PROPOSALS FOR THE FUTURE REGULATION OF BIOTECHNOLOGY IN AUSTRALIA

The advent of biotechnology has been widely described as the second scientific and technological revolution of the twentieth century . . . Its revolutionary character lies in the fact that many of its varied applications are concerned with basic human needs.[1]

Biotechnology consists of a range of revolutionary biological scientific techniques, such as genetic manipulation (or genetic engineering), genome analysis and IVF processes, which have emerged during the past two decades. It was recognized in a recent Commonwealth House of Representatives Standing Committee Report that genetic manipulation is a developing area urgently in need of legislative regulation.[2] This note examines some of the important policy issues which will have to be considered by the Commonwealth Parliament if it decides to enact legislation regulating the biotechnology industry. In particular, community concerns about the possible adverse impact of genetically modified organisms upon the environment should be addressed. There needs to be a process by which both scientific and ethical considerations are taken into account in making a policy decision on whether a particular release of a genetically modified organism should be permitted. One important issue is *who* should be responsible for making such policy decisions. Should emphasis be given to the input of scientists, or should the input of lay persons such as politicians or consumers prevail?

1. *Background*

Genetic manipulation consists of the manipulation of genes through modifying the existing genes in an organism or more usually removing genetic material from one organism and transplanting it into another organism, which may be of a different species or genus. The changed genetic composition may then influence the development and functioning of the organism.

Current applications of this technology include the production of disease and pest-resistant plants to increase crop yields,[3] the treatment of human genetic

[1] Bromnlea, A., Burch, D., Hindmarsh, R., Hulsman, K., 'Biotechnology, Policy and Industry Regulation: Some Ecological, Social and Legal Considerations', *Submission to the House of Representatives Standing Committee on Industry, Science and Technology Inquiry into Genetically Modified Organisms* (1990) 13.

[2] Commonwealth House of Representatives Standing Committee on Industry, Science and Technology, *Genetic Manipulation: The Threat or the Glory?* (March 1992) ('the *Genetic Manipulation Report*').

[3] *Genetic Manipulation Report*, *ibid. e.g.*, Dr Bruce Roser, a scientist at Cambridge University has recently made a discovery that could lead to the creation of drought-resistant crops. By the insertion of the gene that instructs cells to produce a sugar molecule known as trehalose, it may be possible to create varieties of wheat and maize with the ability to withstand severe drought.

disorders,[4] the insertion of growth hormone genes into pigs to increase meat production[5] and the use of genetically modified bacteria to break down the components of crude oil in the event of an oil spill.[6] It has been suggested that the technology will benefit the food, agricultural, pharmaceutical and mining industries, as well as offering major benefits for human health and for the protection of the natural environment.[7]

In Australia, groups such as the Australian Conservation Foundation (ACF) and the Australian Council of Churches have opposed the technology since its inception, attacking its legitimacy on both ethical and scientific grounds. The Australian Council of Churches states that genetic engineering 'reveals a tendency to view nature in mechanistic terms . . . We run the danger of turning our image of life itself into that of a consumer commodity'.[8] In addition, the technology possesses many 'biohazards' which, according to Bob Phelps, the ACF's Genetic Engineering Officer, warrant a far more stringent process to be implemented for the assessment of genetically modified organisms (GMOs).[9] The ACF argues that 'once released, some genetically engineered organisms may establish themselves in the environment and present even more long-lasting problems than nuclear wastes or chemicals'.[10]

In light of these concerns and the increasing commercialization of the technology,[11] a number of government and law reform reports have examined the experimental techniques of genetic manipulation and the hazards associated with the release of GMOs into the environment. The latest report, produced by the House of Representatives Standing Committee on Industry, Science and Technology, was tabled in March 1992.[12] This report, reinforcing the earlier recommendations made in the reports by the Australian Environment Council in 1987[13] and the Victorian Law Reform Commission in 1989,[14] called for national legislation to be introduced to regulate the biotechnology industry.

2 *The Regulatory System*

The regulation of genetic engineering in Australia began in 1975 when guidelines were released by the Australian Academy of Science. In October 1981 the Commonwealth Government established the Recombinant DNA Monitoring Committee (RDMC) which was replaced by the Genetic Manipulation Advisory Committee (GMAC) in September 1987. Unlike the RDMC, GMAC is not

4 *E.g.*, Joyce, C., 'Pioneers Push Back the Limits of Gene Therapy' (August 1991) *New Scientist* 7.
5 *Genetic Manipulation Report*, *op. cit.* n. 2, 73.
6 *Ibid.* 79-80.
7 *Ibid.* 49.
8 *Ibid.* 85.
9 Lecture given by Bob Phelps at the University of Melbourne, Parkville, Victoria, 26 March 1992.
10 Australian Conservation Foundation, 'Genetic Engineering, Science Before Its Time', (April 1992) insert in *The Gene Report*.
11 *E.g.* Crawford, M., 'Wall Street takes stock of Biotechnology' (November 1991) *New Scientist* 28.
12 *Genetic Manipulation Report*, *op. cit.* n. 2.
13 Australian Environment Council, *Environmental Protection and Biotechnology — A Discussion Paper on the Implications and Regulations of the Release of Genetically Manipulated Organisms to the Environment of Australia* (1987).
14 Victorian Law Reform Commission, *Genetic Manipulation*, Report No. 26 (1989).

confined to monitoring recombinant DNA techniques. Rather, GMAC is responsible for regulating all innovative genetic manipulation techniques including micro-injection[15] and protoplast fusion.[16]

GMAC is primarily composed of scientists but also includes a barrister, a member of the ACF and a representative from the Department of the Arts, Sport, the Environment, Tourism and Territories (DASETT). The Minister for Administrative Services has been responsible for GMAC since July 1988.[17]

Since first meeting in December 1988, GMAC has published updated guidelines for small scale genetic manipulation work[18] and large scale genetic manipulation work.[19] These guidelines regulate the industry at the experimental level and operate in addition to the RDMC's published guidelines regulating the release of GMOs into the environment.[20] These three sets of guidelines coexist with those published by the National Health and Medical Research Council (NHMRC) on both human[21] and animal experimentation.[22]

The guidelines are of a voluntary nature only. Apart from the threats of adverse publicity and public scrutiny, sanctions for non-compliance are limited to the withdrawal of funds provided to research centres by the Commonwealth Government and the forfeiture of the 150% tax concession[23] for industrial research and development. These sanctions are only enforceable at the discretion of the minister acting on the advice of GMAC. They are even less effective for private research laboratories and biotechnology corporations which do not rely on public funding. Barry Lloyd, the managing director of a large biotechnology company Metrotec, hinted at this lack of efficacy in his comment that Australia's voluntary code of conduct applied only to institutions such as universities and the CSIRO and not to private companies.[24]

Members of the biotechnology industry contend that the lack of comprehensive accountability and clear regulations are discouraging potential investment in

15 Micro-injection involves the insertion of molecules into a cell through the use of a glass pipette.

16 Protoplast fusion is a process in which plant membranes are fused. This purported increase in jurisdiction is really illusionary since RDMC already supervised these areas in practice.

17 Formerly, GMAC was under the administration of the Department of Industry, Technology and Commerce, headed by Senator John Button. Senator Nick Bolkus is the current Minister for Administrative Services.

18 GMAC, *Guidelines for Small Scale Genetic Manipulation Work* (December 1989). Small scale guidelines apply to the growth of less than ten litres of a culture of cells. GMAC can, however, vary that limit on a case-by-case basis.

19 GMAC, *Guidelines for Large Scale Work with Genetically Manipulated Organisms* (December 1990). Large scale guidelines apply to the growth of more than ten litres of a culture of cells, the production of a larger number of plants or animals than can be accommodated in a single laboratory and commercial activities involving the production of whole plants or transgenic animals (or animals produced by the process in which fertilized eggs are injected with foreign genes and the new genetic code is passed to the offspring).

20 RDMC, *Procedures for Assessment of the Planned Release of Recombinant DNA Organisms* (May 1987).

21 See Supplementary Note 7 in NHMRC, *Statement on Human Experimentation and Supplementary Notes* (1987).

22 NHMRC/Commonwealth Scientific and Industrial Research Council/Australian Agricultural Council, *Australian Code of Practice for the Care and Use of Animals for Scientific Purposes* (1990).

23 It was recommended by the Commonwealth Government in the 'One Nation Economic Statement' that a 125% tax concession should apply for industrial research and development: *Australian Financial Review*, (Melbourne) 5 May 1992.

24 ABC Radio, *Country Hour*, 7.30pm, 27 April 1990.

the Australian biotechnology market. This view was exemplified by Monsanto Australia Limited, which said in its submission to the Standing Committee: '[w]e are looking for a firming up of rules ... it is the lack of regulations that is discouraging [investment in Australia]. We do not have a predictable framework in which to operate'.[25]

3 *Prospective Reform*

As the introduction of legislation regulating biotechnology becomes increasingly likely, a central issue which needs to be addressed is who will have the authority to supervise compliance with legislative requirements. The House of Representatives Standing Committee Report has suggested that GMAC should continue to monitor genetic manipulation at the research level,[26] but has recommended the establishment of a new body, the Genetically Modified Organism Release Authority (GMORA), to oversee the release of GMOs.[27]

The report has recommended that the governing committee of GMORA ought to be comprised predominantly of persons with some scientific background in genetic manipulation, environmental science or the commercial development of GMOs. These persons are supposed to represent some of the major participants in the genetic manipulation industry.[28] Despite the attempt to widen the range of expertise on this new committee, it is likely that discussions would focus largely on the scientific and environmental issues surrounding the potential release into the environment of GMOs, as opposed to the possible social and ethical issues associated with genetic manipulation. GMORA would have an advisory role with final approval for the release of GMOs onto the market still resting with the appropriate state or federal department. Both GMORA and GMAC would be presided over by the Minister for Science and Technology, Ross Free.[29]

The report has been criticized as being biased towards industry and advocating industry self-regulation, in that biotechnology companies would be answerable to an authority which promotes the technology.[30] Support for this argument lies in the fact that the department overseeing the two regulatory bodies, namely DITAC, has consistently adopted a pro-genetic engineering stance and is responsible for the funding of many genetic engineering projects.[31]

The regulation of genetic engineering, like all other pursuits of economic and

25 *Genetic Manipulation Report, op. cit.* n. 2, 45.
26 *Ibid.* recommendation 38, 268.
27 *Ibid.* recommendation 40, 274.
28 It was recommended by the standing committee that the GMORA membership comprise 15 persons, drawn from the following: a chairperson, the chairperson of GMAC, two persons chosen for their expertise in genetic manipulation technology, two persons chosen for their expertise in environmental science, a nominee from each of four federal government departments, two persons chosen for their involvement in commercial development or use of GMOs, two persons chosen for their interest in environmental or consumer affairs and one person chosen for knowledge in law. *Genetic Manipulation Report, op. cit.* n. 2, recommendation 47, 280.
29 *Ibid.* recommendation 41, 274.
30 See Hindmarsh, R., and Hubsman, K., 'Gene Technology: The Threat or the Glory?' in Science and Education Discourse' at 4, inserted in (April 1992) *New Scientist.*
31 *Genetic Manipulation Report, op. cit.* n. 2, 17-18.

scientific endeavour, should support commercial productivity and market competitiveness. It would be retrogressive to adopt an approach which inhibited the emergence of a potentially productive industry. It is important, however, to include environmental and ethical issues within the decision-making process. Ethics has a substantial role to play in the development of the industry, a role enlarged by the nature of the technology and entrenched community attitudes towards it.[32] Scientists, qualified to assess scientific and environmental issues, are likely to favour the development of the technology without proper reference to the ethical implications of that development. Accordingly, there is a place for the involvement of ethics committees in decision-making.

It appears that the existing structure enables the discussion of issues regarding the ethical implications of proposals for experimentation into humans and animals in a competent forum. The Medical Research Ethics Committee oversees the regulation of experimentation on humans. Every institution which conducts research using animals is required to establish (or to have access to) an animal experimentation ethics committee to review proposals for experimentation on live, non-human vertebrate animals.

There is, however, a need for the establishment of an ethics committee to review the social and ethical issues that arise from the possible market release of a GMO. In 1988, the Danish parliament set up the Danish Council of Ethics to advise the Minister of Health on a number of issues, including the treatment of genetic disorders. The seventeen members of that committee are comprised of three doctors, two theologians, two lawyers, three teachers, two writers, a pharmacist, a social worker, a nurse, a biologist and a dentist.[33] The creation of a similar ethics committee in Australia, with representation from a variety of fields, would facilitate a proper discussion of the ethical implications of a release.

Considerations taken into account in the Ethics Committee's decision-making would include any public concerns associated with the potential release of a product, whether the product would benefit the community and the likely impact of the product's release on the market into which it is released. Possible releases that might be considered by the Ethics Committee would include: the release of genetically-altered foods;[34] the use of genetically modified plants in agriculture; and the release of genetically modified organisms to attack pests affecting agriculture. In considering the latter release, for example, the Ethics Committee would have to look at the economic benefits for farmers of combatting the pests and minimizing crop losses; and at the possible consequences of releasing the organisms for the environment's biological balance. It would have to decide whether the balance of these factors justified the release of the GMO into the environment. The recommendations of this committee should be provided

[32] See MacKenzie, D., 'People's Poll Shows Confusion Over Biotechnology' (July 1991) *New Scientist* 32.

[33] See Rix, B. A., 'A Report From Denmark: Should Ethical Concerns Regulate Science? The European Experience with the Human Genome Project' (1991) 5 *Bioethics* 250.

[34] The issue of whether such foods should be specifically identified as genetically-altered foods has been considered and rejected by the U.S. Drug and Food Administration: *Age* (Melbourne), 28 May 1992.

together with the recommendations of GMORA to the relevant government department which should then assess both reports before deciding whether to authorize the release of the GMO.

It is, however, important to minimize the potential delays arising out of an overly complicated decision-making process. This type of delay has occurred in Germany where scientists have complained about the enormous bureaucracy and long delays which they encounter when seeking approvals for new experiments. This has effectively discouraged innovation and creativity in the area.[35]

The scientific and ethics committees' regulation of the biotechnology industry should be supervised by the Commonwealth executive. It is the executive, acting through the minister of the appropriate department, which decides upon the composition of GMAC, and would decide, if it comes into existence, the composition of GMORA. The executive clearly has the democratic right and duty to intervene in the internal activities of these committees if the need ever arises. Yet up to now, the advice of GMAC has been followed without exception and politicians, being unlikely to possess specialist qualifications, should not intervene in the activities of either scientific or ethics committees or fail to heed their advice unless exceptional circumstances exist to justify such recourse.

4 *Conclusion*

It is evident from recent views expressed by scientists, the biotechnology industry and the ACF that legislation needs to be introduced into the area. In line with the recommendations of the House of Representatives Standing Committee Report, legal support should be given to GMAC and the voluntary guidelines should be enacted as regulations under an umbrella legislation, regulating both the experimentation of GMOs and the release of those organisms into the environment. Such regulations would need to be capable of being regularly updated to take into account developments in the field. As regards experimentation, it is suggested that GMAC should be authorized to take appropriate proceedings against renegade researchers in a manner similar to the Australian Securities Commission or the Trade Practices Commission. But the applications seeking approval for experiments with GMOs should be dealt with in a manner that minimizes bureaucracy and delay.

Regarding the release of GMOs, an independent body, GMORA, should be created to oversee the field-testing and market suitability of GMOs. The focus of this body should concentrate on the evaluation of scientific and environmental concerns. An ethics body, modelled loosely on the Danish experience, ought to be created by the Commonwealth Parliament. Its members and activities should be chosen by the DASETT. Efficient communication between the suggested ethics committee, GMAC, GMORA, scientists and both the State and Commonwealth governments should ensure minimal bureaucracy and delay. A compromise must be achieved between science and ethics. For, while ethics should

[35] See Kahn, P., 'Germany's Gene Law Begins to Bite' (1992) 255 *Science* 524.

define the boundaries of science, science must be afforded freedom within those boundaries. By adopting sensible and researched compromises, both the ethics and science committees will hopefully function concurrently to offer a unified response to many of the issues threatening to retard the new biotechnology industry's development.

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