

## **Response from Women's and Children's Health Network Institutional Biosafety Committee to the**

OGTR - Technical Review of the Gene Technology Regulations 2001

Discussion paper: **Options for regulating new technologies**

### **Consultation questions and comments from the WCHN IBC**

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

We are in support of option 4. We consider that methods SDN-1 and SDN-2 result in genetic modification that are (1) indistinguishable from naturally occurring mutations, and hence natural habitats (2) in line with outcomes produced from other exempt technologies, such as radiation and chemical methods. We consider that organisms produced with method SDN-3 however should be classified as a GMO, as (1) it clearly results in additional functions to endogenous genes (e.g. gene tagging) or introduce new ectopic gene or gene regulatory elements and (2) is in line with other methods of transgene insertion (only done in different way that facilitates precise control of transgenic elements into the genome), which are considered GMOs.

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

No, we did not identify additional risks. We did discuss risks outlined in the document however, in particular the risks of off-target effects of nuclease technologies. That other random mutagenesis approaches are exempt provided precedence in our decision.

#### **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?**

Not that we are aware of.

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

Very little difference in the regulatory burden would be felt at this time by our committee. The technologies of nuclease editing are being used, but not at high volume by our stakeholders currently. Regardless, this new technology replaces older technologies that have been previously used, and as such, we see little change. If anything, under option 3 and 4, it may reduce burden, as the creation of gene knockouts using nuclease technologies replaces other technologies which traditionally employed insertion of foreign gene sequences and hence classified as GMO.

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

No impact if the proposed changes were made, as we routinely deliver this technology in lentivirus vectors, and these are automatically a PC2 NLRD.

#### **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.**

No 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.**

Researchers at WCHN routinely use transfectable small interfering RNA reagents (not a GMO) and short hairpin RNAi reagents in lentiviral vectors, which are a PC2 NLRD. New CRISPr CAS vectors also in a lentivirus will also be PC2 NLRD, so there is no doubt of their classification, and no change required.

We do not believe these pose additional environmental threats than already covered by PC2 NLRD status.

- 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 comment