

Review of the Gene Technology Regulations 2001

Submission by University of Wollongong IBC (Gene Technology Review Committee)

We welcome the Regulator's review of the Gene Technology Regulations (2001) in response to recent technological advancement, particularly genome editing.

We have comments on consultation questions 1, 4, 5 and 7:

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

Our Committee favours option 2: Regulate certain new technologies.

All genetic manipulation processes to generate new organisms/cell lines using these new techniques, including oligo-directed mutagenesis and all site-directed nuclease techniques, should be regulated at the current time. We note that some of the organisms generated by these techniques could be exempt, if proved safe. Organisms verified without introduced foreign nucleic acid and, after a period of time, observed/proved to have no risk to humans, other living organisms and the environment may be excluded from GMO list.

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

Not significantly.

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

Schedule 1 Organisms that are not genetically modified organisms (regulation 5)

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

Based on this current definition, those organisms without introduced foreign nucleic acid, but still generated by gene technology, will not be regarded as GMOs. We agree that "depending on the option pursued following consultation, the above item may need to be changed to improve clarity of the legislation". If option 2 is adopted, all these new organisms need to be registered as GMOs. Regardless, we would intend to register all products generated by gene technology at UoW.

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.

At the University of Wollongong there have been only a few recent RNAi research projects involving some cultured cell lines and animal models. siRNAs are transiently expressed. No concern has been expressed by the researchers.

Dr Ren Zhang
Chair, Gene Technology Review Committee
University of Wollongong
