**Email Submission: Department of Agriculture and Fisheries Institutional Biosafety Committee**

**Department of Agriculture and Fisheries IBC Consultation Questions Response**

1. Which option/s do you support, and why?
   - Option 3 is supported.
   - The IBC believes that an assessment system which also reviewed the risks associated with the product produced by genetic modification would be more pragmatic and efficient rather than the current system based on the processes used.
   - The majority of IBC scientific members initially preferred option 4.They appreciated the need to review current policy settings of the scheme and regulatory issues that would be involved for its implementation. They support option 3 which would have less regulatory impact under current legislative constraints.
   - In the longer term, the IBC supports modification of the overarching legislation. Legislation which is solely process regulated and suffering from the uncertainty which comes about when technology rapidly changes, could be changed to legislation which is based on assessment of risks associated with both process used and product produced.

2. Are there other risks and benefits of each option that are not identified in this document?
   - If legislation is found to need modification then the trigger should be the risk based on a combination of the process used and potential products produced.

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?
   Under the proposed regulatory framework options, there is potential to increase the regulatory burden as the regulation is potentially technology based. For example, a number of the host/vector systems listed in Schedule 2 Part 1 and 2 could have an altered classification if products were produced using technologies such as CRISPR/CAS9.This is problematic as the actual risk of the GMO has not been altered, just the methodology used to create the GMO.
   The inherent risks in GMOs are not based on how they were made in most cases, but what the impact of the modification made is, which is how the current exemption legislation is worded. As an example from Schedule 2 Part 1:

   2 A dealing with a genetically modified *Caenorhabditis elegans,* unless:
   a. an advantage is conferred on the animal by the genetic modification.

   Currently modifications to *C. elegans* which do not confer an advantage are exempt. If the regulation is technology based, the same modifications made using genome editing would not be exempt. Having the same outcome regulated differently is clearly problematic.

4. How might options 2-4 change the regulatory burden on you from the gene technology regulatory scheme?
   - Option 2 could mean more work for researchers and organisations.

- Option 3 and 4 should have the same burden.

5. How do you use item 1 of Schedule 1, and would it impact you if this item was changed?
   - Improved clarity of terminology should be helpful for an IBC. These definitions should also be worded to be clear to lay people on committees.

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.
   - Yes, they would pose more risk if there is escape into the environment as wild populations will be changed, though risk is highly dependent on generational time and should be assessed on a case by case basis.
   - Currently with standard Mendelian inheritance there is a much lower likelihood of release of a GMO resulting in a change in the wild population.
   - The IBC supports:
     - higher containment requirements for GM gene drive organisms
     - reclassification from the lower monitoring of NLRDs to more monitoring as in DNIR classed activities.

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.

   RNAi is an important biological process involved in regulating gene expression, and protecting cells from parasitic nucleotides such as viruses and transposons. As per the answer to Question 3 above, the proposed regulatory framework options will have an impact on the use of this technology. As an example, with current exempt/low risk dealings, studying gene function and functional genomics where the primary goal is to only identify gene function.

   RNAi is a 'knockdown' technique where gene expression may be down-regulated significantly but not entirely. In this context, the organism is likely to be less fit, rather than more fit; i.e. an *advantage* to the modified organism is not conferred. The technology is used in plant science to knockdown the negative effects of plant allergens, carcinogens and toxins on human health. Where the outcome is increased host resistance to pests and pathogens, then an *advantage* is conferred.

   Under the proposed regulatory framework options, both advantageous and non-advantageous outcomes incur the same regulatory burden because the regulation is based on the technology used, rather than the outcome (product).

   As mentioned above, the inherent risks in GMOs are not how they were made, but the impact of the modification to the organism. While the proposed regulatory framework is technologically based, it has the potential to increase the regulatory burden for exempt/low risk dealings. Where the regulations are in line with major trading partners, i.e. being outcome based, the need for review of the regulation would not be required every time a new technique is developed.

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 recommendations or comments at this time.