2013 – 2014 – 2015

The Parliament of the Commonwealth of Australia

**HOUSE OF REPRESENTATIVES**

**Gene Technology Amendment Bill 2015**

Explanatory Memorandum

(Circulated by authority of the Minister for Health, the Hon Sussan Ley MP)

**Gene Technology Amendment Bill 2015**

### OUTLINE

The purpose of this Bill is to amend the *Gene Technology Act 2000* (the Act) in order to improve its operation without changing the underlying policy intent or overall legislative framework of the regulatory scheme.

The Act is the Australian Government's component of the nationally consistent regulatory scheme for gene technology. Under the Gene Technology Agreement 2001, all States and Territories have committed to maintaining corresponding legislation. The object of the Act is to 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 genetically modified organisms (GMOs).

An independent review of the Act, conducted in 2011 on behalf of the Legislative and Governance Forum on Gene Technology (LGFGT), found that the Act is working well and the Office of the Gene Technology Regulator is providing a rigorous, highly transparent regulatory system. The review made 16 recommendations to improve the operation of the gene technology regulatory system, and the LGFGT subsequently agreed to 14 of these recommendations.

Five of the agreed recommendations proposed minor and technical amendments to the Act to make gene technology regulation more efficient, more effective or clearer. This Bill proposes to implement these recommendations, which include:

* discontinuing quarterly reporting to the Minister (Part 1 of Schedule 1 of the Bill);
* clarifying which dealings may be authorised by inadvertent dealings licences (Part 2 of Schedule 1 of the Bill);
* updating advertising requirements for public consultations (Part 3 of Schedule 1 of the Bill);
* removing information about genetically modified (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);
* changing licence variation requirements to provide greater flexibility for licence-holders (Part 5 of Schedule 1 of the Bill);
* updating the considerations required before dealings may be scheduled as notifiable low risk dealings (Part 6 of Schedule 1 of the Bill); and
* clarifying ambiguous wording (Part 6 of Schedule 1 of the Bill).

### Financial Impact Statement

The amendments made by this Bill would not have any financial impact on the Commonwealth.

### Statement of Compatibility with Human Rights

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

**Gene Technology Amendment Bill 2015**

This Bill is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

**Overview of the Bill**

The purpose of this Bill is to amend the *Gene Technology Act 2000* (the Act) in order to improve its operation without changing the underlying policy intent or overall legislative framework of the regulatory scheme. An independent review of the Act, conducted in 2011 on behalf of the Legislative and Governance Forum on Gene Technology, made five recommendations on areas where gene technology regulation could be made more efficient, more effective or clearer. This Bill proposes to implement these recommendations.

**Human rights implications**

The proposed amendments are compatible with the right to an adequate standard of living and the right to the enjoyment of the highest attainable standard of physical and mental health as contained in article 11(1) and article 12(1) of the International Covenant on Economic, Social and Cultural Rights.

The proposed amendments are designed to ensure that Australia’s regulation of dealings with genetically modified organisms (GMOs) manages potential risks posed by GMOs so as to protect public health and safety (and the environment). Each of the changes proposed in this Bill improves the operation of the legislation and better enables the achievement of this objective.

**Conclusion**

This Bill is compatible with human rights as it promotes the human right to an adequate standard of living and the highest attainable standard of physical and mental health.

**The Hon Sussan Ley MP, Minister for Health**

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**Notes on clauses**

**Clause 1 - Short title**

This clause provides that the name of the Bill, when enacted, is the *Gene Technology Amendment Act 2015*.

**Clause 2 - Commencement**

This clause provides that the Schedules of the *Gene Technology Amendment Act 2015* which amend the *Gene Technology Act 2000* would commence on a single day fixed by Proclamation, or if no day is fixed within six months of the Act receiving Royal Assent, on the next day after the end of that period. Commencement of the amending provisions is delayed to allow States and Territories time to update their own gene technology legislation, to maintain national consistency of the scheme.

**Clause 3 - Schedule(s)**

This clause provides that each Act specified in a Schedule to the Bill would be amended or repealed as set out in the applicable items in the Schedule concerned, and that any other item in a Schedule to the Bill would have effect according to its terms. The Bill contains a single Schedule which would amend the *Gene Technology Act 2000*.

**Schedule 1 – *Gene Technology Act 2000***

**Part 1 – Reporting requirements**

**Item 1** would amend section 136 (Annual Report) to require that the information previously included in quarterly reports be included in annual reports. Public accountability and transparency of the regulatory system is maintained by public reporting on GMO licences issued, breaches of GMO licence conditions, emergency dealing determinations made, breaches of conditions of emergency dealing determinations and auditing and monitoring of dealings with GMOs by the Gene Technology Regulator (the Regulator).

**Item 2** would repeal requirements that the Regulator prepare quarterly reports and provide them to the responsible Minister, and that the Minister table the reports in the Parliament.

**Item 3** (transitional provision) would require that if the Regulator has provided a quarterly report to the Minister and that report has not yet been tabled in Parliament at the time this item commences, the Minister must table the report within 15 sitting days of receiving the report.

**Part 2 - Inadvertent dealings**

The inadvertent dealings provisions of the *Gene Technology Act 2000* allow the Regulator to promptly authorise the disposal of a GMO which has inadvertently come into someone’s possession. Part 2 serves to remove doubt as to the dealings which may be authorised for purposes relating to disposing of a GMO.

**Item 4** would make this amendment at paragraph 46A(a), which relates to initial consideration of Dealings Not involving Intentional Release (DNIR) licence applications.

**Item 5** would make this amendment at paragraph 49(a), which relates to initial consideration of Dealings involving Intentional Release (DIR) licence applications.

If a person or organisation believes that they may have inadvertently come in to the possession of a GMO, confirming whether the organism is a GMO requires sampling and performing tests. These activities would fall under the dealing described as ‘conducting experiments with the GMO’. Testing is considered to be an activity related to disposing of a GMO, as organisms confirmed to be GMOs would then be disposed of. While some individuals or organisations may choose to dispose of material on the basis of a suspicion that it is a GMO and without confirming whether it is a GMO or not, if material is otherwise valuable and is confirmed not to be a GMO it would not need to be disposed of.

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. This situation may apply where organisms are suspected to be GMOs or are already known to be GMOs. As an example of the latter, if broad, generic tests were used to confirm that an organism is a GMO, further testing would be necessary to determine the specific identity of the GMO. Identification of the genetic modification would facilitate managing any risks posed by the GMO and aid in tracing the origin of the GMO.

Transporting 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.

**Item 6** (application) would require that the amended provisions apply to inadvertent dealings applications made to the Regulator but not decided at the time of commencement, and to inadvertent dealings applications made on or after commencement.

**Part 3 – Public notification of risk assessment etc.**

The Regulator is required to consult the public on risk assessment and risk management plans prepared for DIR licence application assessments. Consultation notices must be published in a newspaper, in the Australian Government Gazette and on the Regulator’s website. **Item 7** would remove the requirement that the chosen newspaper circulate generally in all states, instead allowing the Regulator to decide the most appropriate newspaper(s) given the geographic area in which the dealings proposed to be authorised by the licence may occur. This discretion would allow the Regulator to tailor newspaper notices to best reach interested members of the public, for example through a rural newspaper for a release proposed to occur in a rural area. Email and web-based notifications from the Regulator are known to generate the vast majority of submissions on consultations, so more targeted use of newspaper notices is a cost-effective measure for engaging interested members of the public who may not have access to the internet or email.

**Item 8** would omit the words ‘(if any)’ from paragraph 52(1)(c) to clarify that the Regulator does have a website, on which notices must be published.

**Part 4 – GM Products**

Part 4 would remove the requirement that the Regulator maintain a record of GM product approvals made by other agencies, retaining the requirement to record the Regulator’s own approvals for dealings with GMOs.

**Items 9-16** would amend references to the Record of GMO and GM Product Dealings (the GMO Record), or descriptions of its contents, to remove references to GM products.

**Item 17** would remove the requirement that the GMO Record include information about GM product approvals by other regulatory agencies. Information about GM product approvals 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).

**Item 18** would remove the requirement that information about GM products be entered on the GMO Record as soon as practicable, and would include that information about emergency dealing determinations be entered as soon as practicable. The latter was an apparent oversight when amendments were made to introduce emergency dealing determination provisions.

**Item 19** (transitional provision) would provide that the Regulator may remove all historical information about GM products from the GMO Record.

**Part 5 – Restrictions on licence variations**

The Regulator is restricted in how licences can be varied. This is so that variations cannot be used to extend the coverage of licences unreasonably. **Item 20** would modify one of these restrictions to broaden the information which may be taken into account by the Regulator when assessing variation applications from licence holders.

Previously, the Regulator could only vary a licence if the risk assessment and risk management plan (RARMP) prepared for the original licence application covered the risks posed by the dealings proposed to be authorised by the licence as varied. This ensured that a comprehensive RARMP considered any risks posed by dealings conducted under a varied licence. As the same or similar GMOs and dealings may be subject to more than one application and assessment, Item 20 would allow the Regulator to take into account RARMPs prepared for licence applications (for which licences have been issued) other than the licence to be varied. This would allow licence variations to proceed provided potential risks associated with the dealings are adequately assessed in an existing RARMP, and would avoid some circumstances where applicants would need to seek a new licence.

In considering licence variation applications that utilise risk assessments contained in RARMPs for other licences, the Regulator would consider whether the two licences involve similar GMOs or similar dealings. For example, a limited and controlled plant DIR licence could potentially be varied to include dealings with a GMO of the same parent species carrying another gene or new methods of destroying GMOs, provided that these dealings had been assessed in the RARMP for another licence relating to the same parent species. For DNIRs, licences could potentially be varied to include, for example, *in vivo* experiments with a GMO which is licenced for *in vitro* experiments, provided another RARMP considers *in vivo* dealings with the same GMO or with GMOs from the same parent organism with similar modifications.

Item 20 would also remove an unintended restriction on the Regulator’s ability to initiate licence variations. Amended subsection 71(2B) would apply only to variations which have been applied for, not to variations initiated by the Regulator. This is necessary because if the Regulator becomes aware of risks posed by licenced dealings which are not covered in the original RARMP or any other RARMP, the Regulator would then be able to initiate a variation to manage those risks, to protect the health and safety of people and the environment.

**Item 21** (application) would require that the amended provisions apply to variation applications made to the Regulator but not decided at the time of commencement, and to new variation applications made on or after commencement.

**Part 6 - Technical amendments**

**Item 22** would clarify ambiguous wording of a phrase in paragraph 30(a).

**Item 23** would amend the list of considerations which the Regulator must make before the Governor-General can declare dealings to be Notifiable Low Risk Dealings (NLRDs). The amended considerations would require the Regulator to consider any risks to the health and safety of people and the environment and, if there is any risk, whether generic NLRD requirements prescribed under subsection 75(2) would be sufficient to manage that risk.