Submission to OGTR
Dec 20 2016
Discussion paper: Options for regulating new technologies

Preferred option

My preferred option is option 4.
The reasons are;

1. I agree with the assessment provide in the guidance document[1] of the cons of option 1.
2. Option 2 is not acceptable in my view because
    a. I agree with the view presented in the guidance document[2] that "organisms altered by some site-directed nuclease techniques and oligo-directed mutagenesis are unlikely to pose risks that are different to natural mutations…"
    b. Organisms generated by some of these techniques (particularly ODM) will not be able to be identified as having been generated using the process.
    c. The ODM technology is unlikely to be regulated in the international sphere[3][4] and Australia's policy should be harmonised with this lead.
3. Option 3 seeks to make a distinction between processes which result in a few nucleotide changes and use of longer genome alterations but the outcome would be to regulate ODM technology. I have given the reasons for rejecting option 2 and the same rationale applies to option 3, which proposes ODM is regulated.
4. Option 4 is consistent with the overview provided by Wolt et al[5] and the rationale given in points (2) and (3) for rejecting options 2 and 3.

Response to consultation questions

1. Which option/s do you support, and why?
Please see above.

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

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?
I provide no comments in answer to this question.

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

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[1] Technical Review of the Gene Technology Regulations 2001, Discussion paper. Options for regulating new technologies, October 2016
[2] Technical Review of the Gene Technology Regulations 2001, Discussion paper. Options for regulating new technologies, October 2016
[3] Sauer, N. J., Mozoruk, J., Miller, R. B., Warburg, Z. J., Walker, K. A., Beetham, P. R. et al.. (2016). Oligonucleotide□directed mutagenesis for precision gene editing. *Plant biotechnology journal*, *14*(2), 496-502.
[4] Breyer, D., Herman, P., Brandenburger, A., Gheysen, G., Remaut, E., Soumillion, P. et al. (2009). Commentary: Genetic modification through oligonucleotide-mediated mutagenesis. A GMO regulatory challenge?. *Environmental biosafety research*, *8*(02), 57-64.
[5] Wolt, J. D., Wang, K., & Yang, B. (2016). The Regulatory Status of Genome□edited Crops. *Plant Biotechnology Journal*, *14*(2), 510-518.

There would be no impact. I am not involved in any work that is utilising these new technologies at present.

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

I have in the past used item 1 of schedule 1 to determine whether laboratory work should be classified as exempt. It would not impact me if the item was changed.

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.

My experience is limited to work with GM plants. At the laboratory stage, where all GM plants are contained during the regeneration and selection process, I do not consider work with gene drive organisms poses risks different to other GM plants.

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.

I have in the past worked to get commercial release permissions for ornamental plants which contain sense-antisense or double stranded DNA (co-suppression) genetic elements. These GMOs have been regulated as GMOs because these genetic elements were only part of the transformation vector. The regulatory status of the GMO was therefore clear.

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.

No.