Chapter 1
Introduction

Referral of inquiry

1.1 The Gene Technology Amendment Bill 2015 (the Bill) was introduced into the House of Representatives on 18 June 2015. On 24 June 2015, pursuant to the Senate Selection of Bills Committee report, the provisions of the Bill were referred to the Senate Community Affairs Legislation Committee for inquiry and report by 18 August 2015.[1]

1.2 The committee was asked to consider the Bill in the context of:

- changes to license variation, including extending licenses beyond the scope of the original Risk Assessment and Risk Management Plan (RARMP);
- amendment to the list of factors which the regulator must consider before dealings can be declared Notifiable Low Risk Dealings (NLRDs) by the Governor-General, including removing the requirement that the genetically modified organism (GMO) be biologically contained so that it is not able to survive without human intervention; and
- any other matter of the committee's interest.[2]

Conduct of the inquiry

1.3 The committee advertised the inquiry on its website and in *The Australian* newspaper on 8 July 2015, calling for submissions to be lodged by 24 July 2015. The committee also wrote directly to a range of people and organisations likely to have an interest in the Bill, drawing their attention to the inquiry and inviting them to make written submissions.

1.4 The committee received five submissions to the inquiry. These submissions are listed at Appendix A and are published on the committee's website.

1.5 The committee agreed to not hold a public hearing.

Background

1.6 The *Gene Technology Act 2000* (the Act) is the Commonwealth component of the nationally consistent regulatory scheme for gene technology in Australia. The object of the Act is:

> [T]o protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with GMOs.[3]

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1 Selection of Bills Committee, *Report No. 8 of 2015*, Appendix 4.

2 Selection of Bills Committee, *Report No. 8 of 2015*, Appendix 4.

3 *Gene Technology Act 2000*, s. 3.

1.7 The Act establishes a regulatory framework to provide an efficient and effective system for the application of gene technologies that operates in conjunction with other Commonwealth and State regulatory schemes relevant to GMOs and Genetically Modified (GM) products.[4]

1.8 In 2011, the Department of Health (formerly the Department of Health and Ageing) commissioned a review of the Act on behalf of the Legislative and Governance Forum on Gene Technology (LGFGT) (formerly the Gene Technology Ministerial Council).[5] The review investigated:

- emerging trends and international developments in biotechnology and its regulation;
- the efficiency and effectiveness of the operation of the Act consistently across the national scheme for gene technology regulation in Australia; and
- the interface between the Act and other systems (e.g. other Acts and schemes).[6]

1.9 The review found that, overall, the Act is working well and the Office of the Gene Technology Regulator is functioning in an effective and efficient manner, but that there are aspects of the Act's implementation at State and Territory level that require attention. The review also noted that current consultation processes in relation to applications under the Act are working well. The review made 16 recommendations;[7] 14 of which were agreed to by the LGFGT.[8]

Purpose and key provisions of the Bill

1.10 The Bill amends the Act to implement five of the agreed recommendations, comprising minor and technical amendments to the Act. These amendments improve the Act's operation without changing the underlying policy intent or overall legislative framework of the regulatory scheme. The Bill:

- discontinues quarterly reporting to the Minister (Part 1 Schedule 1 of the Bill);
- clarifies which dealings may be authorised by inadvertent dealings licenses (Part 2 of Schedule 1 of the Bill);

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4 *Gene Technology Act 2000*, s. 4.

5 Allen Consulting Group, *Review of the Gene Technology Act 2000: Final Report*, August 2011, p. 1.

6 Allen Consulting Group, *Review of the Gene Technology Act 2000: Final Report*, August 2011, p. 1.

7 Allen Consulting Group, *Review of the Gene Technology Act 2000: Final Report*, August 2011, p. vi.

8 Department of Health, *All Governments' Response to the recommendations of the 2011 Review of the Gene Technology Act 2000*, http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-techact-review accessed 9 July 2015.

- updates advertising requirements for public consultations (Part 3 of Schedule 1 of the Bill);
- removes information about GM products authorised by other agencies from the Record of GMO and GM Product Dealings maintained by the Gene Technology Regulator (Part 4 of Schedule 1 of the Bill);
- changes licence variation requirements to provide greater flexibility for licence-holders (Part 5 of Schedule 1 of the Bill);
- updates the considerations required before dealings may be scheduled as NLRDs (Part 6 of Schedule 1 of the Bill); and
- clarifies ambiguous wording (Part 6 of Schedule 1 of the Bill).[9]

Provisions of the Bill

1.11 The provisions of the Bill, contained in Schedule 1, amend the Act to implement five recommendations from the *2011 Review of the Gene Technology Act 2000*, comprising minor and technical amendments to the Act.

Part 1 – Reporting requirements

1.12 Item 1 amends section 136 of the Act to require that annual reports include information about the following:

- GMO licences issued during the financial year;
- any breaches of conditions of a GMO licence that have come to the Gene Technology Regulator's (the Regulator) attention during the financial year;
- emergency dealing determinations made by the Minister during the financial year;
- any breaches of conditions of an emergency dealing determination that have come to the Regulator's attention during the financial year; and
- auditing and monitoring of dealings with GMOs under the Act by the Regulator or an inspector during the financial year.

1.13 Item 2 repeals section 136A of the Act, which requires that the above information be reported quarterly.

1.14 Item 3 provides that subsection 136A(3) will continue to have effect for quarterly reports that the Regulator has provided to the Minister, under subsection 136A(1), but which have not yet been tabled in Parliament at the time of the Item's commencement. Any such reports must be tabled in Parliament within 15 sitting days of the receipt of the report by the Minister.

Part 2 – Inadvertent dealings

1.15 The inadvertent dealings provisions of the Act allow the Regulator to promptly authorise the disposal of a GMO which has inadvertently come into

9 Explanatory Memorandum (EM), p. 1.

someone's possession. Part 2 clarifies the dealings which may be authorised for purposes relating to disposing of a GMO.

1.16 The Explanatory Memorandum (EM) explains that if an individual or organisation believes that they have inadvertently come into possession of a GMO, it must be tested and sampled to confirm whether the organism is a GMO. These testing activities fall under the dealing described as 'conducting experiments with the GMO.' Testing activities are considered to activities related to the disposing of a GMO, as the person or organisation will dispose of any organisms that are determined to be a GMO. The EM notes that:

> In some circumstances material for testing may be limited, and it would be necessary to propagate, grow, raise or culture the organism to obtain enough material for testing, for example, if only a small number of seeds are available…Transporting of the GMO to places with appropriate facilities or necessary equipment may be required in the course of testing or destruction of material as authorised by an inadvertent dealings licence.[10]

1.17 Item 4 amends subparagraph 46A(a), which relates to initial consideration of Dealings Not involving Intentional Release (DNIR) licence applications, and Item 5 amends subparagraph 49(a), which relates to initial consideration of Dealings involving Intentional Release (DIR) licence applications. The amendments for both subparagraphs 46A(a) and 49(a) provide the following clarifying details describing dealings authorised by the licence for purposes relating to the disposal of a GMO:

- conducting experiments with the GMO;
- propagating the GMO;
- growing, raising or culturing the GMO;
- transporting the GMO; and
- any other dealings to be undertaken for the purposes of, or for purposes relating to, disposing of the GMO.

1.18 Item 6 provides that, at the time of commencement, the amendments to subparagraphs 46A(a) and 49(a) will apply to undecided inadvertent dealings applications as well as inadvertent dealings applications made on or after commencement.

Part 3 – Public notification of risk assessment

1.19 Subsection 52 of the Act requires the Regulator to publish a notice stating that a risk assessment and a risk management plan (RARMP) has been prepared regarding dealings proposed to be authorised by a licence and inviting comment and submissions. Subsection 52(1) requires that the notice must be published in *The Gazette*, in a newspaper circulating generally in all States; and on the Regulator's website '(if any)'.

10 EM, p. 4.

1.20 Item 7 amends paragraph 52(1)(b) to provide the Regulator with greater discretion regarding the newspaper/s in which a notice may be published. The amendment allows the Regulator to choose one or more newspapers that the Regulator considers appropriate to publish the notice, having regard to the geographic area in which the dealings are proposed to be authorised by a licence.

1.21 Item 8 amends paragraph 52(1)(c) to omit the words '(if any)' to clarify that the Regulator does have a website, on which notices must be published.

Part 4 – GM products

1.22 Part 4 removes the requirement that the Regulator maintain a record of Genetically Modified (GM) product approvals made by other agencies. However, it does not alter the requirement that the Regulator record its own approvals for dealings with GMOs.

1.23 Items 9–16 amend references to the Record of GMO and GM Product Dealings (the Record), or descriptions of its contents, removing references to GM products.

1.24 Item 17 repeals subsection 138(5), removing the requirement that the Record contain information regarding GM products approved by other agencies that are mentioned in designated notifications given to the Regulator under the *Agricultural and Veterinary Chemicals (Administration) Act 1992*; the *Food Standards Australia New Zealand Act 1991*; the *Industrial Chemicals (Notification and Assessment) Act 1989*; and the *Therapeutic Goods Act 1989*. Information about GM products can be sought directly from the relevant agency (the Australian Pesticides and Veterinary Medicines Authority, the Therapeutic Goods Administration, Food Standards Australia New Zealand, and the National Industrial Chemicals Notification and Assessment Scheme.)

1.25 Subsection 138(8) requires that the Regulator ensure that information mentioned in subsections 138(3), 138(4), 138(5) or 138(6) is entered on the Record as soon as reasonably practicable. Item 18 amends paragraph 138(8) to reflect Item 17 repealing subsection 138(5) and to include subsection 138(3A), correcting an oversight from a previous amendment. The amended subsection 138(8) will require the Regulator to enter the information mentioned in subsections 138(3), 138(3A), 138(4) or 138(6) to the Record as soon as reasonably practicable.

1.26 Item 19 (transitional provision) provides that, after the item's commencement, the Regulator may remove historical information about GM products from the Record.

Part 5 – Restrictions on licence variations

1.27 Subsection 71(2B) states that the Regulator must not vary a licence if the RARMP, which had been submitted for the original application of the licence, does not cover the risks of the dealings proposed to be authorised by the licence as varied.

1.28 Item 20 amends subsection 71(2B) to allow the Regulator to consider both the RARMP from the original application for the licence as well as RARMPs that have been accepted for other licences, which have already been issued.

1.29 The amended subsection also removes an unintended restriction on the Regulator's ability to initiate licence variations.[11] The amended 71(2B) will only apply to applications to vary a licence, not to variations initiated by the Regulator. Under the amended subsection, the Regulator will be able to initiate a variation whenever the Regulator becomes aware of any risks posed by licenced dealings which are not covered by the original RARMP or any other RARMP. This will allow the Regulator to manage these risks to protect the health and safety of the public and the environment.

1.30 Item 21 provides that, after the item's commencement, the amended subsection 71(2B), will apply to applications for variation of licence made on or after the commencement as well as to any applications for variation of licence that have been made, but not decided, before commencement.

Part 6 – Technical amendments

1.31 Section 30 of the Act guarantees the independence of the Regulator, stating that the Regulator has discretion in the performance or exercise of his or her functions or powers and that the Regulator is not subject to direction from anyone in relation to the issuing of GMO licences and the conditions to which a GMO licence is subject. Item 22 clarifies the ambiguous wording of paragraph 30(a).

1.32 Under section 74 of the Act, the Governor-General can make regulations to declare a dealing with a GMO to be a notifiable low risk dealing (NLRD). Item 23 amends subsection 74(3) regarding the conditions that the Regulator must consider before regulations are made declaring a dealing with a GMO to be a NLRD. The amended conditions require the Regulator to consider any risks to the health and safety of people, or to the environment; and, if there is any risk, whether the NLRD requirements prescribed under subsection 75(2) would be sufficient to manage the risk. The amendment also removes the requirement, under the paragraph 74(3)(a) of the Act, that the Regulator consider whether the GMO is biologically contained so that it is not able to survive or reproduce without human intervention.

11 EM, p. 6.