12 December 2016

Office of the Gene Technology Regulator
MDP 54
GPO Box 9848
CANBERRA ACT 2601
ogtr@health.gov.au

Dear Colleague,

Re: Discussion paper – Options for regulating new technologies (October 2016)

Victoria University (VU) would like to thank the Gene Technology Regulator for the opportunity to provide feedback on the Review of the Gene Technology Regulations 2001 titled ‘Discussion paper – Options for regulating new technologies (October 2016)’.

Please find responses to Questions 1, 2, 4, 5 and 6 below:

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

The Victoria University Institutional Biosafety Committee supports Option 2. There is currently no compelling scientific evidence to suggest that current techniques and products are safe for the environment or public health. Therefore, the OGTR should be required to assess, regulate and, where necessary, license them as dealings under the Gene Technology Act 2000.

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

More evidence is needed on all the risks and potential benefits of the new gene technologies and their products, so the Precautionary Principle, as noted in the Gene Technology Act 2000, should apply. All new gene technologies and their products should be regulated until there is compelling scientific evidence, that they pose only manageable risks to health and the environment. Deregulation may then be considered through a broad public consultation process.

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

The Victoria University Institutional Biosafety Committee classifies all gene technologies and their products as requiring assessment and approval. We do not anticipate any additional regulatory burden.

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

The Victoria University Institutional Biosafety Committee uses item 1 of Schedule 1 to help classify Genetically Modified Organisms that are regulated by the OGTR. The Committee reviews all projects using Gene Technologies (including Gene editing e.g. CRISPR/Cas9) to determine if the process of production and the end products are potential biohazards, irrespective of whether the OGTR and its legislation define them as genetically modified dealings or products. We do not anticipate any additional regulatory burden.
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.

The Victoria University Institutional Biosafety Committee does not currently have any dealings with gene drives and we do not foresee any such research being undertaken in our organisation in the future. Research using gene drives has the deliberate intention of rapidly disseminating genes and genetic traits through entire populations. The ecological and other potentially negative consequences of such modifications are as yet unknown. We therefore propose that all research with gene drives, and the organisms created, be more rigorously regulated. A temporary moratorium should be placed on all “Irreversible (or Global)” gene drive work that involves intentional release while more scientific evidence is commissioned and accumulated on potential negative impacts on public health, safety and the environment, so that the OGTR is better informed and equipped to regulate these dealings. The period and terms of a moratorium require further discussion and agreement.

Thanks again for the opportunity to provide feedback as part of this consultation. We look forward to receiving advice on the outcome of this important process and encourage you to contact the Institutional Biosafety Committee should you have any further queries.

Yours sincerely,

Dr Thomas Yeager
Chair, Victoria University Institutional Biosafety Committee
IBC OGTR No. 331