LA TROBE UNIVERSITY

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21st February 2018

Dr Raj Bhula
Gene Technology Regulator
Regulations Review
Office of the Gene Technology Regulator
GPO Box 9848
Canberra ACT 2601

Re: Updating Gene Technology Regulation in Australia

Dear Dr Bhula,

The La Trobe Institutional Biosafety Committee (LTIBC) appreciates the opportunity to provide this submission in response to the Regulation Impact Statement for Updating Gene Technology Regulation in Australia.

The LTIBC values input into Australia's gene technology regulatory system and is committed to providing appropriate governance and oversight to biosafety across the University's teaching, research and development portfolio. The Committee strongly supports a regulatory system that is science based and commensurate to risk.

The LTIBC commends you on your leadership in proposing greater clarity around the regulation of New Breeding Technologies (NBTs) as well as other aspects of the regulations. We understand that there are limitations to the changes that can be proposed under the current policy framework and hope that in the event of changes to the framework, further amendments can be proposed for expeditious implementation.

Yours Sincerely,

Dr Carl Ramage
Chair, La Trobe Institutional Biosafety Committee
Ethics and Integrity, Research Office
La Trobe University

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La Trobe Institutional Biosafety Committee Submission

Introduction

La Trobe University has a fine history as an excellent university with an enduring social conscience. As part of our 'Future Ready' strategy, our plan is to grow and develop La Trobe's traditional leadership in areas of research, scholarship and learning that matter to the Australian community. Having taken a detailed investigation of our capabilities and strengths, we have identified five Research Focus Areas (RFAs) and seven Disciplinary Research Programs (DRPs). La Trobe University's RFAs are:

- Securing food, water and the environment
- Sport exercise and rehabilitation
- Understanding disease
- Building healthy communities
- Transforming human societies.

La Trobe University conducts research using gene technology and potentially harmful biological material in a safe, secure, ethical and environmentally responsible framework. This framework helps us meet the needs of national legislative schemes and the Australian community.

At La Trobe University, all activities involving hazardous biological materials and genetically modified organisms (GMOs) or gene technologies must be assessed and approved by the LTIBC. LTIBC must apply a set of principles as outlined in the Australian Standard for Microbiological Safety in Laboratories AS/NZS 2243.3:2010, the *Gene Technology Act 2000* (the *'Act'*)and *Gene Technology Regulations 2001* and any amendments that govern biosafety, biosecurity, the classification of dealings with GMOs, the containment of hazardous biological materials and dealings with GMOs and the conduct of people whose work involves hazardous biological materials, recombinant DNA or gene technology. Activities involving hazardous biological materials, GMOs or gene technologies must not commence prior to the receipt of written approval by the LTIBC. The LTIBC assesses activities to ensure that any real or potential hazards concerning biological materials and dealings with GMOs are identified and managed appropriately, research environments conform to internal and OGTR certification rules and informs the OGTR of relevant dealings with GMOs at La Trobe University.

The LTIBC welcomes this opportunity to respond and comment on the *Regulation Impact Statement for Consultation: Updating Gene Technology Regulation in Australia.*

LTIBC Response to Consultation Questions

1. **What is your preferred Option? Please explain why.**

The LTIBC supports **Option 2** that proposes to amend the Gene Technology Regulations (GT Regulations) by introducing all elements of the draft amendments, as detailed in full in Section 3 of the Consultation Regulation Impact Statement.

It is the view of the LTIBC that whilst there is more to be done to amend the GT Regulations to allow for current and future changes and advances in science, to do nothing (**Option 1**), will only serve to further confuse the regulated community and is not consistent with a science/risk-based

regulatory system. The LTIBC recognises that many of the proposed changes aim to provide clarity, particularly for IBCs and therefore support all of the changes.

The LTIBC understands that the Regulator is limited in the amendments that can be undertaken within the current policy framework. As such we support the amendments that have been put forward as an interim measure for further changes in line with an updated policy framework.

There is a need for a system that is flexible, agile and able to keep pace with rapid changes in technology. This must be done in line with the principle that the Gene Technology Policy is science based and that GT Regulations are commensurate to risk.

2. **Do the draft amendments clearly implement the measures described in Section 3 of the Consultation RIS? If not, which areas of the draft amendments do you think require additional clarification, and what clarification is needed?**

The LTIBC believes that the proposed amendments largely implement the measures described in Section 3 of the Regulation Impact Statement for Consultation. However, as put forward in our earlier submission, we believe that the proposed changes around NBTs does not go far enough. The GT Regulations should also allow SDN-2 and ODM not to be regulated as GMOs. The regulation of these techniques imposes unnecessary regulation on techniques that are functionally equivalent to other mutagenesis techniques, including the proposed changes that allow for SDN-1 to be considered a technique that is not gene technology. How can the LTIBC differentiate between a product that is developed using SDN-1 from one developed using SDN-2 or ODM?

Additionally, the term SDN-1 is not defined in the proposed GT Regulations as a technique that is not gene technology (Schedule 1A). Given there are a number of techniques/technologies currently available and potentially available in the future that don't specifically rely on Site Directed Nucleases, there is perhaps a need for some clarification/definition of what is not considered gene technology. The term SDN-1 refers to the use of Site Directed Nucleases. Should the GT Regulations consider any technique that creates a targeted or non-targeted DNA break, whereby the DNA is repaired through the same mechanism as repair of 'natural' DNA breaks, not gene technology? The LTIBC suggests that for the avoidance of doubt, a definition be included in the revised Schedule 1A.

3. **If your preferred option is Option 3, please indicate which amendments (or parts thereof) you support being progressed and why.**

N/A

4. **What are the costs and benefits to you or your organisation from the proposed amendments? Please describe these compared to current arrangements, for each area of amendment:**

4.1 Clarifying the GT Regulations to take technological developments into account (i.e. in relation to SDN-1, SDN-2, ODM and RNAi)

The proposed changes will require the LTIBC to undertake a review of all current approvals to ensure that they are appropriately classified. The Committee will also need to undertake consultation with stakeholders to gain clarity around their use of gene editing and RNAi so that we can provide appropriate guidance and support to ensure compliance with the proposed changes.

4.2 Repeal of Schedule 1 item 1, specifically whether you currently work with organisms that are not GMOs solely because of this item

The LTIBC would prefer that the Regulator maintain Schedule 1 Item 1. This item is the only one that specifically addresses mutagenic techniques that have a long history of safe use. The removal of this item may lead to greater confusion than currently exists. The proposed addition of Item 4 provides some context to Item 1.

4.3 Updating the categorisation of contained dealings with GMOs

The LTIBC supports the proposed amendments to require a DNIR licence for gene drives. The case-by-case evaluation of risks is an important aspect of our regulatory system.

4.4 Clarifying the regulatory status of organisms derived from GMOs that are not themselves GMOs minor administrative changes.

The LTIBC supports this clarification, however there may still be some confusion. It is clear how this relates to traditional GMOs and gene cassettes designed to confer a specific trait (e.g. herbicide tolerance). The proposed Schedule 1, Item 8 clarifies this whereby an organism that has '....not inherited any traits that occurred in the initial organism because of gene technology' would not be considered a GMO.

How would this proposed change relate to products derived from gene editing? The term trait is often associated with a gene and a gene product. However, some gene edits may involve changes to non-coding regions. For the avoidance of doubt this should be clarified further.

5. **Are the proposals to change the classification of certain NLRDs and exempt dealings (identified in Appendix B of the Consultation RIS) commensurate with any risks to the health and safety of people and the environment posed by the dealings?**

The LTIBC supports the proposed change to the classification of certain NLRDs and exempt dealings identified in Appendix B. However, the LTIBC is of the view that organisms modified by SDN-2 and ODM should not be classified as GMOs. Further, dealings with some GM mouse models should be considered Exempt. Some of the NLRD PC1 requirements seem to not be

commensurate to risk and impose unnecessary infrastructure requirements on Accredited Organisations.

6. **Are there any features in the options presented that you have concerns with? Or, are there any particular features that you believe should be included? Please explain why and give substantiating evidence where possible.**

The LTIBC notes that in Schedule 1, reference is given to NoGall and Vaxsafe PM. Both of these are trade names and should not be listed in the GT Regulations. The strains listed should be sufficient.

The LTIBC also notes that other suggested changes proposed in our previous submission have not been addressed. The LTIBC understands that these will require an amendment to the policy framework and may be considered in the 2017 Review of the National Gene Technology Scheme. This includes, for example, allowing IBCs greater powers and flexibility in the management of containment facility certification. The suspension and reinstatement of Physical Containment (PC) certification is largely an administrative process for the OGTR with on the ground oversight already provided by IBCs. Amendments to PC certification is an unnecessary burden on the OGTR and risks significant delays to research and business continuity at the institutional level. This is further compounded by the promotion of larger and fewer certification areas that limits future flexibility in the PC certification composition of an area, without research impost. Currently, this is largely managed through lab processes such as spatial and temporal separation of GM and non-GM activities.

The LTIBC advocates greater responsibility for IBCs to manage the suspension and reinstatement of PC certification.

Impact on La Trobe University

The proposed changes will have a moderate impact on the LTIBC and the stakeholders we support. Should the proposed changes be ratified, the LTIBC will need to undertake a review of all current approvals and Records of Assessment to ensure that they are in line with the new GT Regulations. Further, the LTIBC will need to consult with stakeholders that utilise gene editing and RNAi as research tools to ensure that they fully understand their obligations with respect to differences in the regulations proposed. In particular, the LTIBC will need to be able to justify to stakeholders why SDN-1 won't be regulated but and other techniques such as SDN-2 and ODM will be.