2017 Review of the National Gene Technology Regulatory Scheme
Queensland University of Technology submission

The Queensland University of Technology, (QUT) welcomes the opportunity to provide comment on the 2017 Review of the National Gene Technology Scheme. In making our recommendations we are very cognisant of the need to bring the greater Australian community on the journey to changes that may result from this review. We appreciate that the Review as outlined in the Background Paper (http://health.gov.au/internet/main/publishing.nsf/Content/gene-technology-review) is being conducted in an overall context that involves the Technical Review, the House of Representatives Standing Committee on Agriculture and Industry Smart farming – inquiry into agricultural innovation 2016 report 3, and the Productivity Commission 2016 report on the Regulation of Australian Agriculture. The US National Academies of Sciences, Engineering, and Medicine (NASEM; www.nap.edu) have also produced three forward looking reports relevant to this area:

- Preparing for Future Products of Biotechnology (2017)
- Human Genome Editing: Science, Ethics, and Governance (2017)
- A Proposed Framework for Identifying Potential Biodefense Vulnerabilities Posed by Synthetic Biology: Interim Report (2017)

We are now entering an era where recent advances in genome editing, gene drives and synthetic biology have the potential to change the landscape of how the National Gene Technology Scheme works. The first of the listed NASEM reviews above states "it is clear that making accurate predictions of what will be possible is a difficult task, but some trends are clear: there will be a profusion of new products that will in many cases be very different in terms of their type, scope, and complexity, and the number of actors who will be able to contribute to biotechnology will be even more diverse as engineering biology becomes more accessible. At the same time, there is increased public awareness (and in some cases controversy), and the regulatory agencies are faced with the challenge of balancing the many competing interests from industry, society, government, and academia."

In its National Innovation & Science Agenda (http://www.innovation.gov.au/) the government has highlighted the need for Australia to embrace innovation and science to deliver new sources of growth, maintain high-wage jobs so we can seize the next wave of economic prosperity. The recent advances in genome editing, gene drives and synthetic biology have the potential to open up new industries and treatments for disease that up until now have not been possible. It is our belief that the National Gene Technology Scheme has been a very effective frame work for Australia. This is based on our understanding of risk-assessment endpoints related to human health and environmental outcomes, where illness, injury, death, or loss of ecosystem function have not been negatively impacted. The positive impacts of the Scheme also need to be

highlighted, if we are to fully gauge its fitness for purpose in promoting gene technology within Australia. In this context we think it is appropriate to charge The Australian Council of Learned Academies (ACOLA) with the task of reviewing the risk management paradigm of the past and horizon spanning potential new developments in gene technology. Because of the highly technical nature of genome editing, gene drives and synthetic biology we would recommend that a charge be given to ACOLA that embraces the thrust of the three American reports. However, such an exercise should not reinvent the assessment process but focus on how Australia can be adept in exploiting recent advances in knowledge and project what skills and safe guards are required for 2020 and beyond.

First Phase Recommendations

The QUT University Biosafety Committee (UBC) wish to raise the following key issues for consideration during the first phase of consultation:

1. **Schedules for the classification of dealings unable to be modified quickly or easily**

The system for classifying GMO dealings is currently embedded within the Gene Technology Regulations 2001 under Schedules 1 to 3. Any proposed amendment of the classification system must follow the pathway for amending legislation, which can be a lengthy process. Should changes to this classification system be required, they could not be implemented quickly or easily.

With the rapid emergence of new technology, it is unclear how the current system would be able to be modified, within a suitable time frame, to encompass these technologies. There is a risk that rapidly emerging technologies may not be regulated appropriately if they cannot be encompassed into the classification scheme. The current classification system is already unable to be amended easily in regards to current technology. For example, there does not seem to be a way for the addition of new host/vector system to the list of exempt systems. There is also no options for downregulating older technologies that have been proven to have a safe track record (e.g. GM mice). A classification system with a documented pathway that allows for timely amendments is required.

2. **Downregulation of dealings with a proven track record of being safe**

Technologies that have been shown to be safe over a sufficient period of time should be downregulated to a lower classification. For example, GM mice (especially when the strain has already been established) could be downgraded to an exempt dealing, rather than an NLRD, provided the mice are not expressing a toxin or conferring an advantage over wild type mice. We would suggest the OGTR review the most frequent types of applications received, to see what technology, which has now been established and has a safe track record, could be downgraded to a lower classification requirement. This would allow the OGTR and IBCs to focus on newer technologies, where the risks and consequences have not yet been fully established.

3. **Rapidly emerging technologies**

With the emergence of new technology, there is an obligation to regulate their use so that the public can have confidence in the system and the technologies to be used. However, there is also a need to ensure that research can proceed without being impeded by highly restrictive requirements. It is important that a cautious approach is taken, yet it must be based on the relevant risks of the work being undertaken. Achieving this balance will be difficult, especially as some of the technology likely to emerge in the next 5-10 years may not have even been considered yet. Consideration will also need to be given to how new GM technologies may be used (e.g. security concerns for some applications) and how this will affect their classification.

IBCs are likely to require additional support and training to assist with the assessment and classification of new technologies, as there may be new technologies that they are not yet familiar with. They will also need assistance applying whatever classification system is used to encompass the new technology.

4. **New technology more accessible**

With changes in new technologies, there will be an increase in the number of people and companies who have access to the technology and the diversity of groups who access it will also change. We are likely to see GM technology moving into new fields of use and this will pose new challenges when considering the risks of the work and how dealings should be classified. This also poses challenges for IBCs where they may be assessing GM technology from increasingly diverse areas, of which they may not be considered to have the necessary expertise. This accessibility issue also goes to the heart of interactions between universities and industries to grow a vibrant innovation climate where expertise move seamlessly and at pace between these sectors. QUT's University Biosafety Committee has just signed off on its first formalised interaction with an industry partner. This was a learning experience that took time. If such interactions are to become the norm, it is opportune to develop protocols for such interactions that reflect activities from a whole of an Australian perspective and not just on a case by case university basis.

5. **Process vs product based approach**

Consideration needs to be given to whether the system for assessing dealings should be a process based or product based approach (or a combination). This will become increasingly important with new technologies. The risk of the genetic modification being introduced, the trait being modified and the new properties of the organism will become more important questions rather than the process by which the change was made. There will be increasing scenarios where the same process can result in vastly different products, and differing risks associated with them. It will be important to ensure material that is higher risk is regulated appropriately, but that material of lower risk is not caught up under the same requirements.

6. **Better training and guidance for IBC members**

While IBC members have sufficient scientific expertise when reviewing applications, better training and guidance is required on how to apply the regulations to the work being assessed, to allow correct classification. This is of particular importance when the work may fall under a number of different classifications and members need to be able to separate the work into different components to classify it. Most IBCs rely on current members assisting new members on how to apply the regulations to a dealing. Understanding the requirements and how to classify dealings can be an obstacle when trying to source new IBC members.

7. **90 day review of applications**

A review of the 90 day review process should be undertaken to determine if the requirement is necessary for all of the applications that fall under it. For example, an IBC submitting a renewal for a PC2 facility requires a 90 day window so it can go to the Regulator for signing. What risk is this mitigating, given that the IBC is confirming they are still compliant? Does this really need to go to the Regulator for resigning? Would continuous approval subject to routine monitoring/annual reporting be a more efficient process?

8. **IBC identifiers**

The need to reissue NLRD variations with new IBC identifiers is time consuming and confusing (many IBCs do not do this). It can make it difficult for IBCs and investigators to keep track of their dealings and increases the risk of unapproved work being undertaken. New identifiers are not issued when there is a variation to a licence, so it is not clear why IBCs are required to do so for other variations. This can be very time consuming for IBC's when new identifiers are required for every variation (e.g. addition of new mouse strains could be added many times throughout a year resulting in numerous new identifiers being issued). It would make sense for the original identifier to remain in place.

There should be an option for IBCs to 'renew' approvals when they reach the 5 year deadline. This would allow the identifier to continue for the life of the work, making it easier for investigators and IBCs to keep track of their approvals. It also minimises the burden on IBCs and investigators, through reapplying and reassessing the same dealings.

9. **Harmonisation**

While a lot of work has been done over the years to improve harmonisation between different legislation and Regulators, this is an area that can still be improved on. It is important that there is alignment between OGTR requirements, Australian Standards and other legislative requirements (e.g. Biosecurity) to ensure that they are working together. Currently there is a lot of duplication and this can be quite onerous on organisations.