Australian Academy of Science

SUBMISSION TO THE

SENATE COMMUNITY AFFAIRS LEGISLATION COMMITTEE INQUIRY INTO THE GENE TECHNOLOGY AMENDMENT BILL 2015

FROM THE AUSTRALIAN ACADEMY OF SCIENCE / JULY 2015

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ABOUT THE AUSTRALIAN ACADEMY OF SCIENCE

The Australian Academy of Science promotes scientific excellence, disseminates scientific knowledge, promotes international engagement, and provides independent scientific advice for the benefit of Australia and the world. The Academy is made up of over 500 of Australia's leading scientists, each elected for their outstanding contribution to science. The Academy welcomes the opportunity to provide a submission to the Senate Community Affairs Legislation Committee inquiry into the *Gene Technology Amendment Bill 2015* and would be pleased to provide further information or explanation on any of the points made in this submission.

SUMMARY OF THE PROPOSED LEGISLATIVE CHANGES

The *Gene Technology Act 2000* (the Act) underpins the Australian Government's component of the national gene technology regulatory scheme. 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 i(n 2011 on behalf of the Legislative and Governance Forum on Gene Technology (LGFGT), previously known as the Gene Technology Ministerial Council, found that the Act is working well and the Office of the Gene Technology Regulator (OGTR) is providing a rigorous, highly transparent regulatory system.

The LGFGT subsequently agreed to 14 of the 16 review recommendations to improve the operation of the gene technology regulatory system. Five of these recommendations proposed minor and technical amendments to the Act to make gene technology regulation more efficient, more effective or clearer.

To implement these recommendations the *Gene Technology Amendment Bill 2015* proposes number of changes which have been agreed by all jurisdictions to:

1. improve efficiency of reporting and public notifications;
2. provide greater flexibility for licence-holders through licence variations; and
3. improve efficiency, effectiveness and clarity of the Act.

ASSESSMENT OF PROPOSED CHANGES

discontinuing quarterly reporting to the Minister (Part 1 of Schedule 1 of the Bill)

The proposed changes to **subsection 136(1)** enable the Gene Technology Regulator (the Regulator) and the responsible Minister to implement an orderly transition from a quarterly to an annual reporting cycle to Parliament. This represent a significant reduction to the administrative overheads of the regulatory scheme without compromising the transparency and accountability of the regulatory system, as the Regulator's public reporting obligations remain unchanged.

clarifying which dealings may be authorised by inadvertent dealings licences (Part 2 of Schedule 1 of the Bill);

The proposed changes to **paragraphs 46A(a)** and **49(a)** to clarify the types of dealings with GMOs that can be authorised to enable the disposal of a GMO that has inadvertently come into someone's possession are valuable. These now include provisions to authorise a range of activities that may be necessary to check whether the organism suspected to be a GMO is in fact genetically modified and/or the exact nature of the modification(s).

updating advertising requirements for public consultations (Part 3 of Schedule 1 of the Bill);

Experience with the operation of the regulatory system has confirmed that the majority of responses to public consultations on licence applications for Dealings involving Intentional Release (DIR) are submitted in response to web-based notifications and emails to individuals who have subscribed to the OGTR Client Register (hard copy via post is also available).

The proposed changes to **paragraph 52(1)(b)** to provide the Regulator with more flexibility in print media advertising, and to select publications that are most likely to reach people in geographic area(s) where a release is proposed to occur, will improve the efficiency, accountability and cost effectiveness of the regulatory system.

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);

The inclusion of a requirement in the Act for the Regulator to maintain a Record of GMO and GM Product Dealings (the GMO Record) was intended to provide a 'one stop shop' where information about all development, trialling and approval for use of GMOs in Australia was collated. However, including information on GM product approvals by other agencies represents considerable practical difficulties and unnecessary duplication.

The multiple proposed amendments to require the inclusion of only the Regulator's own approvals on the GMO Record represent a pragmatic solution. The correction to require information about emergency dealing determinations to be entered as soon as practicable is supported.

changing licence variation requirements to provide greater flexibility for licence-holders (Part 5 of Schedule 1 of the Bill);

Experience with the operation of the regulatory system has led to the accumulation of substantial information and practical experience with dealings with certain organisms and genetic modifications. Accordingly, the proposed changes to **subsection 71(2B)** to enable the Regulator to take into account the assessment of another licence application when considering an application to vary a licence in some instances are justified, and represent an appropriate potential for reduction of the regulatory burden.

The removal of the unintended constraint on the Regulator's ability to initiate licence variations to enable newly identified risks to be managed is strongly supported.

clarifying ambiguous wording (Part 6 of Schedule 1 of the Bill);

This minor technical amendment to **paragraph 30(a)** provides a useful clarification

updating the considerations required before dealings may be scheduled as notifiable low risk dealings (Part 6 of Schedule 1 of the Bill).

The proposed changes to **subsection 74(3)** provide enhanced specificity regarding matters that the Regulator should take into account regarding the declaration of a dealing with a GMO to be a low risk dealing, and creates an appropriate link to **subsection 75(2)** regarding the management of any identified risk.

SUMMARY COMMENTS

The changes proposed to *the Gene Technology Act 2000* by the *Gene Technology Amendment Bill 2015* are conservative and justified on the basis of the OGTR's accumulated experience of implementing Australia's system for the regulation of dealings with GMOs.

The Academy concurs with the Explanatory Memorandum's assertion that the changes, if approved, would improve the Act's operation without changing the underlying policy intent or overall legislative framework of the regulatory scheme.