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29th November 2019

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

Re: Implementing Recommendations of the Third Review of the National Gene Technology Scheme: Phase1

Dear Implementation Secretariat,

The La Trobe Institutional Biosafety Committee (LTIBC) appreciates the opportunity to provide this submission to *The Issues Paper: Implementing Recommendations of The Third Review of the National Gene Technology Scheme: Phase 1*.

La Trobe University is accredited by the Office of the Gene Technology Regulator (OGTR) for the purposes of undertaking activities that use gene technology. At La Trobe University, all activities involving potentially hazardous biological materials or gene technologies must be assessed and approved by the La Trobe Institutional Biosafety Committee. The core role of the LTIBC is to ensure that personnel, projects and facilities used for the purposes of gene technology fulfil the requirements set out in the *Gene Technology Regulations 2001*.

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 the case-by-case, science/risk based National Gene Technology Scheme and appreciated input into the reviews of the Scheme, including the Technical Review undertaken by the OGTR. However, the Committee is concerned that, to date, the Legislative and Governance 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. That coupled with a protracted process of implementing recommendations from the Third Review does not provide confidence in the review process and undermines the credibility of the Scheme. Further, it shows a lack of recognition of the efforts already made by key stakeholders that provided significant input into the review of Scheme.

The LTIBC offers feedback on the questions posed in *The Issues Paper*. Should you require any clarification of our position or our dealings involving gene technology, then please don't hesitate in contacting me.

Yours Sincerely,

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

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 Issues Paper: Implementing Recommendations of The Third Review of the National Gene Technology Scheme: Phase 1 (The Issues Paper).*

LTIBC Response to Questions Posed in the Issues Paper

Part 1: Definitions to support the National Gene Technology Scheme

Question 1:

What other objectives might guide the updating of definitions?

The LTIBC supports the objectives that were outlined in *The Issues Paper*, but notes the following:

- Having the right definition is pivotal as it is the 'trigger' for regulatory oversight. As such, the definition must allow the Scheme to be agile and able to keep pace with changes in technology as well as consider evidence that points to an increase or decrease in risk of gene technology to human health and the environment
- The LTIBC has previously suggested 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
- In previous submissions, the LTIBC noted that the Scheme should not undermine scientific credibility when similar products may be subject to vastly disparate regulatory requirements (e.g. some products generated using New Breeding Technologies vs processes listed in Schedule 1). The end-product of a process is the key consideration in risk-determination; therefore, it is inconsistent and illogical to have such contrasting regulations based on a process generating the same output/outcome. The current definition focuses on the process of gene technology as the trigger for regulation under the Scheme. Over time, it is likely that a process-based regulatory system will become increasingly discredited[1]
- 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 definition should take into account the more than 20 years of biosafety and provide the Regulator greater flexibility in application of the Regulations
- Any changes to the definition must lead an alignment with other regulations (e.g. Food Standard Code). Inconsistency in what is or is not regulated creates uncertainty and negatively impacts innovation and the pathway to market for products of gene technology
- Changes to the definition should align with Australia's international reputation and ensure market access for Australian products. It must also allow Australian innovators and industries the freedom of choice to use the same technologies as international competitors.

[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

Question 2:

How might we improve the regulatory flexibility of definitions within the Scheme, whilst maintaining protections for human health and the environment?

The LTIBC supports the underlining principle of the Scheme; that is: "..*the protection for human health and the environment*". The LTIBC suggests that the current definition could be simplified, taking into consideration more than 20 years of gene technology.

The Scheme should also draw from the evolution of the *Gene Technology Regulations 2001.* The Regulations have developed to become more outcome focused based on principles, allowing for a greater level of flexibility in achieving the desired outcome. For example, compliance within a physical containment facility with the decontamination of hands can be achived via various methods:

Principle: Decontamination of hands is considered an important means of preventing unintentional release of GMOs and protecting the health of facility personnel.

Objective: A behavioural requirement that persons dealing with a GMO wash their hands when they leave a certified physical containment facility.

Requirement/methodology: The facility must contain EITHER a dedicated washbasin fitted with taps of the hands-free operation type OR some other means of decontaminating hands.

Outcome: Hands are decontaminated before persons leave a physical containment facility.

Question 3:

What other issues should be taken into account when considering how best to ensure that humans are not regulated as GMOs?

The LTIBC supports the national initiatives to consider the appropriate regulatory oversight for humans who may receive or inherit germline therapies or other somatic therapies not within the remit of the Scheme. La Trobe University will contribute to this discussion, as required.

The Committee notes that there is a need for greater clarity around the use of gene therapies to ensure that the Scheme is applied consistently and fairly across all sectors. Specifically, when a therapeutic is a 'dealing' under the Scheme and handled accordingly vs post-treatment of a human subject.

The Committee also recommends clarity and transparency on the roles and responsibilities of regulatory agencies such as the OGTR and the Therapeutic Goods Administration as a dealing moves from research and development through to clinical application.

Question 4:

Given the benefits and challenges of defining terms in legislation, what other mechanisms might be used to provide the clarity required?

The LTIBC supports consideration of a principles-based regulatory framework rather than a rules-based one. Such systems have been highly effective in the application of other legislation such as the *Privacy Act 1988*.

The LTIBC recognises that for some technologies, a hybrid system may be more applicable whereby principles may be supported by rules-based processes. For example, for technologies and organisms that have a higher potential risk such as gene drives, synthetic biology, Risk Group 3 and Risk Group 4 microorganisms. A caveat to the approach is that there remains a need for provisions and mechanisms that allow the Regulator to rapidly adjust to changes in technology and information around potential risks to human health and the environment.

Part 2: Risk proportionate regulation through risk tiering and appropriate regulatory approaches

Question 5:

Are there any other key objectives/considerations that should be taken into account in designing a risk-proportionate approach to regulation?

The LTIBC supports the principles outlined in *The Issues Paper*. The Committee notes that risk-proportionate regulation of gene technology should recognise more than 20 years of biosafety. This includes, for example, the risk/safety assessments of a number of gene classes and their products by multiple regulatory agencies around the world and the more than 2000[2] food safety assessments and approvbals conducted on genetically modified crops.

Question 6:

What additional risk tiers could be considered and what criteria could be applied to determining what falls in or out of any required tiers?

See the LTIBC response to Question 7.

Question 7:

Is the introduction of additional risk tiers the only way to ensure regulation is proportionate to the level of risk?

The LTIBC supports the introduction of further risk tiering, including, where the risk to human health and the environment is negligible, that no regulatory oversight be an option for the Regulator.

The LTIBC notes that other sectors have introduced or operate risk tiering (e.g. management of contaminated sites, security risk management). Such approaches apply tiers to the management of the risk, not the risk itself. This approach would align with principles-based regulation and recognise, for example, the extensive self-regulation of many research organisations and industries. The LTIBC would support a similar approach to the Scheme.

[2] Data gathered from: ISAAA Brief #54 for 2018: http://www.isaaa.org/resources/publications/briefs/54/; The International Service for the Acquisition of Agri-biotech Applications (ISAAA): http://www.isaaa.org; The FAO GM Foods Platform: http://www.fao.org/food/food-safety-quality/gm-foods-platform/en/.

Question 8:

What principles or criteria should be applied in moving an organism/technique across risk-tiers?

The LTIBC notes the principles outlined on Page 14 of *The Issues Paper*. In particular, changes in scientific understanding. Further, the Regulator should have the ability to, where applicable, mutually recognise risk/safety assessments undertaken by other regulatory agencies, both domestic and abroad. The LTIBC notes that risk/safety assessment of the products of gene technology are undertaken in accordance with the Risk Analysis Framework[3] that aligns with international guidelines and standards such as those published by the OECD[4] and Codex Alimentarius[5].

Question 9:

Are there any elements of the Scheme that would NOT benefit from a principles/outcome-based approach?

The LTIBC recognises that for some technologies a hybrid system may be more applicable whereby principles may be supported by rules-based processes. For example, technologies and organisms that have a higher potential risk such as gene drives, synthetic biology, Risk Group 3 and Risk Group 4 microorganisms. This has been further discussed in the response to Question 4.

[3] OGTR Risk Analysis Framework http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/raffinal5-toc
[4] OECD Safety Assessment Consensus Document https://www.oecd.org/env/ehs/biotrack/safetyassessmentoftransgenicorganismsoecdconsensusdocuments.htm
[5] Codex Alimentarium Food Safety Assessment http://www.fao.org/fao-who-codexalimentarius/en/

Part 3: Streamlining regulatory requirements and processes to reduce regulatory burden

Question 10:

What other objectives might guide streamlining of regulatory requirements?

The LTIBC supports the principles outlined in *The Issues Paper* and commends the OGTR on the streamlining initiatives already undertaken or that are currently underway. The Committee supports continuous improvement of the Scheme and streamlining to increase efficiency and reduce regulatory burden whilst maintaining the core principles of the Scheme.

Question 11:

Are there any particular issues to be considered when streamlining any of these regulatory requirements?

The LTIBC supports the streamlining of regulatory requirements. In particular, around low risk dealings and the physical containment facility type applied to certain dealings. For example, the marine organism Placazoa is a small amoeba-like organism (1-3mm in size) that can be grown in aquaria containing artificial sea water. They have been found in all oceans sampled including off the coast of Australia. They are not considered pathogenic or associated with any diseases of humans or other animals. Further, they are not considered an aquatic pest and do not survive outside of a saltwater environment. However, under the current Regulations, dealings involving GM Placazoa (e.g. a gene knockout) would likely fall within Schedule 3, Part 2.1a, requiring PC2 containment. There are currently no provisions for the Regulator to allow these dealings at a lower level of containment or as an Exempt Dealing. The LTIBC contends that this restriction is not commensurate with risk and is prohibitive to innovative research with this organism.

Similarly, the Committee questions the requirement for a PC2 Plant Facility for non-flowering genetically modified plants (e.g. when selecting for null segregants).

The LTIBC would prefer that a principle be adopted that allows the Regulator and/or IBCs to assess, and where applicable, approve the use of a facility ‘suitable’ to prevent the unintentional release of a GMO into the environment rather than specific rules that stipulate a level of containment.

Question 12:

What mechanisms or tools would reduce the regulatory and administrative burden on the end user interacting with the regulator/regulatory system?

The LTIBC supports the suggested process improvements outlined in *The Issues Paper*. Including, for example, that the Scheme recognise the role that Institutional Biosafety Committees (IBCs) already play in administering legislative requirements such as low risk dealings and facility certifications.

Through previous submissions, the LTIBC has suggested providing IBCs with greater powers and flexibility in the management of physical containment facility certification. The suspension and reinstatement of physical containment certification is largely an administrative process for the OGTR with on the ground oversight already provided by IBCs. Amendments to 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 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.

Question 13:

Are there any particular issues to be considered when streamlining any of these regulatory processes?

The LTIBC recognises the diversity of views across Australia regarding the value and risks associated with the application of gene technology. As such, the Committee 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 Scheme, such that the public gain confidence in the Scheme and the role of the regulated community.

The Committee strongly recommends that the Department exercise caution when considering alignment of facility requirements with other similar regulators. There is a general consensus that alignment with the Department of Agriculture (Biosecurity Containment) particularly for level 1 and level 2 containment would place unnecessary restrictions on many gene technology dealings. Importantly, it would be cost prohibitive for regulated entities to try and comply with the stringent requirements of the Department of Agriculture that are not proportionate to potential risks posed by many GMOs as a result of gene technology.

Question 14:

Are there any other key processes that might be streamlined without impacting the safety of people or the environment?

The LTIBC supports the processes identified in *The Issues Paper*. The Committee notes that the Scheme must recognise and support an increase in the number of small to medium enterprises and start-up companies that seek to commercialise products of gene technology. Administrative processes need to be amended to assist rather than prevent a pathway to market for potential products with a commercial focus.

Question 15:

What specific areas are suitable for harmonisation between regulators? Are there any overlaps that could be removed?

The Committee reiterates the need for caution when considering alignment of facility requirements with other similar regulators. Further, there is a need for a greater level of clarity on the roles and responsibilities of agencies where there is overlap in regulatory oversight. Consistency is required and the LTIBC supports consideration of mechanisms from other schemes that could ensure a pragmatic approach that maintains the integrity of the Scheme.

Question 16:

What are some of the ways in which the role of IBCs could be strengthened to achieve efficiencies in a co-regulatory model?

The biennial IBC Forum has been a hugely successful meeting. The Forum provides a great opportunity for IBC members 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 and represwntatives from other regulatory agencies.

Similarly, the annual Association for Biosafety Australia and New Zealand (ABSANZ) conference offers insights into the latest thinking and approaches to biosafety and biocontainment. ABSANZ is the peak body for Australia and New Zealand in biosafety and biosecurity with a purpose to protect people, the community and the environment through advancing knowledge in biosafety and biorisk management.

Through these two events, there is an opportunity for the government to provide professional development for IBCs and their members on best practice in providing appropriate governance and oversight to biosafety and biocontainment. The LTIBC would support professional development of IBCs through such meetings.

Question 17:

What could be some avenues that would empower the Regulator to make decisions about changes to regulatory requirements and processes deemed low risk?

The LTIBC support the enabling of a principles based regulatory model and risk tiering as mechanisms that would empower the Regulator to make decisions about changes to regulatory requirements and processes deemed low risk. Further, the principles and opportunities for process improvements have been well documented and consulted on through the Scheme Review and the Technical Review undertaken by OGTR.

The Committee notes that there is high regard for the Scheme both domestically and internationally. However, the credibility and integrity of the Scheme's governance structure is undermined through delays in, or the lack of, implementation of the recommendations from

reviews. There are rapid changes occurring globally in biosafety regulatory systems to address new technologies, particularly systems in other countries that enable low risk products to be commercialised. Delays in the implementation of the Scheme Review recommendations places Australia at great risk of losing our competitive advantage and undermining the high regard with which the Scheme is placed.

The social impact of regulation is often forgotten but is nevertheless an important consideration. Delays in implementation of the recommendations signals to the public and our markets that the Australian Parliament does not have faith or trust in the review process. The Committee notes that the Scheme is currently out of sync with the Food Standards Code and out of step with international trade competitors. This is not a desirable position for an economy that has had more than 20 years of being seen as a global leader in gene technology regulation.