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GENE TECHNOLOGY, RISK, REGULATION AND COMMUNICATION

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SUBMITTED IN FULFILMENT OF THE REQUIREMENTS OF THE DEGREE OF

DOCTOR OF PHILOSOPHY,

UNIVERSITY OF TASMANIA,

JANUARY 2005

CANDIDATE'S STATEMENT

I declare that the work presented in this Thesis contains no material which has been accepted for a degree or diploma by the University or any other institution except by way of background information and duly acknowledged in the Thesis, and to the best of my knowledge and belief no material previously published or written by another person except where due acknowledgment is made in the text of the Thesis.

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Brendan Gogarty

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REFERENCE GUIDE

KEYWORDS

Law, Regulation, Legislation, Gene Technology, Regulatory Theory, Regulatory Reform, Gene Technology Act 2000, Risk, Risk Theory, Risk Governance, Deliberative Risk Governance, Regulatory Communication, Risk Communication, Public Involvement, Consultation, Public Engagement, Science & Society, Risk Society, Blame Society, Australia

MeSH LIBRARY TERMS

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ABSTRACT

This thesis examines the social, political and legal basis for the establishment of a national regime for the oversight of risks posed by **gene technology** in Australia. It provides an overview of the public debate about gene technology and considers how that debate served to motivate and shift the focus of regulatory reform which led to the *Gene Technology Act 2000 (Cth)* (GTA).

The debate about gene technology belies a much deeper social preoccupation with novel risk generally – something described by risk theorists as the ‘**risk society**’. This risk society has placed pressure on legislatures to manage the perceived risks posed by novel technologies or to use novel technologies to manage man-made or natural risks. Yet the traditionally prescriptive and cumbersome process of regulatory reform is ill-suited to the pace and transient nature of scientific innovation. Consequently, legislatures have developed a new legislative form, **risk governance**, designed to provide a more flexible scientifically based response to novel technologies. This form of legislation is exemplified by the GTA. Yet risk governance has proved to create problems of its own. Maintaining regulatory flexibility necessitates that rule making is virtually, if not officially, undertaken outside of the parliamentary process. Furthermore, because risk governance adopts a scientifically based assessment and management process (**risk analysis**) it must co-opt technical specialists (the subjects of regulation) into the decision making process. These factors have contributed to risk governance being perceived as anti-democratic in some quarters. Such perceptions are agitated by a growing distrust of technocrat’s ability to serve the public interest in the risk society. Lack of trust was a major theme throughout the Australian gene technology debate.

The response to public distrust in technocratic oversight of novel technology has been the inception of **risk communication**, a process that encourages public involvement in risk analysis. Unfortunately, best practice risk communication has tended to be promulgated in policy but avoided in practice – something revealed with the commercialisation of gene technology. This has resulted in increased

pressure to put promise into practice by institutionalising participatory risk communication principles within risk governance. I have referred to this more democratic regulatory form as '**deliberative risk governance**'.

The GTA was enacted with the promise that it would involve the public in all aspects of regulating risks posed by gene technology. I consider how we arrived at such a system, if it matters and whether the promise of deliberative risk governance is real, efficacious and genuine within this act.

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ALRC. Australian Law Reform Commission.

Biosafety Protocol. Cartagena Protocol on Biosafety 1999.

CBD. Convention on Biodiversity.

CCI. Confidential Commercial Information.

Codex. Codex Alimentarius Commission.

Community Committee. Gene Technology Community Consultative Committee.

CSCG. Commonwealth State Consultative Group on Gene Technology.

Ethics Committee. Gene Technology Ethics Committee.

EU. European Union.

GMAC. Genetic Manipulation Advisory Committee.

GMO. See Genetically Modified Organism.

GTA. Gene Technology Act 2000 (Cth).

GTCCC. Gene Technology Community Consultative Committee.

GTCCG. Gene Technology Community Consultative Group.

GTEC. Gene Technology Ethics Committee.

GTTAC. Gene Technology Technical Advisory Committee.

IOGTR. Interim Office of the Gene Technology Regulator.

IPPC. International Plant Protection Convention.

LMO. See Living Modified Organism.

NAS. United States National Academies of Sciences

NAS-NRC. United States National Academies of Sciences (NAS) and National Research Council

NHMRC. National Health and Medical Research Council.

NHP Guidelines. Guidelines For Assessing Human Health Risks From Environmental Hazards 2002.

NHP. Commonwealth and State Government National Health Partnership.

NLRD. Notifiable Low Risk Dealing.

OGTR Risk Framework. Risk Analysis Framework For Licence Applications To The Office Of The Gene Technology Regulator.

OGTR. Office of the Gene Technology Regulator

OIE. Office International Des Epizooties (International Office of Epizootics)

R&D. Research and Development.

Red Book. The NAS-NRC Report, 'Risk Assessment in the Federal Government: Managing the Process' 1983.

SPS. Sanitary and Phytosanitary

TBT. Technical Barriers to Trade

Technical Committee. Gene Technology Technical Advisory Committee.

The Regulations. The *Gene Technology Regulations* 2001 (Cth).

The Regulator. The Gene Technology Regulator.

UNIDO. United Nations Industrial Development Organisation.

US. United States

WTO. World Trade Organisation