Australian Government
Department of Health
Office of the Gene Technology Regulator

Committee Secretary
Standing Committee on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Ms Radcliffe,

Thank you for the opportunity to provide input to the Community Affairs Legislation Committee inquiry into the Gene Technology Amendment Bill 2015 (the Bill).

As the Gene Technology Regulator I administer the national regulatory scheme for genetically modified organisms, which is underpinned by the Commonwealth *Gene Technology Act 2000* (the Act). My submission is made from this perspective. I support the minor and technical amendments proposed in the Bill. I consider that the amendments would clarify and enhance the operation and administration of the Act and support achieving its object "to protect human health and safety, and the environment, from risks posed by or as a result of gene technology, by managing those risks through regulating certain dealings with genetically modified organisms". The amendments would not alter the policy settings of the regulatory scheme.

These amendments would implement minor and technical recommendations from an independent review of the Act conducted in 2011 for the Legislative and Governance Forum on Gene Technology (LGFGT), which were agreed by the Commonwealth and states and territories in 2013. The LGFGT has also agreed the proposed amendments. The former Gene Technology Regulator's submission to the 2011 review raised these issues, amongst others, for consideration.

I have attached additional material to supplement the Explanatory Memorandum for the Bill, providing:

- background information on the operation of the national regulatory scheme, and
- further detail on the effect of the provisions of the Bill, focusing on the two issues raised in the proposal to refer the Bill to a Senate committee.

I would be happy to discuss this submission with the Committee or address any questions the Committee has on the operation of the relevant parts of the Act.

Yours sincerely

Dr Robyn Cleland
Acting Gene Technology Regulator
23 July 2015

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

SUBMISSION FROM THE ACTING GENE TECHNOLOGY REGULATOR

Introduction

The national gene technology regulatory scheme
The national scheme for regulating gene technology is comprised of the Commonwealth *Gene Technology Act 2000* (the Act) and corresponding state and territory legislation, and these laws are administered by the Gene Technology Regulator (the Regulator). The national scheme is underpinned by the intergovernmental Gene Technology Agreement and overseen by the Legislative and Governance Forum on Gene Technology (the LGFGT, formerly known as the Gene Technology Ministerial Council, GTMC).

The object of the Act is "to protect human health and safety, and 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".

The independent 2011 review of the Act
Under the Gene Technology Agreement the LGFGT must review of the regulatory scheme every five years. The Act was first reviewed in 2005-6.

In 2011, a second independent review of the Act was conducted (the 2011 Review), which found that the Act is working well and "the [Office of the Gene Technology Regulator] OGTR is operating in an effective and efficient manner". The review also concluded that "current consultation processes in relation to applications under the Act are working well", that "the OGTR is providing a rigorous, highly transparent regulatory system" and that "the regulatory burden and compliance costs appear justifiable compared with the benefits achieved".

Further details of the 2011 Review and the LGFGT response can be found on the Department of Health website at http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-techact-review.

Overview of the proposed amendments
The Gene Technology Amendment Bill 2015 (the Bill) would implement five minor and technical recommendations of the 2011 Review, as agreed by the LGFGT in 2013. The issues addressed in the Bill are restricted to minor and technical matters which do not alter the policy settings of the regulatory scheme. The amendments aim to improve clarity of the legislation and increase efficiency and effectiveness of the regulatory scheme.

The Explanatory Memorandum for the Bill outlines the functioning of specific clauses, and the reasoning for each part of the amendments is given in greater detail below.

Part 1 - Reporting requirements

The Act currently requires that the Regulator provide a quarterly report to the Minister for tabling in Parliament, and prescribes a list of information which must be included in the report. The 2011 Review observed that while quarterly reporting was considered necessary at the commencement of the regulatory scheme, there is now sufficient experience with operation of the scheme that reporting annually is more appropriate.

To maintain openness and transparency, the amendments would require the Regulator's annual report to address the same topics currently addressed in quarterly reports.

Part 2 - Inadvertent Dealings

The Regulator can issue an 'inadvertent dealings licence' if a person inadvertently comes into possession of an unlicensed GMO, to authorise disposal of the GMO. Any dealings with an unlicensed GMO, including disposal, are prohibited under the GT Act. Inadvertent dealings licences can avoid situations where people might be prosecuted when they had no intention of breaking the law.

The amendments would elaborate on what activities with GMOs may be permitted by inadvertent dealings licences to provide greater clarity. For example, the amendments would make clear that transporting the GMO to a laboratory to confirm the identity of a suspected GMO would be allowed.

Further detail on the operation of this amendment is in the Explanatory Memorandum.

Part 3 – Public notification of risk assessment and risk management plans

Wide public consultation on DIR application assessments would still occur under the amendment, including through newspaper advertisements, with the Regulator being given the discretion to better target newspaper advertising to potentially interested communities. This is particularly relevant to small scale field trial releases which occur for a limited duration in specified locations.

At the commencement of the scheme in 2001 national newspaper notices were considered the most cost-effective way to broadly consult the community on applications to release GMOs into the environment. The rise of electronic communication since then has led to the majority of public submissions coming as a result of notices on the OGTR website and direct letters and emails to OGTR's client register.

The Act currently requires that consultations be notified in the Gazette, on the OGTR website and in a national newspaper. This amendment would allow the Regulator the discretion to decide which newspapers to place notices in, having regard to the geographic area in which the dealings proposed to be authorised by the licence may occur.

Part 4 – Genetically Modified (GM) Products

This amendment would remove the requirement that the Regulator maintain a record of GM products (non-viable products derived from GMOs) approved by other agencies. The OGTR's operational experience over almost 15 years indicates that the public is most interested in releases of GMOs into the Australian environment, and in GM food approvals. The Regulator's approvals of GMOs will still be published on the OGTR website. A comprehensive list of approved GM foods is published on the Food Standards Australia New Zealand website.

Information about veterinary and human therapeutics and industrial and agricultural chemicals that are also GM products can be sought directly from the relevant agencies (the Australian Pesticides and Veterinary Medicines Authority, the Therapeutic Goods Administration, and the National Industrial Chemicals Notification and Assessment Scheme).

Part 5 – Restriction on licence variations

The proposed amendment would improve the Regulator's ability to ensure licence conditions are appropriate to the circumstances, and increase flexibility for variations sought by the Regulator and licence-holders. This amendment was specifically mentioned in Senator McEwen's proposal to refer the Bill to a Senate committee, and so is described in detail below.

Variation of GMO licences
Variation of GMO licences provides a practical mechanism for small changes that do not impact the risk profile of the GMO dealings authorised and that do not necessitate or warrant the full

licence application and assessment process. Amendments to the Act in 2007 implementing recommendations from the 2006 Review made licence variations an application category. Restrictions on the scope of licence variations were also introduced to prevent variations being used to avoid the full assessment and consultation process by extending licence coverage unreasonably.

Licence variations initiated by the Regulator
Licence variation is an important tool for the Regulator to ensure that risk management conditions can be adjusted if necessary, for example in response to new information about risks posed by licensed GMO dealings. This minor amendment would provide clarity and certainty by making explicit that the requirement for risks to have been considered in an existing RARMP relates only to variation applications from the licence holder, not variations initiated by the Regulator.

Licence variations initiated by the licence-holder
This amendment would broaden the range of variations the Regulator may allow on application from licence-holders while ensuring that the appropriate level of risk assessment continues to be undertaken for licence variations. The amendment would allow the Regulator to vary licences if the risks from activities with GMOs that would be allowed by the varied licence have been considered in the RARMP for *any* licence, rather than *only* the RARMP for the licence in question.

This amendment would increase the ability of licence-holders to vary GMO licences, because the same or similar GMO dealings can be subject to more than one application and assessment. This would avoid some circumstances where applicants would need to seek a new licence so as to authorise GMO dealings for which a full risk assessment has already been carried out.

This amendment would ensure continued transparency of the information underpinning variations sought by licence-holders to environmental release licences (DIR licences, eg GMO field trials and commercial releases). Finalised RARMPs and licence conditions for all DIR licences are publicly available on the OGTR website. Thus, under the amendment, all risk assessments which inform the consideration of DIR licence variation applications will continue to have previously undergone public consultation and be publicly available.

Part 6 – Technical amendments

Factors that must be considered before the Governor-General declares dealings to be Notifiable Low Risk Dealings (NLRDs)

The proposed amendment to NLRD considerations was specifically mentioned in Senator McEwen's proposal to refer the Bill to a Senate committee, and for this reason this Part of the Bill and the notion of 'biological containment' is described in detail below. The proposed amendment would update the scientific matters that must be considered before GMO dealings can be declared to be NLRDs in the regulations, to bring them up to date with current scientific understanding.

Notifiable Low Risk Dealings
NLRDs are a category of low-risk GMO dealings undertaken with standard conditions and containment and which may be conducted with notification to the Regulator, rather than under a licence from the Regulator. GMO dealings may be declared NLRDs provided they are assessed to pose low risk after certain considerations are made. This Bill would amend the required considerations to bring them up to date with current scientific knowledge and enable evidence and experience of safety to be better taken into account. The Regulator would still need to be

satisfied that any risks to human health and safety and the environment posed by NLRDs could be managed by standard NLRD requirements.

Subsection 74(3) of the Act sets out the considerations that the Regulator must take into account before the Governor-General makes regulations declaring a dealing with a GMO to be a NLRD. Essentially, these are scientific considerations forming the basis of an assessment of whether a dealing is 'low risk' for the purposes of the regulatory scheme.

'Whether the GMO is biologically contained'
A current consideration is "whether the GMO is biologically contained so that it is not able to survive or reproduce without human intervention". It should be noted that 'biological containment' is not a requirement in order for GMO dealings to be declared NLRDs, rather this is simply a consideration to be taken into account in assessing whether particular GMO dealings are appropriate for the NLRD category. Indeed, GMOs that are not biologically contained form a significant portion of the dealings scheduled as NLRDs, and include dealings with a range of GM animals and GM plants

The proposed amendment
This amendment would remove consideration of whether the GMO is biologically contained as this notion does not contribute significantly to assessments of whether dealings are appropriate for the NLRD category.

Current items (b) and (c) of subsection 74(3) relate to whether the dealing with the GMO would pose a risk, and whether that risk can be appropriately managed. The proposed amendment would re-frame these considerations to:

- emphasise identifying *any* risk, rather than determining whether the dealings involve *minimal* risk to human health and safety and the environment
- explicitly invoke requirements for conduct of NLRDs prescribed in subsection 75(2), which includes the appropriate containment level, for determining whether any risk can be sufficiently managed
- remove the undefined terms 'minimal risk' and 'minimal conditions'
- make explicit that the Regulator may consider any other appropriate matter.

This re-framing of the considerations would provide more definitive language which aligns with current scientific understanding of risk assessment and risk management of GMOs. In this way, the amendment would provide greater clarity and specificity about the matters the Regulator must consider.

Operation of the amendment
The proposed technical amendment would change how future proposals to reclassify particular GMO dealings as NLRDs would be considered. It would enable the risk assessment case to be made more clearly by regulated stakeholders, and ultimately help to ensure that regulatory burden is commensurate with risk. It would not alter the risk profile of NLRDs or the requirement that NLRDs not involve intentional release of the GMO to the environment.

The amendment would not change the classification of any GMO dealings, and would not change the process for making of regulations declaring GMO dealings to be NLRDs (including tabling in, and potential disallowance by, Parliament).