapes of GMOs. The polluter could be subject to certain sanctions under these Acts and there may be provisions concerning the removal of the polluting substance. Mention was also made of common law actions which might apply.

8.5 The VLRC felt that there was adequate power under existing legislation to deal with any emergency that may arise from a release of GMOs to the environment. They acknowledged, however, concerns expressed to them that "criteria for invoking these laws are generally commercial loss or public health damage" rather than environmental damage.[1]

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1 VLRC: Report No 26, *Genetic Manipulation*, June 1989 p 35

8.6 Dr David Burch et al. recommended provision for an emergency disaster safety net program, "allowing seizure and destruction of bioproducts, sterilisation of fields and clean-up of spills."[2]

8.7 Dr Chris Green, Director of Plant Pathology, NSW Department of Agriculture and Fisheries, commented on the need for contingency planning to allow rapid responses to accidents. He mentioned that, for outbreaks of disease or occurrences of exotic pests, rapid decisions and responses are required. The same could be necessary in relation to escapes of GMOs or when unintended effects resulted from authorised releases.

> "... action has to be taken very often within days if it is a bacterial infection. This is mostly done by departments in the States being fairly ready to take the immediate action and take the cost. The departments hope to recover costs by Federal-State partitioning of costs.
>
> ... Until now the State departments have generally borne this. ... State department finance is getting tighter and tighter. ...
>
> If we are taking genetic engineering organisms, it is almost the same. I regard a genetically modified organism as being an exotic. It is a different gene combination to what occurs in nature. You have got exactly the same problem. If you do get an escape, who is going to deal with it? Who is going to pay for it and who is going to make the decisions as to whether we try to eradicate it or whether we let it run loose? I am not going to try to make those decisions."[3]

8.8 The VLRC report recommended specific legislation to control the experimental releases of altered organisms - enacted by Commonwealth, or complementary State/Commonwealth legislation. The VLRC said this legislation should:

> . include mandatory notification to GMAC and relevant State and Federal Government Departments of proposed releases;
> . require the supervising agency to conduct an environmental impact assessment on proposed releases;
> . require advertisement by the supervising agency and public input before any approval;
> .provide for the supervising agency to have power to impose conditions, such as containment and monitoring requirements, when approving a release proposal and power to "take steps to prevent injury or damage to people or property and to eradicate or otherwise deal with organisms in the environment".[4]

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2 Burch, Dr D et al.: Submission 106 pp 5 & 56

3 Green, Dr C, Director of Plant Pathology, NSW Department of Agriculture and Fisheries: Transcript pp 757, 756

4 VLRC: Report No 26 p vi, Recommendation 13

8.9 The VLRC emphasised the importance of Federal co-ordination of "advice, assessment, approval, and monitoring of proposed releases" through GMAC and the Group of Officials on Biotechnology Regulations.[5]

8.10 There was broad support among those who made submissions to the inquiry for many of the measures included in the above VLRC recommendations, and in particular for: a uniform national approach; mandatory notification of proposed releases; an approval procedure (although not uniform support for a detailed environmental impact assessment in every case); public input into decision making about releases; and provision for the supervisory agency to impose conditions as part of the approval for release.

8.11 Biotechnology companies stated a preference for a comprehensive national regulatory system over one which was less uniform and more uncertain. Monsanto Australia Ltd commented that uncertainty about regulatory requirements at present was inhibiting commercialisation of biotechnology in Australia.[6]

Recommendation 35

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

A.2 Existing product legislation - gaps

8.13 The VLRC inquiry found that, in the State of Victoria at least:

> "Most of the potential applications of genetic manipulation probably fall within existing legislation and the responsibilities of Government Departments ... Although produced by genetic manipulation techniques, they are not radically different from products produced by other means....
> It is essential, however, that every proposed release falls within the responsibility of some Department. ... legislation generally requires that a new product may not be sold or used unless it is registered, or the subject of a permit.
> There are ... some agricultural activities that are subject to few controls, such as the breeding of transgenic animals and the propagation and sale of new plants. Also, it is conceivable that, as new products are

5 ibid., p vii, Recommendation 14

6 Sheers, M, Regulatory and Environmental Affairs, Monsanto Australia Ltd: Transcript pp 443-445

> developed, or are used in novel ways, they will not fall readily, or at all, within the review responsibilities of a Government Department. ...
> ... It is evident from the Commission's discussions with representatives of various Government Departments that even they are uncertain about some of the matters that might fall within their responsibilities and the applicability of the legislation they administer to the new technology."[7]

8.14 Prof Nancy Millis, from GMAC, like Mrs Loane Skene from the VLRC, referred to existing legislation being inadequate to cover the case of releases of live plants which have been genetically modified.[8] The GMAC submission commented that

> "Although there are many Acts and sets of regulations that are directly applicable or can be readily invoked, there is great variability and lack of a clear path for clearance, and uncertainty about responsibilities within State and Commonwealth agencies."[9]

8.15 Previous chapters in this report have included discussion of the existing regulatory framework in the following areas: food, food additives and pharmaceuticals (in chapter 6); product labelling requirements for food, pharmaceuticals, and agricultural and veterinary chemicals (in chapter 7).

8.16 The Committee has already commented that there was an apparent gap in the food clearance procedures. The Committee has accordingly recommended in chapter 6 that new foods, new strains of existing foods, or new food additives which are developed using genetic manipulation techniques should be referred to GMAC before release.

8.17 It was noted in chapter 6 that the procedures for clearance of therapeutic goods, although focussed on the type of product and its intended use, allow consideration of the process of manufacture to be taken into account. Indeed, recent amendments to the Health Department guidelines specifically relate to the information required for the products of genetic manipulation. There may be scope, however, for 'dietary supplements,' which are marketed without making claims about therapeutic properties, to slip through without the same consideration which therapeutic goods receive.

8.18 It was noted in chapter 7 that the Australian Agricultural and Veterinary Chemicals Council (AAVCC) has been established to co-ordinate the pre-registration assessment and clearance process for agricultural and veterinary chemicals. It was also noted that such chemicals can include biological agents, either naturally occurring or genetically modified. The working procedures of the AAVCC involves GMAC in an assessment of the possible hazards which might result from any manufacturing process involving GMOs.

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7 VLRC: Report No 26 pp 29, 30
8 Millis, Prof N, Chairman, GMAC: Transcript p 80
9 GMAC: Submission 88.1

8.19 There were conflicting opinions expressed concerning the adequacy of the AAVCC process when dealing with GMOs.

8.20 "ICI Australia would like to emphasise that a competent regulatory framework already exists for farm chemicals and pharmaceuticals. ... [The authorities] have developed the experience and flexibility to establish the safety of products and processes involving biotechnology."[10]

8.21 However, Biotech International did not share this satisfaction with the applicability of the procedures.

> "Many sections of the data required ... are not applicable to living organisms. Many of the questions that should be answered when assessing biological control agents are not asked. A great deal of space in the submission is taken up in defining ... chemical and physical properties (boiling point, solubility etc) of constituent compounds and end products."[11]

8.22 The Committee indicated in chapter 7 that it favours an approach whereby products are regulated on the basis of their intended use rather than on the basis of the manufacturing process employed in their production. The Committee recommended in chapter 7 that those seeking approval for registration or sale of new products should indicate the method of manufacture so that this could be taken into account in considering the safety or efficacy of the product.

8.23 A distinction could be made between products which are merely chemical products and those which do or could include live organisms. Existing approval procedures for some types of products have been developed including consideration of the possibility of the inclusion of live organisms in the product. For example, clearance procedures for vaccines have long had to encompass vaccines incorporating live organisms. It should not be difficult to adapt these kinds of procedures to allow appropriate consideration of products incorporating live genetically modified organisms.

8.24 The approval procedures for other types of products, such as agricultural chemicals, have been developed with non-living products in mind. It may be more difficult to accommodate consideration of GMOs within such procedures.

8.25 **The Committee considers that existing product clearance and registration procedures are not fully adequate to cope with products which consist of or include live GMOs.**

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10 ICI Australia Ltd: Submission 121 p 12

11 Biotech International Ltd: Submission 90 p 6

A.3 Existing guidelines for contained work - voluntary or compulsory adherence

8.26 In chapter 2 of this report the existing GMAC guidelines for small and large scale genetic manipulation work, and the *Australian code of practice for the care and use of animals for scientific purposes* were described. The Committee has already recommended in chapter 4 of this report that legislative force be given to the *Australian code of practice.*

8.27 It was noted in chapter 2 that adherence to the GMAC guidelines is voluntary; although there are some sanctions which could be applied such as withdrawal of government grants or tax incentives. There were different opinions among those who made submissions to the inquiry concerning the need to make adherence to the guidelines compulsory.

8.28 Prof Jim Pittard, Chairman of the Scientific Sub-Committee of GMAC, argued that the fifteen year history of regulation of contained work by voluntary guidelines, "without any major mishap or non-compliance", indicated that no new legislation was necessary.[12] The Australian Veterinary Association,[13] the Australian Academy of Science,[14] the Department of Microbiology, Monash University,[15] and the Department of Industry, Technology and Commerce[16] similarly argued against the need for compulsory adherence to guidelines for contained work.

8.29 On the other hand, the Australian Conservation Foundation,[17] the Department of Primary Industries and Energy,[18] the Biotechnology Industry Association[19] among others argued in favour of mandatory guidelines. It was argued that the limited existing sanctions will not be sufficient to ensure compliance as the use of the technology becomes more widespread. Mr Nelson Quinn, First Assistant Secretary of the Environment Protection Division of the Department of the Arts, Sport, the Environment, Tourism and Territories stated:

> "I think our expectation would be that the demands of the public and probably parliaments and so on would make it pretty much inevitable that there would have to be some kind of formality attaching to those guidelines. The level of it would be an issue for decision, I guess. You would expect to find at least codes of conduct and so on endorsed by

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12 Pittard, A J, Professor of Microbiology, University of Melbourne and Chairman of Scientific Sub-Committee, GMAC: Submission 2, p 12

13 The Australian Veterinary Association Ltd: Submission 133 p 3

14 Gibson, Prof F, Australian Academy of Science: Transcript p 5

15 Bayley, Prof R, Chairman, Department of Microbiology, Monash University: Submission 59 p 2

16 Delroy, B and Clarke, B; Department of Industry, Technology and Commerce: Transcript p 1100

17 Phelps, R, Australian Conservation Foundation: Submission 140 p 28

18 McLean, Dr G, Bureau of Rural Resources, Primary Industries and Energy: Transcript p 1148

19 Biotechnology Industry Association: Submission 157 p 10

> the Authority. In the real world that really would amount to a mandatory system."[20]

8.30 The Committee considers that there is no substantial argument against adherence to the GMAC guidelines for small and large scale genetic manipulation work being made compulsory. Giving those guidelines statutory backing will help improve public confidence in the system, without making more stringent the requirements that researchers and commercial operators state that they already meet in practice.

Recommendation 36

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

A.3.(i) Sanctions

8.32 Making adherence to the guidelines mandatory raises the question of the sanctions which might be imposed.[21] The VLRC report recommended that: "Research funding and taxation incentives for genetic manipulation work should be conditional on compliance with Genetic Manipulation Advisory Committee guidelines."[22]

8.33 Biotech Australia went slightly further suggesting that sanctions for non-compliance could be "withdrawal of Government grants, tax incentives" as well as withdrawing "the right to conduct research or manufacturing until GMAC is satisfied there is compliance".

Recommendation 37

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

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20 Quinn, N, Environment Protection Division, Department of the Arts, Sport, the Environment, Tourism and Territories: Transcript p 1116

21 Biotech Australia Pty Ltd: Submission 37 p 5

22 VLRC: Report No 26 p vi, Recommendation 10

A.3.(ii) Registration of researchers, premises or projects

8.35 The sanction of withdrawing the right to conduct research or manufacturing would imply a process of registration of individuals, companies, laboratories or manufacturing premises, or of projects.

8.36 Dr John Davies and Prof Bruce Holloway from Monash University advocated, on the grounds of efficiency, that any regulation of GMO work should involve licensing experimenters and facilities to carry out certain kinds of experiments, rather than requiring approval for individual projects. The penalty for failing to follow the appropriate guidelines would be to lose the licence.[23]

8.37 Professor Barry Rolfe also advocated the registration with GMAC of people and laboratories working in molecular biology. One result of such registration would be increased control over the purchase of equipment and chemicals used in molecular biology.[24]

8.38 The VLRC did not consider that genetic manipulation work was "so intrinsically dangerous that it should only be conducted in specially certified or licensed laboratories or by specially certified or licensed researchers".[25] However, the Commission stated that, "in order to appease community concern", legislation should be introduced in relation to "potentially hazardous scientific work" in general.[26]

8.39 The VLRC recommended legislation to require prior notification of potentially hazardous scientific work in Victoria to the State Department of Labour at least 30 days before commencement.[27] This could include genetic manipulation work if GMAC considered that the proposed work warranted it.[28] The Department of Labour would be empowered to "prohibit or to impose conditions on proposed projects".[29]

8.40 The VLRC noted that such a requirement would assist the Department of Labour in enforcing occupational health and safety laws. The Committee agrees that such a requirement would be useful from an occupational health and safety view-point and has recommended, in chapter 6, that State Governments be encouraged to require the notification of all potentially hazardous scientific work to the responsible authorities.

8.41 The ACF recommended not only the notification of all genetic modification research proposals, and their registration with the Commonwealth Environment

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23 Davies, Dr R; Holloway, Prof B: Transcript pp 348, 349
24 Rolfe, Prof B: Transcript pp 209-211
25 VLRC: Report No 26 p 19
26 ibid., pp 16, 17
27 ibid., p v, Recommendation 3
28 ibid., Recommendation 4
29 ibid., Recommendation 5

Protection Authority,[30] but also the notification of each stage in the transition of a project from initial research proposal to commercial production with penalties for non-compliance. Such notifications should be kept in a public register. This would make it easier to trace any unauthorised releases.[31]

8.42 The ACF further recommended that State environment protection authorities should have responsibility for assessing and monitoring the establishment and operation of all laboratories and factories using GMOs. The GMAC Scientific sub-committee, the National Association of Testing Authorities, the Standards Association and other like bodies could be involved in an advisory capacity.[32]

Recommendation 38

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

Recommendation 39

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

8.45 The Committee considers that if the above recommendations and recommendation 25 (para 5.277) (to impose legal responsibilities on IBCs for supervision and control of projects) are implemented, registration of researchers and/or premises should not be necessary.

30 Phelps, R, Australian Conservation Foundation: Submission 140 p 27
31 ibid., p 30
32 ibid., p 28

A.3.(iii) Guidelines - by legislation or regulations

8.46 There was broad support for the idea that, if compliance with the guidelines was to be made compulsory, the guidelines should be set out in regulations under the Act rather than incorporated in it. This would enable them to be more easily amended to keep pace with developments in technology.

> "... if there were new technological developments which were demonstrably safe or which significantly reduced the level of risk yet fell outside ... the legislative framework, delays [would be] incurred due to the need to make changes to the law ...
>
> ... legally obligating all institutions and individuals to operate through GMAC and according to the guidelines ... would retain the necessary flexibility [allowing] decisions on a case-by-case basis without the need to resort to changes in the law."[33]

8.47 A contrary view - that the code of practice or guidelines should "have some basis in the legislation itself" - was expressed by Mr Kevin Andrews, Acting Director of the Bioethics Centre of St Vincent's Hospital.

> "Parliament ultimately is the final barometer, if one can put it that way, of public concerns in this area and public acceptability of new technology and therefore the code of practice ought to have some basis in the legislation itself. ... the Parliament then can place parameters upon the way in which it says this technology can go forward. If one is looking at it from, say, an environmental concern, then that environmental concern ought to fundamentally, in my opinion, be the principle that there is no degradation of the environment. That principle could be embodied in the legislation, just as, in an analogous situation, the principle of the best interests of the child is contained in the Family Law Act".[34]

8.48 **The Committee considers that, while a general statement of principles could be included in legislation, the detailed guidelines themselves should be contained in regulations issued under the Act. This would allow the flexibility needed to update the guidelines in accordance with changes in technology and experience.**

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33 Biotech Australia Pty Ltd: Submission 37 pp 4, 5

34 Andrews, K, Acting Director, Bioethics Centre, St Vincent's Hospital, Fitzroy: Transcript pp 487, 488

B. Options for National Supervisory Body

8.49 There are three broad alternatives for a national body to regulate the release of GMOs: an expanded GMAC; or some other existing body, perhaps in an enhanced form; or a new federal body.

B.1 A new enlarged GMAC

8.50 The VLRC report recommended a continuing advisory and monitoring role for GMAC.[35]

8.51 In the case of planned releases, Prof Jim Pittard felt that if GMAC is not to be the body making the final decision on releases then: "there needs to be a detailed identification of the appropriate government bodies for all the types of release and they need to be contacted and made aware of the necessity of GMAC's involvement (as the chief advisory body)."[36]

8.52 The Australian Academy of Science suggested that GMAC be responsible for overseeing approvals for release because "it will usually be familiar with the previous history of the project, having been concerned with the work during the research phase. It has also been concerned with formulating the existing guidelines for release proposals."[37]

8.53 Biotech International argued: "Extension and modification of the existing system is likely to be more cost effective and practical than the formation of an entirely new structure."[38]

8.54 Metrotec recommended a coordinating role for GMAC.

> "GMAC should act as a clearing house, streamlining the collection and dissemination of information between research groups and Government regulatory bodies. It should be GMAC's responsibility to ensure that research groups target all the required regulatory groups in the correct format and to co-ordinate the response. This clearing house system should operate nationally".[39]

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35 VLRC: Report No 26 p v, Recommendation 7

36 Pittard, Prof A J, Professor of Microbiology, University of Melbourne; Chairman of Scientific Sub-Committee GMAC: Submission 2 p 13

37 Australian Academy of Science: Submission 118 p 6

38 Biotech International Ltd: Submission 90 p 6

39 Metrotec Pty Ltd: Submission 61 p 3

8.55 Should this option be pursued, the membership of GMAC might need broadening.

> "As the membership of GMAC ... is limited and the opportunity for public debate and input into the regulatory making process is inadequate, the body remains technically oriented. Nor are the deliberations of the Committee generally open to members of the Australian public. In contrast, the operation of the American Recombinant DNA Advisory Committee is much more inviting of public participation."[40]

B.2 Existing bodies other than GMAC which could regulate releases

8.56 It was suggested that existing or proposed environmental bodies, such as the Environmental Protection Agency (EPA), could fulfil the function of regulating releases.

> "... the Australian and New Zealand Environment Council (ANZEC) could play a more formal role ... [a] working party within ANZEC would be appropriate (or within an appropriate federal agency or EPA, in liaison with ANZEC)."[41]

> "The proposed federal EPA would be the ideal body to coordinate and respond to biotechnology proposals. This would include mechanisms which would allow public participation, conflict resolution and principles for evaluation of GMOs in an ecologically sustainable framework."[42]

8.57 The ACF suggested that the proposed Commonwealth Environment Protection Authority should have responsibility for national aspects including:

> ". receiving notification and registering all GE research proposals
> . informing the public and nationally advertising all proposed GMO releases
> . commissioning and receiving the GMAC's genetic assessment
> . commissioning and co-ordinating all non-genetic (environmental and social) assessments
> . establishing forums in which public interest representatives can contribute to decision-making
> . maintaining a public register and information base of all work, especially deliberate releases."[43]

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40 Andrews, K, Director, St Vincent's Bioethics Centre: Submission 112 p 8
41 Burch, Dr D et al.: Submission 106 p 57
42 Queensland Department of Environment and Heritage: Submission 73 p 4
43 Phelps, R, Australian Conservation Foundation: Submission 140 p 27

8.58 State Departments of the Environment would have responsibility for implementing Commonwealth decisions concerning GMOs - in particular post-release monitoring with assistance from GMAC's Live Release sub-committee.[44]

8.59 A different review agency was raised during evidence by Prof Nancy Millis.

> "I think we should consider whether we need anything further than the existing quarantine regulations. ... I believe it is appropriate for quarantine for all novel organisms, be they genetically modified or otherwise. At present there is a mechanism for handling them ... It seems to me that anything coming in as a totally novel organism is probably best handled by the group that is accustomed to that activity."[45]

8.60 A major advantage of using the Australian Quarantine and Inspection Service to regulate the release of all novel organisms would be that an Australia-wide organisation already exists. AQIS has evaluation and monitoring expertise and experience and its State offices could act as a conduit through which release proposals could be submitted to a central body.

8.61 Legislation would need to be enacted to alter AQIS's charter and to broaden its membership so that the broad issues surrounding release of novel organisms could be canvassed.

B.3 A new body to control releases

8.62 A number of submissions proposed that a two-tiered system be established. There would be a scientific advisory body like the present GMAC and another body with broader membership which would have the responsibility for decisions about releases of GMOs to the environment.[46] DITAC envisaged that there would be community representatives on the regulatory body as well as people with environmental expertise.[47]

8.63 A model for the regulation of releases was proposed by CSIRO.

> "(1) A Federal Registration Board to be established as the focal point for receipt of all release proposals. Notification of proposed releases to the Board to be made mandatory.
> (2) Regulations governing GMO release to be prepared and updated by this Board.

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44 ibid., p 28

45 Millis, Prof N, Chairman, GMAC: Transcript pp 1213, 1214

46 Sleigh, Dr M, Division of Biomolecular Engineering, CSIRO: Transcript pp 1065, 1066

47 Clarke, B, Aerospace and Biological Industries Branch, Department of Industry, Technology and Commerce: Transcript pp 1095, 1096

(3) Provisions for public notification of proposed releases but for extended public involvement (e.g. public hearings) only when this is warranted by public response.
(4) A time frame for decision-making.
(5) Assessment of proposals to be carried out by expert committees advising the Board (e.g. GMAC). GMAC could become, in effect, a subcommittee of the Board.
(6) The Board to act as a point of despatch of proposals to other State and Federal agencies either to provide expert advice or assessment or to give final approval for release where this falls under existing legislation.
...
(7) All final permits for releases, endorsed by other bodies as required, to be issued by the Board."[48]

8.64 Government Departments, both State and Federal, indicated their support for this type of arrangement which would use, where possible, existing clearance procedures:

> "Wherever possible, [the Board] refers the GMO to the lead agency of an existing scheme for assessment. Control is achieved through existing [State or Territory] mechanisms ... [if this is not possible, the Board] has statutory requirements to ensure a suitable assessment is done."[49]

8.65 Thus existing clearance procedures would be used; an advantage because they would be familiar to industry.

8.66 If CSIRO's Release Board model were to be adopted, there would be a need to amend existing legislation to ensure referral to the Board, and accommodate the particular characteristics of genetically modified organisms or, alternatively, enable the Board to cover the deficiencies of existing procedures.

8.67 GMAC recommended that:

. there should be a Commonwealth Committee with legal responsibility for making determinations concerning the release of novel living organisms and its permission should be a legal requirement before releases can occur
. permission by the Release Committee would not remove the responsibility to obtain other permits
. the Release Committee would have members appointed for their knowledge of environmental and ecological matters, including one representative from GMAC
. GMAC would advise the Release Committee, which would also be free to seek advice from other relevant agencies

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48 Stocker, Dr J, Chief Executive, CSIRO: Submission 109 p 29

49 Department of the Arts, Sport, the Environment, Tourism and Territories: Submission 138 p 25

. the Release Committee should have responsibility for producing minimal standards and procedures associated with releases where such do not already exist; but State authorities would be free to make further conditions.[50]

8.68 Prof Millis stated that under the system recommended above, a proponent of a release would have to apply to the relevant IBC which would have to come to GMAC for advice. GMAC then would have to refer the proposal to the Release Committee, which then would have to consult the relevant State agencies. The Release Committee, together with the State agencies, would make a decision. The Release Committee would inform the proponent of the outcome. This would provide a one-stop-shop for the proponent.[51]

Recommendation 40

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

Recommendation 41

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

50 GMAC: Submission 88.1

51 Millis, Prof N, Chairman, GMAC: Transcript p 80

Recommendation 42

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

. it should be mandatory that those seeking approval for the release of GMOs in field trials should forward their applications to the GMO Release Authority

. the Release Authority should consider such applications with advice from GMAC and relevant State and Commonwealth authorities (such as Health or Environment Departments)

. the Release Authority should have the authority to publicly advertise proposed field trial releases if it considers this desirable and to allow a reasonable time (to be specified in regulations) for expressions of opinion before proceeding to a decision concerning approval

. the Minister should be advised of all proposed releases and have the discretion to order public hearings in relation to a proposed release

. the Release Authority should forward a copy of all applications to any appropriate existing State and Commonwealth bodies for parallel consideration

. these other State and Commonwealth bodies should indicate to the Release Authority whether the proposed release has their approval

. the approval of any other relevant State and Commonwealth bodies and of the Release Authority should be required before the GMO is released

. the Release Authority should be responsible for informing the applicant whether the release is authorised.

Recommendation 43

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

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

Recommendation 44

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

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

Recommendation 45

8.74 The Committee recommends that legislation require:
. the notification of any unauthorised release of genetically modified organisms from contained facilities as soon as possible to the Institutional Biosafety Committee, the national GMO Release Authority and the responsible State and Commonwealth environment and health authorities
. the GMO Release Authority to co-ordinate any remedial action by the relevant authorities
. the keeping by the GMO Release Authority of a register of any unauthorised releases of GMOs, indicating the nature of the organism, the quantities released, the location, and the institution involved.

B.4 Membership of the Release Authority

8.75 Calls were made for tight regulation, with a committee to monitor experiments composed of community representatives such as environmentalists and animal health and welfare people as well as scientists. The ACF wanted a "decision-making body representing a broad range of interest groups and the general public".[52] Similar comments were made by Dr David Burch et al.[53]

8.76 The Department of Primary Industries and Energy (DPIE) suggested that the "receiving and approving authority" for environmental release proposals should be

> "... comprised of persons of standing in the community and preferably with no more than two or three members ... After taking into account all relevant factors, (Scientific, economic and social expert advice, and public input) the ultimate approvals would need to be [their] responsibility".[54]

8.77 DPIE did not have a firm position on whether the public should be represented on the regulatory body but one of the Departmental witnesses stated:

> "I think our view so far ... has largely been that the members of a group like that would need to be certainly expert based. We would not see all the expertise needing to be scientific - clearly there are economic and social concerns. But having a representative of particular public interest groups I think is probably something that we do not particularly like. We see it more as needing people who have sufficient stature in the

52 Phelps, R, Australian Conservation Foundation: Submission 140 p 17
53 Dr Burch, Dr D et al.: Submission 106 p 2
54 Department of Primary Industries and Energy: Submission 143 p 21

> field to gain public confidence that they are in fact impartial and that they are not driven by a particular group".[55]

8.78 A small authority was also suggested by the Department of the Arts, Sport, the Environment, Tourism and Territories. They proposed:

> "... between three and five members, which would be appointed on the basis of the expertise the members could bring to bear in making the decisions the authority was required to take. ... such a body would not, in any sense, be representative of interest groups. ... [the authority] can have paraded before them whatever kind of information ... that the authority would be dealing with".[56]

8.79 The CSIRO submission suggested that "membership should include scientific representation as well as other experts and public representatives"[57], a view supported by the Australian Biotechnology Association[58].

8.80 Dr Merilyn Sleigh from the CSIRO commented in oral evidence:

> "... whether particular interest or lobby groups should be represented on an overall decision making body. My instinct on this is to say, 'No, they should not', because, after all, what you are really after there is people who are there to make decisions rather than, in a sense, to represent particular constituencies or the policies of those constituencies.
> On the other hand, the British ACRE committee has, in fact, representatives of such interest groups in its membership. Their perception seems to be that this functions very well....
> I think that, on balance, there would be advantages in having different viewpoints represented, as far as possible, on an actual decision making body, while still reinforcing the view that that body needs to be receiving excellent scientific advice, and also containing scientific representation as a fairly strong element within it."[59]"

8.81 The ACRE committee which regulates releases in the UK has a membership which "comprises academics, experts, representatives of trade unions, representatives of employees, and also around the table we have assessors from all the relevant government departments".[60]

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55 Quinn, A, Research and Development Policy, Corporate Policy Division, Department of Primary Industries and Energy: Transcript pp 1140

56 ibid., p 1110

57 Stocker, Dr J, Chief Executive, CSIRO: Submission 109 p 30

58 Australian Biotechnology Association: Submission 142 p v, Recommendation 5

59 Sleigh, Dr M, Division of Biomolecular Engineering, CSIRO: Transcript pp 1066-1068

60 Poole, Prof N, Manager, Biotechnology and Regulatory Affairs, ICI Seeds and Pacific Seeds Pty Ltd: Transcript p 407

8.82 Monsanto Australia Ltd considered that

> "... the board should include wide representation so that ethical, social and economic views - all views - can be adequately addressed. ... there is a place for the wider interest of the public to be represented by people adequately qualified to make those representations ... for people with wide interests but specific qualifications."[61]

8.83 Monsanto also argued that the science aspects of a proposal should be separated from the social aspects.

> "The technical aspects of any proposal - the science, efficacy, health, environmental safety - must be assessed by an objective, scientifically independent expert review panel. ... that information should then be taken to the board level, where other considerations can be imposed. But you cannot really make adequate economic and social decisions unless you have that hard base of science and the facts on which to make those decisions. Those two functions must be clearly separated."[62]

8.84 Prof Nancy Millis, Prof David Danks and Prof Jim Pittard of GMAC were concerned that the professional expertise of GMAC and the Release Committee not be too diluted by representatives of community interest groups.[63]

8.85 Biotech Australia went even further:

> "The inclusion of individuals solely because they are very vocal or because they represent an antagonistic view (in the mistaken belief that this will result in a 'balanced committee') could result in a divided, ineffectual committee which, in turn, could lead to unnecessary restriction".[64]

Recommendation 46

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

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

62 ibid., p 445

63 Millis, Prof N; Danks, Prof D; Pittard, Prof A J; GMAC: Transcript pp 99-101

64 Biotech Australia Pty Ltd: Submission 37 p 4

Recommendation 47

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

. a chairperson
. the chairperson of GMAC
. two people chosen for their expertise in genetic manipulation technology
. two people chosen for their expertise in environmental science
. a nominee from each of the following Commonwealth Departments - Industry Technology and Commerce; Primary Industries and Energy; Arts Sport Environment and Territories; and Health Housing and Community Services
. two people chosen for their involvement in commercial development or use of genetically modified organisms
. two people chosen for their interest in environmental or consumer affairs issues.
. one person chosen for knowledge of law and/or philosophy.

Recommendation 48

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

B.5 Regulation of GMOs or all novel organisms?

8.89 Suggestions were made by a number of people in submissions and in oral evidence that all novel organisms should be regulated in the same way - that a distinction between novel organisms produced by genetic manipulation techniques and those produced by other methods is artificial. Similarly, organisms which are 'naturally produced' may be defined as novel organisms if introduced into an environment which has not previously been exposed to them.

8.90 Some of the comments the Committee received in favour of this approach are set out below:

> **Monsanto Australia Ltd:** "... Federal legislation covering 'new biota' should also include exotic species as well as other strains which while not genetically altered are new to [a] particular ecosystem or will be introduced at different population levels than would naturally occur."[65]

65 Monsanto Australia Ltd: Submission 74 p 6

Mrs Loane Skene (VLRC): "It must become mandatory for anybody proposing to release a new organism into the environment to notify somebody in advance and for compulsory environmental assessment, before an organism is released for the first time into the environment."[66]

Dr Chris Green (NSW Dept of Agriculture and Fisheries): "... this is the type of control which is probably needed to bring all organisms to be released into the environment into one umbrella grouping at the end. ... There are environmental organisms that are going to get released - ones for dealing with oil spills and that type of organism. These come under such a miscellaneous collection of legislation that environmental impact statements that might apply will either be duplicated or will not be done."[67]

Dr Merilyn Sleigh (CSIRO): "Another question which we have debated within CSIRO is whether, following the British model, it is appropriate to bring under the umbrella of an authority like the ACRE committee a much broader range of things, perhaps including biological control agents. Scientific logic certainly says that you should, but I have heard other arguments which say that would make the process too unwieldy."[68]

8.91 Bunge Australia Ltd presented a contrary view.

> "There is a danger, we believe, in sweeping in with ... coverage of all novel living organisms. We believe this definition and other such definitions would be far too broad in their compass. Although the intention is clear, we believe that such definitions would legally include the current activities of farmers, fish breeders, other breeders, and horticulturalists who are currently involved, and have been for many hundreds of years, in the selective breeding of animals. ... The issues of traditional selective breeding are becoming more complex ... it is equally true for, say, livestock or improved strains of yeast for the bread baking industry or, indeed, alternative production processes for the pulp and paper manufacturing business."[69]

8.92 As Dr Sleigh's comments above indicate, the committee established in the United Kingdom to examine proposals for releases of GMOs is concerned with

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66 Skene, L, Victorian Law Reform Commission: Transcript p 1201

67 Green, Dr C, Director of Plant Pathology, NSW Department of Agriculture and Fisheries: Transcript p 1212

68 Sleigh, Dr M, Division of Molecular Engineering, CSIRO: Transcript p 1205

69 Davidge, M, Scientific and Technical Services Division, Bunge (Australia) Pty Ltd: Transcript p 462

releases of all non-indigenous organisms in the UK.[70] Similarly, amendments being drafted to the *Wildlife Conservation Act 1950* in Western Australia would result in all novel organisms being treated the same. A licence would be required for the release of any

> "... animal or class or description of animal; plant or description of plant; other lifeform or genetic material capable of being reproduced or replication in the wild; which could ... become or threaten to become injurious to naturally occurring native organisms."[71]

8.93 **The Committee has not examined the production of organisms by methods other than genetic manipulation or whether there may be special dangers involved in their release. The Quarantine Service already provides a mechanism for examining the risks of importing exotic organisms. The Government should consider whether the production within Australia of organisms by means other than genetic manipulation and the release of such organisms requires special clearance procedures.**

M J Lee, MP
Chairman
Report adopted by Committee 27 February 1992

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70 Poole, Prof N, Manager, Biotechnology and Regulatory Affairs, ICI Seeds and Pacific Seeds Pty Ltd: Transcript pp 406, 407

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

APPENDIX I

CONDUCT OF THE INQUIRY

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

The Committee advertised the inquiry nationally in major metropolitan newspapers. In addition, Commonwealth, State and Territory government departments and several hundred individuals with an interest in the subject were written to and invited to make a submission. The Australian Biotechnology Association and the Australian Conservation Foundation provided the secretariat with address lists which greatly assisted this task. Appendix II lists those who made submissions to the inquiry. One hundred and sixty-seven submissions were received (not including supplementary submissions).

The files relating to genetic manipulation of the Australian Conservation Foundation in Melbourne and of the Law Reform Commission of Victoria were examined with the full co-operation of those bodies. The CSIRO conducted the Committee on an inspection of research facilities in the ACT where genetic manipulation work is carried out.

Ten public hearings were held in Adelaide, Brisbane, Canberra, Melbourne and Sydney. One hundred and twenty-two witnesses gave evidence. These are listed in Appendix III. Over twelve hundred pages of evidence were received at these public hearings. A transcript of all the evidence is available for inspection at the Committee Office of the House of Representatives and at the National Library of Australia.

APPENDIX II

LIST OF SUBMISSIONS

Submission No	Date	Person or Organisations
1	27/7/90	Mr Bryan Wells
2	30/7/90	Prof A J (Jim) Pittard
3	28/7/90	Ms Katherine Thirkell
3.1	21/11/90	Supplementary to Sub No 3
4	30/7/90	Dr Richard Cotton
5	6/8/90	Ms Christine Jones
6	1/8/90	Mr Geoffrey Lawrence
7	9/8/90	Prof Michael Hynes
8	16/8/90	Prof Peter Outteridge
9	18/8/90	Ms Geraldene Killmier
10	27/8/90	Dr Judith Blackshaw
11	26/8/90	Dr David Murray
12	22/8/90	Mr Ron Smith
13	24/8/90	Dr Alan Bailey and Dr Peter Mather
14	27/8/90	Dr Ian Johnsson
15	27/8/90	Dr Alfred Cheung
16	25/8/90	Ms Dorothy Davies
17	27/8/90	The Genetics Dept., The Queen Elizabeth Hospital Woodville SA (Dr Graham Webb)
18	26/8/90	P Atkins

19	27/8/90	Dr Alan Blackshaw
20	30/8/90	Prof Peter Singer
21	30/8/90	School of Medicine Flinders University SA (Mr Ross Kalucy)
22	3/9/90	Mr Steven Munro
22.1	18/2/91	Supplementary to Sub No 22
23	29/8/90	Calgene Pacific (Mr Michael Dalling)
24	31/8/90	Mr Vernon Molesworth
25	30/8/90	Dept Community Services & Health (Dr Robert Hall)
26	3/9/90	Waite Agricultural Research Institute
27	30/8/90	Dr David Straton
28	30/8/90	Ms Clare Gravenall
29	31/8/90	Mr David John Ellery
30	2/9/90	Ute Mueller
31	3/9/90	Ms Robin McCarthy
32	3/9/90	School of Biological Sciences Flinders University of SA (Dr D Catcheside)
33	3/9/90	Mr William Killmier
34	3/9/90	United Scientists for Environmental Responsibility & Protection USERP (SA) (Dr Ross Nable)
35	4/9/90	Women's Environmental Education Centre (Ms B Whiteman)
36	5/9/90	ANU Institutional Biosafety Committee (Mr Alick Dodd)

37	6/9/90	Biotech Australia P/L (Dr David Harrison)
38	6/9/90	Mr Bill Speer
39	5/9/90	University of QLD Biosafety Committee (IBC) (Mr Jim Holt)
39.1	10/9/90	Biosafety Committee Dept of Microbiology University of Queensland
40	1/8/90	Prof Ian Frazer
41	4/9/90	Mr Dominic Wilkinson
41.1	7/2/91	Supplementary to Sub No 41
42	5/9/90	Mr Duncan Hartshorne
43	5/9/90	CSIRO Division of Animal Production (Dr Oliver Mayo)
44	6/9/90	The Institute of Patent Attorneys of Australia (Mr John Slattery)
45	6/9/90	Prof Bruce Holloway
46	7/9/90	Mr David Gasteen
47	7/9/90	Mr Lee Nightingale
48	7/9/90	Ms Mandy Kirsopp
49	7/9/90	University of Adelaide (Prof Kevin Marjoribanks)
50	5/9/90	Dr Murali Nayudu
51	3/9/90	Ms Anne Benson
52	5/9/90	Mr W E (Edward) Fisher
53	6/9/90	Garvan Institute of Medical Research (Assoc Prof Donald Chisholm, Ms Julie Ferguson, Prof John Shine, Mr Colin McCaskill)

54	6/9/90	Human Genetics Society of Australia (Prof David Danks)
55	6/9/90	Monash University (Prof S Faine)
56	7/9/90	Ms Alex Hodges and Mr Ivan Laundy
57	10/9/90	Pig Research & Development Corporation
58	7/9/90	Mr Mark Callinan
59	4/9/90	Dept of Microbiolgy, Monash University (Acting Prof R Bayly)
60	7/9/90	Australian Registered Cattle Breeders' Assoc
60.1	1/11/90	Supplementary to Sub No 60
61	7/9/90	Metrotec (Dr John Smeaton, Dr Barry Lloyd, Dr Robert Seamark, Dr Julian Wells)
62	20/9/90	Animal Research Review Panel (NSW Govt) (Dr Margaret Rose)
63	5/9/90	Mr Paul Recher
64	6/9/90	Dr Geoffrey Lacey
65	7/9/90	Conservation Council of South Australia (Mr Marcus Beresford)
66	11/9/90	Development Education Network (Mr Lee O'Gorman)
67	14/9/90	Ms Paris Kostakos, Ms Karen Lacheta, Mr Craig Nobbs, Ms Gabrielle Taloni, Ms Angela Telfer
68	14/9/90	Arthur Webster P/L
69	8/9/90	Mr B Loudon
70	14/9/90	Alcoa of Aust Ltd CONFIDENTIAL IN PART

71	12/9/90	University of WA Prof R Parfitt)
72	14/9/90	Burns Philp & Co Ltd (Dr John Friend)
73	13/9/90	Dept of Environment and Heritage, QLD
74	17/9/90	Monsanto Australia Ltd
75	4/9/90	Australian Federation of Consumer Organizations Inc
75.1	5/10/90	Supplementary to Sub No 75
75.2	25/9/91	Supplementary to Sub No 75
76	11/9/90	The Royal College of Pathologists of Australasia
77	17/9/90	Mr S A (Arnold) Ward
78	18/9/90	Mrs Doris Metcher
79	17/9/90	Campbell Environmental Ltd WA
80	17/9/90	Chicken Meat Research & Developmental Council
81	18/9/90	Australian Agricultural & Veterinary Chemicals Council
82	18/9/90	Carlton and United Breweries Limited
83	18/9/90	Mahinda Seneviratne
84	19/9/90	Australian Council for Overseas Aid
85	20/9/90	Mrs Annie Scott
86	26/9/90	Bunge (Australia) P/L
86.1	22/11/90	Supplementary to Sub No 86
87	24/9/90	Australian National Parks and Wildlife Service
87.1	16/11/90	Supplementary to Sub No 87

88	25/9/90	Genetic Manipulation Advisory Committee (GMAC)
88.1		Supplementary to Sub No 88
88.2		Supplementary to Sub No 88
88.3	6/8/91	Supplementary to Sub No 88
89	20/9/90	APM Forests Proprietary Limited
90	3/10/90	Biotech International Limited
91	20/9/90	Dept of The Premier and Cabinet (SA)
92	5/10/90	Ms Laurelle Williams
93	3/10/90	Mr Ed Baxter
94	10/10/90	Mr G McConnell
95	20/9/90	People for Nuclear Disarmament (NSW) Inc
96	7/10/90	The Religious Society of Friends (Quakers)
97	8/10/90	Church & Society Commission Australian Council of Churches (QLD)
98	10/10/90	Mrs Patricia Naus
99	10/10/90	Mr Brian Engris and Mrs Joan Engris
100	11/10/90	Mr Frank Fisher
101	10/10/90	Cotton Research and Development Corporation
102	15/10/90	National Farmer's Federation
103	17/10/90	Australian and New Zealand Federation of Animal Societies Inc
104	11/10/90	Queensland Department of Primary Industries
105	12/10/90	Mr D Wallace

106	7/10/90	Dr David Burch, Dr Kees Hulsman, Mr Richard Hindmarsh, Prof Arthur Brownlea
106.1	7/3/91	Supplementary to Sub No 106
106.2	17/4/91	Supplementary to Sub No 106
106.3	1/5/91	Supplementary to Sub No 106
107	15/10/90	Ms Gillian Tucker
108	15/10/90	Ms Gisela Gardener
109	16/10/90	CSIRO Canberra
110	16/10/90	Ms Dianne Martin
111	17/10/90	Dr Robyn Sharp
112	18/10/90	St Vincent's Bioethics Centre (Mr Kevin Andrews, MP)
113	17/10/90	Ms Claire Sandford
114	19/10/90	Miss Helena Mills
115		University of NSW Dept of Biotechnology
116	12/10/90	NSW Department of Agriculture and Fisheries
117	24/10/90	Commonwealth Department of Community Services and Health
117.1	13/12/90	Supplementary to Sub No 117
118	24/10/90	Australian Academy of Science
119	24/10/90	Ms Bronwyn Dekker
120	19/10/90	Prof Daniel Simberloff
121	26/10/90	ICI Australia Ltd
122	1/9/90	Prof Barry Rolfe
122.1		Supplementary to Sub No 122

123	25/10/90	Dr Neil Ormerod and Rev Dr Greg Moses
124	21/10/90	Mr Dennis Murray
125	30/10/90	Blue Mountains Community Enterprises Ltd
126	31/10/90	Department of Industry Technology & Commerce
126.1	20/2/91	Supplementary to Sub No 126
126.2	26/3/91	Supplementary to Sub No 126
127	31/10/90	Patent Trade Marks and Design Office
128	26/10/90	Threatened Species Network (NSW)
129	1/11/90	Wholefoods Co-operative Limited
130	29/10/90	Australian Conservation Foundation (NSW Branch)
131	2/11/90	Mrs Lisa Earles
132	30/10/90	Australian Consumers' Association
132.1	24/4/91	Supplementary to Sub No 132
133	2/11/90	The Australian Veterinary Association Ltd
134	24/10/90	Prof Sheldon Krimsky Massachusetts USA
135	1/11/90	Social Responsibilities Commission - Anglican Diocese of Melbourne (Rev A Dargaville
136	1/11/90	Ms Robyn Buschmann
137	9/11/90	Mr Vin Heffernan MP (Victorian Parliament)
138	7/11/90	Department of The Arts, Sport, The Environment, Tourism and Territories
138.1	26/3/91	Supplementary to Sub No 138

138.2	22/5/91	Supplementary to Sub No 138
139	4/10/90	Dr Maarten Ryder
140	14/11/90	Australian Conservation Foundation
141	12/11/90	Dr Angela Lensiak
142	15/11/90	Australian Biotechnology Association
143	19/11/90	Department of Primary Industries & Energy
144	26/11/90	Mr J Thomas
145	13/11/90	Government of Western Australia
146	3/12/90	Ms Patricia Holmes
147	5/12/90	The Australian Federation for the Welfare of Animals (Inc)
148	3/12/90	Mr David Elder
149	9/12/90	W Latona
150	5/12/90	Environmental Release Committee of the Council for Responsible Genetics (Prof Philip Bereano)
151	14/12/90	Ms Anne Cossins
152	14/1/90	Galloway Cattle Society of Australia Incorporated
153	1/2/91	Centre for Molecular Biology and Biotechnology, University of Queensland
154	11/1/91	The Victorian Government
155	15/2/91	The Australian Society for Microbiology
156	4/3/91	Mr John Scott and Mrs Annie Scott
157	28/2/91	Biotechnology Industry Association Australia (Dr Elizabeth Monger)
158	17/5/91	Australian Pharmaceutical Manufacturers Association

159	3/7/91	Mrs S A Cooper
160	8/7/91	Ms Betty McKell
161	8/7/91	Ms Gazelle Wicks
162	10/7/91	A Keogh
163	22/7/91	J Allan
164	6/8/91	B Harris
165	26/8/91	Ms Elizabeth Fitzpatrick
166	2/10/91	Mrs Gloria Stirrat
167	4/12/91	University of Wollongong

APPENDIX III

LIST OF HEARINGS AND WITNESSES

Canberra, 15 November 1990

Australian Academy of Science
Prof F J Fenner, Fellow
Prof P W Gibson, Fellow

Australian Federation of Consumer Organisations
Mr S Holt, Director
Dr F E Peters, Councillor

Australian National University
Mr C D S Buller, Secretary, IBC
Dr M J Howell, Reader in Zoology

Pig Research and Development Corporation
Dr R Campbell, Director
Dr M R Taverner, Executive Director

Canberra, 16 November 1990

Australian National Parks and Wildlife Service
Mr M A Hill, Deputy Director
Mr R J Moore, Senior Wildlife Conservation Officer
Dr B J Reville, Manager, Endangered Species Unit
Dr B J Richardson, Survey Director
Dr D W Walton, Scientific Audit

Department of Community Services and Health
Dr R M Brazenor, Director Toxicology Technical Support Section
Dr R G Hall, Director, Communicable Diseases Section
Mr G M James, Assistant Secretary, Environmental Health Branch
Dr G J Maynard, Director, Food Policy Section
Dr A Proudfoot, Principal Medical Adviser, Therapeutic Goods Administration
Mr J Withell, Director, Therapeutic Goods Administration Laboratories

Department of Primary Industries and Energy
Mr G N Hooper, Chemicals Coordinator, Australian Agricultural and Veterinary Chemicals Council
Mr B Hill, Chairman, Australian Agricultural and Veterinary Chemicals Council

Genetic Manipulation Advisory Committee
Prof D M Danks, Deputy Chairman
Prof N F Millis, Chairman
Dr I M Parsonson, Member
Prof A J Pittard, Member

National Farmers' Federation
Mr G P Goucher, Director of Policy
Mr J W MacKenzie, Chairman, Research Committee

National Health & Medical Research Council
Dr W P Anderson, Chairman, Animal Experimentation Ethics Committee

Private Citizen
Prof B Rolfe
Ms P Kostakas
Ms K J Lacheta
Dr M Nayudu
Mr C K Nobbs
Ms G Talloni
Ms A Telfer

Melbourne, 21 November 1990

Australian and New Zealand Federation of Animal Societies Inc.
Ms G K Oogjes, Director
Ms R A Sullivan, Executive Member

Law Reform Commission of Victoria
Mrs L Skene, Project Manager
Mr R Wright, Executive Director

Monash University
Dr J K Davies, Biosafety Officer, Department of Microbiology
Prof P Nagley, Department of Biochemistry

Private Citizens
Dr R G Cotton
Mr F G Fisher
Prof B W Holloway
Dr G C Lacey
Mr D G McConnell
Prof P A Singer
Mrs K A Thirkell

Melbourne, 22 November, 1990

Australian Conservation Foundation
Mr R E Phelps, Genetic Engineering Campaign Officer

Bunge (Australia) Pty Ltd
Mr M R Davidge, Marketing Manager, Scientific and Technical Services Division

Calgene Pacific Pty Ltd
Dr E Cornish, Principal Research Scientist

Human Genetics Society of Australasia
Prof D M Danks, Chairman, Gene Therapy Expert Committee

ICI Australia Ltd
Dr R H Brown, Manager, Research and Technology, Crop Care
Mr R A Davies, Research Business Manager, Research Group

ICI Seeds and Pacific Seeds Pty Ltd
Prof N J Poole, Manager, Biotechnology and Regulatory Affairs

Monsanto Australia Ltd
Mrs M J Sheers, Regulatory and Environmental Affairs Manager

St Vincent's Hospital
Mr K J Andrews, Acting Director, St Vincent's Bioethics Centre

Private Citizens
Ms G E Gardener
Mr M D Niski, Representing State Member for Ivanhoe

Adelaide, 23 November, 1990

Bresatec/Metrotec
Dr B Lloyd, Managing Director, Metrotec Ltd
Dr J R Smeaton, Managing Director, Bresatec Ltd
Dr J R Wells, Consultant

Conservation Council of South Australia
Mr M R Beresford, Executive Officer

Flinders University
Dr D E Catcheside, Senior Lecturer, School of Biological Sciences

South Australian Department of Industry, Trade and Technology
Mrs E Jacka, Manager, Biotechnology Projects, Office for Special Projects

United Scientists for Environmental Responsibility and Protection, South Australia
Dr P A Davies
Dr M A Keller
Dr R O Nable
Dr P M Rogowsky

University of Adelaide
Prof J Bowie, Pro-Vice-Chancellor and Chairman of the Biohazards Committee
Mr R J Fowler, Senior Lecturer in the Department of Law
Prof A Kerr, Department of Plant Pathology, Waite Agricultural Research Institute
Dr B K May, Associate Professor of Biochemistry

Private Citizen
Dr G C Webb

Sydney, 6 February 1991

Australian Biotechnology Association
Prof P P Gray, Vice-President
Dr S D Meek

Australian Consumers Association
Dr S Chapman, Consultant
Ms J M Isles, Policy Officer

Australian Registered Cattle Breeders' Association
Dr R W Gee, President

NSW Department of Agriculture and Fisheries
Dr C Green, Director of Plant Pathology, Biological and Chemical Research Institute
Mr R Toffolon, Registrar of Pesticides

Sydney 7 February, 1991

Animal Research Review Panel
Dr M A Rose, Chairman
Dr R M Taylor, Executive Officer

Arthur Webster Pty Ltd
Dr P Lehrbach, Manager, Genetic Research

Australian Conservation Foundation
Ms K Hennessy, Sydney Branch Committee Member
Ms A F Sutton, Councillor, Sydeny Branch Committee Member

Australian Meat and Livestock Research and Development Corporation
Dr J Hackett, Consultant
Dr I D Johnsson, Program Manager

Australian Veterinary Association Ltd
Dr J R Cornwall, National Veterinary Director
Dr P E Greenwood, Secretary, Standing Committee on National Affairs

Biotech Australia Pty Ltd
Dr D E Harrison, Managing Director
Dr N S Willetts, Director, Research and Development

Burns Philp & Co Ltd
Dr R J Evans, Strain Development Manager, Food and Fermentation Division
Dr J P Friend, General Manager, Technology and Research, Food and Fermentation Division
Mr I Jenson, Divisional Microbiologist, Food and Fermentation Division

Private Citizen
Dr D R Murray

Brisbane, 8 February 1991

Australian Federation for the Welfare of Animals
Dr A W Blackshaw, Council Member,

Queensland Department of Environment and Heritage
Dr K A Lyonns, Environmental Officer

Queensland Department of Primary Industries
Mr R J Dalgliesh, Deputy Director, Pathology Branch, Animal Research Institute
Dr R G Dietzgen, Plant Pathologist
Mr R E Nieper, Director, Division of Animal Industry

University of Queensland
Prof P Outteridge, Head, Department of Farm Animal Medicine Production
Dr J M Pemberton, Member, Institutional Biosafety Committee

Private Citizens
Dr J K Blackshaw
Prof A Brownlea
Dr K Hulsman
Dr D Straton

Canberra, 22 February 1991

Commonwealth Scientific and Industrial Research Organisation
Dr E S Delfosse, Principal Research Scientist, Division of Entomology
Dr D J Llewellyn, Senior Research Scientist, Division of Plant Industry
Dr M J Sleigh, Assistant Chief, Division of Biomolecular Engineering
Dr C K Williams, Senior Research Scientist, Division of Wildlife and Ecology

Department of the Arts, Sport, the Environment, Tourism and Territories
Mr R M Ireland, Science 2
Mr N J Quinn, First Assistant Secretary, Environment Protection Division

Department of Industry, Technology and Commerce
Ms B Clarke, Assistant Secretary, Aerospace and Biological Industries Branch
Mr B J Delroy, Director, Biotechnology Section

Department of Primary Industries and Energy
Mr A Catley, Senior Assistant Director, Plant Quarantine and Inspection Branch, Australian Quarantine and Inspection Service
Mr J F Landos, Director, Quarantine Imports and Exports Division, Australian Quarantine and Inspection Service
Dr H L Lloyd, Director, Plant Variety Rights Office
Dr G D McLean, Senior Research Scientist, Bureau of Rural Resources
Dr J M Morrison, Senior Veterinary Officer, Animal Quarantine and Exports Branch, Australian Quarantine and Inspection Services
Dr M A O'Flynn, Director, Animal Welfare Unit, Livestock and Pastoral Division
Mr J Owusu, Principal Veterinary Officer, Agricultural and Veterinary Chemicals Unit
Ms A G Quinn, Director, Research and Development Policy, Corporate Policy Division

Canberra, 19 April 1991

Australian Biotechnology Association
Dr S D Meek, Chair of Subcommittee on Deliberate Release

Australian Conservation Foundation
Mr R E Phelps, Genetic Engineering Campaign Officer

Australian Consumers Association
Ms J M Isles, Policy Officer

Burns Philp & Co. Ltd
Dr J P Friend, General Manager, Technology and Research, Food and Fermentation Division

Commonwealth Scientific and Industrial Research Organisation
Dr M J Sleigh, Assistant Chief, Division of Molecular Engineering

Department of Primary Industries and Energy
Ms A G Quinn, Director, Research and Development Policy

Genetic Manipulation Advisory Committee
Prof N F Millis, Chairman

ICI Australia Ltd
Dr R H Brown, Research and Technology Manager, ICI Crop Care

Law Reform Commission of Victoria
Mrs L Skene, Project Manager, Genetic Manipulation Review

NSW Department of Agriculture and Fisheries
Dr C D Green, Director of Plant Pathology, Biological and Chemical Research Institute

University of Queensland
Associate Prof J M Pemberton, Member with Special Area of Expertise in Molecular Genetics, Institutional Biosafety Committee

Private Citizens
Dr R G Cotton
Prof B W Holloway
Dr K Hulsman

APPENDIX IV

LIST OF EXHIBITS

Exhibit No	Title/Document
1	*Biotechnology & Development*, in *BMJ*, Vol 301 21 July 1990 p 137 (attachment to Submission 4)
2	Lawrence, G: *Structural Change in Australian Agriculture: The Impact of Agri-Genetics*, Paper presented at the Annual Conference of the Sociological Association of Australia and New Zealand ANU Canberra 28 November - 2 December 1988 (attachment to Submission 6)
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21 Baskin, Yvonne: *Getting the Bugs Out*, in *Atlantic Monthly*, June 90 (attachment to Submission 69)

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APPENDIX V

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APPENDIX VI

COMPOSITION OF GMAC SUBCOMMITTEES

Member	Expertise
1. Scientific Subcommittee	
Prof Jim Pittard	Microbiology
Dr Ashley Dunn	Molecular biology/oncogenes
Dr Wayne Gerlach	Biochemistry
Dr Peter Hudson	Microbiology
Mr David Martin	Biocontainment Engineering
Prof Kevin Marshall	Microbiology
Dr John Oakeshott	Molecular biology/entomology
Dr Ian Parsonson	Veterinary
2. Large Scale Subcommittee	
Prof Nancy Millis	Microbiology
Dr Brian Booth	Industrial Chemist
Dr Peter Hudson	Microbiology
Mr David Martin	Biocontainment Engineering
Co-opted Members	
Mr Norman Ackland	Operational fermentation facilities expert
Mr Geoffrey Connellan	Plant house expert
3. Planned Release Subcommittee	
Prof Nancy Millis	Microbiology
Prof Randall Albury	History/Philosophy of Science
Mr Eric Anderson	Environmental consultant
Dr Annabelle Bennett	Law/Biochemistry
Prof Alastair Gilmour	Environmentalist
Prof Rhonda Jones	Zoology
Prof Kevin Marshall	Microbiology
Dr Ian Parsonson	Veterinary
Dr Margaret Roper	Microbiology/ecology
Mr Phillip Toyne	Law/conservation
Mr John Whitelaw	DASETT representative/agricultural science

4. Public Liaison Subcommittee

Prof David Danks	Medicine/genetics
Prof Randall Albury	History/Philosophy of Science
Mr Eric Anderson	Environmental consultant
Dr Annabelle Bennett	Industrial Chemist
Prof Alastair Gilmour	Environmentalist
Prof Nancy Millis	Microbiology

APPENDIX VII

GMO RELEASES IN AUSTRALIA

Date[1]	Institution	Title of Release Project
18.11.88	WA Dept of Agriculture	Field trial of a live *Salmonella* vaccine to prevent death during live sheep export
(19.11.90	Extension of work)	
18.11.88	Australian National University, Canberra	Field trial of a *Rhizobium* strain marked with the transposonal Tn5 lac 2 [a genetic marker] in a controlled field release experiment.
28.2.89	Qld Dept Primary Industries	Inoculation of cattle with thymidine kinase deletion mutant infectious bovine rhinotracheitis vaccine virus.
2.3.89	Vic Dept of Agriculture	Preliminary proposal towards the release of live *Salmonella typhimurium* vaccine strain DD30 for use in sheep. (Not proceeded with.)
13.6.89	Biocare Technology	National clearance and registration of *Agrobacterium radiobacter K1026* for the control of crown gall disease.
2.5.89	CSIRO Biotechnology/ Burns Philp	Commercial evaluation of melibose utilising bakers yeast.
27.6.90	CSIRO Division of Soils	Field release of a live genetically modified strain of *Pseudomonas* for the purpose of testing a microbial tracking system.
20.12.90	Australian National University, Canberra	Controlled field release experiment of a *Rhizobium* strain containing a Sym plasmid marked into the transposon Tn 5.
20.12.90	University of Melbourne	Construction of lactic acid bacteria with improved technological properties.
17.6.91	CSIRO Division of Plant Industry	Synthetic resistance genes to potato leafroll virus.

1 Indicates the date of GMAC advice approving the release

APPENDIX VIII

CASE STUDY 1 - THE FIELD RELEASE OF A MODIFIED STRAIN OF *BACTERIA FOR THE PURPOSE OF TESTING A MICROBIAL TRACKING* SYSTEM.

Naturally occurring *Pseudomonas* bacteria, added as a coating on wheat roots, are able to control the fungus disease 'Take-all'. An imported strain of genetically modified *Pseudomonas* was released in October 1990 by CSIRO Division of Soils, Adelaide, to measure the distribution, survival and activity of the bacteria over a period of 15 to 18 months. This will help to predict the behaviour of the naturally occurring *Pseudomonas* when it is trialled as a biological control agent.

Date	Other bodies consulted	Researchers	Division of Soils IBC	GMAC
9 Jan 1990			IBC established	
Feb 1990	Discussions with S.A. Dept. Industry, Trade & Technology			
7 Mar 1990	Letter from S.A. Dept. of Agriculture indicating containment requirements			
4 Apr 1990	Inspection of containment equipment by S.A. Dept. of Ag. on behalf of AQIS			
Apr 1990		Release proposal submitted to IBC		
18 Apr 1990			IBC assesses proposal	
27 Apr 1990			IBC approved proposal forwarded to GMAC	
9 May 1990		Small scale proposal submitted to IBC		
24 May 1990			IBC approved proposal forwarded to GMAC	

Date	Other bodies consulted	Researchers	Division of Soils IBC	GMAC
24 May 1990	Approval of containment equipment by S.A. Dept. of Ag. on behalf of AQIS			
1-7 June 1990				Scientific Subcommittee considers both proposals
18 June 1990				Planned Release *Subcommittee considers* release proposal
27 June 1990				Request for more information
		Laboratory testing to collect additional data		
4 July 1990		Modified protocol sent to GMAC		
5 July 1990				Researchers advised of GMAC approval of small scale proposal under Category A(ix) & B(iv); AQIS advised of decision
23 July 1990	Cultures cleared for use by S.A. Dept. of Ag. on behalf of AQIS			

Date	Other bodies consulted	Researchers	Division of Soils IBC	GMAC
Aug/Sep 1990	Discussion with Adelaide Univ. Biohazards Committee			
10 Sep 1990		Results of laboratory tests sent to GMAC		
4 Oct 1990				Researchers advised of GMAC approval for proposed release
12 Oct 1990		Release experiment begins		
Sept 1991		Interim report due		

APPENDIX IX

CASE STUDY 2 - THE DEVELOPMENT OF A COMMERCIAL VACCINE AGAINST THE CATTLE TICK.

Cattle ticks are a major problem in the more tropical areas of Australia. Infested cattle can develop an allergic response, contract blood-born diseases and can also die from anaemia and the toxic effects of the parasite. Biotech Australia in collaboration with CSIRO Division of Tropical Animal Science have developed a vaccine using tick antigens which are made by *E. coli* genetically modified to contain the gene for the antigens. The research involved Small Scale work which eventually was scaled up and came within the Large Scale guidelines.

Date	Researchers	Biotech IBC	RDMC and GMAC
8 Aug 1983	Small scale proposals for cloning tick antigens submitted to IBC		
26 Aug 1983		IBC approval under category C1; RDMC notified	
13 Sep 1983			Proposal sent to RDMC members for comment
27 Sep 1983			Comments received - no concerns
20 May 1985	Extension of small scale work proposal submitted to IBC		
27 June 1985		IBC approves proposal; RDMC notified	
11 July 1985			Proposal sent to RDMC members for comment
15 Aug 1985			Biotech advised that C1 containment was appropriate
Early 1986	Discussion with RDMC about containment for large scale fermenters		

Date	Researchers	Biotech IBC	RDMC and GMAC
- Mar 1986	C1-LS facility proposals sent to RDMC		
24 Mar 1986			Proposals sent to Large Scale Sub-committee
23 May 1986			Comments about eight concerns sent to Biotec
19 Aug 1986	Revised containment plan sent to RDMC; facility modified		
10 Sep 1986			Biotech's response sent to Large Scale Sub-committee
29 Oct 1986			Facility approval discussed at RDMC meeting
9 Feb 1987			Further discussions by RDMC
10 July 1987			Biotech advised of concerns
19 Aug 1987	Further discussions with RDMC about containment		
- May 1988	Large scale proposal submitted to IBC		

Date	Researchers	Biotech IBC	RDMC and GMAC
31 May 1988		Discussions with researchers concerning proposal and draft Operating Manual	
- July 1988	Modifications to Draft Operating Manual (completed by September)	Large Scale proposal submitted to GMAC	Received 1 Aug 1988
9 Aug 1988			Proposal sent to GMAC members
21 Sep 1988	Facility inspection by GMAC; examination of Operating Manual		
22 Sep 1988			Inspection team reports basic compliance with C1-LS; requests four improvements
10 Oct 1988			Biotech advised of approval of facility as C1-LS, provided improvements are made; Operating Manual approved
28 Oct 1988			Biotech advised of approval of Large Scale project under C1-LS containment

APPENDIX X

GLOSSARY OF TERMS

adenine
One of the small molecular building blocks, called bases, which make up the coding units of DNA and RNA. Often abbreviated to A. In DNA, pairs with thymine(T).

adenosine diphosphate (ADP)
A molecule consisting of adenine plus a sugar plus two phosphate groups important in the energy economy of a cell. Oxidation of fuel molecules such as glucose permits ADP to take up an extra phosphate and thereby to trap energy.

adenosine triphosphate (ATP)
A molecule consisting of adenine plus a sugar plus three phosphate groups which acts as the universal currency of free energy in biological systems. Conversion of ATP to ADP releases energy which drives the work of the cell.

adjuvant
A substance which increases the efficacy of a vaccine, i.e. stimulates the immune response.

adsorption
The principle underlying chromatography. Materials form a layer on the surface of the adsorber and different materials can be separated according to the strength of their attachment to the surface.

agrochemical
Chemicals which are manufactured for use in agriculture.

AIDS
Autoimmune deficiency syndrome. A syndrome caused by the sexually transmitted human immunodeficiency virus (HIV). Similar viruses infect monkeys and cats.

alkaloid
A group of nitrogen containing-compounds present in some plants which are of great importance because of their poisonous and medicinal properties e.g. morphine, nicotine, quinine, strychnine. The chemicals are probably designed to deter plant eating animals.

allele
Alternative genes which occupy the same position on a chromosome.

allosteric effect
A protein molecule is caused to change shape through union with another molecule. As a result, a new active site is exposed.

amino acid
Building block of proteins. There are twenty naturally occurring amino acids.

amniocentesis
A medical procedure in which amniotic fliud is removed during pregnancy for diagnostic purposes.

anoestrous
Failure of an organism to go through the normal reproductive hormone cycle.

anterior pituitary
A gland situated beneath the floor of the brain which produces 6 hormones including growth hormone.

antibody
A special protein molecule made by the immune system of vertebrate animals, specifically tailored to fit other molecules, for example bacterial toxins, much as a given key fits a particular lock.

antigen
A generic term for a molecule with which an antibody reacts.

asepsis
Sterile conditions.

attenuated virus
A virus which has been damaged and so is unable multiply in its host. Attenuated viruses are used as vaccines.

autoclave
Apparatus for sterilisation by high temperature. Essentially a large pressure cooker.

autoimmune disease
A disease in which the body manufactures antibodies against some component of itself; thus a form of civil warfare in the body, one cell attacking another.

bacteria
Unicellular microorganisms containing a single very large DNA molecule per cell (the chromosome). Many species of bacteria can be grown very easily, very inexpensively, and in very large amounts in solutions consisting of a few salts and a carbon source.

bacteriophage
A virus that grows in bacteria.

bases
See adenine, guanine, cytosine, thymine, uracil.

biocide
A chemical which kills living things.

biodegradable
Broken down by living organisms. It is also a technical term denoting that a certain percentage of the chemical is broken down in a set time, e.g. for detergents to meet the Australian standard, 80% must be broken down in 21 days ('Choice' magazine, Sept. 1990).

biological containment
Use of genetically altered organisms that are unable to perform essential functions such as growth, DNA replication, transfer of DNA to other cells, infection of cells, etc., except under rigidly specified laboratory conditions. An example of biological containment would be the use, as a host organism for recombinant DNA molecules, of an *E. coli* cell that can grow only at a temperature of less than 32° C and only if both streptomycin and diaminopmelic acid, neither of which is normally found in the environment, are provided in its growth medium.

biopesticide
A genetically engineered microbe producing a naturally occurring poison which is used to control a pest.

biota
The living things in a particular region.

blastocyst
A stage in early development where the embryo consists of a small ball of cells.

botulism
A lethal food poisoning caused by the toxin of the bacterium *Clostridium botulinum*. The spores of the bacterium can be present in the soil and can contaminate food which is imperfectly preserved, especially canned food.

carcinogen
A cancer inducing chemical. (q.v. mutagen)

cDNA
Stands for copy DNA - A stretch of DNA synthesized by enzymes as a faithful copy of a particular stretch of RNA, which thus preserves the information content of that RNA.

cell
A fundamental organizational unit of all living matter. The simplest forms of life consist of just one cell, e.g. bacteria, algae or certain parasites. Higher life forms are multicellular organisms, permitting specialization of cellular function, i.e. a division of labour between cells.

cell membrane
The fatty outer skin of a cell which separates it from the next cell, from the fluid bathing cells, or from the environment.

cell membrane receptors
Protein molecules, frequently with some sugars attached, which reside in the cell membrane and possess the capacity to bind specifically some molecule which floats past, e.g. a hormone, a nutrient, or a trigger for cellular activation.

chain
Used in the context of a chain of amino acids which follow a sequence determined by the gene for that chain; many proteins consist of two or more chains linked together chemically. Thus insulin has an *a* and a *b* chain; many antibody molecules have four chains, two smaller ones called light, and two larger ones called heavy. Usually accompanied by the adjectival noun polypeptide (q.v.) meaning many amino acids.

chemical poration
The introduction of genetic material into a cell using chemicals e.g. polyethine glycol (antifreeze).

chloroplast
A membrane-enclosed subcellular organelle found in cells of plants. Chloroplasts are the site where photosynthesis occurs, they contain DNA and they are capable of replication.

chromosome
A very long double-stranded DNA molecule packed together with certain proteins which forms a sausage-like entity readily visualized under the microscope when a cell divides. The number of chromosomes per cell is a characteristic of a species; thus man has forty-six chromosomes per cell.

chymosin
An enzyme used to clot milk in cheese making. The traditional source of the enzyme is rennet obtained from the stomachs of calves. Chymosin produced from a genetically modified yeast has been approved for use in the UK.

clone
Members of a clone are genetically identical.

cloning
Causing asexual division. Frequently used as jargon in genetic engineering to describe the sequence of events by which a gene is caused to replicate a large number of times in some foreign host cell.

codon
A sequence of three bases of DNA or RNA which codes for one amino acid.

coenzyme
A large carbon containing molecule which is needed to enable an enzyme to carry out its function; the coenzyme is changed in the reaction.

cofactor
Small chemicals, usually a charged atom/s, which are required to enable an enzyme to function properly; the cofactor is not used up in the reaction.

colony
A clustered group of cells which arose from a single cell by asexual division, thus a bacterial colony may be a visible spot of 1-2 millimetres diameter consisting of millions of bacteria that are growing in a jellified medium.

commensalism
The association of organisms of different species without either receiving benefits essential or highly significant to survival.

compound
A substance consisting of two or more types of atom which are chemically joined.

conjugation
The transfer of DNA from one bacterial cell to another during bacterial mating. The DNA can be either chromosomal or plasmid DNA.

conjugative plasmid
A plasmid that can spontaneously transfer its DNA to another cell.

con-specific
A member of the same species.

cosmid
A virus-like vector used by genetic engineers that combines some of the advantages of phages and of plasmids as instruments for the cloning of genes.

covalent bonds
The type of relatively strong chemical bonds involving electron sharing that hold together most of the atoms in a molecule. The bases within one strand of a DNA molecule are linked together by covalent bonds. The two strands of a double-stranded DNA molecule are held together by the hydrogen bonds in the specific base pairs. Hydrogen bonds are weaker; they involve magnetic attraction rather than sharing of electrons.

covalently closed DNA
A DNA molecule that is circular and in which both strands are covalently continuous. Plasmids are examples of convalently closed DNA molecules.

Creutzfeldt-Jakob disease (Jakob-Creutzfeldt disease)
A genetic disease of middle life with mental disorientation, dementia, and neurological disturbances such as tremor and other involuntary movements. Death usually ensues within a year of the onset of symptoms.

cytoplasm
That portion of a cell which is not the nucleus; the site where proteins are made and where chemical energy is generated; the 'factory' portion of the cell.

cytosine
One of the four small molecular building blocks, called bases, which make up the coding units of DNA. Often abbreviated to C. In DNA, C pairs with guanine (G).

differentiation
The process whereby cells gain more specialized function. Thus, as a cell destined to turn into a red blood cell gradually builds up more and more haemoglobin, it is said to differentiate.

dioxin
A highly toxic chemical made up of chlorine, hydrogen and carbon atoms which is formed at high temperatures from a reaction between chlorine and hydrocarbons. The chemical was a contaminant of the herbicide 2,4,5-T and has been shown to be a potent mutagen and carcinogen in laboratory animals.

diploid
Having the chromosomes in pairs in the nucleus. Normal cells contain chromosomes in pairs. Thus twenty-three pairs make up the forty-six chromosomes in a normal diploid human cell. Cancer cells are frequently hyper-diploid, i.e. contain more than forty-six chromosomes. (See also haploid.)

disulphide bond
A chemical linkage between two sulphur-containing amino acids either within a single polypeptide chain or between the component chains of a multichain protein. The disulphide bonds stabilize the shape of a protein and help to keep multichain proteins as a single molecule.

DNA
Deoxyribonucleic acid. A double helical molecule consisting of a sugar-phosphate backbone and a sequence of base pairs constituting the coding units of the genetic code. Particular stretches of DNA constitute a gene, one gene being that stretch which encodes one polypeptide chain.

DNA ligases
Enzymes which catalyse the formation of the chemical bonds needed to weld pieces of DNA together. Thus, DNA ligases may join a gene from an animal cell with DNA from a phage virus, creating recombinant DNA.

DNA polymerase
An enzyme that can fill in single-stranded gaps in double-stranded DNA by inserting the proper complementary bases opposite the bases in the intact strand.

DNA replication
The process by which the two complementary strands of a DNA molecule separate and a new complementary strand for each of the separated strands is synthesized by DNA polymerase. This process gives rise to two daughter DNA molecules, each of which has a nucleotide sequence identical to that of the parental molecule.

dominant gene
A gene which will mask the activity of a recessive gene when both are present.

donor organism
The organism from which genetic material was obtained.

drenching
A procedure whereby drugs are administered to livestock by mouth.

E.coli
Escherichia coli. A harmless bacterial species which resides in the human intestine. Frequently used in genetic research, e.g. as a host cell for phages or plasmids carrying recombinant DNA.

ecology
The study of the relationships of animals and plants, especially of their communities with their living and non-living surroundings.

ecosystem
A community of organisms, interacting with one another, plus the environment in which they live and with which they interact, e.g. a wetland, a forest.

electrophoresis
A procedure in which a mixture of molecules is subjected to an electric current ensuring that each molecule moves at a rate influenced by its net electric charge; thus a useful way of analysing and separating complex mixtures of molecules, e.g. proteins.

electroporation
The introduction of genetic material into a cell via the application of a strong electrical field.

embryo transfer
A procedure whereby fertilized eggs are transferred into surrogate mothers for future development. The method is used to maximise the number of offspring produced.

endogenous
Developing or originating within an organism.

endonuclease
An enzyme capable of cutting DNA.

endoplasmic reticulum
A system of channels inside the cytoplasm of a cell for the assembly and export of protein molecules.

endotoxin
A molecule derived from the cell wall of bacteria which is highly toxic to animals.

enzyme
A protein that facilitates specific processes necessary for a cell's functioning. The enzyme is itself unchanged at the end of the process. Enzymes are produced continuously under instruction from the genes; old enzymes are eventually broken down by the cell, thus the genes ultimately control the cell's functioning.

eosinophilia myalgia syndrome
A disease associated with the use of L-tryptophan (q.v.) which reached epidemic proportions in 1989/90. Symptoms included skin rashes, muscle pain and raised levels of eosinophils, a type of white blood cell. Over 1500 cases were reported in the USA with 27 deaths. It has been alleged that the disease resulted from the genetic modification of the bacterium used to produce the L-trptophan. This has been disputed.

epithelium
A layer of cells which lines cavities or covers exposed surfaces. One surface of the layer is free. Cells of the epithelium can be involved in the secretion or absorption of chemicals.

ethology
The study of the behaviour of an animal in its normal environment.

eukaryotes
Organisms having cells containing a defined nucleus, multiple chromosomes, and a defined apparatus for mitosis. Eukaryotes can be either unicellular (yeasts, protozoa) or multicellular (animals and plants). (As opposed to prokaryotes.)

exogenous
Developing or originating from outside an organism.

exon
That portion of the gene which encodes a portion of the amino acid sequence of the protein. One gene may contain several exons. (Also see intron.)

expression vectors
Tools of the genetic engineer which permit a gene to be inserted into a cell in such a manner that, on appropriate signalling, the cell will manufacture large amounts of the protein for which that gene codes.

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

fermenter
Apparatus, principally a large tank, use in various laboratory and industrial processes for the manufacture of products such as alcohols, acids, and cheeses by the action of yeasts, molds and bacteria.

flora
Strictly, the plants peculiar to a region, but used by microbiologists to refer in general to the local organisms, particularly bacteria or viruses.

gel electrophoresis
A procedure in which a mixture of proteins, nucleic acids or other molecules is made to penetrate into a jellified medium under the influence of a strong electric current. Molecules migrate at a rate dependent on their net electric charge and, on this basis, different molecules can be separated from one another.

gene
A segment of chromosome which determines a characteristic of a living organism. The material of genes is deoxyribonucleic acid (DNA), which contains an ordered sequence of nucleotide bases. The sequence in a specific gene may be regarded as a 'code' for a polypeptide, which is 'decoded' when the polypeptide is manufactured, or in some cases the gene may control the start or cessation of polypeptide synthesis. In higher organisms, genes consist of exons and introns (q.v.).

gene activation
A process in which a command is given which ensures that messenger RNA molecules will be made as copies of the particular gene being activated. Thus, gene activation is the first step in protein synthesis.

gene shears
A procedure for destroying messenger RNA (mRNA) produced by specific genes. Gene shears can therefore be used to prevent the action of harmful genes or defend the cell against attack by viruses. The gene shears techniques were discovered at CSIRO in 1987 and a company has been formed to exploit the discovery.

gene targeting
The process in which genes are inserted at precise sites in the host chromosome.

genetic code
The code whereby the structural information for proteins is encoded in the nucleotides of the DNA. Proteins are strings of amino acids, one amino acid out of twenty being chosen for each spot in the string. Nucleic acids are strings of nucleotides, one nucleotide out of a possible four at each spot. A sequence of three nucleotides specifies one amino acid.

genetic engineering
The technology by which genes can be isolated, transferred to other cells, replicated and activated.

genetic fingerprinting
Process by which an individual can be identified by determining their combination of various DNA sequences. The stretches of the chromosomes which are analysed vary greatly between individuals and the process has potential for great accuracy. However, it has been subject to several court cases in the USA.

genetic manipulation
Technology used to alter the genetic material of an organism, so that it produces new substances or performs new functions. The altered characteristic may or may not be inherited by the next generation.

genetic tag
A distinctive stretch of DNA which is inserted into the GMO's genetic information to enable identification.

genome
A noun used to denote the total complement of genes in a cell or individual.

genotype
The genetic constitution of an organism; its total array of genes (as contrasted with the characteristics manifested by an organism - the phenotype).

germ cell gene therapy
Introduces a new gene into the 'germ' or reproductive cells - sperm, eggs or fertilised eggs. The genetic change would then be inherited by the offspring of the treated person (as contrasted with somatic cell gene therapy).

germ-plasm
Cells in an organism containing the genes which will be conveyed to future generations.

glyphosate
The active ingredient of 'Roundup' and 'Zero'. The chemical is absorbed through the leaves and disrupts protein production in plants only. It has low toxicity to animals, does not spread through soil and is broken down by micro-organisms.

Golgi apparatus
A packaging centre for the concentration and temporary storage of protein molecules destined for export by the cell.

guanine
One of the small molecular building blocks, called bases, which make up the coding units of DNA and RNA. Often abbreviated to G. In DNA and RNA, pairs with cytosine(C).

haemoglobin
An iron-containing pigmented protein contained in the red blood cell which is responsible for carrying oxygen around the body and releasing it for the use of the cells.

haemoglobinopathies
A group of diseases resulting from an abnormality in the gene for one of the chains of haemoglobin.

haemophilia
An inheritable disease in which a protein essential for blood clotting is defective. Patients bleed too readily, particularly after injury.

haploid
Having a single set of unpaired chromosomes in each nucleus. Most cells contain pairs of chromosomes, known as a diploid set, but the cells for reproduction, the sperms and ova, contain only half this number, e.g. twenty-three chromosomes in the human, instead of forty-six in other cells. This constitutes a haploid set. The number is restored to forty-six when sperm and egg fuse.

hemizygous
A region of a chromosome of a diploid (q.v.) which is not matched by the other member of the pair of chromosomes; i.e. the genes in this region are unpaired.

HEPA filter
High Efficiency Particulate Air filter, used in containment levels C2 and higher.

heterozygous
The condition in which the two genes for a characteristic are different.

HIV
Human immunodeficiency virus - the virus which causes AIDS. Similar viruses infect monkeys and cats.

homopolymer tailing
A procedure by which a string of nucleotides, all the same, is added to the end of one strand of a DNA molecule. This string, e.g. A-A-A-A-A will readily stick to another DNA molecule tailed with the complementary nucleotides, e.g. T-T-T-T-T.

homozgous
A condition in which both genes for a particular character are the same.

hormone
A class of chemical messenger molecules, travelling in the blood stream, synthesized by cells in an endocrine gland and capable of influencing growth and metabolism within other, perhaps distant, cells which possess receptors for that hormone.

host organism
The organism into which the genetic material was placed.

Huntingdon's disease
A genetic disease caused by a dominant gene (q.v.). The disease, which results in progressive loss of mental capacity and physical coordination in late middle age, can be identified before the onset of symptoms using a gene probe.

hybrid
Organism resulting from parents that are genetically distinct e.g. from different species or well-marked varieties within a species. A hybrid may be fertile or sterile.

hybridoma
A cell which results from the fusing a normal cell with a cancer cell; the hybridoma is able to continuously divide continuously.

hydrocarbon
An organic compound containing only hydrogen and carbon atoms.

hyperplasia
Increase in the amount of tissue by an increase in the number of cells which individually retain their usual size (contrasts with hypertrophy).

hypertrophy
Increase in the size of a tissue or organ via an increase in individual cell size without an increase in cell number (contrasts with hyperplasy).

immunobiological
A biological substance used to create immunity to disease.

immunoglobulins
Molecules found in the plasma and tissues of vertebrates that act as antibodies.

insulin
A hormone made by *B* cells in the pancreas necessary for the proper utilization of glucose within the body.

interferon
A generic term used to describe three groups of molecules. These molecules are synthesized by cells as a result of virus infection and temporarily interfere with the growth of other viruses in that or nearby cells.

intron
Stretch of DNA occurring within a gene which, however, does not code for amino acids of the relevant protein. When a gene is activated, the RNA molecules made as copies of the gene faithfully reflect both introns and exons(q.v.), but before this RNA travels to the cytoplasm, the sequences corresponding to introns are cut out and the (shorter) RNA corresponding only to copies of exons is joined up to constitute the final messenger RNA template.

in utero
Refers to development inside the uterus.

in vitro
Refers to biological processes made to occur outside an organism (usually in glass).

in vivo
Refers to biological processes which occur inside a living organism.

lac operon
A group of genes and control elements responsible for the proper utilization of lactose by bacterial cells. Frequently used by genetic engineers as a switching device for gene activation.

lesion
Any structural change in a bodily part resulting from injury or disease.

ligase
An enzyme that catalyses the covalent bonding of two segments of an interrupted strand of double-stranded DNA.

lipase
An enzyme capable of catalysing the digestion of fats.

lipid
A technical term for describing fatty molecules in biology.

liquid chromatography
A process used to separate components of a liquid mixture. The mixture is allowed to pass slowly through adsorbent (q.v.) material and the various components become adsorbed in different layers.

locus
The position on a chromosome which is occupied by a particular gene.

lymphoma
Tumours arising from cells of the lymphatic system and primarily affecting the lymph nodes, e.g. Hodgkin's disease.

lysosomes
Small pouches within the cytoplasm of cells containing enzymes capable of digesting particles or molecules that enter the cell.

major histocompatibility complex
A group of genes which determine the tissue type of an individual, i.e. compatibility with another for organ transplantation. Also involved in the regulation of immune responses.

mastitis
An infection of the mammary gland, common in cows.

meiosis
A special type of cell division which creates the reproductive cells, the sperm and the ova. During the process, not only is the number of chromosomes halved, e.g. in the human from forty-six to twenty-three, but also the paternal and maternal genes become recombined in new ways. As this happens differently in each meiotic division, no two sperms or no two ova in any individual are exactly the same. (Contrast with mitosis)

messenger RNA (mRNA)
A copy of the DNA which moves from nucleus to cytoplasm and serves as the immediate coding entity which is decoded as proteins are made.

metabolism
The chemical processes that occur within organisms. Metabolism is controlled through the actions of enzymes (q.v.) which are produced under instructions from the genes.

micro-injection
Technique by which genetic material is physically injected into the nucleus of a cell.

micro-nutrients
Substances which are only required in minute amounts.

micro-organism
A living entity too small to be seen by the unaided eye. Also called microbes.

microtubule
Fibre-like structures within the cytoplasm which are involved in the movement of materials and organelles around the cell.

mites
Animals related to spiders and ticks, having eight legs. Mites are often serious pests and many have become resistant to pesticides.

mitochondria
Subcellular particles within the cytoplasm which generate chemical energy for use by the cell.

mitosis
The non-sexual division of cells whereby each daughter cell receives the full diploid number of chromosomes. (Contrast with meiosis.)

mobile genetic element
Portion of the genome which, unlike most DNA, does not occupy a fixed position but can jump from spot to spot on a chromosome or even move between chromosomes.

model
A computer model, which is an attempt to represent a real-life situation to enable predictions to be made without having to undertake costly and time-consuming experiments.

molecule
A grouping of atoms which together make a stable substance.

monoclonal antibody
An antibody made by the progeny of a single cell, thus extremely pure, precise and homogeneous.

monoculture
The common agricultural system in which only one type of plant is grown in an area.

morphology
The form and structure of an organism.

mosaic
Refers to an individual organism which is made up of genetically different cells.

multivalent vaccines
Vaccines which are engineered so as to confer immunity to several diseases. The immunity stimulating chemicals from several disease organisms are incorporated into the virus which is used for the vaccine.

mutagen
An agent which causes mutations, or changes, in the sequence of bases in the genetic material of an organism. May be chemical or physical (eg ionising radiation). (q.v. carcinogen)

mutant
An organism with a mutation in it.

mutation
A change in the genetic material of an organism. Mutations can be base-pair changes, deletions, additions, or inversions of a series of base pairs. Mutations can be deleterious, neutral, or advantageous, depending on their nature and on the environment in which the organism must survive.

nematode
Roundworms. Widespread, numerous, and usually microscopic animals often causing serious diseases of both animals and plants.

niche
An ecological term referring to the way of life of the organism e.g. soil dwelling predator.

Niemann-Pick disease
A rare genetic disorder in which a defect in a gene inside the lysosome causes accumulation of lipid inside the cell. Somewhat related to Tay-Sachs disease (q.v.).

nitrogen fixation
A process occurring in legumes and some other plants in which gaseous nitrogen is converted to nitrogen salts which can then be used by the plant to form proteins etc.. The process is made possible by bacteria which live in nodules formed by the roots of the plant.

nonconjugative plasmid
A plasmid that cannot transfer its DNA to another cell. Many nonconjugative plasmids can, however, be 'mobilized' to transfer their DNA in the presence of a conjugative plasmid in the same cell.

nucleic acids
Two types of polymer molecules,DNA and RNA(q.v.), which act as the repositories of genetic information. They consist of a backbone of alternating sugar and phosphate portions, with a coding unit or base attached to each sugar.

nucleotides
The building blocks from which nucleic acids are made, i.e. a sugar with an attached coding unit (i.e. a base) and a phosphate group.

nucleus
The control centre of the cell, where the DNA resides, separated from the 'factory' portion of the cell, the cytoplasm, by a double membrane.

oncogene
A gene or genes which, when inappropriately activated, can be involved in the production of cancer.

organelles
Small subcellular particulate structures within the cytoplasm of a cell, recognizable in the electron microscope and frequently separable from other organelles or the fluid, structureless part of the cell by biophysical techniques. Many organelles possess specific functions known in detail.

organic compound
A compound based on carbon; other types of atom may be present but at least some carbon atoms must be connected.

organo-metallic compounds
Organic compounds containing metal atoms. Often these compounds are more toxic than the metal because they are more easily absorbed by cells.

osteochondrosis
Refers to bone and cartilage tissue.

palindromic sequences
Stretches of DNA the sequence of bases in which read identically backwards or forwards.

pathogen
In microbiology, a virus or bacterium that causes disease.

PCB
Polychlorinated biphenyl. A fat soluble toxic pollutant which is stable and can accumulate through food chains. It may lower immunity and has been implicated in the recent deaths of marine mammals in the North Sea.

peptide synthesis
The process by which amino acids are joined together to form short or long chains.

pesticide treadmill
The cyclical process in which the application of a pesticide reults in the evolution of resistance, necessitating the use of higher concentrations or a new pesticide. Eventually, if new pesticides cannot be developed fast enough, the pest wins the battle.

pH
The acidity of a solution. The scale runs from 0 to 14 with 7 being neutral. Below 7 is acid while above is alkaline; the acidity increases or decreases 10 times for each unit of pH.

phage
Abbreviation of bacteriophage virus, a virus capable of infecting and destroying bacteria. Frequently used as a vector (q.v) by genetic engineers.

phenotype
The total array of observable characteristics or an organism; its morphological and physiological properties. In a given environment, a given genotype will always determine the same phenotype. Any change in the phenotype in that given environment implies a change in the genotype - a mutation.

phosphorylation
The metabolic process whereby a phosphate group is added to a molecule; a chemical method of increasing its energy prior to subsequent reactions.

photoperiod
Relates to the length of light and dark an organism experiences - behaviour and many processes within organisms are affected by daylength or nightlength.

physical containment
Equipment or practices that put a physical barrier of some sort between the experimenter and part or all of his/her experiment. Examples of physical containment are the use of glove boxes and laminar air flow safety cabinets, the avoidance of mouth-pipetting, the autoclaving of contaminated material, the maintenance of a laboratory under negative air pressure with respect to surrounding laboratories, the wearing of laboratory coats and gloves.

physiology
The processes which occur within an organism.

plant tissue culture
A process which enables plants to be reproduced in test tubes using a variety of plant hormones.

plaque
A clear area, e.g. where a phage population has destroyed bacteria growing on a jellified medium.

plasmid
A circular piece of DNA capable of self-replication within a cell independently of nuclear DNA. Frequently used as a vector (q.v.) in genetic engineering.

pleiotropic
When a gene affects more than one characteristic in a phenotype (q.v.).

polymer
A molecule made up of a number of smaller subunits.

polymerase chain reaction
A technique which enables DNA fragments to be multiplied in the test tube. It allows measurable quantities of DNA to be obtained for subsequent use from amounts which normally would be undetectable.

polypeptide
A stretch of two or more amino acids joined by peptide bonds constituting a protein or one chain (q.v.) of a multichain protein.

polyribosome
A collection of ribosomes (q.v.) attached to a messenger RNA molecule engaged in aiding the synthesis of proteins according to the coded instructions in the RNA.

polysaccharide
A large molecule made up of many sugar units. E.g. starch.

porcine somatotropin (PST)
A hormone which stimulates growth in the pig. It is a protein which can be broken down by the digestive system and has to be given by injection or some sort of slow release implant. It affects growth in cells and influences metabolic pathways, channelling nutrients towards the production of lean tissue rather than fat.

primary transcript
That molecule of RNA first synthesized as a faithful copy of a whole gene when a gene is activated. Portions of the primary transcipt (the introns) are cut out before the messenger RNA moves to the cytoplasm.

probe
A stretch of DNA or RNA labelled with a radioactive isotope, capable of binding to, and thus 'finding' a stretch of DNA with a complementary sequence.

projectile transfer
Technique by which genetic material is fired into the nucleus of a cell on a projectile.

prokaryotes
Simple unicellular organisms such as bacteria and blue-green algae. Prokaryotes have their genetic material in the form of simple filaments of DNA and lack a defined nucleus and nuclear membrane.

promoter sequence
The sequence of genes which act as a switch and turn on another set of genes.

pro-nucleus
The nucleus of either sperm or egg before their fusion during fertilization; pro-nuclei are haploid (q.v.).

protein
Complex, often very large Molecules composed of amino acids, which perform most of the cell's work. Includes enzymes, hormones, antibodies, carriers for other molecules, receptors and structural molecules. Protein molecules are made up of folded chains of polypeptides.

protein kinase
An enzyme which catalyses the addition of a phosphate group to certain amino acids of proteins.

protein synthesis
The process by which the amino acids are joined together to form proteins. Almost synonymous with peptide synthesis, except that the latter usually refers to shorter stretches of amino acids.

protoplasts
Cells of bacteria or plants from which the cell wall has been removed.

pseudorabies (false rabies)
A disease usually of cattle and pigs caused by the DNA containing herpesvirus. The infection which affects the nervous system is not transmissable to humans. Infected animals are not aggressive.

rabies
A disease, usually of foxes, wolves, bats and domestic animals, which is caused by an RNA virus. In wild animals it is characterised by a loss of fear, unpredictable rages, and excess saliva production. The disease can be transmitted to humans where it causes general malaise followed by hyperexcitability, hydrophobia, coma and death.

range
An area or volume of the environment in which a particular organism can be found. (Compare with 'territory'.)

rDNA
Shorthand for recombinant DNA; genetic information which has been created or rearranged prior to experimentation.

recessive gene
A gene which will masked by the activity of a dominant gene when both are present.

recombinant DNA
DNA molecules of different origin that have been joined together by biochemical techniques to make a single molecule, usually circular and usually capable of some specific biological function, especially *self-replication* in an appropriate cell.

redundancy of function
Describes the situation in which several species perform similarly in the same ecological role.

restriction endonucleases
Enzymes which cut the DNA double helix only where a particular sequence of base pairs is present.

retrovirus
A virus which uses RNA as the genetic material but possesses the enzyme reverse transcriptase (q.v.) and which can thus cause a DNA copy of itself or some part of itself to be made inside the cell.

reverse transcriptase
An enzyme capable of using RNA as a template and creating a DNA copy of the relevant sequence.

ribosomes
Small, particulate entities within the cytoplasm which attach to messenger RNA and help to translate that message into a particular amino acid sequence. Essential for protein synthesis in the cell.

RNA
Ribonucleic acid. A single-stranded molecule consisting of sugar, phosphate and a string of bases. Different sorts of RNA have different functions. Messenger RNA is the immediate template for protein synthesis.

sarcoma
Cancer deriving from cells which perform a support or packing function in the body (connective tissue).

sequencing
The process of determining the sequence of nucleotides (in DNA or RNA) or amino acids (in proteins).

solanine
A toxic alkaloid present in a group of plants which includes the potato and tomato.

solutes
The substances that are dissolved in a solvent to form a solution.

somaclonal variation
During the process of producing clones (q.v.) occasional variation occurs due to mutation.

somatic cell gene therapy
Will introduce a new normal gene into the patient's body or 'somatic' cells. It would treat only that patient; the change would not be passed onto the patient's children. (Constrast with germ cell gene therapy.)

somatotropin
Growth hormone. Bovine somatotropin (BST) is used to increase milk production. Work is proceeding in using the hormone to decrease the fat content of meat in pigs and sheep.

sticky ends
Short single-stranded sequences of DNA capable of binding to short, complementary stretches on other DNA molecules.

substrate
The target for an enzyme's action.

Tay-Sachs disease
An inherited disease, occurring predominately in Ashkenazi Jews, due to a genetic defect in an enzyme, hexosaminidase A, which leads to abnormal accumulation of certain fats in nerve cells causing severe mental retardation and death.

territory
An area or volume of the environment which is defended by a particular organism. Territories are often associated with breeding behaviour. (Compare with 'range'.)

tetanus
Also called 'lockjaw'. A disease caused by the toxins of the bacterium *Clostridium tetani.* Spores of the bacteria can be present in the soil and can gain access to the body via cuts. Symptoms include sustained muscular spasm, contraction and convulsion.

thymine
One of the small molecular building blocks called bases, which make up the coding units of DNA and RNA. Often abbreviated to T. In DNA, pairs with adenine (A).

tissue plasminogen activator
An enzyme used to dissolve blood clots. The chemical has been produced by biotechnology.

tissue typing
The process by which scientists determine the genes of a person which are important for organ transplantation.

toxin
A poison.

TPA
Tissue plasminogen activator - a chemical produced via genetic engineering which is used to dissolve blood clots. It is an alternative treatment to the use of streptokinase which is derived from a bacterium.

transcription
The process whereby the DNA double helix unwinds and an RNA copy of a gene is synthesized complementary to one of the strands.

transduction
The transfer of genetic information from one bacterium to another through the agency of a bacteriophage. Bacterial genes become incorporated into the phage particles which, after release from the dead host cell, act as vectors in transporting this genetic material into other bacterial cells.

transfection
Insertion of DNA into a cell without a vector and integration of that DNA with the cell's own genes. Generally an inefficient process but occurs sufficiently frequently that, if transfected cells can be selectively grown, genetic engineering can be achieved.

transfer RNA (tRNA)
An abbreviation of amino acid transfer RNA. Each particular transfer RNA molecule can ferry a particular amino acid to the right spot on the ribosome, thus helping in protein synthesis.

transformation
When applied to bacteria, this term means acquisition by a bacterium of new genes following infection of that bacterium by DNA carrying these genes. When applied to animal cells, this terms means conversion of the cell from a normal, noncancerous cell to an abnormal, cancerous cell capable of causing a tumour when injected into an animal. Transformation in animal cells can be 'spontaneous' or can be caused by certain oncogenic animal viruses or by carcinogens.

transgenic animals
Are produced by genetic manipulation techniques. Fertilised eggs are injected with foreign genes, such as those that promote growth, modifying the animal's genetic makeup. This new genetic code is then passed on to the offspring.

translation
The process by which the coded message in messenger RNA is read, resulting in the formation of a corresponding protein.

transposons
Mobile stretches of DNA which can move around within the genome instead of (like most DNA) residing in one place in the one chromosome.

triazines
A group of herbicides based on a six member ring structure containing three nitrogen atoms. Applied to the soil, the chemical inhibits photosynthesis. One type is a fungicide.

tryptophan
An amino acid which was taken to alleviate insomnia and premenstrual tension. It was associated with a disease, eosinophilia myalgia syndrome (q.v.).

uracil
A base unique to RNA informationally equivalent to thymine in DNA. Abbreviated to U.

vaccine
A substance which confers protection against a pathogen. The vaccine is sufficiently similar to the pathogen to evoke an immune response which is effective against the pathogen, but the vaccine does not itself cause an acute form of the disease.

vacuole
A sack-like subcellular entity in a cell which looks relatively translucent in the electron microscope. Frequently involved in transporting food into the cell or some product out of the cell.

vector
A tool of the genetic engineer used to transport recombinant DNA into a host cell and to permit its extensive replication there independently of the replication of the cell's own DNA; a generic term covering phages, plasmids, cosmids and other types of mobile DNA.

viroid
A class of viruses that occurs in plants and animals as a naked strand of RNA, which is infectious but lacks the genetic information to specify a protein coat.

virulent
Extremely infectious.

virus
The smallest and simplest form of life. Micro-organisms which are obligatory parasites, capable of multiplying only inside living cells.

APPENDIX XI

DISSENTING REPORT

Three Members of the Committee would have preferred the following alternative recommendations.

1. **Recommendation 2**

   The Committee did **not** investigate somatic cell gene therapy. It should therefore **not** make any recommendations as to how it should be regulated.

2. **Recommendation 47**

   GMO Release Authority
   Because of the importance of releasing genetically modified organisms into the environment, each release should be subject to GMAC recommendations.

   The release should then be considered by a Joint Parliamentary Committee of Members and Senators and if recommended by that Committee for release, the matter should be subject to debate in the Parliament and the release authorised by Parliament.

FRANK FORD, MP

BRUCE REID, MP

GRAEME CAMPBELL, MP