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24th May 2018

Gene Technology Review
Department of Health
GPO Box 9848
CANBERRA ACT 2601
Gene.technology.review@health.gov.au

Re: The Third Review of the National Gene Technology Scheme (Phase 3)

Dear Review Committee,

The La Trobe Institutional Biosafety Committee (LTIBC) appreciates the opportunity to provide this submission to The Third Review of the National Gene Technology Scheme (the Review).

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 the committee for the comprehensive assessment of the scheme and the findings presented in the Preliminary Report.

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. We continue to support access, diversity and inclusivity while undertaking world- class research that aims to address the global forces shaping our world and make a difference to some of the world's most pressing problems, including climate change, securing food, water and the environment, building healthy communities, and creating a more just and sustainable future

This approach is based on our values of:

- Inclusiveness, diversity, equity and social justice
- Pursuing excellence and sustainability in everything we do
- Championing our local communities in Melbourne's north and regional Victoria
- Being willing to innovate and disrupt the traditional way of doing things.

Our Mission

Advancing knowledge and learning to shape the future of our students and communities.

Our Vision

To promote positive change and address the major issues of our time through being connected, inclusive and excellent.

In line with our strategic plan, the LTIBC welcomes this opportunity to respond and comment on *The Third Review of the Gene Technology Scheme Preliminary Report (March 2018).*

LTIBC Response to Preliminary Report Findings

1. Overarching Findings.

The LTIBC supports the Overarching Findings (1 and 2) and **agree** that the object of 'the Act' remains appropriate and should be maintained. The LTIBC further **agrees** that the Gene Technology Agreement (2001) should be maintained but submits that more should be done to ensure national consistency, particularly in relation to restrictive state and territory government interventions and the duplication of risk assessment data required by multiple agencies (e.g. FSANZ, APVMA and TGA).

2. Review Theme One: Technical Issues.

The LTIBC **agrees** with Finding 3 that the existing definitions in the *Gene Technology Act 2000* and *Gene Technology Regulations 2001* are not aligned with advances in technology. The LTIBC supports consistency in definitions and the consideration of national and international context.

The LTIBC further supports Findings 4, 5 and 7 that synthetic biology and gene drives are within the scope of the Scheme and that the regulation of humans is not.

The LTIBC **does not agree** with Finding 6 that suggests additional regulatory burden for the broader environmental release of GMOs is needed. The current case-by-case assessment of GMOs for intentional release into the environment is comprehensive and has worked well. The pretext that a GM biological control agent presents greater risk than some current practices is not in keeping with the science/risk based nature of the Scheme. It is the view of the LTIBC that the assessments undertaken in the current Scheme are appropriate.

3. Review Theme Two: Regulatory Issues

The LTIBC **does not agree** with Finding 8 that a 'process trigger' remains the most appropriate or effective entry point for regulation under the Scheme. The LTIBC does not consider a process-based trigger to be sustainable. Regulation must be risk based, backed by scientific rigour, and not generalist in application. With the advent of many techniques and processes that could deliver essentially the same 'product' there will inevitably be an increase in regulatory discrepancies. As such, this review offers an opportunity to reassess the current definitions. The LTIBC suggests that definitions be considered that examine the risk/characteristics of the 'end-product' rather than the process by which it was generated. Further, the definitions should clarify what modifications would require assessment and approval (e.g. modifications that impact allergenicity, toxicity, spread and pathogenicity). Other changes that have a history of safe use should not require such assessment.

It should be acknowledged that the current Scheme largely considers risk to human health and the environment through case-by-case assessment of the GM product (i.e. biology of the host organism and the outcomes from genetic modification). Assessment of the 'process' itself is not a significant component of the evaluation. Further, certain products were excluded from regulation based on a history of safe use.

The introduction of 'new pieces of DNA' should not in itself imply that a product poses additional risk to human health or the environment. In fact, there are multiple technologies and approaches available that can lead to products with the same trait. For example, crop herbicide tolerance can be achieved via plant cell or tissue culture and other traditional plant breeding techniques, chemical/radiation-mediated mutagenesis breeding, transformation of a plant with either native or

mutant resistant genes (i.e. transgenesis, cicgenesis or intragenesis) and more recently gene editing. Currently, the use of some of these breeding techniques in the development of new and improved herbicide tolerance varieties are excluded from assessment and approval on the basis of a demonstrated history of safe use.

La Trobe University recognises many of the products that have been assessed and approved by the Regulator could now be considered as having a history of safe use. However, La Trobe University does not support a system that would undermine the scientific credibility of the regulatory system when similar products are subject to vastly disparate regulatory requirements. The end-product of a process is the key consideration in risk-determination, therefore it is inconsistent and illogical to have such contrasting regulations associated with processes generating the same output. Over time, it is likely that a process-based regulatory system will become increasingly discredited[1].

The LTIBC agrees with Findings 9–15 and recognises that the current approach to assess risk to human health and the environment has worked very well over the past 18 years and endorses the need to increase the efficiency and effectiveness of the Scheme.

The LTIBC supports opportunities to streamline regulatory requirements and has through previous submissions sought providing 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 instruments is an unnecessary burden on the OGTR and risks significant delays to research and business continuity at the institutional level.

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

4. Review Theme Three: Governance Issues

The LTIBC agrees with Findings 16 and 17, particularly that the Scheme has shown to be credible and that it operates with a high level of integrity and legitimacy. The LTIBC believes that Accredited Organisations and their Institutional Biosafety Committees have made a significant contribution to this by providing supportive guidance and oversight of those undertaking Dealings under the Scheme.

The National IBC Forum provides a great opportunity for IBCs to share information and experiences and discuss their roles and challenges with adhering to the Scheme. It also provides an important opportunity to meet with the Regulator and members of the Office of the Gene Technology Regulator.

The LTIBC **does not support** Finding 18 that there is a lack of evidence on the impacts of state and territory moratoria legislation. Several published reports provide evidence of the negative impact

[1] Morris and Spoillane (2008). GM directive deficiencies in the European Union. EmBO Rep 2008; 9:500-4; PMID:18516083; http://dx.doi.org/10.1038/embor.2008.94

that the legislation has had to agriculture in Australia[2][3][4][5][6][7]. The LTIBC **agree** that the focus of moratoria legislation extends beyond market and trade (Finding 19) and is used to promote and agenda which is both political and ideological and which appears to have a detrimental effect on the agriculture sector[7].

The LTIBC further **agrees** with Findings 20 and 21 that the Scheme should remain risk based, backed by scientific rigour and not influenced by the inclusion of economic, environment or health benefits that could significantly undermine the effectiveness of the Scheme.

The LTIBC **does not agree** with Findings 22 or 23. To date, the Legislative and Governance Forum (the Forum) has been ineffective in ensuring Australia has a Scheme that remains agile and able to keep pace with rapid changes in technology and opportunity. The Forum has failed to fully implement recommendations from previous reviews of the Scheme. This undermines the credibility of the Scheme and shows a lack of engagement with key stakeholders that play an important role in the Scheme (i.e. the OGTR, Accredited Organisations, Institutional Biosafety Committees and peak industry groups). Further, the policy principle (s21(1)(aa) in the *Gene Technology Act 2000*) that has allowed for moratoria in some states and territories is a failure to adhere to the underlying principle of the national Scheme, to protect human health and the environment.

The LTIBC **cautions the wider use** of Policy Principles that have the potential to stifle innovation and investment in Australia. This would have a detrimental effect to education and research sectors that already face the challenge of and struggle to keep pace with global competition.

The LTIBC **supports and agrees** with Findings 24 to 28. In particular, there is a need to clarify the roles and responsibilities of agencies where there is overlap in regulatory oversight and identify potential gaps. Consistency is required and the LTIBC supports consideration of mechanisms from other schemes which offer a pragmatic approach to maintaining the integrity of the Scheme.

5. Review Theme Four: Social and Ethical Issues

Communication is essential in order to foster trust and provide transparency to the Scheme. The LTIBC commends the OGTR for their efforts in being open, accessible and transparent in their process. The LTIBC supports ongoing communication efforts and agrees with efforts to increase the public awareness and understanding of the Scheme (Findings 29 and 30).

La Trobe University recognises the diversity of views across Australia regarding the value and risks associated with the application of gene technology (Finding 31). As such, the university supports initiatives that increase the public awareness and understanding of the Scheme. The emphasis of these initiatives must reinforce the independent, robust, case-by-case, risk-based nature of the

[2] Smyth SJ, Falck-Zepeda J, Ludlow K (2016). The Costs of Regulatory Delays for Genetically Modified Crops. Journal of International Law and Trade Policy 17:173-195

[3] Biden S, Smyth SJ & Hudson D. (2018). The economic and environmental cost of delayed GM crop adoption: The case of Australia's GM canola moratorium. GM Crops & Food, 9:1,13-20.

[4] Smyth, SJ (2017) *Genetically Modified Crops, Regulatory Delays, and International Trade*. Food and Energy Security 6:78-86.

[5] Whitelaw A (2016) 'Is the GM ban in South Australia providing a premium?'. Mercado Expert Market Analysis: 25 July 2016; and Whitelaw A (2017) 'Controversial canola'. Mercado Expert Analysis: May 25 2017.

[6] Whitelaw A, Dalgleish M and Agar O (2018). 'Analysis of price premiums under the South Australian GM moratorium'. Mercardo Expert Market Analysis, March 2018

[7] Productivity Commission 2016, Regulation of Australian Agriculture, Report no. 79, Canberra.

Scheme, such that the public gain confidence in the Scheme and the role of the regulated community.

La Trobe University takes its role as an Accredited Organisation seriously and is committed to the health and safety of its staff and students, the community and the environment. All personnel who intend to conduct research or teaching projects that involve the use of biological material must consider the risks associated with the work and, where applicable, seek guidance and approval from the LTIBC. This commitment is set out in the La Trobe Biosafety and Biosecurity Policy, a pledge to providing governance and oversight in managing the actual and potential biosafety and/or biosecurity risks associated with the University's biological research and teaching activities. Specifically:

a. ensure the health and safety of university personnel, the community and the environment;

b. promote best practices in research and teaching;

c. ensure adherence and compliance with the principles of research integrity, relevant biosafety and biosecurity legislation, and other regulatory requirements.

The LTIBC contends that Finding 31 is an observation rather than a Finding as set out within the Terms of Reference of this review. The LTIBC acknowledges the concerns of some sections of the community (Finding 31), but reiterates the track record of nearly 20 years of regulation and the ongoing commitment of the Regulated community to ensuring the health and safety of people and the environment.

The LTIBC **supports** the role of Australia's agriculture and biomedical industries and their associated supply chains in the role they already play in post-release monitoring and review and **does not support** increased oversight or surveillance by the Gene Technology Regulator (Finding 32). Such efforts are likely to have detrimental effects to industry sectors such as Agriculture[8] and a duplication of monitoring already undertaken and required for food, clinical trials and therapeutic goods.

The LTIBC supports and **agrees** that the Gene Technology Regulator provides a high level of transparency and access to information (Finding 33). However, the LTIBC **cautions** that there is a need to balance the provision of information to maintain regulatory transparency and the protection of individual or organisational private information and/or intellectual property rights given the products of gene technology have often required significant investment and represent highly novel outcomes.

[8] Productivity Commission 2016, Regulation of Australian Agriculture, Report no. 79, Canberra.