Consultation questions

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

Option 1 We agree with the points made in the Cons of option 1 and hence option 1 is untenable. In addition technology has advanced and the use of the new technology and its outcomes needs to be clarified or regulated.

Option 2 seems to be prohibitively harsh. SDN-1 technology does not require the introduction of nucleic acids into an organism, and produces organisms of the same type as those created by chemical- or radiation-mutagenesis, the latter two techniques currently being excluded from regulation. Regarding the arguments outlined in the discussion paper under the "pros" for this option:

1: Not enough understanding as the techniques are new. As the techniques using SDN-1 technology produce organisms of the same type as those produced by conventional mutagenesis, we have many years of understanding of the consequences of using such technologies.

2: Interference with the functioning of an organism's genome. The same argument can be made for the use of conventional mutagenesis, yet there has never been a move to regulate plants produced by these technologies.

3: Lack of precision. The use of SDN-1 (and other) techniques is much more precise than conventional mutagenesis and any unintentional effects would be the same or less than those posed by the use of conventional mutagenesis.

Option 3 seems the best option. It provides clarity, GMOs can be more easily identified than under Option 4 and it fits with the policy settings of the current legislation.

Option 4 seems to be ruled out given that the policy settings of the current legislation are driven by process rather than product. Any change in policy settings appear to be the concern upcoming Legislative and Government Forum on Gene Technology and can be left to the forum. As per below, it would be easier for us as the BRSC to decide if an organism is a GMO based on process rather than product. However, I note that the report of a workshop hosted by Food Standards Australia New Zealand on New Plant Breeding Techniques considers that food derived from plants produced using targeted mutagenesis, including ODM and ZFN, should not be regarded as GM food as in the plants producing them are small and definable and similar to traditional mutagenic techniques used in conventional plant breeding.

Additionally, while modification using SDN-2 can result in mutations that are no different to those generated via exempt methodologies, successive rounds of targeted SDN-2 mutagenesis may pose risks similar to the insertion of foreign DNA. As such, while not totally ideal, Option 3 seems to be the most appropriate.

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

None that I am aware of.

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?**

Again, none that I am aware of.

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

If Option 3 were adopted, i.e., regulation based on the process used to create an organism rather than on the type of organism used (Option 4), there should be little debate about whether the dealing is regulated or not.

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

Item 1 of Schedule 1: A mutant organism in which the mutational event did not involve the introduction of any foreign nucleic acid (that is, non-homologous DNA, usually from another species).

To my knowledge the WSU BRSC have not had any instances where we have had to refer to this item.

As written, organisms produced by SDN-1 technologies appear to fall within the scope of this exclusion and are not GMOs. This item becomes ambiguous if SDN-2 technologies are used, as introduced nucleic acids are used in the production of the modified organism but could be considered as being absent from the final product. If organisms produced using SDN-2 technologies are to be regulated, they need to be removed from the exclusion due to the process by which they were made. The item is also ambiguous with respect to cis- and intragenics. This is pertinent to organisms produced using SDN-3 technologies.

Therefore, this item needs to be amended.

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.**

Given the nature of gene drives and their inherent risks and also the nature of dealings considered as DNIRs, I feel that it would be better for such work to be considered as a DNIR.

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.**

We have had no applications in this area?

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.

CRISPR is a technology that is similar to RNAi and should be given consideration. It is a mechanism that prokaryotes use as a memory type immune defence. This is just a belief, but it could be used to make very resistant bacterial strains.