



Department of Primary Industries

Office of the Director General

DGPO16/168

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The Gene Technology Regulator
GPO Box 9848
CANBERRA ACT 2601

ogtr@health.gov.au

Dear Regulator

Review of Gene Technology Regulations

NSW Department of Primary Industries (DPI) welcomes the review of the Gene Technology Regulations (the GT Regulations) and is grateful for the opportunity to provide this response.

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

DPI considers that option 3 provides an appropriate balance between enabling advances and ensuring regulatory control, is consistent with past approaches to regulation, and provides clarity to ensure that significant modifications are appropriately regulated.

Option 3:

- Retains a conservative approach by regulating anything other than the simplest cut and natural repair technologies, thereby providing assurance to the community but without imposing an excessive regulatory burden on research and the innovations that arise from it.
- Provides clarity on exactly what is regulated and certainty for researchers and industry by ensuring legal clarity.
- Retains the current policy settings in that the process by which organisms are modified is the central consideration in whether they are regulated as GMOs.
- Leaves as unregulated those technologies producing mutations with a risk profile unlikely to be different to natural, chemical or radiation induced mutations.
- Regulates the "highest" risk technologies that introduce changes substantially different from naturally occurring mutations.

DPI does not support Option 4 at this time but encourages the regulator to begin to explore the practicalities of implementing this option. This option may offer longer term benefits but presents challenges in terms of its requirement for comprehensive revision of the regulations, the need to effectively deal with public perception, the significant task to clearly prescribe the parameters determining whether a genetic

outcome is regulated, and the practical imperative to avoid continual review of the regulations in the face of emerging technologies.

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

No.

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?**

DPI views Option 2 as overly conservative in terms of risk management and would be difficult to enforce, given that genetic changes generated can be indistinguishable from natural mutations and changes produced by chemical or radiation induced mutagenesis.

Option 3 remains a conservative regulatory scheme that in DPI's view appropriately regulates risk in the short term. Option 4 requires a comprehensive revision of the regulations, leaving ambiguity and exposure to risks in the interim.

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

All Options increase the regulatory burden to different degrees but DPI welcomes the improved clarity that each brings regarding the use of gene editing techniques. Option 2 demands a significant increase to the regulatory burden for researchers while Option 3 requires an increase that is commensurate with risk and offers the opportunity to address public perceptions in the first instance. DPI consider this additional regulatory burden to be manageable.

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

DPI would welcome improved clarity in the wording of item 1 of Schedule 1 to reflect the Option that is implemented. We note that the revised wording should also clearly indicate whether the use of exogenous nucleic acids to direct DNA cleavage, in and of itself constitutes the creation of a GMO.

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.**

Possibly, given the implications at a population level posed by gene drive technologies, particularly in the case of inadvertent or malicious release. Research could be enabled within a regulated environment that required extensive and ethical consideration of social and environmental consequences, the implementation of a range of containment measures (molecular, physical, reproductive and ecological), modelling of gene flow using benign changes in the first instance, and the parallel development of appropriate safeguards such as gene drives to "immunise" a population or "reverse" problematic drives.

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.**

RNA interference techniques are currently not being used in NSW DPI because of a lack of clarity on the regulatory status of the method and the resulting organism. An example of where DPI might seek to use RNA interference if the resulting organism was not judged to a GMO would be to generate “knockout” mutations to prevent rhizobium from transferring genes for nodulation to other soil borne bacteria (that then nodulate plants but are incapable of fixing nitrogen).

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.**

The issue of gene drive is receiving some current attention. If gene technology is used to introduce or create a gene drive in an organism, the resulting organism will be a GMO and subject to regulation under the *Gene Technology Act 2000*. DPI considers that OGTR’s proposed guidelines on this are clear.

Gene drive has a range of technical and ethical questions that would need to be resolved before such approaches could be accepted by industry, consumers and community. To date, proposed gene drive processes would be facilitated through gene editing techniques such as CRISPR/Cas9, further supporting the “product” based approach to regulating gene editing as outlined in Option 3 of the OGTR review supporting documents.

DPI is a major investor in the Australian node of the international “Yeast 2.0” consortium that is using synthetic biology to synthesise a modified version of the genome for *Saccharomyces cerevisiae* (common yeast). This global project will enable the testing of biological assumptions, allow the assembly of new biological pathways and will develop a deeper understanding of gene function. DPI envisages the delivery of benefits to a broad range of primary industries through its ability to leverage its investment, developing “spin off” projects with outcomes across primary industries more broadly.

DPI also encourages OGTR to consider the regulatory environment in which synthetic biology techniques are being, and will be used, in Australia in future.

Thank you for the opportunity to comment on the review.

Yours sincerely

**SCOTT HANSEN
DIRECTOR GENERAL**