Queensland University of Technology Biosafety Committee Submission on New Technologies

1. **Which option/s do you support, and why?**

In considering the four options presented in the discussion paper, there is clearly a **long-term advantage in considering option 4 as the most favourable**. There are two major principles underpinning this preference:

a. Option 4 allows for future development of new technologies without continual revision of the regulations.
b. It would also instil confidence in the general public that there would be regulatory oversight for products developed from existing and emerging technologies.

The discussion paper on "options for regulating new technologies" has a strong emphasis on the GT Act (in the current state) being process driven. While this has historically allowed for the relatively clear treatment of Genetically Modified Organisms (GMOs) in the legislation based on the risks they pose, the development of new technologies described in the discussion paper has changed this approach. In particular, the development of site-directed nuclease (SDN) techniques has raised questions about the interpretation of the current GT regulations and whether some of the products of these techniques are considered to be GMOs. Similar questions can be raised about the outcomes of using techniques such as RNAi (depending on the methods used) and reverse breeding/seed production technology discussed in the FSANZ New Plant Breeding Techniques workshops held in 2012 and 2013.

Option 4 proposes to exclude certain new technologies from regulation on the basis of the outcomes they produce. This option would allow researchers to develop 'modified' organisms using a range of different technologies but not determine their status as GMOs until the final products are being considered for release. In some instances the new technologies described in the discussion paper are capable of introducing small changes to the genetic material of host organism/s. In particular, SDN-1 type techniques that result in DNA breaks that can be repaired naturally are in principle not distinct from other methods involving mutagenesis. These techniques are not covered Schedule 1A and 1 of the Regulations. Similarly, some research using techniques described as SDN-2 may also be excluded from regulation if the final outcome involves the exchange of DNA where the donor species is also the host species (Schedule 1); risks associated with the product have not been increased. Although organisms modified using these types of technologies may be subject to regulation as Exempt or Notifiable Low Risk Dealings (NLRDs) during their development, the final product may be considered non-regulated based on these similarities with current definitions in the regulations.

CRISPR technology is a relatively new technique and has been disruptive to the regulatory processes. While options 2 and 3 help address this technology they provide no guidance for equally disruptive technologies that are yet to emerge; Option 4 would provide some future proofing for such technologies.

Herein lies the major challenge in the current arrangements with the regulations. New technologies currently in use may require approval from IBCs as Exempt or NLRD type dealings. In anticipation of further technology development in the future, for example the availability of purified nuclease preparations, clear guidelines are required for institutions to determine the category of work being described. Researchers using SDN-type technologies should be subjected to regulation during the research phase to ensure work is conducted within approved facilities and IBC oversight is assured. To accommodate this within the current framework each new technology needs to be considered separately. Where SDN-1 and SDN-2 technologies are used to introduce small changes (or in the case of SDN-2 where the donor species is also the host species) these techniques may be more easily accommodated as Exempt dealings (providing other descriptions of Schedule 2 apply) or NLRDs as appropriate to the methods employed and host used. Where SDN techniques employing larger templates or where the donor is not the host then the current framework describing NLRDs should apply.

Whilst GMO technologies currently in use are technically safe there are public concerns to existing gene technology products and processes. Where confidence does exist, it is due in the main part to existing regulatory oversight that has been in place for a considerable amount of time. Although the new technologies may not fall within an Exempt or NLRD category, regulatory oversight of this work would provide confidence to the general public.

2. Are there other risks and benefits of each option that are not identified in this document?

Option 1 would not provide any confidence to the general public and would not assist IBCs in determining the category of the process.

Option 2 and 3 would not assist IBCs in determining the category of potential new technologies that will be developed.

The main benefits of Option 4 allows for future development of new technologies without continual revision of the regulations and the confidence to the general public that there would be regulatory oversight. QUT UBC believes that a certain level of regulation is required. During development of products from new technologies, an IBC (and the organisation) would have more confidence knowing there was some level of oversight of new areas of research and that there was a requirement for that research to be contained.

3. **Is there any scientific evidence that any of options 2-4 would result in a level of regulation not commensurate with risks posed by gene technology?**

The following examples of 'traditional' technologies have led to the release of product that would otherwise have benefited from regulation:

- The potato variety that was naturally bred, then removed from cultivation. See:
  - https://en.m.wikipedia.org/wiki/Lenape_(potato) and
  - "Toxic L-tryptophan: Shedding Light on a Mysterious Epidemic" William E. Crist; The Institute for Responsible Technology (July, 2005)

- Intensive conventional pig breeding programs to select for increased muscle mass resulted in an unintended mutation in the ryanodine-receptor gene that causes Porcine Stress Syndrome (PSS) (Wendt et al., 2000).
  Pigs with PSS that are harvested at packing plants have pork that is pale in color, exudes excessive water, and is soft in texture. Postmortem, pork from PSS pigs is referred to as PSE—pale, soft, and exudative. PSE pork has significant adverse meat quality attributes, and many consumers find the product objectionable. See:
  - Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects (2004). Chapter 3: Unintended Effects from Breeding

4. **How might options 2-4 change the regulatory burden on you from the gene technology regulatory scheme?**

If either Option 3 or 4 was adopted, the QUT UBC does not anticipate that the regulatory burden from the gene technology regulatory scheme would significantly increase. We are saying this based on our current practices as we have no substantial prior experience classifying research that uses the new technologies outlined in the OGTR Discussion paper.

5. **How do you use item 1 of Schedule 1, and would it impact you if this item was changed?**

Our IBC has rarely received an application where this Schedule is relevant.

If new technologies were written into a Schedule similar to Schedule 1, it would provide IBCs with the clarity they currently do not have.

6. **Might contained laboratory research on GM gene drive organisms pose different risks to other contained research with GMOs, and how could these risks be managed? Supporting information and science-based arguments should be provided where possible.**

If containment of new technology research is to be required, this type of research could be considered an Exempt or NLRD dealing, or written into a new Schedule for describing new technologies that require containment.

7. **What RNA interference techniques are you using, and are there RNA interference techniques that you believe have unclear regulatory status? Please provide details of the techniques and science-based arguments for whether these techniques pose risks to human health or the environment.**

We believe that the current regulation is quite clear when it comes to dsRNA generated through gene transformation. It is perhaps unclear, if the RNA is synthesised and applied exogenously, would this be captured under current regulations.

8. **Do you have proposals for amendments to any other technical or scientific aspects of the GT Regulations? All proposals should be supported by a rationale and a science-based argument.**

The existing regulations are adequate for our purposes, except for the how we address the new technologies.

We believe cis- and intra-genic will be considered as transgenic for regulatory purposes. If option 4 is adopted then the products of cis-genic will be regulated and the risk from introducing a gene from a 'sexually compatible' genotypes will be taken into consideration.