



Response from the Australian Academy of Health and Medical Sciences to the 2017 Review of the National Gene Technology Regulatory Scheme

The call for contributions to the Review of the National Gene Technology Scheme will no doubt elicit many specific responses to the questions which are raised. The institutions at which Academy members work will have provided their expert feedback on this matter. As a collective, the Academy would like to raise a higher level question: Is it necessary to maintain the National Gene Technology Scheme at all?

Concern about genetically modified organisms was at a fever pitch when the potential to alter the DNA sequences by recombinant DNA technology was discovered and brought into use several decades ago. The fear of the unknown certainly justified caution, but it is not true that the technology or the outcomes of its use are unknown today. This therefore begs the question as to whether it is necessary to have an administrative burden imposed on researchers in order to monitor the use of a particular technology. In passing, it should be noted that the implications of CRISPR-CAS technologies apparently escape the purview of the NGTS. The organisms that have been generated in laboratories using the gene technology scheme have no track record of generating any public health problem. By contrast, naturally occurring micro-organisms such as viruses, parasites and bacteria are real threats to the health of the community, and exotic animals and plants pose real threats to the environment and the economy, but none fall under the ambit of the National Gene Technology Scheme. They are dealt with on the basis of health and safety issues in a manner that has worked very well for many years.

The expansion of the controls over gene technology to include laboratory animals, which are useful for preclinical studies but totally incapable of survival outside the pampered conditions of a laboratory, adds a further burden to the work of researchers at the preclinical stage. The wellbeing of animals is a matter of great concern to all involved in the research process and to society and it is well monitored by the Animals Ethics Committees and the DAFF. Again, the

National Gene Technology Scheme is an extra layer of control over a non-threatening development.

The Academy notes that in some details of the processes of the National Gene Technology Scheme unnecessary delays are introduced. Matters which have to be controlled locally have nonetheless to be submitted for a confirmation of acceptance by the OGTR which can introduce delays which are not productive or add to safety or provide extra information on the constructs involved.

The Academy accepts as absolute the need to maintain the highest level of safety for the community and in doing so extends this to potential environmental impacts related to the programmed release of genetically modified organisms. That step is one which again seems to be potentially covered by use of an agency such as the Environmental Protection Agency.

The Academy is well informed on the burdens on administration which are stultifying the ability of Australian researchers to advance their work in the most efficient manner. The benefits of the controls which are imposed in the National Gene Technology Scheme are minimal and duplicative whereas the loss to society and the reduced productivity of researchers is major and expanding.

The Academy therefore would welcome a renewed consideration of the necessity for the National Gene Technology Scheme and suggest that it is one area where red tape could be reduced without detriment to society, the environment or researchers.