Griffith UNIVERSITY

Submissions can be made by email to ogtr@health.gov.au or by mail to:
the Regulations Review
Office of the Gene Technology Regulator (MDP 54)
GPO Box 9848, Canberra ACT 2601.

Dear Director, Regulatory Practice and Compliance Branch, OGTR

I write further to the invitation to provide a public submission with regard to the *Options for regulating new technologies* (technical review) discussion paper.

Griffith University agrees it is timely, given the emergence of the described new technologies/techniques and the pace of change in this area, to explore what changes should usefully be made to the regulations in the immediate term. Possibly in the longer term a change may also be warranted to the enacting legislation.

Any regulatory framework pertaining to genetically modified organisms requires a degree of risk mitigation while also ensuring onerous oversight does not make scientific enquiry in this area impossible. While Australia's interests have been served well to date by the current arrangements it is timely that these arrangements be refined and clarified. Focusing upon the nature of the site-directed nuclease (SDN) techniques is a useful approach which can then be usefully defined and monitored.

Griffith University does not support Option One introduced by the discussion paper because of the very real risk of unintended consequences and lasting ecological harm (as outline in page 9 of the discussion paper) that may occur if such work is completely unregulated. It is important to recognise that Option One is likely to be out of step with community expectations with regard to the regulation and oversight of genetic modifications.

Options Two and Three both provide a balanced approach to these matters and we believe Option Three to be the best approach. Despite the comments on page 14 of the paper that DNA damage is not random but designed by SDN-1 and is therefore targeted (compared to radiation and chemical mutagens), we suggest that there are also chemical mutagens that elicit their effects in a targeted manner (e.g. 5-bromouracil, hydroxylamine) but the resulting organisms would not be classified as GMOs. Also as stated in the paper, SDN-1 uses non-homologous end-joining so the exact nature/type of mutation is random (this is the same as radiation and chemical mutagens), although as stated above the site is not. Together this provides a clear argument for the exclusion of SDN-1 from regulation. Therefore, Option Three is a more balanced approach and will provide clarity to researchers (and institutions) as to what is regulated and represents something a monitoring body could use to correctly identify whether an organism has been modified inappropriately. Option 3 may capture other industries (e.g. breweries who utilise genetically modified yeast) but it is likely that regulation of such activities would be consistent with community expectations.

Griffith University does not prefer Option Four because it would unhelpfully expand the remit of what is regulated and make it exceedingly difficult to identify whether an organism has been modified inappropriately. In addition it is possible to use current DNA manipulation techniques

(although they would utilise recombinant DNA which SDN-1 and SDN-2 does not) to introduce mutations that occur in nature and these would make it a GMO under the current rules. Therefore to exclude the techniques under consideration in Option Four that can generate the same sort of changes/mutation would add a degree of uncertainty and potentially confusion. Further and importantly SDN-2 uses homology-directed repair to specifically direct not only the site but also the nature/type of the mutation incorporated. SDN-1 does the former but not the latter, and as such makes a clear delineation/distinction between what is regulated and what is not.

With regard to gene drives (pp18-19) Griffith University believes there should be registration of gene drives, because of the danger of unanticipated harms to ecosystems and the wider environment, but this should be a balanced approach and utilise self-regulation.

Please contact me if you would like to discuss these matters further and I will arrange for a member of our biosafety committee to be made available to you.

Yours sincerely

Dr Gary Allen on behalf of
Professor Ned Pankhurst
Senior Deputy Vice Chancellor, Griffith University