Australian Academy of Science

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15 July, 2005

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Review of the operations of the *Gene Technology Act 2000* and the *Intergovernmental Agreement on Gene Technology*

Australian Academy of Science submission

The Australian Academy of Science is well placed to comment on the operations of the *Gene Technology ACT 2000* and the *Intergovernmental Agreement on Gene technology Act*, given its history of involvement in the process of regulation of research regarding the genetic manipulation of organisms. Many of the Academy's Fellows are actively involved in research and serve on the committees relating to the Acts.

The Academy is satisfied that the Act provides evidence-based decisions to "protect the health and safety of people and the environment". The independence of the Regulator - or the perception of it - is an important part of public confidence in the regulatory process. The Regulator's powers deal exclusively with health, safety and environmental issues, ensuring that the assessment of these risks cannot be compromised by economic issues. This does not mean that the decisions of the regulator do not have an economic impact on investors of GM technology.

The Academy notes the formation of private consultancies specializing in biosecurity and bio-containment. The existence of such companies could be interpreted as an indication of the increased pressure that research organisations are under simply to comply with the regulations. There should be no need for an interpreter to ensure an agency complies with the regulations, and no need for the agency to pay an independent consultant for their services. There is a need to encourage dialogue between the OGTR and agencies throughout the regulatory process, rather than in the compliance phase of the regulatory process.

An opportunity exists for the OGTR to strengthen ties with the research community, encouraging an atmosphere of co-operation, rather than compliance, with regulations. The OGTR could play more of a role in education and support of the research community to facilitate interpretation and compliance with the Act, and by offering realistic and practical measures to implement regulations. This would result in less need for monitoring and compliance activities on behalf of the Regulator, and a more harmonious relationship between the OGTR and the research community.

Members of the committees, including the Gene Technology Community Consultative Committee and the Gene Technology Ethics Committee, might also benefit from being better informed before submitting advice to the regulator on proposals.

The Academy is concerned about moratoria on commercial releases of GM crops currently in place in each of the states. The moratoria are evidence that the *Gene*

Technology Act 2000 and the *Intergovernmental Agreement on Gene Technology* are not operating in "a seamless manner" between Commonwealth and State regulatory schemes. Nor is it "nationally consistent", because the moratoria are in place for different lengths of time in different states. The state imposed moratoria are contrary to the decision of the Regulator, and act as a disincentive for further investment in research in agricultural biotechnology and development. If the outcomes from research cannot be marketed, investors will withdraw from Australia and go elsewhere.

The moratoria may not be in place if the community had "access to quality information about biotechnology, the potential risks and benefits of its application". This highlights the necessity for the OGTR to be involved in increasing public awareness of GM technology, to assist the Regulator in applying the Act. The moratoria also prevent the generation of data for informed decision making about GM crops. In this respect the Act has failed to "capture the benefits of biotechnology for the Australian community, industry and the environment ", that is part of the *National Biotechnology Strategy*.

The Academy is concerned by the possible implementation of cost recovery measures. The overall level of funding available for infrastructure and other costs is already inadequate to maintain an effective research capacity. At present, research and development is being done by universities, CSIRO and a number of Australian private companies with little or no commercial profits. The gene technology industry is currently unable to fund regulatory costs. Cost recovery would put important research at risk.

Cost recovery will weaken the links between the biotechnology research sector and industries that apply biotechnology that the *National Biotechnology Strategy* aims to strengthen. If any form of cost recovery is implemented, and it becomes financially prohibitive to do research in Australia, the research will go offshore. Field trials of transgenic crops for example would be done in conditions not appropriate to Australian soil and climate. Further, the potential impact on Australian species by introduced crops would remain unknown. Australia will miss out on potential benefits offered by the uptake of the technology.

Without a cap on the size of the *Office of the Gene Technology Regulator*, the cost of funding the bureaucracy could escalate, with a corresponding increase in costs to the research community. Research agencies are currently carrying the cost of regulation with the time and effort of researchers and their agencies to comply with the Act.

It is difficult to enforce compliance with the notifiable low risk dealings of laboratory activities regulated by the Act. Adding a cost to complying with the regulations may encourage non-disclosure of all activities, in an effort to cut costs. The Act aims to manage the risks presented by the technology. By definition, most of the notifiable low risk dealings are minimal risk. There is a need to ensure that the level of monitoring and compliance with the notifiable low risk dealings is commensurate with the level of risk.

The Academy is satisfied that the Act provides a transparent regulatory process and an accessible public record of GMO dealings and GM products. An appropriate balance has been found in the regulatory process by the Regulator acting on advice from three committees: the scientific, ethical and community consultative committees.

The Act needs to "remain relevant to the science it oversees, the community it protects and the industry it regulates". Australia has the capacity for high quality research, but not without the continued support of the agencies established to regulate their activities.

The Academy hopes that this submission is useful and would welcome an opportunity to discuss the matter with reviewers.

Yours Sincerely
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