CHAPTER 1

INTRODUCTION

Terms of Reference

1.1 The Gene Technology Bill 2000 and two related Bills, the Gene Technology (Consequential Amendments) Bill 2000 and the Gene Technology (Licence Charges) Bill 2000, were introduced into the House of Representatives on 22 June 2000. The Bills were debated in the House on 28, 29 and 30 August. The Bills passed the House on 30 August and were introduced into the Senate on the same day.

1.2 On 28 June, the Senate referred the provisions of the Gene Technology Bill 2000 to the Committee for inquiry and report, with particular reference to:

Objectives

(a) whether measures in the Bill to achieve its object 'to protect health and safety of people and to protect the environment' are adequate;

(b) whether the proposed regulatory arrangements and public reporting provisions will provide sufficient consumer confidence in the regulation of the development and adoption of new gene technologies;

The Office of Gene Technology Regulator

(c) the structure of the Office of the Gene Technology Regulator (OGTR) and its assessment processes compared with other proposed stakeholder models and similar overseas bodies;

(d) whether the powers and investigative capability of the OGTR are adequate to ensure compliance with conditions imposed in licences;

(e) whether the proposed cost recovery and funding measures for the OGTR are appropriate and will allow for adequate resourcing of the Office;

Other proposed bodies

(f) the role and membership of the proposed Ministerial Council;

(g) the functions and powers of the Gene Technology Community Consultative Committee and the Gene Technology Advisory Committee;

(h) procedures for review of decisions and, in particular, the rights of third-parties to seek review of decisions;

Other issues

(i) liability and insurance issues relating to deliberate and accidental contamination of non-genetically modified crops by genetically-modified crops and how those issues are being addressed in international regulatory systems;

(j) the validity and practicability of any proposed clause allowing individual States the right to opt out of the scheme and the implications of such an option in the context of Australia's international trade and related obligations; and

(k) the alleged genetically-modified canola contamination in Mount Gambier and the processes followed by the Interim Office of Gene Technology in investigating and reporting on the allegations.

Conduct of the inquiry

1.3 The inquiry was advertised in the *Sydney Morning Herald*, *The Age*, *Australian Financial Review*, *Advertiser* and *Mercury* on 7 July, and *The Weekend Australian* on 8 July 2000 and through the Internet. Submissions were also invited from Federal, State and Territory Governments, professional and community organisations, and other groups and individuals involved with the gene technology debate in Australia. Due to the tight timeframe for the inquiry, the closing date for submissions was originally 4 August 2000, although the Committee continued to receive submissions throughout the course of the inquiry.

1.4 The inquiry attracted interest throughout Australia with the Committee receiving 125 public submissions. The Committee also received a substantial amount of additional material from witnesses. The list of submissions and other written material received by the Committee and for which publication was authorised is at Appendix 1. Submissions that were received electronically may be accessed through the Committee's website at www.aph.gov.au/senate_ca. The Committee held public hearings in Canberra on 14 and 25 August, Adelaide - 22 August, Hobart - 23 August, and Melbourne - 24 August. A list of witnesses who appeared at the public hearings is included in Appendix 2.

Development of the Gene Technology Bill 2000[1]

1.5 The development and use of gene technology in Australia has been overseen variously since 1975 by the Academy of Science on Recombinant DNA, the Recombinant DNA Monitoring Committee (created in 1981) and from 1987 by the Genetic Manipulation Advisory Committee (GMAC).

1.6 GMAC is an independent committee of scientific experts which assesses the risks to human health and the environment that may be presented by the application of gene technology and provides advice on how the risks can be managed. GMAC recommendations are sought, and complied with, voluntarily. However, in the absence of regulatory powers, GMAC has limited capacity for independent, legally enforceable auditing and monitoring of compliance. There is no legal basis for the imposition of penalties or other action in the event of non-compliance.

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1 Much of the background information in this section has been drawn from Submission No.77 (IOGTR), the Explanatory Memorandum and Explanatory Guide to the Gene Technology Bill, and the Parliamentary Library Bills Digest No.11 2000-01.

1.7 In 1992, a report by the House of Representatives Committee on Industry, Science and Technology, *Genetic Manipulation: The Threat or the Glory?*, recommended that the Commonwealth should pass legislation to regulate genetically modified organisms (GMOs) and, in particular, their release outside contained facilities. During 1992-95 there were on-going Commonwealth-State discussions regarding legislative options to implement regulation. However, negotiations ceased in 1995 when agreement could not be reached on a legislative model.

1.8 The proposal for a national legislatively-based regulatory system for gene technology was revived in October 1997 and a Commonwealth-State Consultative Group on Gene Technology (CSCG) was formed. Community and industry perceptions and expectations were a major driving force behind the need to move from a voluntary to a regulatory system of controls.

1.9 The development of a new national regulatory system has been approached from a whole-of-government perspective and involved a number of stages. The process has drawn upon the collective knowledge of agencies responsible for health, environment, agriculture, industry and primary production across Commonwealth, State and Territory jurisdictions. Active consultation has been on-going during this period with a broad range of individuals and organisations, including universities conducting research involving GMOs; consumer, environmental, health professional, industry, retailer and food industry; and primary producer groups.[2]

1.10 The CSCG considered a range of options to improve the current administrative controls, finally opting for full government regulation. By November 1998 the CSCG had prepared a paper 'Regulation of Gene Technology' that was circulated for public consultation. Consultations were held throughout Australia seeking views about the broad policy principles that might underpin the new regulatory scheme. As a result of these consultations, the CSCG agreed to a set of policy principles that it used to develop proposals for the operational details of the new regulatory system.

1.11 The CSCG, in collaboration with the Interim Office of the Gene Technology Regulator (IOGTR)[3], prepared a further discussion paper entitled 'Proposed national regulatory system for genetically modified organisms – How should it work?'. This paper was widely circulated in October 1999, with a broad range of individuals and organisations invited to attend targeted consultations which were held in all States and Territories during November and December 1999.

1.12 A draft Gene Technology Bill was then prepared based on the input from relevant Commonwealth agencies, States and Territories, non-government

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2 Submission No.77, p.24 (IOGTR) and Explanatory Memorandum, p.36.

3 The IOGTR was established in May 1999 within the Commonwealth Department of Health and Aged Care to oversee the development of the legislation to implement a national regulatory system and work with GMAC.

stakeholders and the general community. The draft was released, with a plain language explanatory guide, for public consultation in late December 1999. Again a wide-ranging consultative process took place with public forums in all capital cities and a number of regional areas.

1.13 On the basis of these consultations changes were made to the draft Bill before being introduced into the House of Representatives on 22 June 2000. A summary of views elicited from the main affected parties as a result of consultation is described in the Explanatory Memorandum. Although not intended as a comprehensive summary of the views of all parties, it does emphasise areas of support and dissension in relation to proposed options and areas where costs and benefits of various approaches were raised.[4]

1.14 The fundamental importance of the cooperation and agreement that has been reached between the Commonwealth and the States and Territories in developing the regulatory system proposed in the legislation was emphasised in submissions from a number of State Premiers.[5] The significance of this agreement was underlined by State officials, some of whom had been involved in the previous unsuccessful attempts to develop a nationally consistent approach to regulation. Dr Susan Meek from Western Australia encapsulated this point by stating that this Bill 'represents the highest level of agreement ever achieved between the Commonwealth, States and Territories on this issue to develop a gene technology regulatory system'.[6]

1.15 To implement the comprehensive regulation of gene technology as is proposed requires both Commonwealth and State legislation which, to be as effective and efficient as possible, must be complementary. The importance of the national regulatory scheme, as agreed by the Commonwealth, States and Territories after such a lengthy consultative process, passing the Commonwealth Parliament in a form not materially different from that which was introduced, was also stressed by the States. The Committee notes the comments that any significant amendment of the Commonwealth Bill would require additional renegotiation that could subsequently jeopardise the legislation's implementation. However, this will not prevent the Senate from giving the Bill its usual thorough review during its consideration of the legislation.

1.16 The Tasmanian Government, however, while participating at officer level in the CSCG negotiations since late 1997, does not endorse all aspects of the proposed regulatory system. Of particular concern is the exclusion of an opt-out clause in the legislation, which is addressed in term of reference (j). A parliamentary inquiry has

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4 Explanatory Memorandum, pp.37-41. More detailed information about the consultation process and changes made to the draft legislation arising from the process may be found in Submission No.77 (IOGTR), additional information dated 18 September, pp.8-11 and Attachments C and D.

5 Submission Nos.84 (Mr Peter Beattie, Qld); 91 (Mr Richard Court, WA); 110 (Mr John Olsen, SA); 115 (Mr Steve Bracks, Vic).

6 *Committee Hansard*, 14.8.00, p.23 (Dr Meek).

been established in Tasmania as part of the process of assisting Tasmania develop its own policy in relation to GMOs. In the interim, the Tasmanian Government has recognised that appropriate regulatory controls must exist if GMOs are to be accepted into agricultural systems.[7]

1.17 The IOGTR acknowledged in its submission that during consultations on the draft Bill, people indicated that 'it is often difficult to understand how the legislation will work by simply looking at the draft Bill because a lot of the administrative detail is included in the regulations'.[8] The same point was made repeatedly to the Committee during the inquiry, complicated by the fact that no draft regulations were available for consideration at that stage. A draft of the Regulations was released in late August and will be subject to national consultations during the latter months of 2000. Model State legislation, which is substantially similar to and will complement the Commonwealth legislation, has also been released for public comment.

1.18 The final component of the proposed regulatory system is the Gene Technology Intergovernmental Agreement, which underpins the entire national scheme. The Agreement will set out many of the understandings between the governments that have allowed the national scheme to be developed, thereby helping to minimise the number of disputes which may arise during the scheme's operation. It is expected that the Agreement will:

- describe the main components of the cooperative national scheme and commit all governments to introduce substantially similar legislation;
- set out the functions and membership of the Gene Technology Ministerial Council;
- provide for the maintenance of a nationally consistent scheme over time;
- describe the roles and responsibilities of each jurisdiction in the administration and enforcement of the scheme; and
- provide for the review of the implementation and effectiveness of the national scheme in five years time.[9]

The Agreement is yet to be considered by the Heads of all Australian Governments, prior to it being released publicly.

1.19 In discussing why Australia needs a national regulatory framework for GMOs, the IOGTR offered the following comments which recognise and highlight many broadly held concerns:

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7 Submission No.89 (Tasmanian Government, Mr Jim Bacon, Premier).

8 Submission No.77, p.25 (IOGTR).

9 Explanatory Guide to the Gene Technology Bill, July 2000, pp.81-2.

> While the level of concern about possible risks is growing in the community, there remains inadequate information available to the community and consumers to evaluate the reality of these risks and their likelihood of occurrence. Individuals may also have difficulty in assessing and processing available information to help them make informed choices about comparative levels of risk from other technologies and what levels of risk they consider to be acceptable to their health and safety.
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> There is a perception that industry cannot be relied upon to be sufficiently rigorous and objective in evaluating risk and implementing appropriate management strategies and that government should fulfil this role.
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> However, given the rapid growth in the use of gene technology, the government's current capacity for intervention is inadequate…
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> The current system also attracts criticism for not being sufficiently open and transparent in its risk assessment and management processes, and for not having adequate enforcement capabilities. The resulting lack of credibility (particularly in relation to decisions regarding the release of GMOs into the environment) may undermine public confidence and jeopardise the ability of industry to market GMOs and GM products assessed as safe. In addition, unnecessary costs may be generated through less than optimal coordination between regulators.
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> A national, uniform regulatory system is fundamental to the development of industry based upon gene technology in Australia.[10]

1.20 As can be seen from the terms of reference, it has been the Committee's duty to examine the proposed national regulatory system to ensure that the concerns expressed in the above comments have been satisfactorily addressed in the legislation.

1.21 Although the Committee acknowledges the extended consultative process undertaken prior to the Bill's introduction into Parliament, it is concerned at the timeframe with which the Parliament and the Committee have been expected to consider such fundamentally important legislation. Draft Regulations have only been recently released and the Intergovernmental Agreement has not been sighted. The Committee agrees that the implementation of a nationally effective and enforceable regulatory scheme is critical to the development of gene technology in Australia and to boost public confidence in the development and use of gene technology generally. However, the Committee considers that it is imperative that before passing this legislation, Parliament and the Committee be allowed sufficient time for a thorough examination of the proposed scheme and, in particular, of the risks associated with the different applications of gene technology and their possible long term effects.

10 Submission No.77, pp.20-21 (IOGTR).

Acknowledgments

1.22 The Committee expresses its appreciation to the individuals and organisations who made submissions to the Committee or gave evidence to the inquiry. As always, the Committee places great value on the submissions it receives as primary sources of information. Many witnesses provided additional written information and copies of published articles. This material was most helpful to the Committee during its deliberations on the inquiry.

1.23 The Committee would also like to thank the staff of the Antarctic Cooperative Research Centre at the University of Tasmania and of the CSIRO Division of Health Sciences and Nutrition at Parkville in Melbourne for their assistance in enabling the Committee to hold public hearings at their facilities. In particular, the Committee would like to thank Dr Colin Ward and Mr Doug Gale from the CSIRO at Parkville for enabling the Committee to inspect their facilities and gain a first hand appreciation of the successful research being undertaken within their Division.

1.24 The Committee commends the IOGTR for the comprehensive consultative process it has undertaken in the development of this legislation. The Committee was impressed with the volume of detailed information, including the Explanatory Guides, that has been made publicly available, and especially with the Explanatory Memorandum accompanying the Bill, the detail of which is rarely seen in such documents. Finally, the Committee thanks Ms Elizabeth Cain and the officers of the IOGTR for their assistance through the timely provision of detailed information in response to requests from the Committee.