Curtin University

Office of Research and Development
Chair – Curtin University Institutional Biosafety Committee

GPO Box U1987
Perth Western Australia 6845

9 November 2017

Review of Australia's Gene Technology Scheme

We would firstly like to thank the Legislative and Governance Forum on Gene Technology for the opportunity to provide information into the review of the National Gene Technology Scheme. We believe that the OGTR is doing a commendable job in an extremely agile environment. We have had a significant level of interaction with the OGTR in recent years due to an increase in the research profile of our University and the OGTR has been very helpful in deliberations.

Please find below our thoughts on the problems and issues with the scheme as it currently stands. Our responses have taken into account the need for our researchers to be able to effectively perform their research in Australia and maintain internationally competitive, but to also consider broader considerations of the risks posed in extreme cases.

Definition of a Genetically Modified Organism, Gene Technology and Genetic Material

During the recent discussion of new technologies initiated by the OGTR there was much debate of the definition of a genetically modified organism or GMO. The current definition hinges on the use of gene technology to modify the genes or other genetic material, which is stated in the Act. The regulations however exclude an organism from being a GMO if foreign nucleic acid (specifically DNA) is not introduced. Our concern is that with new technologies, such as CRISPR Cas9, a gene deletion or targeted small mutation to an organism would not result in that organism being classified as a GMO, even though it has been clearly modified by gene technology. In most cases the inherent risk may be low (for example changing the nucleotide sequence of a receptor gene in a plant that prevents a fungal pathogen from infecting the plant), however the same technology could be used to produce a high risk effect (mutating the promoter sequence, switching on an oncogene).

In defining a GMO the Act refers to “other genetic material” however this is not defined. This has led to some ambiguity in the interpretation of the Act and the associated regulations. Genetic material may just refer to nuclear genetic material (the genome) or could also refer to any nucleic acid within a cell, which would also cover mRNA, rRNA, tRNA etc.. This therefore raises conjecture as to whether RNA silencing technologies should be regulated under the Act. There therefore needs to be a clear definition of what genetic material is within the Act or regulations.

The Act also refers to gene technology as “modifying” genetic material. Again, there is currently conjecture surrounding this and a better definition is required either in the Act or in the regulations. Are targeted techniques that change the methylation status of DNA included in this definition? Also, would techniques that change the expression of gene without modifying the DNA be included under this? For example, modifying histones to “open up” sections of the genome to make them more transcriptionally active.

What is the “trigger” for regulation?

During the recent discussion surrounding new technologies the OGTR repeatedly stated that the Gene Technology Scheme is a process driven scheme and that the trigger for regulation has to be the process and it cannot be the inherent risk posed by the product. It was also repeatedly stated that any change to the “trigger” would require changes to the Act. Our interpretation of the Act is that the Act puts more onus on the risk posed by a GMO (the product) than it does on the process itself. We therefore feel that there is ambiguity around the trigger for regulation and this should be made clearer in either the Act or regulations.

For contained dealings, we would prefer to see the regulatory system adopt a product driven focus. We do acknowledge that there is some need to have a tighter level of regulation around a sub set of “processes”, such as lentiviral transduction, but this could be accounted for in a risk based regulatory system.

Time taken for licenced dealings and certification of facilities

The time taken for licensed dealings to be approved is currently a hindrance to the ability of researchers in Australia to stay internationally competitive. While we recognise the effort required to produces a risk assessment and risk management plan for a licensed dealing is large, the time that is required to complete

this is negatively impacting on researchers. We have encountered issues with funding bodies due to the time taken to receive a licensed dealing and we would not like for this to happen again. Our concern is that the OGTR is not sufficiently resourced for licences to be reviewed in a timely fashion and that if more resources were provided this process may be sped up. The time of 90 working days for an DNIR, which is still a contained dealing, could be reduced, allowing researchers in Australia to stay competitive.

There are also long lead times for the certification of facilities. At the recent OGTR Forum, we were told that the OGTR have a significant back log of applications and that applications would take the full 90 days to process. Again our concern is that the OGTR is not sufficiently resourced to deal with the number of applications for certification being put before it and this is leading to the long certification times. If more resources were provided in the certification area this could reduce the amount of time taken for certification to be approved. The long lead times taken for certification puts Australian researchers at risk of staying competitive.

We see that extra resourcing could be in both the form of more staff to process applications in a more timely manner but also in better supporting services. The application processes for both licences and certifications is still very paper based and could be improved with a web based portal similar to that has recently been adopted by the Dept of Agriculture and Water Resources. Such a system could also be used to manage individual accredited organisations reporting requirements to the OGTR.

Alignment of OGTR PC2 requirements with other regulatory standards

Currently there are multiple laboratory standards for PC2 style facilities. The OGTR have their own build requirements for laboratories, which differ from those outlined in Australian and New Zealand Standard 2243.3 and again from the Dept. Agriculture and Water Resources. We have encountered confusion from architects, engineers and even some researchers when discussing the built requirements for different types of facilities. At a minimum a better alignment between the OGTR regulations and the ASNZS would be a considerable improvement.

Ability to perform Dealings Involving Release

With the continual broader acceptance of gene technology in the wider community we believe that the potential for GM products to greatly increase. Our university has several groups that are involved in commercial agriculture research where gene technology is becoming a more and more attractive option. One of the largest hurdles in furthering this research is the regulation surrounding dealings involving release. Given the time taken to obtain a dealing and the costs associated with compliance, commercial funding bodies do not see this as an attractive option. We believe a system that takes in to account the level of the associated contained dealing with the licence for a dealing involving release may reduce the time taken to process and the cost associated with compliance.

Closing remarks

We would again like to thank the review for the opportunity to provide feedback about the Gene Technology Scheme in Australia. We believe that with better definitions surrounding gene technology and with further resources supplied to the OGTR, the Scheme could be improved. We would welcome the opportunity to be involved further with any aspect of the review.

Regards,

Chair – Curtin University Institutional Biosafety Committee.