Comment on the Office of the Gene Technology Regulator discussion paper: options for regulating new technologies.

Submission on behalf of an Institutional Biosafety Committee.

The comments below have been compiled from members of our Institutional Biosafety Committee. Our committee oversees IBC matters for two large medical research facilities, whose research is supported by grants from NHMRC, ARC and a variety of disease-specific funding bodies. Our chief dealings are Notifiable Low Risk and Exempt dealings that predominantly cover genetic manipulations of human and mouse cultured cells and whole mice.

Below we consider each of the questions posed in the discussion paper:

Consultation questions

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

   We support Option 2 as the favored option. Given that CRISPR and other site-directed repair mechanisms all use a directed and targeted gene editing strategy we believe that these technologies should be regulated, even though the mechanism underpinning the technology is a natural repair mechanism. The targeted nature of the technology distinguishes these techniques from "random" mutations such as would be generated by chemical or radiation mutagenesis. In particular, given that these technologies are only relatively recently developed, it is not yet possible to predict any/all deleterious side-effects. While SDN-1 has apparently more in common with the random mutagenesis techniques, this is still based on template guided mechanisms. We acknowledge that as per the discussion paper the organisms derived from SDN-1 and SDN-2 would be indistinguishable from those mutations occurring naturally. However, this is not an issue for our researchers as none of our dealings are released.

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

   None for our purposes.

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?

   None for our purposes.

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

   We do not anticipate that any of the three options would give undue burden to our committee. Clarification around the classification of techniques such as CRISPR would in fact reduce our burden by removing uncertainty and thus the need for debate. No one option of 2-4 would impose a bigger burden to our committee and research community than any other. Our researchers already are required to submit applications covering CRISPR etc so this would not significantly increase the work load of the researchers.

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

   Any clarity provided with regard to the site-directed mutagenesis techniques would be welcomed. The fact that many of these techniques use “naturally occurring” mechanisms makes it difficult to assign GMO status to some applications that come before our committee.

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.

   We have no experience with gene drive approaches and so are not qualified to comment.

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.

   Our researchers use both siRNA-type approaches and vector-borne shRNA approaches. We believe that the classification of these approaches is clear under the current regulations.

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.

   We have nothing additional to add.