RESEARCH SERVICES
OFFICE OF RESEARCH ETHICS, COMPLIANCE & INTEGRITY

AMANDA HIGHET
RESEARCH COMPLIANCE OFFICER (GENE TECHNOLOGY)
LEVEL 4, RUNDLE MALL PLAZA
50 RUNDLE MALL
THE UNIVERSITY OF ADELAIDE SA 5005
AUSTRALIA
TELEPHONE
FACSIMILE

CRICOS Provider Number 00123M

19th February 2018

Office of the Gene Technology Regulator
MDP 54
PO Box 9848
CANBERRA ACT 2601

Dear Sir/Madam

Re: Technical Review of the Gene Technology Regulations 2001

Thank you for the opportunity to provide feedback on the proposed amendments for the upcoming Technical Review of the Gene Technology Regulations 2001.

Please find enclosed a submission prepared on behalf of The University of Adelaide Institutional Biosafety Committee (IBC) for consideration by the Gene Technology Regulator.

Yours sincerely

Amanda Highet
Secretary, Institutional Biosafety Committee, The University of Adelaide

Thank you for the opportunity to provide feedback on the proposed amendments to the Gene Technology Regulations 2001.

Members of the University of Adelaide Institutional Biosafety Committee (IBC) evaluated the consultation documents provided by OGTR then met on the 8th February 2018 to discuss the three amendment options and provide comment on the proposed changes. Here we report our recommendations for consideration by the Gene Technology Regulator.

Overall, members were satisfied that the proposed amendments were an improvement on the current regulations. Two principles that were key to our discussion were:

> -That ambiguity in the guidelines must be avoided, to ensure the purpose of the amendments (to resolve ambiguities) is achieved, and to facilitate replicable and timely assessment of dealings.
>
> -It is crucial that the public foster faith in the gene technology regulatory process. The amendments to the Regulations should be clear enough to discourage any perception that they are susceptible to manipulation.

Answers to Consultation Questions

1. What is your preferred option? Please explain why.

The Committee favoured Option 2 – amend the GT Regulations by introducing all elements of the draft amendments, as detailed in full in section 3 of the Consultation RIS – with the condition that some additional terms be clearly defined. We have addressed these in Question 2 below.

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 IBC recommends defining the term 'trait' as used in Schedule 1, Item 8 *(An organism that is descended from a genetically modified organism (the **initial organism**), but which has not inherited any traits that occurred in the initial organism because of gene technology)* and Item 9 *(An organism that was modified by gene technology but in which the modification, and any traits that occurred because of gene technology, are no longer present)*
Trait has a broad definition in the field of genetics and would be open to interpretation as a genetic element or as a phenotypic characteristic. A further definition such as "…where the trait is any part of the DNA or tool used to make the modification" should be included in these items.

Clarity is particularly important when considering that the Regulations provide guidance for agricultural research and commercial partnership stakeholders. The amendments do improve clarity for some areas such as genome editing and null segregants. However absolute clarity is crucial to prevent work-around of poorly defined terms such as "trait".

Furthermore, the regulations should clarify what measures must be taken to confirm whether any modifications that occurred because of gene technology are no longer present. We believe no less than whole genome sequencing would be required to demonstrate the absence of a transgene, as there is always a risk that DNA introduced into a cell will

unintentionally incorporate randomly into the genome. In cases where an organism cannot, or has not, been shown to have lost the "trait", it may be safer to regulate as a GMO (i.e. the organism is a GMO unless convincingly proven otherwise).

Schedule 1

Repeal of Item 1 is appropriate and in line with the changes made to Schedule 1. The addition of RNAi techniques into Schedule 1A is also appropriate and we did not identify any potential issues arising from the change.

Oligonucleotide-directed mutagenesis should be defined in the Definitions of the Regulations

Schedule 3 Part 3 (3.1) (r) and (s)

The risk averse approach to regulation of engineered gene drives is not surprising. In the IBCs 2016 submission to the Review of the Regulations consultation, we reasoned against an increase in regulation for Gene Drive technologies. In the current submission we have no opposition to the proposed amendments to require a licence for Gene Drives.

- For this amendment we recommend further clarification of *when do the separate components of the gene drive actually become a gene drive system*?
- Is it the *organism* or *virus with the gene drive* that is the DNIR?

Schedule 3 (1.1)

The clarification that a viral vector may or may not have a host is useful

It would be useful for OGTR to further define "classes of persons" as used in Regulation 13B(vi)

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 amended regulations closely reflect the University IBCs current position on regulation of gene editing technologies, so clarification of these in the Regulations would not result in any increased cost. The benefits of the amendments may be that researchers are clearer on technologies requiring a dealing application and less hesitant to embrace new technologies (with a more predictable assessment outcome).

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

Researchers use Schedule 1 to determine whether a dealing application to the IBC is required. As such, item 1 may be used in this decision process. The Committee Secretary is unaware of any instances where Item 1 of Schedule 1 was used solely to class an organism as non-GM.

- 4.3 Updating the categorisation of contained dealings with GMOs
- 4.4 Clarifying the regulatory status of organisms derived from GMOs that are not themselves GMOs (p18)
- 4.5 minor administrative changes.
  The Committee considered these minor administrative changes as an improvement to the Regulations. We do have further comments regarding the item titled *GMO risk group requirements*: see our answer to Q5 below

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?

Schedule 3 Part 2 2.2 (2)

This means if the unmodified parent microorganism satisfies the criteria in AS/NZS 2243.3.2010 for classification as Risk Group 3, then a GMO derived from that parent organism would also require at least PC3 containment. This definition would place unnecessary regulatory burden on vaccination research where, for example, a *Mycobacterium Tuberculosis* strain attenuated using gene technology to create a live vaccine would require PC3 level containment.

AS/NZS 2243.3:2010 will need to be updated to AS/NZS 2243.3:2016 once the new Standards are published.

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.

No

To support further analysis of impacts, particularly changes to regulatory burden, OGTR encourages submitters to provide information on how the amendment proposals could directly impact them, including:

- the number of required NLRD, DNIR and DIR authorisations that would change (and in what way)
- how the need to maintain facility certifications would change, and
- how the amount of time needed to administer authorisations would change.

We would need to apply for one DNIR licence to replace an NLRD involving gene drives.
No current NLRD authorisations would change as result of the addition of two new exempt organisms.
Apart from the increased time required to apply for one DNIR, we anticipate that there will be no increase in assessment time as a result of the proposed amendments.

Thankyou.