

10 December 2016

Regulations Review
Office of the Gene Technology Regulator (MDP 54)
GPO Box 9848
Canberra
ACT 2601
(ogtr@health.gov.au)

Dear Regulator,

Re: Response to discussion paper: Options for regulating new technologies

1. Which option do you support and why?
Over the past few years the Austin Health IBC has reviewed a number of applications relating to the generation of GMO's using gene editing techniques such as CRISPR/Cas9, TALENs and shRNA across a spectrum of organisms. We have not experienced confusion from our staff as to whether these techniques involve the generation of GMO's. We are therefore of the opinion that the current regulations are adequate (Option 1). However, given the issues in the broader community alluded to in the discussion paper, we agree that options 2-4 are worth considering. In our opinion options 2 and 3 perhaps have the greatest merit.
2. Are there other risks and benefits of each option that are not identified in this document?
One risk with options 2, 3 and 4 is that they may unnecessarily complicate risk assessment as they may distract review committees from focusing on the GMO by overstating the importance of the gene-editing tool.
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 the gene technology. Not that we are aware of.
4. How might options 2-4 change the regulatory burden on you from the gene technology regulatory scheme? Options 2-4 may increase the burden of work for an IBC and researchers but the greater concern is that regulatory changes may dilute the focus from the risks posed by the GMOs and focus unnecessary attention on the gene-editing tool.
5. How do you use item 1 of Schedule 1, and would it impact you if this item was changed?
No response.
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? No response.
7. What RNA interference techniques are you using, and are there RNA interference techniques that you believe have unclear regulatory status? We presently use RNA

interference mediated through vector free delivery of siRNA and vector mediated delivery of shRNA. This appears to be adequately captured in the GT regulations.

8. Do you have a proposal for amendments?

No.

Regards,

John Mariadason
Chair Institute Biosafety Committee
Austin Health