HARRY PERKINS INSTITUTE OF MEDICAL RESEARCH

INSTITUTIONAL BIOSAFETY COMMITTEE

RE: Harry Perkins Institute IBC Submission to OGTR on technical review "options for regulating new technologies"

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

   Of the 4 options presented, the Harry Perkins Perkins IBC supports Option 4. The Committee considers it preferable to regulate the resultant modification to the organism, rather than the process to get there. This option will result in the GMO-classification and regulation of SDN-3, but not SDN-1 or SDN-2. This option will allow the use of CRISPR/Cas9 (or other techniques yet to be developed) to make a single point mutation in one organism that could be made by ENU mutagenesis, or already exists in nature. Both would result in genetically identical organisms, but currently the one made by CRISPR/Cas9 would be classed as a GMO and restricted, while the other would have no regulation.

2. Are there other risks and benefits of each option that are not identified in this document?
   It appears there has been considerable risk assessment of the new techniques and that the risks appear very low indeed. It may be possible to create a high-risk GMO through the repeated application of an excluded technique which would be exempt from regulation eg. SDN-1 could potentially result in large-scale deletions and/or chromosomal translocations, if two SDN-directed cuts are made at the same time.

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?

   Outcomes which could potentially occur naturally could end up regulated due to the technique used to create them, so why regulate it?

4. How might options 2-4 change the regulatory burden on you from the gene technology regulatory scheme?
   If Option 2 is selected it would have a large increase in workload for IBCs. Option 3 would lead to an increase. Option 4 there will be extra projects to oversee, but generally we do not forsee any great burden.

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

   Not sure what change is being considered. The impact would be dependent on the change being considered.

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?

   Yes. Definitely. This needs further consideration. We believe this requires a separate discussion paper and call for submissions.

The Harry Perkins Institute of Medical Research Institutional Biosafety Committee

Chair: Kathy Davern