

Technical Review of the Gene Technology Regulations 2001
Discussion paper: Options for regulating new technologies October 2016
Submission from the Curtin University IBC

Consultation questions

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

Our first preferred choice is option 4. Understanding that option 4 might allow successive rounds of SDN-2 short changes to result in a large change equivalent to SDN-3, we want to limit the size of the allowed SDN-2 modification to the size of a stop codon. We want to try to mitigate the risks of option 4 by risk assessing the outcome and assigning suitable controls, and screening the off-target effects.

We choose option 4 as our first preferred choice, because it would make it easier for us to do our research. One of our major research streams involves making GM agricultural crop plants and/or their symbiotic microbiome, and releasing them from containment for assessment in the field and then to commercial release. If option 4 were available, then we could make small modifications to the crop plants and/or their microbiome without regulation and progress through field trials without delay.

Our second choice is option 3. If a change to the GT Act is required to allow option 4 and that may not be possible currently, and a change to the GT Regulations can give us option 3 and that may be possible currently, then option 3 is a good compromise that gives us the ability to do our research. It would allow us to disrupt genes at a single point, and progress the resulting crop plants and/or their symbiotic microbiome to field trials.

We accepted different options depending on whether we wanted to perform contained Dealings or uncontained Dealings. For our contained Dealings, we could easily do our work under all options 2/3/4. Our contained Dealings include work with human pathogens, and those researchers preferred the safety of option 3 over the other options. For our uncontained Dealings, option 4 is the preferred, option 3 is the second choice, with option 2 being undesirable.

We accepted different options depending on whether we wanted to perform Dealings with GM plants or Dealings with GM pathogens. For work with plants, option 4 was considered safe. For work with pathogens, option 4 was not considered to be safe enough, but option 3 was considered safe.

Option 1 is not an option at all, because it doesn't give us a clear and confident way forward to plan our research projects.

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

We believe that option 2 would make Australia uncompetitive in the agricultural industry. Other countries would be able to expedite their plant breeding programs, and that seed would dominate the industry. It would no longer be viable to do plant breeding work in Australia under option 2.

We believe that option 3 would also limit our ability to be competitive in plant breeding, but to a lesser extent than option 2.

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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?

We believe that option 2 would result in a level of regulation not commensurate with risks posed by gene technology. We believe that SDN-1 technology is similar to technologies that have safely been used in agricultural breeding programs for many years. We do not provide any scientific evidence to support these beliefs.

We believe that option 3 would result in a level of regulation not commensurate with risks posed by gene technology. We believe that SDN-2 technology is similar to natural processes of DNA repair and variation. We do not provide any scientific evidence to support these beliefs.

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

We believe that options 2 and 3 would significantly increase the regulatory burden on us from the gene technology regulatory scheme. Since the results of these technologies could be difficult to detect or prove that they were not the result of natural processes, we believe that identifying internal non-compliance in our business would be burdensome. When developing new crop plants for commercial release, we would also have an added burden of going through the process of seeking and carrying out DIRs.

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

We currently use mutant plant populations developed using chemical-induced mutagenesis and UV irradiation-induced mutagenesis. These plants are destined for use in breeding programs to produce commercial cultivars for release. We use item 1 of Schedule 1 to work on these plants without them being regulated under the Gene Technology regulatory system.

If item 1 of Schedule 1 was changed such that our mutant plant populations became subjected to increased regulatory burden, it would negatively impact our plant improvement programs.

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 had mixed views about whether or not GM gene drive organisms pose different risks to other contained research with GMOs. Some of our researchers said “no”, that there are lots of harmful technologies used in labs, and that gene drives were just another risk to be controlled. Some of our researchers said “yes”, that the consequence of a GM gene drive organism escaping containment was higher and that more precautions would be required than for other GMOs. Some of our researchers said that gene driven modifications that result in wiping out a species need higher controls than gene driven modifications that do not effect the viability of the species.

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 are using plasmid-driven RNAi techniques. We believe that they clearly are GMOs and we have them covered by GM Dealings.

We are using transient RNA oligo introduction RNAi techniques. We believe that they clearly are not GMOs and we do not have them covered by GM Dealings.

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 previously struggled with the risk assessment process for Licences. We have found it to be difficult and would prefer if it were easier. We would prefer that the risk assessment process were based on the outcome of the modification.