

***Governing Genes for Climate Change: Analysing Values
and Ideologies in Australia's Gene Technology Regulation.***

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Abstract

This thesis analyses some of the multidimensional aspects of Australia's gene technology regulation associated with the intended novel use of this technology. It demonstrates that deliberations about the commercial gene technology licenses have been deeply shaped by competing social and scientific paradigms associated with gene technology in Australia. The contentions between the social and scientific paradigms were in turn influenced by the personal interpretations, values, ideologies, and disciplinary knowledge held by the actors who were (directly or indirectly) involved in the regulation. By analysing the scholarly literature related to this multidisciplinary topic, I was able to demonstrate that the Australian gene technology framework favoured scientific concerns in comparison to broader social concerns as it fails to incorporate or adequately address the opinions of the GTECCC members and the Australian public (both lay and informed). The contentions amongst the social and scientific paradigms were further identified and analysed at the level of expert committee stakeholders by interviewing two members from the GTECCC and the GTTAC, respectively. The resulting discussions reflected the deep chasm that lay between the working of these two integral committees by elucidating the personal opinions and values of these two members.

Declaration

I, Sumit Salaria, hereby declare that the work presented here has not been submitted for a higher degree to any other university or institution. This thesis is an original piece of research and work of others has been duly acknowledged in the text. The ethics approval was sought for this research work and granted by The Faculty of Science Human Research Ethics Sub-Committee, Macquarie University (5201400423).

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List of Abbreviations

AAS:	Australian Academy of Science
ABC:	Australian Broadcasting Corporation
ASCORD:	Academy of Science Committee on Recombinant DNA Molecules
Bt:	<i>Bacillus thuringiensis</i>
DNA:	Deoxyribonucleic Acid
EU:	European Union
GM:	Genetically Modified
GMO:	Genetically Modified Organism
GT Forum:	Gene Technology Forum
GTCCC:	Gene Technology Community Consultative Committee
GTEC:	Gene Technology Ethics Committee
GTECCC:	Gene Technology Ethics and Consultative Committee
GTSC:	Gene Technology Standing Committee
GTAC:	Gene Technology Technical Advisory Committee
MUHREC:	Macquarie University Human Research Ethics Committee
NCF:	Network of Concerned Farmers
NSW:	New South Wales, Australia
NT:	Northern Territory, Australia
OECD:	Organisation for Economic Co-operation and Development
OGTR:	Office of the Gene Technology Regulator
QLD:	Queensland, Australia
RARMP:	Risk Assessment and Risk Management Plan
STS:	Science and Technology Studies
USA:	United States of America
VIC:	Victoria, Australia
WA:	Western Australia, Australia

Chapter 1 – Introduction

Australia's ratification of the Kyoto Protocol ("Protocol") represented a significant commitment from the Australian nation to identify and reduce its green-house gas emissions.¹ Ratification of the Protocol has resulted in the Australian government providing tangible targets for reductions in the amounts of green-house gases being produced in Australia.² In order to meet these targets, the Australian government has sought to quantify gaseous emissions and identify major sectors of the Australian economy, which are contributing towards green-house gas emissions.³ Out of the major contributing sectors, the Australian transportation sector and the agricultural sector combined, produce the highest amount (approximately 34%) of green-house gas emissions in Australia.⁴ Apart from the conventional methods suggested to reduce green-house gas emissions in both the sectors, gene technology may be utilised to assist with this effort.⁵ The Australian transportation

¹ Department of the Environment, Australia. "Quantified Emission Limitation or Reduction Objective (QELRO), Accessed April, 2014, <http://www.climatechange.gov.au/international/negotiations/australias-unfccc-submissions/quantified-emission-limitation-or-reduction>

² Department of the Environment, Australia. *Australia's emissions projections*, Accessed April, 2014, <http://www.climatechange.gov.au/reducing-carbon/reducing-australias-emissions/australias-emissions-projections>

³ Department of the Environment, Australia, *Quarterly Update of Australia's National Greenhouse Gas Inventory: December 2013, Commonwealth of Australia 2014*, Accessed April 2014, <http://www.environment.gov.au/system/files/resources/d616342d-775f-4115-bcfa-2816a1da77bf/files/nggi-quarterly-update-dec13.pdf>

⁴ Department of the Environment, Australia, *Quarterly Update of Australia's National Greenhouse Gas Inventory: December 2013, Commonwealth of Australia 2014*, Accessed April 2014, <http://www.environment.gov.au/system/files/resources/d616342d-775f-4115-bcfa-2816a1da77bf/files/nggi-quarterly-update-dec13.pdf> . See page 6 for the breakdown of sectors and respective emissions data; Department of the Environment, Australia, *Quarterly Update of Australia's National Greenhouse Gas Inventory: December 2013, Commonwealth of Australia 2014*, Accessed April 2014, <http://www.environment.gov.au/system/files/resources/d616342d-775f-4115-bcfa-2816a1da77bf/files/nggi-quarterly-update-dec13.pdf> .See pages 6, 11 and 13.

⁵ Evans, Caroline, David Cosgrove, David Gargett, Paul Graham, Adam Ritzinger, and Paul Davies. "Greenhouse gas abatement potential in the Australian transport sector." *Routes/Roads* 358 (2013). Accessed April 2014, <http://www.csiro.au/~media/CSIROau/Flagships/Energy%20Transformed%20Flagship/ALCTF%20Summary%20Report.pdf>. See figure 4 on page 13 for a list of conventional abatement options in the transportation sector; Australia's *Gene Technology Act 2000* defines "gene technology" as "any technique for the modification of genes or other genetic material". Although simplistic, this definition captures the core aspect of gene technology research, which is to genetically manipulate organisms for an intended benefit. For the scope of this research, the term "gene technology" would be referred to as the technique of biological sciences which involves study of gene expression and further involves genetic manipulation by either addition or deletion of

sector's green-house gas emissions may be reduced with the substitution of conventional fossil fuels (for example, petroleum and diesel) with biofuels (for example, bioethanol and biodiesel), derived from either genetically modified plants or bio-organisms.⁶ The agricultural sector may benefit from, firstly, the utilisation of genetically modified feed crops (or genetically modified enzymes) for ruminating animals to reduce enteric fermentation and secondly, from genetically modified varieties of staple crops (for example, rice) which have reduced green-house gas emissions and are less dependent on nitrogenous fertilisers and pesticides, as compared to traditional crop varieties.⁷ The use of biofuels derived from genetically modified crops, as suggested for the transportation sector, may also be extended to agricultural farm management equipment and heavy machinery.

The gene technology-based techniques mentioned above may be considered as novel modification to the existing green-house gas mitigation solutions in the agricultural and transportation sectors. For example, firstly, the use of biofuels to power internal combustion engines has already been in practice for the last decade.⁸ As compared to fossil fuels, biofuels have been found to provide higher energy yields upon combustion and produce less green-house gas emissions.⁹ Secondly, breeding practices to create hardy crop varieties, which are capable of better nitrogen fixation and less methane generation, have also been used since the

genetic material in a given organism for desired results, mostly conducted artificially in a controlled environment of a laboratory (either for intended laboratory based results or widespread commercial use).

⁶ Lü, Jing, Con Sheahan, and Pengcheng Fu. "Metabolic engineering of algae for fourth generation biofuels production." *Energy & Environmental Science* 4, no. 7 (2011): 2451-2466; Sticklen, Mariam. "Plant genetic engineering to improve biomass characteristics for biofuels." *Current Opinion in Biotechnology* 17, no. 3 (2006): 315-319.

⁷ Glover, Julie, Hilary Johnson, Jacqueline Lizzio, Varsha Wesley, Paul Hattersley, and Catherine Knight. "Australia's crops and pastures in a changing climate—can biotechnology help." *Canberra: Australian Government Bureau of Rural Sciences* (2008). See part 2 and part 3; Van Nevel, Christian, and Daniel Demeyer, "Feed additives and other interventions for decreasing methane emissions," in *Biotechnology in animal feeds and animal feeding*, eds. Wallace, R. John, and Andrew Chesson, (Weinheim: John Wiley & Sons, 2008), 329.

⁸ Rimmer, Matthew, and Griffith Hack. "Intellectual Property and Biofuels: The Energy Crisis, Food Security, and Climate Change." (2015). *Social Science Research Network*. Accessed January 2016, <http://dx.doi.org/10.2139/ssrn.2610985>

⁹ Hill, Jason, Erik Nelson, David Tilman, Stephen Polasky, and Douglas Tiffany. "Environmental, economic, and energetic costs and benefits of biodiesel and ethanol biofuels." *Proceedings of the National Academy of Sciences* 103, no. 30 (2006): 11206-11210.

advent of modern agricultural techniques.¹⁰ Finally, the addition of nutritional additives to animal diets to curb methane production via enteric fermentation has also been actively used in the agricultural sector.¹¹ The gene technology applications mentioned in this research, are genetically engineered versions of the existing products with the premise that the end product may be able to work as a new solution that fits the existing human practices in both the agricultural and transport sectors and more importantly, leads to a reduction of green-house gas emissions.

It may be argued here that use of gene technology applications cannot exclusively be based on its scientific functionality and there are other important factors that may need to be considered, for example, concerns related to human and environmental safety, economic impacts, social impacts, food security and ethical considerations.¹² Brush (2001) suggested that the use of gene technology could not be solely based on the premise that it represents a “product of progress”.¹³ An analogy that may be considered here is that of the nuclear technology. As suggested by Applegate (2001), nuclear technology too represents scientific progress (in the field of energy generation) to some but catastrophe to others, especially its potential for wide-ranging and long-lasting effects on human and environmental health as seen in the sphere of nuclear-related accidents and nuclear warfare.¹⁴

¹⁰ Tester, Mark, and Peter Langridge. "Breeding technologies to increase crop production in a changing world." *Science* 327, no. 5967 (2010): 818-822.

¹¹ Smith, Pete, Daniel Martino, Zucong Cai, Daniel Gwary, Henry Janzen, Pushpam Kumar, Bruce McCarl et al. "Greenhouse gas mitigation in agriculture." *Philosophical Transactions of the Royal Society B: Biological Sciences* 363, no. 1492 (2008): 789-813. For a summary, see page 794.

¹² Kariyawasam, Kanchana. "Legal Liability, Intellectual Property and Genetically Modified Crops: Their Impact on World Agriculture." *Pac. Rim L. & Pol'y J.* 19 (2010): 459. See pages 462-468 for a good summary of concerns associated with genetically modified organisms resulting from gene technology science; Dibden, Jacqui, David Gibbs, and Chris Cocklin. "Framing GM crops as a food security solution." *Journal of Rural studies* 29 (2013): 59-70. For a summary, see page 68.

¹³ Brush, Stephen B. "Genetically modified organisms in peasant farming: social impact and equity." *Indiana Journal of Global Legal Studies* (2001): 135-162. See page 140.

¹⁴ Applegate, John S. "The Prometheus principle: Using the precautionary principle to harmonize the regulation of genetically modified organisms." *Indiana Journal of Global Legal Studies* (2001): 207-263. See page 217.

Further, Brush (2001) suggested that “the potentially negative ecological impacts of GMOs have received extensive attention, while social impacts are relatively understudied.”¹⁵ In relation to the application of gene technology to farming practices, Brush (2001) argued that “while unwanted environmental impacts of the new technology can be partially assessed in controlled, experimental settings, assessment of social impacts requires experience and observation in particular farming systems.” The lack of adequate social and economic impact assessments and the subsequent adverse effects of gene technology application can be illustrated by analysing the effects of introduction of GM Cotton to the Indian agrarian economy. According to Herring (2005), the dependency of Indian farmers on proprietary GM Cotton seeds supplied by Monsanto (from 1988 to 1995), created a “social tragedy” which led to a series of suicides by the farmers of the Warangal district in the state of Andhra Pradesh.¹⁶ As noted by Shiva et al. (1999), GM Cotton seeds were engineered by Monsanto in such a way that they only propagated for one sowing cycle. This caveat eventually led the farmers back to Monsanto for the procurement of next batch of seeds for the forthcoming seasons.¹⁷ The high prices associated with GM seeds, and the need for special fertilisers and insecticides to farm the crops, forced the farmers into a nexus comprised of monetary debt and proprietary seed dependence. Shiva et al. (1999) further suggested that the introduction of GM seeds by private companies (like Monsanto) resulted in a threat to the food security of the Indian agrarian economy as “instead of growing food and maximising ecological security and food

¹⁵ Brush, GMOs: Social impact and equity, 135; Genetically modified “GM” and genetically modified organism “GMO”.

¹⁶ Herring, Ronald J. "Miracle seeds, suicide seeds, and the poor." in *Social Movements in India: Poverty, Power, and Politics*, eds, Ray, Raka. and Mary F. Katzenstein., (Lanham:Rowman & Littlefield Publishers, Inc., 2005): 205-206.

¹⁷ Shiva, Vandana, Ashok Emani, and Afsar H. Jafri. "Globalisation and threat to seed security: case of transgenic cotton trials in India." *Economic and Political Weekly* (1999): 601-613. See page 603;

security,” farmers were “induced to grow cash crops for high profits, without assessment of risks, costs and vulnerability”.¹⁸

Gene technology, as compared to other traditional variants of biological sciences, is still relatively new and lacks a strong scientific assessment lineage, as compared to, for example, medical science. The advent of gene technology can be traced back to 1973, when for the first time it was demonstrated that it was artificially possible to introduce genetic material from one organism to the other. A team of researchers based at the Stanford University, United States, headed by Stanley Cohen and Herbert Boyer, from University of California, Berkeley, were successful in extracting genetic material from one bacteria and introducing it to the genetic material of another.¹⁹ The product of this experiment was a bacterium with a mix of two separate genetic materials, successfully propagating in-vitro.²⁰ Based upon this research, the scientific lobby in the United States conducted further experimentation to explore the potential of artificially introduced genetic material in other organisms (apart from bacteria). But shortly after, in 1974, concerns of uncertainty related to human health and the potential of disruption to the “natural balance” of the environment, led gene technology researchers to implement a voluntary self-imposed moratorium on any gene technology based research.²¹ The call for the moratorium originated via the means of an article published in the journal *Science*, by a committee of prominent US life-scientists associated with gene technology.²² The “Berg’s committee” recommended for an immediate halt on gene technology

¹⁸ Shiva et al., Threat to Seed Security: India, 601; In a similar study of GMO seed manufacturing companies in Canada (including Monsanto), Santilli (2012) highlighted the concerns of farmer dependency and threat to food security related to GMO seeds, which were being marketed under the pretext of “climate-ready”. Santilli, Juliana. *Agrobiodiversity and the Law: Regulating Genetic Resources, Food Security and Cultural Diversity* (Oxon, Routledge, 2012). Please see page 247.

¹⁹ Cohen, Stanley N., Annie CY Chang, Herbert W. Boyer, and Robert B. Helling. "Construction of biologically functional bacterial plasmids in vitro." *Proceedings of the National Academy of Sciences* 70, no. 11 (1973): 3240-3244.

²⁰ Cohen, Construction of Plasmids, 3240-44.

²¹ Stevenson, Leslie, and Henry Byerly, *The Many Faces of Science: An Introduction to Scientists, Values, and Society* (2nd ed.) (Boulder:Westview Press, 1995). For a good summary, see pages 190 to 194.

²² Berg, Paul, David Baltimore, Herbert W. Boyer, Stanley N. Cohen, Ronald W. Davis, David S. Hogness, Daniel Nathans et al. "Potential biohazards of recombinant DNA molecules." *Science* 185, no. 4148 (1974): 303.

(recombinant DNA) experiments until its risks were better understood and appropriate measures were formally designed to contain those risks.²³ The Berg's committee also recommended to set up an international meeting to "review scientific progress" in gene technology and to "further discuss appropriate ways to deal with the potential biohazards of" artificially modified DNA molecules.²⁴ Shortly after, in 1975, the follow-up meeting was organised at the International Conference on Recombinant DNA Molecule Research, held at the Asilomar Conference Centre, California, United States.²⁵ The Asilomar conference resulted in identification and categorisation of the risks associated with gene technology and set the grounds for an internationally recognised system of scientific risk assessment and abatement.²⁶ The voluntary moratorium was finally lifted following Asilomar conference and "it was agreed that the research should continue but under stringent guidelines".²⁷

Although the moratorium was lifted in 1975 and gene technology science has since developed significantly, the concerns associated with gene technology have also grown.²⁸ These concerns may seem justified, considering the nascent stage of application of gene technology for reduction of green-house gas emissions and also considering the scientific uncertainty (and discussion) surrounding genetically modified organisms and gene technology science.²⁹

²³ Swazey, Judith P., James R. Sorenson, and Cynthia B. Wong. "Risks and benefits, rights and responsibilities: A history of the recombinant DNA research controversy." *Southern California Law Review* 51 (1977): 1019-1078. See page 1024; Jasanoff, Sheila. *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton: Princeton University Press, 2005). See page 46.

²⁴ Berg et al., Biohazards DNA molecules, 303.

²⁵ Swazey et al., DNA Research Controversy, 1031.

²⁶ Wright, Susan. "DNA Technology: Asilomar Conference and 'Moratorium' on Use." *eLS* (2006). See page 2.

²⁷ Berg, Paul. "Meetings that changed the world: Asilomar 1975: DNA modification secured." *Nature* 455, no. 7211 (2008): 290-291. See page 1.

²⁸ Cohen, Construction of Plasmids, 3242; Phillips, Theresa. "Genetically modified organisms (GMOs): Transgenic crops and recombinant DNA technology." *Nature Education* 1, no. 1 (2008): 213.

²⁹ Weaver, Sean A., and Michael C. Morris. "Risks associated with genetic modification:—An annotated bibliography of peer reviewed natural science publications." *Journal of Agricultural and Environmental Ethics* 18, no. 2 (2005): 157-189.; Myhr, Anne Ingeborg, and Terje Traavik. "The precautionary principle: scientific uncertainty and omitted research in the context of GMO use and release." *Journal of Agricultural and Environmental Ethics* 15, no. 1 (2002): 73-86; Buiatti, M., Paul Christou, and G. Pastore. "The application of GMOs in agriculture and in food production for a better nutrition: two different scientific points of view." *Genes & nutrition* 8, no. 3 (2013): 255-270.

Since the lifting of the self-moratorium on gene technology science in 1975, the strategies of regulation have played a significant role in addressing the public and scientific concerns related to the safety of gene technology.³⁰ What is evident is a gradual shift from a technocratic self-regulatory model, where scientists involved in gene technology research weigh the pros and cons of their own research, to a more comprehensive model that includes a mix of government policy underpinned by scientific assessment. A body of researchers, who analyse the health risks associated with the gene technology application, usually undertakes this scientific assessment process.³¹ This has, in-turn led to an increase of actors (directly or indirectly) involved in the process of gene technology regulation, ranging from research scientists, institutions funding and in other ways facilitating the research, governmental administrators and actors involved in the critique of gene technology (both layman and scientific) and finally the gene technology in question.³²

Views about the proposed application of gene technology for reducing green-house gas emissions in Australian transportation and agricultural sectors can be envisaged on a seesaw pedestal, where on one end are the concerns arising out of gene technology research and its application in Australia and on the other end are the proposed benefits for the mitigation of climate change. Australia's gene technology regulation and processes, can maintain the fulcrum or pivot for this seesaw whereby gene technology applications can be regulated to ultimately attain equilibrium between both the ends.

Through the means of this research thesis, I have examined the processes, institutions and actors involved in the regulation of gene technology in Australia. Specifically, I have investigate the values and ideologies that inform (or are evident in) the regulatory actors of gene technology in Australia and how these might influence the adoption of gene technology

³⁰ Hindmarsh, Richard. "Genetic engineering regulation in Australia: An 'Archaeology' of expertise and power." *Science as culture* 14, no. 4 (2005): 373-392. See page 373 to 375.

³¹ Jasanoff, Designs on Nature. See pages 225 to 271.

³² Hindmarsh, Genetic Engineering Regulation, 375.

for green-house gas reduction. The interviews with the stakeholders provided a rare insight and points of comparison between how they perceive gene technology science and its regulation in Australia. It highlighted, how their different academic background (and resulting worldview) and their affiliation to different regulating arms of regulatory mechanism in Australia, shapes the current regulatory system. This analysis hence, when seen through the lens of regulation of new and emerging technologies in Australia (for example gene technology applications to combat climate change) advocates for the development of cohesive regulatory structures, which give equal importance to human and environmental health, social, cultural, economical and ethical concerns. Application of gene technology for combating climate change is currently in its infancy in Australia, and mostly at the level of laboratory based research. A more comprehensive approach for analysis of gene technology applications for the mitigation of climate change would be to analyse not just the regulatory processes (and its actors) but an exhaustive analysis of the research (both private and educational institutions) and also the wider effects of this application, for example within broader social, cultural, and economic contexts.³³ Such an analysis will require more time, resources, and specialised knowledge of the above-mentioned fields of study. I may explore this further at a doctoral level of study, upon completion of the current masters thesis. In keeping with the aims set up by Macquarie University regarding this Masters of Research degree, I have undertaken this thesis to develop a sound understanding of the research preparation techniques required for a Doctor of Philosophy (PhD) in the social sciences domain. Based on my analysis of this topic, intellectual growth and the findings associated with this research, this thesis could be considered as a pilot research project which could be

³³ For example, at a preliminary research level ("low risk") the Australian gene technology is regulated via Institutional Biosafety Committees (IBC). IBCs are accredited through the mechanisms set under the Australian gene technology regulation and supply an annual report of their research involving GMOs to the appropriate authorities. These IBCs hence can become a starting point for analyses for a larger research project, to identify the extent of gene technology research/application being undertaken in Australia aimed at climate change mitigation.

drawn from for future in depth studies which could afford a researcher more time, resources, word count and depth of knowledge.

Chapter 2 - Who, What and Why – The Need for an Analysis.

To recognize the need for this regulatory analysis, it is firstly important to gain a perspective of the current gene technology regulation process in Australia and its various regulatory bodies and secondly, to identify the various actors involved in the process of regulation.

In Australia, gene technology research and its application is regulated by the Gene Technology Regulator (“Regulator”).³⁴ The Regulator works independently at his/her post and is appointed by the Governor-General of Australia.³⁵ The Regulator is directly supported by the staff members constituting the Office of the Gene Technology Regulator (OGTR), which sits within the Australian Department of Health and Ageing.³⁶ Two additional federal bodies, namely, the Gene Technology Technical Advisory Committee (GTTAC) and the Gene Technology Ethics and Consultative Committee (GTECCC), also support the Regulator.³⁷ As the name suggests, the GTTAC primarily provides technical scientific advice to the Regulator and the GTECCC provides advice related to ethics, community consultation, risk communication, policy (code and regulations) guidelines and other general matters.³⁸ At the governance level, two separate bodies, namely, the Legislative and Governance Forum on Gene Technology (GT Forum) (comprised mainly of ministerial heads from the Australian Commonwealth Government and all State and Territory governments), and the Gene Technology Standing Committee (GTSC), oversee the Regulator’s activities.³⁹ The GTSC does not directly govern the working of the Regulator but provides high-level advice to the

³⁴ *Gene Technology Act 2000* (Cth), § 27. One person holds the post of the Regulator for a maximum term of 5 years and minimum 3 years.

³⁵ *Gene Technology Act 2000*, § 118; *Gene Technology Act 2000*, § 30.

³⁶ “About the Office of the Gene Technology Regulator (OGTR),” Office of the Gene Technology Regulator, Accessed April 2014, <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/about-index-1#ogtr>.

³⁷ *Gene Technology Act 2000*, § 101, 47(4.b); *Gene Technology Act 2000*, § 107.

³⁸ *Gene Technology Act 2000*, § 101; *Gene Technology Act 2000*, § 101, 47(4.b).

³⁹ Department of Health, Australia. *Legislative and Governance Forum on Gene Technology*, Department of Health, Australia, Accessed April 2014, <http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-gtmc.htm>; Department of Health, Australia. *Gene Technology Standing Committee*, Accessed April 2014, <http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-gtstandingcommittee.htm>

GT Forum and is composed of corresponding members from the Commonwealth and all States and Territories of Australia (like the GT Forum).⁴⁰ The Regulator in turn regulates gene technology in Australia using an Australia-wide legislative scheme which is comprised of the *Gene Technology Act 2000*, the *Gene Technology Regulations 2001* and the corresponding State and Territory gene technology legislations.⁴¹

Based on the above description, a categorisation of core (decision making or influencing) actors can be identified. The Regulator and the member of the GTTAC are comprised of actors from the scientific community with expertise in gene technology science or related scientific disciplines.⁴² The members of the GT forum, which includes Australian politicians and appointed governmental bureaucrats, represent a political policy (or ideology) based decision-making body.⁴³ The GT Forum can impart its direct influence on the regulatory process by developing policies and guidelines, which are adhered to, by the Regulator and the OGTR. Since the GT Forum has the power to de-establish the post of the Regulator and appoint a replacement on an interim basis, this may also result in indirect influence of political ideology on the post of the Regulator and his/her decision. This current classification can even be extended to the member of the GTSC, which are selected by their corresponding political leaders from the central, state and territorial governments. Lastly, the GTECCC, which is comprised of members from a broader Australian skill set and the composition of which is neither mandated nor limited to the scientific domain (for example, community

⁴⁰ Department of Health, Australia. *Legislative and Governance Forum on Gene Technology*, Department of Health, Australia, Accessed April 2014, <http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-gtmc.htm>

⁴¹ *Gene Technology Act 2000*, § 118; *Gene Technology Act 2000*, § 30.

⁴² *Gene Technology Act 2000*, § 100(5).

⁴³ Tribe, David. "Gene technology regulation in Australia: A decade of a federal implementation of a statutory legal code in a context of constituent states taking divergent positions." *GM crops & food* 3, no. 1 (2012): 21-29. See page 22.

consultation, business, law, religion, ethics and environmental wellbeing, to name a few)⁴⁴. It tends to represent a wider group of informed and educated Australian electorate.

Apart from the above-mentioned categories of actors involved in gene technology regulation in Australia, a fourth category of “general public” or “electorate” is also involved in the regulation process, although in a much diluted fashion.⁴⁵ The dilution results from the lack of mandatory review of direct public opinion in the current regulatory scheme. Under the current scheme, one of the more effective ways (although indirectly) of assertion of public opinion is via the actions of the GT Forum and its composition of elected politicians. In the wake of public outcry over a given gene technology application, the politicians involved may inform the Regulator of the concerns and, if need be, directly impose State-based moratoriums.⁴⁶ Although the Regulator is mandated to provide information to the general public about the GMO’s during the various stages of the approval process, public opinion is only considered at the discretion of the Regulator, who is not under any compulsion to incorporate the same in his/her judgment.⁴⁷ Due to limitations of time, resources and acknowledgement of the general consensus that this fourth group holds extremely limited direct influence on the current gene technology regulatory process, an in-depth analysis of this category may not be pursued at this stage, however, this thesis examines some of the consequences of the regulatory limitations on this fourth group within the broader analysis of regulatory processes.⁴⁸

⁴⁴ *Gene Technology Act 2000*, § 108.

⁴⁵ *Gene Technology Act 2000*, § 52; Schibeci, Renato, Jeff Harwood, and Heather Dietrich. "Community involvement in biotechnology policy? The Australian experience." *Science Communication* 27, no. 3 (2006): 429-445. See page 442.

⁴⁶ Explained further in the thesis.

⁴⁷ Ross, Kerry. "Providing “thoughtful feedback”: Public participation in the regulation of Australia's first genetically modified food crop." *Science and Public Policy* 34, no. 3 (2007): 213-225. See page 216.

⁴⁸ *Gene Technology Act 2000*, § 108, 52; Schibeci et al., Community Involvement, 442; Schibeci, Renato, and Jeffrey Harwood. "Stimulating authentic community involvement in biotechnology policy in Australia." *Public Understanding of Science* 16, no. 2 (2007): 245-255; Robins, Rosemary. "The Limits of Community Consultation in the Governance of Gene Technology in Australia." Accessed April 2014, <http://www.tasa.org.au/uploads/2011/05/Robins-Rosemary-Session-45-PDF.pdf>.

The past interactions and influences of the core actors mentioned above can be observed through the example of GM Canola plants, which were first proposed to be introduced to the Australian agricultural market in 2003. After consulting with the GTTAC, the Regulator chose to provide commercial release licenses to the proponent companies, based on scientific assessment and the lack of strong evidence for any significant risk to human health and the environment as compared to traditional, non-GM varieties of Canola.⁴⁹ This assessment was in accordance with the mandate set by the *Gene Technology Act 2000*, according to which the Regulator only needs to consider the biosafety (or technical) aspects of GMOs and discounts any other concerns (for example, negative economic, social, and cultural impacts as well as any benefits that may be derived from gene technology).⁵⁰ Furthermore, the Regulator ignored the concerns of the then Gene Technology Community Consultative Committee (GTCCC) that advocated against the approval of the commercial release of GM canola by citing reasons of community “unreadiness”.⁵¹ The “unreadiness” of the community was a factor that did not align with the Regulator and GTTAC’s scientific assessment of the risks posed by the GMO.⁵² This example highlights that although the Regulator may request the current GTECCC (in the past, the GTEC or the GTACCC) for an opinion, he/she is not bound to consider those concerns in approving or disapproving of commercial release of the given

⁴⁹Office of the Gene Technology Regulator, *Rigorous Assessment Confirms Gm Invigor®Canola Safe As Non-Gm Canola*, Accessed April 2014, [http://ogtr.gov.au/internet/ogtr/publishing.nsf/Content/2003-1/\\$FILE/canola2.pdf](http://ogtr.gov.au/internet/ogtr/publishing.nsf/Content/2003-1/$FILE/canola2.pdf) ; Office of the Gene Technology Regulator. “Media Release: Joint Regulatory Decision On Monsanto Gm Canola”, Accessed April 2014, [http://ogtr.gov.au/internet/ogtr/publishing.nsf/Content/2003-1/\\$FILE/monsantocanola.pdf](http://ogtr.gov.au/internet/ogtr/publishing.nsf/Content/2003-1/$FILE/monsantocanola.pdf)

⁵⁰ “Risk Analysis Framework 2013,” Office of the Gene Technology Regulator, Accessed April 2014, [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/42D3AAD51452D5ECCA2574550015E69F/\\$File/rffinal5_2.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/42D3AAD51452D5ECCA2574550015E69F/$File/rffinal5_2.pdf). See page 25; *Gene Technology Act 2000*, § 27.

⁵¹ The current GTECCC is a result of a merger between the Gene Technology Ethics Committee (GTEC) and Gene Technology Community Consultative Committee (GTCCC) that happened in 2007 as per the Gene Technology Amendment Act 2007; Office of the Gene Technology Regulator. *Communique of 4th GTCCC Meeting 20 February 2003*, Accessed April 2014, [http://ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gtccc-1/\\$FILE/4thcommgtccc.pdf](http://ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gtccc-1/$FILE/4thcommgtccc.pdf)

⁵² Ross, Australia’s first GM food crop, 216; Robins, Limits Of Community Consultation, 2.

GMO.⁵³ Moving forward, the introduction of GM canola to the Australian agricultural sector became even more convoluted when in 2003, all jurisdictions of Australia, apart from Queensland (QLD) and Northern Territory (NT), imposed a moratorium on GM Canola commercial propagation.⁵⁴

The Regulator's decision to approve commercial cultivation of GM canola seems highly objective as it only considers the scientific merit (or facts) of the given application, as per the guidelines set by the *Gene Technology Act 2000*. However, while assessing any new gene technology license application, the Regulator and the GTTAC members did not conduct in-house scientific testing related to the given gene technology application. They relied on the scientific information provided by the proponent of the technology and verified the facts by consulting peer-reviewed research in that scientific domain.⁵⁵ Jasanoff (1994) suggested that "scientific facts are, for the most part, socially constructed".⁵⁶ According to her, scientific factual information is considered true, not for its accurate calculations of the data involved, but because this information is certified to be accurate by a lobby of scientific researchers. These researchers form the upper echelon of the peer-reviewed system of scientific knowledge and "are those who are considered competent enough to pass upon the truth and falsity of that" scientific claim or fact.⁵⁷ In this way, if scientific claims can be constructed, Jasanoff argued that, similarly these facts or claims could be deconstructed, as "players with

⁵³ *Gene Technology Act 2000*, § 47(4).

⁵⁴ NSW Department of Primary Industries, *GM Canola*, Accessed February 2015, <http://www.dpi.nsw.gov.au/agriculture/broadacre/winter-crops/oilseeds/canola/gm>

⁵⁵ Office of the Gene Technology Regulator. *Fact Sheet GMOs approved for commercial release in Australia: GM Canola*, Accessed April 2014, [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/gmofactsheets-3/\\$FILE/factcanolaApr10.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/gmofactsheets-3/$FILE/factcanolaApr10.pdf)
See page 2.

⁵⁶ Jasanoff, Sheila. *The Fifth Branch*, (Harvard University Press, 1994). See page 12.

⁵⁷ Jasanoff, *The Fifth Branch*, See page 13.

different stakes in the technical controversies arrive at different construction of the scientific reality”.⁵⁸

The absence of in-house scientific experimental testing in the current Australian gene technology regulatory processes (OGTR) hence exposes the risk assessment procedure to the personal interpretations of scientists, at three separate levels. At the first level is the basic testing where the researchers in national laboratories interpret scientific testing data from first hand results (for example, The Commonwealth Scientific and Industrial Research Organisation). At this level, for example, the researchers would conduct broad level analyses of permissible and non-permissible quantities and effects of GMO’s to the environment and the human health and would establish recommended benchmarks for national (or international) use. At the second level is the testing conducted by the researchers in the laboratories of the companies interested in commercialising gene technology. At this level, these researchers would compare their testing results to the national or internationally recommended standards and interpret the data accordingly, before submitting it to the regulating authority. At the third level is the interpretation of data performed by the Regulator and the scientists in GTTAC, in response to the given gene technology license application.⁵⁹ This possibility of personal interpretation of the scientific data further convolutes the notion that “scientific facts are tested and established with reference to objective criteria of validity”.⁶⁰ According to Jasanoff (2004), establishment of facts (or discoveries) are mainly a result “of material and cultural resources with which human actors bring new natural

⁵⁸ Jasanoff, *The Fifth Branch*, See page 13.

⁵⁹ Smith, Joe, and Heidi Mitchell. "Challenges researchers need to consider when dealing with regulators." *Journal für Verbraucherschutz und Lebensmittelsicherheit* 1, no. 9 (2014): 65-70. Please see page 69. Joe Smith (former gene technology Regulator of Australia) acknowledges the prospect of miscommunication between the researchers and the regulating agencies.

⁶⁰ Jasanoff, *The Fifth Branch*, See page 13.

phenomena into view”.⁶¹ As a result the establishment of facts themselves are a result of the social and scientific cultures experienced by a given researcher.

The decisions made by the Regulator and the scientists in GTTAC, hence may be influenced by their underlying personal values and views on ‘environment’ or ‘nature’. The scientists involved in this assessment may already be, knowingly or unknowingly, drawing conclusions based on a set of values while deciding factors such as, what constitutes a risk (and the distinction between high risk and low risk), how to measure that risk and what may constitute ‘human environment’.⁶² Wickson (2006) suggested that this kind of approach is highly misleading and disguises the ways in which scientific decision-making is instilled with particular values.⁶³ For example, as per Lawson (2000), Regulator’s understanding of “low-risk” of a given GMO could be a summation of his/her own personal opinions and perceptions of a given statistical probability of what constitutes ‘low-risk’.⁶⁴ Lawson further suggested that approaches or judgments that ignore adverse effects of low probability (or magnitude) are most likely a product of values that undermine science-based objective reasoning altogether.⁶⁵ Similarly, according to Jasanoff (1994), in cases where scientists may struggle to obtain conclusive experimental results, they are mostly likely to “turn to non-scientific criteria of excellence, such as faith in the experimenter’s honesty, the size and prestige of the laboratory,

⁶¹ Jasanoff, Sheila. *States of Knowledge: The Co-Production of Science and the Social Order* (London, Routledge, 2004). Please see page 16.

⁶² Salleh, Ariel. "'Organised irresponsibility': Contradictions in the Australian government's strategy for GM regulation." *Environmental Politics* 15, no. 03 (2006): 399-416. See pages 401 and 402; Jasanoff, *The Fifth Branch*, See pages 229 and 230; *Gene Technology Act 2000*, § 10. In the *Australian Gene Technology Act 2001*, the definition of the word ‘environment’ does not include social, economic and cultural spheres of human society and mainly focuses on built or physical environment.

⁶³ Wickson, F., “*From risk to uncertainty: Australia’s environmental regulation of genetically modified crops: PhD thesis, School of Biological Sciences/Science, Technology and Society, University of Wollongong.*” (2006) Accessed May 2014, <http://ro.uow.edu.au/theses/510>. See page 44 and 45;

⁶⁴ Lawson, Charles, and Richard Hindmarsh. "Releasing genetically modified canola into the Environment-deconstructing a decision of the Gene Technology Regulator under the Gene Technology Act 2000 (Cth)." *Environmental and Planning Law Journal* 23, no. 1 (2006): 22. See pages 202 and 211.

⁶⁵ Lawson, Risk Assessment, 202.

and even personal qualities like nationality or professional group affiliations".⁶⁶ As noted before in this analysis, gene technology research is comparatively a new branch of science and is still evolving. Long-term effects of gene technology are yet to be fully verified by the scientific community, especially in relation to its secondary effects on the environment.⁶⁷ This observation substantiates the possibility that the researchers involved in the current Australian gene technology regulation may come across GM testing results that are less conclusive.

On the other hand, the moratoriums placed on GM canola by various jurisdictions of Australia, depict an undertone of political ideology and interests (short term or long term). For example, these interests may include decisional sovereignty of the elected political party over matters related to the State's economic growth, and human and environmental welfare. Ludlow (2004) suggested that if factors such as economic, social, and cultural impacts were to be included in the current regulatory scheme of risk analysis, by the Regulator and the GTTAC, the States risked losing their power of sovereignty over commercialisation decisions related to GMO's.⁶⁸ The Regulator's decision to grant a commercialisation license to a GMO proponent is binding on the given State or Territory. If economic, social, and cultural risk analysis were to be included in the current regulatory scheme, the States and Territories risk losing grounds to substantiate their decisions on placing moratoriums. The discussion around the moratoriums of 2003 was mostly fuelled by the lack of provision of above-mentioned factors in the current Australian gene technology regulation.⁶⁹

⁶⁶ Jasanoff, *The Fifth Branch*, 14.

⁶⁷ Lu, Bao-Rong, and Allison A. Snow. "Gene flow from genetically modified rice and its environmental consequences." *BioScience* 55, no. 8 (2005): 669-678; O'Callaghan, Maureen, Travis R. Glare, Elisabeth PJ Burgess, and Louise A. Malone. "Effects of plants genetically modified for insect resistance on nontarget organisms." *Annu. Rev. Entomol.* 50 (2005): 271-292.

⁶⁸ Ludlow, Karinne. "Cultivating chaos: State responses to releases of genetically modified organisms." *Deakin L. Rev.* 9 (2004): 1. See page 39.

⁶⁹ Ludlow, Karinne, Stuart J. Smyth and José Falck-Zepeda. "Introduction to Socio-Economic Considerations in the Regulation of Genetically Modified Organisms" in *Socio-economic considerations in biotechnology regulation* (Springer Science & Business Media, 2013). Please see page 13.

According to Deakin (2008) and Ludlow (2011), the negative effect of commercialisation of GM Canola to the States' agricultural economy was one of the major reasons behind the GM moratoriums of 2003.⁷⁰ Since the members of the GT Forum held direct accountability to their voters, their decision may be guided by the concerns of the interested and influential citizens (at that time).⁷¹ Whatever may be the reasons behind the disapproval from the GT Forum and other concerned politicians, those reasons predominantly have to be other than the risks to human health and environment, since by mandate these risks have already been evaluated by the Regulator and GTTAC members.⁷² The obligations of the GT Forum does not involve actively assessing health risks to human health or environment caused by the GMOs, but to "issue policy principles, policy guidelines and codes of practice to govern the activities of the Gene Technology Regulator (the Regulator) and the operation of the Scheme (the "Scheme" refers to the national legislative scheme to protect the health and safety of people and to protect the environment, by identifying risks posed by, or as a result of, gene technology and by managing those risks through regulating certain dealings with genetically modified organisms)".⁷³

⁷⁰ Deakin, Claire. "Resolving the regulatory conflict: Lessons for Australia from the European experience of regulating the release of genetically modified organisms into the environment." *Environmental Planning and Law Journal*, 25, no.1 (2008):103-29. See page 113; Ludlow, Karinne, and Stuart J. Smyth. "The quandary of agricultural biotechnology, pure economic loss, and non-adopters: Comparing Australia, Canada, and the United States." *Jurimetrics* (2011): 7-41. See page 34.

⁷¹ Tribe, David. "Gene technology regulation in Australia: A decade of a federal implementation of a statutory legal code in a context of constituent states taking divergent positions." *GM crops & food* 3, no. 1 (2012): 21-29.

⁷² Office of the Gene Technology Regulator. *Fact Sheet GMOs approved for commercial release in Australia: GM Canola*, Accessed April 2014, [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/gmofactsheets-3/\\$FILE/factcanolaApr10.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/gmofactsheets-3/$FILE/factcanolaApr10.pdf)

⁷³ Department of Health, Australia. *Legislative and Governance Forum on Gene Technology*, Department of Health, Australia, Accessed April 2014, <http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-gtmc.htm>

Chapter 3 – Methods and Methodology

As highlighted in the introductory chapters of this thesis, due to the multifaceted nature of this problem, this research draws disciplinary knowledge from both the natural and social sciences domain, brought together under Science and Technology Studies (STS).⁷⁴ As a result, I have used a transdisciplinary approach to critically evaluate Australia's gene technology regulation, its core actors and their (personal value and ideology driven) actions (and viewpoints) towards the new and emerging use of gene technology in climate change abatement. I have used a combination of methodologies available under STS, namely, semi-structured interviews to obtain primary data associated with this research, and utilised methods of discourse analysis, content analysis (hermeneutic analysis) and case study analysis, to obtain and reflect on the scholarly literature available on this topic.⁷⁵ Due to a range of factors such as the limited time span, difficulty in getting access to the targeted actors, inhibition and refusal on the part of actors contacted, out of the eleven interview requests, only two stakeholders finally participated in interviews.

I acknowledge that although a data set of two interviews is not an ideal research base (as compared to for example, the original intent of eleven interviews, or more). However, the research process and these two interviews shed important light on some of the key aspects associated with Australian gene technology regulatory structure and its power distribution structures.

This research process highlights the opaque nature of the gene technology regulation in Australia, since many stakeholders involved were not willing to be interviewed and the gaining access to them not straightforward, even though this area essentially falls in the realm

⁷⁴ Bowden, Gary, "Coming of Age in STS: Some Methodological Musings" in *Handbook of Science and Technology Studies*, edited by Sheila Jasanoff, Gerald E Markle, James C Paterson and Trevor Pinch (California: SAGE Publications Ltd, 1995) 64-79.

⁷⁵ Bowden, *Coming of Age in STS*, 64-79.

of public-government participation. The two interviews with the members of GTECCC and the GTTAC respectively, provided a rare insight and points of comparison between how either one perceives gene technology science and its regulation in Australia. It highlighted, how their different academic training and resulting worldview, and their affiliation to different regulating components of regulatory mechanism in Australia, shaped the currently skewed system. Hence, this analysis, when seen through the lens of regulation of new and emerging technologies in Australia (for example gene technology applications to combat climate change) advocates for the development of cohesive regulatory structures, which give equal importance to human and environmental health, social, cultural, economical and ethical concerns.

This research project falls under the umbrella of transdisciplinary research as it aims to evaluate a topic, which is complex, multifaceted and presents many areas of human interaction with their environments.⁷⁶ Three main characteristics can be identified whenever transdisciplinary approach is applied to a given research problem.⁷⁷

Firstly, a transdisciplinary approach can be applied to analyse a topic which it is complex and at the boundary of biological and human systems.⁷⁸ To illustrate the complexity of the GMO regulatory processes, Wickson (2006) noted that:

“While we all might wish to minimize environmental harm when making decisions about releasing GMOs, any person or organisation charged with making these decisions will have to contend with different values and attitudes, different philosophical ideas and ideologies and

⁷⁶ Hoffmann-Riem, Holger, Susette Biber-Klemm, Walter Grossenbacher-Mansuy, Dominique Joye, Christian Pohl, Urs Wiesmann, and Elisabeth Zemp, eds. *Handbook of transdisciplinary research* (Dordrecht:Springer, 2008). See pages 34 and 35.

⁷⁷ Wickson, *From Risk to Uncertainty*, 4.

⁷⁸ Please see, Costanza, Robert. "Escaping the overspecialisation trap: Creating incentives for a transdisciplinary synthesis." *Rethinking the curriculum: Toward an integrated interdisciplinary college education* (1990): 95-106; Hammer, Monica, and Tore Söderqvist. "Enhancing transdisciplinary dialogue in curricula development." *Ecological Economics* 38, no. 1 (2001): 1-5; Balsiger, Philip W. "Supradisciplinary research practices: history, objectives and rationale." *Futures* 36, no. 4 (2004): 407-421; Lawrence, Roderick J., and Carole Després. "Futures of transdisciplinarity." *Futures* 36, no. 4 (2004): 397-405.

alternative visions of reality about what constitutes environmental harm and how we could set about avoiding it”.⁷⁹

The analysis of the Australian gene technology regulatory processes and their interdependence on the interpretation of the key stakeholders is a complex problem, which is deeply rooted in a very social context. This social context contains within itself, not only contested values but suspicions spanning scientific outcomes, social implications, ethical concerns, and legal ramifications.

According to Jasanoff (1994), scientific decision-making is less influenced by the “objective criteria of validity” but mostly by the socially constructed and accepted scientific paradigm of that time period.⁸⁰ Paradigm influences a scientific researcher’s ability to choose between what environmental and human health issues to investigate related to a new technology and further what to expect from the data recovered from his/her analysis.⁸¹ Here, Jasanoff draws from the work of Thomas Kuhn who in his book (1962) *The structure of Scientific Revolutions* used the term “paradigm” to refer to a conglomeration of scientific concepts, techniques, and communal values and beliefs of scientific community of that era. According to Kuhn (1962), the word paradigm “stands for the entire constellation of beliefs, values, techniques, and so on shared by the members of a given community”.⁸² Within the sciences, enquiry of ‘the natural world’ is divided into different disciplines, which are defined by particular topics, methods, hypothesis, and the interest of the researchers.⁸³ Over the course of technological advancements, these disciplines have increased in number and in their sophistication to solve queries associated with the natural world, resulting in a substantial increase in the unified body of knowledge found under the domain of science.

⁷⁹ Wickson, *From Risk to Uncertainty*, 38.

⁸⁰ Jasanoff, *The Fifth Branch*, See page 13.

⁸¹ Jasanoff, *The Fifth Branch*, See page 13.

⁸² Kuhn, Thomas S. *The structure of scientific revolutions* (2nd ed.) (University of Chicago press, 1962), 175.

⁸³ Sarewitz, Daniel. "How science makes environmental controversies worse." *Environmental Science & Policy* 7, no. 5 (2004): 385-403. See page 390.

Khun (1962) claimed that there were more than one scientific paradigm, as each community of scientists had developed their own. He suggested that “a paradigm is what the members of a scientific community share, and, conversely, a scientific community consists of men who share a paradigm”.⁸⁴ According to Kuhn, a particular scientific community evaluates a given problem associated with the natural world, based on scientific paradigms developed by that group over the course of years. He explained that whenever a new problem presents itself, which could not be solved or explained under the given scientific paradigm, it usually results in the development of an alternative paradigm. The ability or the prospective of the alternative paradigm to solve this new problem or to provide a better understanding of old unsolvable questions eventually results in a paradigm shift amongst scientific communities. Further, this paradigm shift results in the development of knowledge, with which, the given communities of scientists view the natural world, determine which problems are worth solving, and how they can evaluate the risks and develop risk mitigation strategies. Finally, each paradigm shift produces a new image of the natural world by creating alternative frameworks of observation, albeit – in Khun’s view – the natural world itself has remained unchanged or has undergone negligible modification.

However, Sarewitz (2004) noted that although this may be the case, there has also been a growing divide between the ways each discipline tackles these queries.⁸⁵ He equates these different approaches to different sets of lenses through which the natural world can be examined. Each lens or approach is scientifically legitimate but may differ in its final result or recommendation. According to him, “it seems entirely plausible to suggest that the formal intellectual framework used by a scientist to understand some slice of the world may be causally related to that scientist’s normative framework for interpreting and acting in the

⁸⁴ Kuhn, *Structure of Scientific Revolutions*, 176.

⁸⁵ Sarewitz, *Environmental Science and Policy*, 390.

world”.⁸⁶ For example, in the case of commercialisation of GMOs, it may be assumed that the researchers trained within the disciplines of science associated with gene technology and its allied fields (for example, geneticists, molecular biologists and biotechnologists etcetera) would be more disposed to examining the intended benefits of GMOs. On the other hand, ecologists, population biologists, evolutionary geneticists, and so on, may be more inclined to enquire into the risks associated with the introduction of GMOs.⁸⁷ Based on Kuhn’s definition of “paradigm” and Sarewitz’s explanation of scientific lenses, it seems adequate that both the concepts of “paradigm” and “scientific lenses” share a contextual similarity.

The second characteristic of transdisciplinary research is that a single methodology may not be able to elucidate the complexities of a multifaceted problem on hand, and therefore, an evolving transdisciplinary approach is adopted which comprises of various disciplinary methodologies and epistemologies.⁸⁸ For example, this research draws from the areas of STS, gene technology science, anthropology of science and technology, governance and public policy (including Australian gene technology legislations), and employs various methodologies, namely, semi-structured interviews, discourse analyse, case study analysis and content analysis.

Kuhn’s work and his definition of paradigm has been examined and adopted by scholars from a range of disciplines. For example, Capra (1988) expanded Kuhn’s definition of paradigm to specifically accommodate a “social paradigm”. According to Capra, a social paradigm can be defined as “a constellation of concepts, values, perceptions and practices shared by a community which forms a particular vision of reality that is the basis of the way the

⁸⁶ Sarewitz, *Environmental Science and Policy*, 390-91.

⁸⁷ Sarewitz, *Environmental Science and Policy*, 391.

⁸⁸ Please see, Horlick-Jones, Tom, and Jonathan Sime. "Living on the border: knowledge, risk and transdisciplinarity." *Futures* 36, no. 4 (2004): 441-456; Wickson, *From Risk to Uncertainty*, 6.

community organises itself”.⁸⁹ Capra’s description of ‘social paradigm’ thus differs from Kuhn’s description of ‘scientific paradigm’ in the sense that the former includes concepts, beliefs, and ideologies that reside outside the sphere of scientific communities. A social paradigm hence forms the constellation of values and beliefs held by the non-scientific community of a given society. In summary, Wickson (2006) suggested that

“The distinction between a social and a scientific paradigm is not really concerned with what a ‘paradigm’ is, (as there is general agreement that this term refers to a overarching framework for structuring beliefs about the world”), but rather the distinction is between what kind of community the concept can be usefully applied to”.⁹⁰

For example, when dealing with complex issues related to gene technology application, the concept of paradigm could equally be applied to the scientific concerns, as well as to the social, economic, and ethical effects of gene technology. It should however be noted that with the increasing advancements in the fields of social and natural sciences, either of the two communities may ultimately claim a very different interpretation and significance of their respective paradigms. Depending on the enquiry on hand, social setting and implied significance of the matter, and the power held by the either of these schools of thought, it is plausible that either one may stake claim to the truer application of their paradigm. This has been observed in the case of Australian gene technology regulation, where, due to the history of formulation of the gene technology law, the current regime favours scientific concerns over other social concerns, and ultimately governs gene technology through a normative framework of biological (natural) sciences and the associated constellation of beliefs held by a select scientific community. This analysis hence involved study of scholarship and data from (but not limited to) regulatory framework surrounding gene technology, human

⁸⁹ Capra, Fritjof. “The role of physics in the current change of paradigms” in *The World View of Contemporary Physics: Does It Need a New Metaphysics?*, ed, Kitchener, Richard F. (Albany: SUNY Press, 1988) 145.

⁹⁰ Wickson, *From Risk to Uncertainty*, 29.

geography, and gene technology science. Although a complex analysis may be attempted using, for example, approaches from human geography, law, or biotechnology alone, that approach may not be able to capture the convolutions of this project. Having said so, this project draws on the form of inquiry and knowledge offered under the social sciences domain and was supplemented, wherever necessary, with gene technology science scholarship. As a result, to span the content involved in this research and to analyse both implicit and explicit information involved, I have used two separate techniques.

Firstly, I sought out to conduct semi-structured interviews with key stakeholders from the Australian gene technology regulation process, which included interviewees from the OGTR, GTTAC, GTECCC, GT Forum, GTSC and members of Greenpeace Australia and the Environmental Defenders Office, New South Wales (NSW), to collect primary data.

Interviewing can be considered as one the most elementary mode of inquiry as it rests on the underlying capability of human beings to communicate amongst each other.⁹¹ Bertaux (1981) suggested that it was an effective mode of enquiry especially for a topic rooted in the social context, as more than often, the subjects of enquiry could think and communicate.⁹² The crux of the interview process is to understand the real world “lived experience” of the stakeholder and to understand the meaning of that experience.⁹³ Similarly, I had opted to use the interview process to attain primary data in order to investigate personal and professional motivations and values that drive the gene regulatory process in Australia.⁹⁴ As noted earlier in this analysis, Australian gene technology regulation appears to be knowledge (or result) centric, where the data is interpreted by individuals at different levels of governance, and this interpretation could be a conglomeration of their shared and disputed personal values and

⁹¹ Seidman, Irving. *Interviewing as qualitative research: A guide for researchers in education and the social sciences* (Teachers College Press, 2013), 7.

⁹² Bertaux, Daniel. *Biography and society: the life history approach in the social sciences* (Sage Publications, 1981), 39.

⁹³ Seidman, *Interviewing as qualitative research*. 9.

⁹⁴ Dunn, Kevin, and Ian, Hay. *Qualitative Research Methods in Human Geography* (2nd ed.) (Oxford University Press, 2005), 80.

ideologies. Although the Regulator (upon consultation with GTTAC) has the final decision making authority, it has been observed through the GM Canola example, that the regulatory process can be influenced directly by the members of GT Forum and indirectly by the recommendations of the GTECCC. The interview process is able to elucidate these values and ideologies, which are not usually documented in the current gene technology regulation decisions.⁹⁵ Furthermore, semi-structured interviews can help in accommodating the different gene technology actors and keep the interview process content focused, rather than question focused, as compared to a structured interview process.⁹⁶ Prior to undertaking interviews, human ethics approval was sought from the Macquarie University Human Research Ethics Committee, including an approval of the questions intended for the interviews. Other scholarly research along with media reports depicting firsthand accounts of opinions of key stakeholders was also analysed, since from a community perspective, gene technology has the potential of turning into a controversial subject and withdrawal of participation was expected from some of the targeted actors.⁹⁷ Due to a range of factors such as the difficulty in getting access to the targeted actors, inhibition and refusal on the part of actors contacted, and limited time span, out of the eleven interview requests, only two stakeholders agreed for the interviews, namely, a member from the GTECCC and another from the GTTAC. A detailed discussion on the results of the interview requests has been discussed in chapter 5 of this thesis.

This technique drew on similar approaches used by scholars such as Hendriks (2005) and Schibeci et al. (2006). In a research comprising of semi-structured interviews conducted with

⁹⁵ As discussed earlier, the prime motto of the Regulator and the GTTAC committee is to analyse the scientific risk involved with commercialisation of given GMO; Royster, Betty. "Australia's Governance of Genetically Modified Organisms: The Political Forces behind Tasmania's and South Australia's GMO Regulations." *ISP Collection* (2009): 771.. See pages 6 and 13; Schibeci et al., *Community Involvement*, 440.

⁹⁶ Hay, *Quantitative Research Methods*, 88.

⁹⁷ Schibeci et al., *Community Involvement*, 440-41; For an example, see the interview from Dr. Joe Smith, the erstwhile Regulator of gene technology in Australia.
<http://www.abc.net.au/catalyst/gmfood/template.swf?revision=1>.

senior bureaucrats from the OGTR, Hendriks (2005) suggested that the current gene technology regulatory scheme operates in a top-down order where the current policy favours the dissemination of information (from OGTR) to public for imparting more awareness regarding risks and benefits of gene technology science.⁹⁸ On the other hand, any information gathered by the OGTR during public hearings and forums is ultimately used with the intent to improve public's understanding and acceptance of gene technology, rather than incorporating those views in the actual gene technology assessment process.⁹⁹ In a similar study conducted by Schibeci et al. (2006), the researchers sought to interview the members of the former GTCCC (now GTECCC). The interviews were aimed at gathering data based on the personal experiences and insights of the GTCCC members and to understand the "actual workings" of the OGTR and the GTCCC in relation to the role of public opinion in the Australian gene technology regulatory process.¹⁰⁰ Central to both of the above-mentioned investigations, was the inquiry to understand the role of public participation and opinion, in the decision making processes of the current Australian gene technology regulatory system. While Hendriks's (2005) research was focused on the effect of the opinions of lay members of the Australian electorate, Schibeci et al. (2006), analysed the effectiveness of a more informed sector of the public, devised in the form of GTCCC. Both acknowledged that there was a lack of clarity in the official communications of the OGTR regarding the importance given (if any) to the public concern. The interviews assisted the researchers to understand the perspective of the key stakeholders and to elucidate the true interpretation of the law and the policies governing gene technology related to public participation.

Secondly, secondary research via analysis of scholarly literature, book chapters, media articles and Australian gene technology law and policy documentation was beneficial in

⁹⁸ Hendriks, Carolyn M. "Participatory storylines and their influence on deliberative forums." *Policy Sciences* 38, no. 1 (2005): 1-20. See page 12.

⁹⁹ Hendriks, Participatory Storylines Influence, 12.

¹⁰⁰ Schibeci et al., Community Involvement, 440.

developing the content of this research thesis. This research project was partly motivated by my desire to examine gene technology within more socially and culturally attuned analytical frameworks. Primary data obtained from the interviews when juxtaposed with official communications from various key stakeholders, also assisted to highlight, firstly, the nonalignment of personal and professional views and secondly, the identified the dominant ideologies and views in regulatory groups.¹⁰¹

The analysis of secondary data collected in this project was not limited to a given analytical technique and evolved through the course of analysis. It was adapted based on the context and the altering perspective of the stakeholders (and researcher) involved. For example, I referred to discourse analysis (and critical discourse analysis), content analysis (hermeneutic analysis) and case study analysis (for example, introduction of GM cotton in Australia and resulting state moratoriums). There is much data available explaining these techniques in depth and their features and as such shall not be discussed in details in this thesis, apart from the analysis of scholarships where it has been previously applied in relation to analysing gene technology regulation (in general, and in Australia).¹⁰²

Content analysis of scholarship analysing the gene technology law, policy and governance were beneficial in understanding the scope of the *Gene Technology Act 2000* and *Gene Technology Regulations 2001*. The understanding of the scope was important as it revealed important aspects of the legislation and identified the gap between decision-making authority's interpretation of law and its original intended use. For example, The *Gene Technology Act 2000* states that

¹⁰¹ *Gene Technology Regulations* (Cth), § 28. To reach a decision, the GTTAC conducts a vote of the present members. Only a majority decision is accepted to approve or disapprove of given GMO commercial release application.

¹⁰² Please see, Bhattacharjee, Anol., "Social Science Research: Principles, Methods, and Practices" (2012). *Textbooks Collection*, Accessed Dec 2015, http://scholarcommons.usf.edu/oa_textbooks/3; Fairclough, Norman, Jane Mulderrig, and Ruth Wodak. "Critical discourse analysis." *Discourse studies: A multidisciplinary introduction* (2011): 357-378; Van Dijk, Teun A. "18 Critical discourse analysis." *The handbook of discourse analysis* 18 (2003): 352.

“In preparing the risk assessment in relation to the dealings proposed to be authorised by the license, the Regulator must take into account the following: (a) the risks posed by those dealings, including any risks to the health and safety of people or risks to the environment, having regard to the matters prescribed by the regulations”.¹⁰³

According to Schibeci et al. (2006), the key word in the above section from the *Gene Technology Act 2000* is “including”.¹⁰⁴ Although, the GTECCC has been established to cater to the ethical, cultural and community concerns related to gene technology, it has been noted previously in this research that GTECCC is a quasi-solution to solve these issues due its non-binding recommendations. Similarly, economic concerns related to gene technology have been addressed via State sanctioned moratoriums, which have the potential to convolute the smooth and uniform functioning of the current Australian gene technology regulatory scheme. A broader interpretation of the word ‘including’ would require the Regulator to also consider economic concerns, ethical concerns, and cultural and community concerns while undertaking scientific health and environmental risk assessment for gene technology license applications in Australia, in-turn making the scheme more robust and seamless in its functioning.¹⁰⁵

Once a clearer understanding was established of the scope of the Australian gene technology law and policies by analysing the existing scholarship in this domain, a discursive analysis of scholarship in human geography and STS, assisted in elucidating the underlying relationship between new technologies and the social paradigms that shape the governance of technologies in the Australian society. Hindmarsh and Gottweis (2005) suggested that current Australian regulation has been shaped by the Asilomar’s legacy of self-regulation (and self-interest) by the scientific elite, and mostly as a political movement rather than a scientific affair.¹⁰⁶

¹⁰³ *Gene Technology Act 2000*, § 51.

¹⁰⁴ Schibeci et al., Community Involvement, 439.

¹⁰⁵ Schibeci et al., Community Involvement, 439.

¹⁰⁶ Hindmarsh, Richard, and Herbert Gottweis. "Recombinant regulation: the Asilomar legacy 30 years on." *Science as Culture* 14, no. 4 (2005): 299-307. See page 306.

According to Hindmarsh (2006), Asilomar's influence on the development of gene technology can be attributed to two main regulatory themes,

“First, keeping the field of bioscience free of intervention from the side of legislative and regulatory agencies, so that scientists could develop and enhance their authority and licence to undertake experiments of their or their patron's desire; and, second, to retain an overall defining influence over the strategic shape (the nature and direction) of r-DNA experimentation and innovation and its normalization to society”.¹⁰⁷

Hindmarsh (2006) further argued that this “bio-elite” comprising of

“A top tier of corporate industrialists (typically representing life science corporations as well as technology developers and financiers), scientists (typically representing the biosciences both in the public and private research and development sectors), bureaucrats (typically those in state agencies of science, technology, commerce, trade, agriculture, health, and industry development), and science and technology advisors to business and government (typically, a mix of the former three, as well as corporate lawyers)”,

have shaped the current Australian gene regulatory scheme primarily for their own vested economic interests.¹⁰⁸ Although, technology structures and methods have been placed (for example, the GTECCC, OGTR communiqués regarding safety of gene technology science, and invitation of public comments by the Regulator) in the regulatory scheme to manage public concerns, their failure is also well documented and discussed¹⁰⁹; an example of this being the moratoriums placed on GM Canola by different States in 2003. As noted in the previous paragraph and the discussion above, the current Australia gene technology scheme

¹⁰⁷ Hindmarsh, Genetic Engineering Regulation, 303.

¹⁰⁸ Hindmarsh, Genetic Engineering Regulation, 376.

¹⁰⁹ Hindmarsh & Gottweis, Recombinant Regulation Legacy, 306.

and the law hence imparts immense power to a group of select individuals, especially the Regulator and the members of GTTAC. Jasanoff (1990), in her analysis of regulatory structures based upon expert scientific knowledge, suggested that, “expert referees may either be formally affiliated with particular interest groups or otherwise have a stake in the outcome of the regulatory process”¹¹⁰. The possibility of these interests and associations may inadvertently influence an assessor’s interpretation of scientific test data and the law. Furthermore, Jasanoff cautioned that, “It has been amply documented that technically trained adversaries can exploit uncertainties in the scientific knowledge base to construct evaluation consistent with their political objectives”.¹¹¹

The third characteristic associated with transdisciplinary research is collaboration. Collaboration results from the evolving fusion of various methodologies and epistemologies when applied to a complex problem. It is an apparent consequence of the previously discussed two factors of transdisciplinary research and develops between different disciplines (evolving methodologies), and also amongst the researcher and the actors involved.¹¹² This need for cooperation demands the researcher to be implanted into the topic of analysis and with the various actors involved. I was able to achieve this, firstly, by interacting with the actors via the means of the interview process. Such collaboration has the capacity to engage the stakeholder in a meaningful discussion by creating an atmosphere of trust and clarity. And secondly, my tertiary background and training in gene technology helped to develop a deeper understanding of the human and health risks of gene technology, the risk assessment process adopted by the OGTR and the technical data based justification of their decisions. As a result I was able to analyse this research topic based on my natural sciences background and

¹¹⁰ Jasanoff, *The Fifth Branch*, 81.

¹¹¹ Jasanoff, *The Fifth Branch*, 81.

¹¹² Wickson, *From Risk to Uncertainty*, 7.

ongoing social sciences training, resulting in collaboration at a personal (researcher) level of understanding and interpretation.

Chapter 4 - Contentions between the Public and Decision Makers.

In Australia, it is the gene technology Regulator (supported by OGTR), the members of GTTAC, and GTECCC who are mainly involved with risk assessment process and making decisions related to the release of GMO's. There can be different possibilities where the members from the Australian gene technology regulatory system will have to contend with the factors such as "different values and attitudes, different philosophical ideas and ideologies and alternative visions of reality about what constitutes environmental harm and how we could set about avoiding it".¹¹³ In accordance with the scope of this analysis, I will discuss two spheres in which these contentions may arise and analyse the mechanisms (where available) set in place to address those conflicts. Firstly, contentions may arise between the Australian general public and the gene technology decision makers and secondly, between the different bodies constituted under the *Gene Technology Act 2000* (inter contentions) and amongst the members of a given regulatory committee (intra contentions).

The contentions that may arise between the core decision makers (represented by the Regulator and the GTTAC) and the general public can also be observed as conflicts between the 'scientific paradigm' and the 'social paradigm'; where the scientifically trained decision makers represent the former, and the general public represents the latter. For the scope of this paper, 'the general public' comprises members of the Australian community who do not have a direct stake in the GM commercialisation but have concerns related to various effects of GM technology. At a micro level, these concerns can be expressed by lay public and/or informed citizens, and at a macro level, by lobby groups, non-governmental organisations (NGOs), environmental groups, and other bodies comprised of community members sharing similar concerns associated with gene technology.

¹¹³ Wickson, *From Risk to Uncertainty*, 38.

The contentions between scientific and social paradigms could be traced throughout the history of gene technology regulation in Australia. The first regulatory body known as the “Academy of Science Committee on Recombinant DNA Molecules” (ASCORD) was set up in 1975 by scientists from the Australian Academy of Science (AAS) comprising mainly of microbiologist, geneticists, and biochemists.¹¹⁴ Prior to the establishment of the ASCORD, two scientists from the AAS had earlier attended the Asilomar conference in United States and “upon their return had relayed the self-regulatory recommendations of Asilomar” and “the AAS had little hesitation in accepting these recommendations, which appears to reflect overall its actions as a significant political player in influencing Australian science policy conducive to reductionist and scientific ideology and practice”.¹¹⁵ It may be ascertained that the establishment of ACSORD by the scientific community of Australia, was a direct result of the adaption of worldwide-accepted scientific paradigm of that era, which was based around self-governance or in-house regulation and mitigation of risks associated with gene technology. This was also seen in the case of other OECD countries, and the recurring theme of self-managed scientific risk assessment with little or no space for public concern, was adopted without much reflection.¹¹⁶ In its most current form, gene technology is regulated via multileveled, technocratic, and precautionary principal based system of governance, established under the *Gene Technology Act 2000*, the *Gene Technology Regulations 2001* and the corresponding State and Territory gene technology legislations. Although, the regulatory model has evolved since 1975 and public concern is formally addressed through some avenues, it can still be observed as a token platform to alleviate public concerns as the decision-making powers rest with the scientific elite regarding risk assessment and commercialisation permits.

¹¹⁴ Hindmarsh, Genetic Engineering Regulation, 378-87.

¹¹⁵ Hindmarsh, Genetic Engineering Regulation, 378.

¹¹⁶ Hindmarsh, Genetic Engineering Regulation, 378.

While analysing the history and development of civic participation in Australian (and New Zealand) gene technology regulation, Hindmarsh (2008) discussed various instances of conflict between the scientific and non-scientific communities of Australia.¹¹⁷ One notable example was of the formation of a new community group in 2003 and their subsequent restrictive effect on the commercial production of GM Canola plants. Comprised of conventional farmers, plant breeders, and commodity dealers and spearheaded by the Network of Concerned Farmers (NCF), the group was concerned about the potential economic losses that may occur due to the cross contamination of crops with the genes from the GM plants.¹¹⁸ It was argued by NCF that the uncertainties associated with the measurement/detection of GM contamination might fuel reluctances towards the intake of Australian grown non-GM Canola in the national and international markets, which could eventually lead to low marketability and sales of Australian non-GM Canola produce. The concerns raised by this group were very effective in mobilising support and attention towards this topic and aided in the issuance of a GM canola sales moratorium by all the canola producing state governments of Australia in 2003.¹¹⁹ The imposition of these moratoriums can be viewed as an example of secondary form gene technology governance in Australia as it was independent to the decision-making processes of the OGTR. The state moratoriums were set in place even before OGTR had released its conclusion on the given GM canola commercialisation application.¹²⁰

It may be argued here that a provision of, and the further implementation of a moratorium via Australian civil governance processes, can be seen as a mechanism which can be used to safeguard the concerns of communities which are currently not addressed by the OGTR (and not covered under the *Gene Technology Act 2000*, for example, economic considerations in

¹¹⁷ Hindmarsh, Richard, and Rosemary Du Plessis. "GMO regulation and civic participation at the "edge of the world": The case of Australia and New Zealand." *New Genetics and Society* 27, no. 3 (2008): 181-199.

¹¹⁸ Hindmarsh, GMO regulation and civic participation, 188.

¹¹⁹ Hindmarsh, GMO regulation and civic participation, 188.

¹²⁰ Hindmarsh, Genetic Engineering Regulation, 386.

the case of GM canola). But the above may not be a viable alternative (or a parallel form of governance) considering the following reasons.

Firstly, to garner support for a public campaign against a given gene technology commercialisation license, the concern in question would need to be addressed by a larger audience or else should be spearheaded by active community groups (for example, NCF in the case of GM Canola) which have the resources and the vigour to reach out (or influence) to the ruling government. In the case of GM canola commercialisation, cross contamination and economic concerns were able to garner such support and were considered pertinent by the State governments of Australia. However, in a scenario where social, cultural, or ethical concerns are concentrated to a given (small) community of Australia or they do not reverberate with the governmental actors, a state of moratoria may be not be achievable. For example, as discussed in the beginning of this thesis, one of the proposed applications of gene technology is to propagate GM plants in arid and inhospitable environments generally devoid of any beneficial flora.¹²¹ Considering that many of the Aboriginal communities are geographical located in mainly rural, remote, arid and arduous regions of the Australian continent, there is a likelihood that a governmental policy to grow GM plants on arid regions, may eventually impinge on lands with religious, cultural, social (or spiritual significance) to the indigenous communities of Australia. Taking into account the poor history and current status of Australian Aboriginal land rights, Aboriginal communities may not be able to garner much support in combating these circumstances or achieving a moratorium. Cultural, social, and spiritual concerns may be overlooked at the cost of lucrative economic benefits promulgated by the gene technology lobby.

Secondly, as the power of moratoriums rests with the governing elite, a change in government or a change of governmental policy related to gene technology, market pressures, or the

¹²¹ Glover, et al., Australia's crop and biotechnology, 34-35.

dilution of community support over time, may result in eventual withdrawal of moratoriums. This was observed in the case of GM Canola, when in 2008, the states of NSW, Victoria (VIC) and Western Australia (WA) dissolved their moratoriums on commercial GM canola production, initially imposed in 2003.¹²² An action like this has the potential of enhancing public distrust towards the gene technology regulation apparatus and furthermore, increasing the strife between the social and scientific paradigms prevalent in Australia surrounding gene technology commercialisation.

In summary, a ruling government's decision to impose or to withdraw a moratorium may rely on the policy goals and values adopted by that political party. Sarewitz (2004) suggested that

“Any political decision (indeed, any decision) is guided by expectations of the future. Such expectations can in turn be less or more informed by technical knowledge, but the capacity of such knowledge to yield an accurate and coherent picture of future outcomes is very limited indeed. Ultimately, most important decisions in the real world are made with a high degree of uncertainty, but are justified by a high level of commitment to a set of goals and values.”¹²³

Based on the above (and the history of GM Canola moratoriums), it may be inferred that both in 2003 and 2008, the respective Australian State governments' actions were based on a set of policy goals and party values. Although the decision from the Regulator on GM Canola commercialisation did not change over these five years (from 2003), what may have changed could be the ideology and perspective of the governments on concerns related to gene technology. Each of the three States conducted reviews of the GM canola moratoriums and

¹²² Office of the Gene Technology Regulator. *GM canola approved for commercial release in Australia - Fact sheet*, Accessed January 2015, <http://ogtr.gov.au/internet/ogtr/publishing.nsf/Content/fact-canolaJan2014-htm>

¹²³ Sarewitz, *Environmental Science and Policy*, 398.

primarily examined the economic concerns associated with commercialisation.¹²⁴ According to Hindmarsh and Parkinson (2013), “the reviews constitute the most recent key policy ‘event’ in Australian GM regulation aiming to facilitate agbiotechnology development”.¹²⁵ The reviewers placed little importance on concerns related to human and environmental health, which were presented in public submissions related to the review process. For example, Greenpeace Australia in its submission cited examples from other nations and concluded that it “does not believe that any potential benefits promised by the technology could ever outweigh the potential risks posed by the technology to human health, the environment and the economy”.¹²⁶ The reviewers deemed human and environmental concerns out of scope for the review, since these were originally covered in the Regulator’s risk assessment of 2003. The final assessment advocated that the

“Review assessed the expected impacts on marketing, trade and investment of extending or amending the Act, or allowing it to expire, and recommended a course of action. The review did not include recommendations on the regulation of human health and safety and environmental impacts, as they are beyond the scope of the Act”.

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¹²⁴ Ministerial GMO Industry Reference Group. “*Information paper on Genetically Modified Canola*”, Ministerial GMO Industry Reference Group, Accessed February 2015, http://archive.agric.wa.gov.au/objtwr/imported_assets/content/fcp/gmcrops/ministerial_gmo_industry_reference_gm_canola.pdf; “NSW Department of Primary Industries. *Gene Technology (GM Crop Moratorium) Act 2003 Review*, Accessed February 2015, http://www.dpi.nsw.gov.au/_data/assets/pdf_file/0006/196278/Final-Report-GM-Crop-Moratorium-Review.pdf http://www.dpi.nsw.gov.au/_data/assets/pdf_file/0006/196278/Final-Report-GM-Crop-Moratorium-Review.pdf

¹²⁵ Hindmarsh, Richard, and Anne Parkinson. “The public inquiry as a contested political technology: GM crop moratorium reviews in Australia.” *Environmental Politics* 22, no. 2 (2013): 293-311. See page 304.

¹²⁶ Office of the Gene Technology Regulator. *Submission to the New South Wales Review of the GM moratorium*, Greenpeace Australia Pacific Ltd, Accessed March 2015, <http://www.gmwatch.org/index.php/news/archive/2007/1435-submission-to-the-new-south-wales-review-of-the-gm-moratorium>

¹²⁷ NSW Department of Primary Industries, *GM Canola*, Accessed February 2015, <http://www.dpi.nsw.gov.au/agriculture/broadacre/winter-crops/oilseeds/canola/gm>

As noted earlier in this analysis, the concerns related to cross contamination were the precursors to the debate involving GM canola commercialisation, in the months leading up to 2003. Although the issue of cross contamination was placed on the States' review agenda, rather than analysing the larger effects of the cross contamination, the governments instead preferred to suggest strategies for containment and segregation. The review committees suggested reliance on common law as a measure for "victims" of genetic contamination rather than thoroughly testing the extent and effects of GM cross contamination.¹²⁸ The shortfall of this approach recently became evident in 2014, when a non-GM Canola farmer lost his court case against a neighbouring GM Canola farmer.¹²⁹ The Western Australian non-GM Canola farmer alleged that his crop was being affected by his neighbour's GM material being blown onto his crops by wind. The judge's ruling in favour of the GM Canola producer had left the conventional Canola farmer with huge economic losses and litigation bills. The ruling was welcomed by the GM agricultural lobby and may have wide-ranging helpful effects for future GM cultivation in Australia. According to the NCF spokeswoman "there is no winner here; the Government should have addressed this issue prior to it (GM Canola) being released".¹³⁰

There are two other, more direct (as compared to the moratorium approach) avenues, which have been incorporated in the *Gene Technology Act* to assist in resolving the contentions between the Australian public and gene technology decision makers. The first is the inclusion

¹²⁸ Ministerial GMO Industry Reference Group. "Information paper on Genetically Modified Canola, Ministerial GMO Industry Reference Group, Accessed February 2015, http://archive.agric.wa.gov.au/objtwr/imported_assets/content/fcp/gmcrops/ministerial_gmo_industry_reference_gm_canola.pdf ; Minister for Agriculture Victoria. *Panel Report to the Minister for Agriculture 2007*, Accessed February 2015, http://www.depi.vic.gov.au/_data/assets/pdf_file/0011/200180/Panel-Report-to-the-Minister-for-Agriculture,-October-2007.pdf; NSW Department of Primary Industries. *Gene Technology (GM Crop Moratorium) Act 2003 Review*, Accessed February 2015, http://www.dpi.nsw.gov.au/_data/assets/pdf_file/0006/196278/Final-Report-GM-Crop-Moratorium-Review.pdf http://www.dpi.nsw.gov.au/_data/assets/pdf_file/0006/196278/Final-Report-GM-Crop-Moratorium-Review.pdf

¹²⁹ Hamlyn. Charlotte, & Rebecca, Trigger. "GM farmer wins landmark canola contamination case in WA Supreme Court," *ABC News*, Accessed February 2015, <http://www.abc.net.au/news/2014-05-28/landmark-gm-decision-wa-supreme-court/5482864>

¹³⁰ Hamlyn. Charlotte, & Rebecca, Trigger. "GM farmer wins landmark canola contamination case in WA Supreme Court," *ABC News*, Accessed February 2015, <http://www.abc.net.au/news/2014-05-28/landmark-gm-decision-wa-supreme-court/5482864>

of provisions within the statute, at different steps of the licensing process, which facilitates public addressal through formal calls of opinion/submissions of concerns, requested by the Regulator. The second avenue of public inclusion was designed with the establishment of the GTECCC, the composition of which includes informed citizens from different sections of the Australian electorate and is not limited to the members of scientific (gene technology) community.

As per the *Gene Technology Act 2000*, one of the functions of the Australian gene technology regulator is to “provide information and advice to the public about the regulation of GMOs” and “invite” written submissions from the public in relation to risk analysis conducted by his/her office.¹³¹ According to the guidelines, prior to an approval of an application for a commercial license (which would entail intentional release of the GMO in question into the environment, apart from trail or controlled experiment) submitted to the Regulator, the process mandates public notification and opinion.¹³² Firstly, the OGTR should inform the public of receiving such an application and provide a summary of the GMO application in question. This is done via publications in the governmental *Gazette*, national newspapers, OGTR website, as well as with personal notification emails to whosoever is voluntarily registered to receive such notifications. The Regulator should then prepare a Risk Assessment and Risk Management plan (RARMP) related to the application and must seek advice from GTTAC, and prescribed agencies and authorities. He/she should also “invite written submissions in relation to the risk assessment and the risk management plan”.¹³³ In addition to the above, the Regulator may also hold public hearings prior to divulging judgment on the commercialisation application. Also, if deemed suitable by the Regulator, he/she has the right to treat any information in public hearings as confidential, restrict the publication of the

¹³¹ *Gene Technology Act 2000*, § 27(f); *Gene Technology Act 2000*, § 52.2(c).

¹³² *Gene Technology Act 2000*, § 52.

¹³³ *Gene Technology Act 2000*, § 52.2(c).

evidence given, and direct to hold the meeting in private and determine who may attend these private meetings.¹³⁴

According to Ross (2007) “the public submission process allowed the public to ‘hear and be heard’ but did not involve a redistribution of power such that public views were necessarily included or heeded throughout the process or, indeed, in response to it”.¹³⁵ The ‘invitation’ and collection of public opinion by the Regulator does not necessarily warrant its inclusion in his/her final judgments, however, invariably, technical/scientific opinion received from the GTTAC and other prescribed agencies, and authorities, is religiously adhered to. This observation has been a commonly occurring theme in the scholarship that have analysed public participation in Australian gene technology regulation and has been reflected (for example, the GM canola commercialisation application) and cited at various intervals in this thesis from the works of scholars such as Schibeci, et al. (2006), Schibeci and Harwood (2007), Hindmarsh and Parkinson (2013), Ross (2007) and Robins (2014).

Ross (2007) suggested that any decision making approach, reduced to a scientific risk assessment and management model, is problematic as it discounts the “more complex public understanding of risk” and eventually leads to a too narrow definition of risk.¹³⁶ In an approach such as this, public concerns are viewed as subjective, perceived risks, in contrast to the ‘real’, objective, scientific risks and are thus ultimately marginalised by the scientific lobby and policy makers.¹³⁷ Wynne (2001) took the example of nuclear power to illustrate how public concern about a new technology was met “with a monumental wall of expert puzzlement at the irrationality of such widespread primitive reflexes”.¹³⁸ According to him, over the course of years, the unfortunate accidents associated with the nuclear technology,

¹³⁴ *Gene Technology Act 2000*, § 53.

¹³⁵ Ross, Australia’s first GM food crop. 223.

¹³⁶ Ross, Australia’s first GM food crop. 215.

¹³⁷ Wynne, Brian. "Creating public alienation: expert cultures of risk and ethics on GMOs." *Science as culture* 10, no. 4 (2001): 445-481. See page 450.

¹³⁸ Wynne, Creating Public Alienation. 448.

dissolved the separation between what the scientific community considered as objective (rational) risks and what the public considered as perceived risks. He suggested that there lay relevant complex (psychometrically proven) qualitative public concerns about nuclear technology, for example, “its unfamiliarity; its potential to produce highly concentrated units of harm; the untrustworthiness of its institutions; and the non-voluntary nature of the risk” which were equally as important as the quantitative health risk analysis conducted by the nuclear scientist and advocates.¹³⁹

In relation to any new technology such as gene technology, governments, decision makers, and policy formulators prefer to include public opinion (irrespective of its influence) in their regulatory frameworks, primarily due to certain vested reasons. If the technology in question is significantly controversial and has the potential to attract public distrust in the government, public involvement assists in depoliticising the issue and promotes the perception of governmental neutrality. Furthermore, governments can gauge the threats to its policies by analysing public opinion and then re-introducing altered versions of these policies. Also, public opinion is usually sought to manage technological systems, which are highly complex or multi-faceted. It should be noted that Hindmarsh and Parkinson (2013) proposed the above-mentioned reasons to elucidate public enquiries that succeeded a decision making process, specifically, the public GM moratorium reviews of 2007.¹⁴⁰ However, the same reasons can also be applied to explain the incorporation of public input that precedes a final regulatory decision concerning a new technology, since both (pre-decision and post-decision contributions) eventually lead to citizen empowerment and policy amendments, in liberal democracies.¹⁴¹ It can hence be deduced that the formulators of Australian gene technology framework were aware of the complex and multi-faceted nature of this technology, and were

¹³⁹ Wynne, *Creating Public Alienation*, 454.

¹⁴⁰ Hindmarsh & Parkinson, *Moratorium Reviews Australia*, 296-297.

¹⁴¹ Hindmarsh & Parkinson, *Moratorium Reviews Australia*, 295.

sensitive towards the factors that deemed it controversial and prone to public distrust; and consequently, they provisioned for the scope of public involvement.

Schibeci and Harwood (2007), and Ross (2007) also agreed that the current Australian gene technology framework provides scope for community involvement, but advised that its extent has been made very limited and convoluted by the terminology present in the *Gene Technology Act 2000* and further, by its vulnerability to personal interpretation by the decision makers.¹⁴² For example, as per the *Gene Technology Act 2000*, the definition of ‘environment’ includes:

“(a) Ecosystems and their constituent parts; and (b) natural and physical resources; and (c) the qualities and characteristics of locations, places and areas”.¹⁴³

This definition lacks the inclusion of economic, social, and cultural aspects of the human environment and mostly focuses on built environments. McGrath (2003) suggested that a better approach would have been to adopt the definition of environment present in the *Australian Environment Protection and Biodiversity Conservation Act 1999*, which includes economic, social, and cultural aspects associated with built environments.¹⁴⁴

Alternatively, Ross (2007) suggested that it was the human interpretation rather than the terminology of the law that resulted in ambiguity associated with Australian gene technology governance.¹⁴⁵ According to her, the Regulator’s interpretation of ‘environment’, while preparing the RARMP for the GM Canola case, was very narrow and anthropocentric. She argued that the Regulator only considered the environment in which there may be harm to human health. That is, the Regulator did not account for any part of the environment except

¹⁴² Ross, Australia’s first GM food crop, 218; Schibeci & Harwood, Community involvement in biotechnology, 247.

¹⁴³ *Gene Technology Act 2000*, § 10.

¹⁴⁴ McGrath, Chris. "A system under strain: The Regulation of Gene Technology." *National Environmental Law Review* 2 (2003): 32-7. See pages 35 and 36.

¹⁴⁵ Ross, Australia’s first GM food crop. 223

this specific combination of human and natural resources in his risk analysis. A broader analysis of the effects of GM canola on the environment may have led to an in-depth study of other factors, original not considered by the regulator.

A wider interpretation of ‘environment’ would have led the Regulator to take into account the risks posed by the cross contamination of GM Canola into the wild variety of plant species present in Australia. For example, the risks posed to weeds, flowers, and shrubbery, which constitute an integral part of the ecosystem of a given Australian landscape.¹⁴⁶ A broader definition would have also taken into account insects and animals dependent on the same area as shared by the GM Canola plants. It would have been important to analyse the long-term cascading effects of introducing an engineered species/variety to a given geographical area as it was later realised in the case of introduction of Cane Toads to the Australian continent and its subsequent deleterious effects.¹⁴⁷ According to Shine (2010) the research on the ecological impacts of Cane Toads in Australia has been “unusually detailed” as compared to other countries, and there is enough data for precise calculation of its spread.¹⁴⁸ On the other hand, due to the complexities associated with the manipulations at the genetic level, the long-term effects of GM plants are yet to occur and hence become pertinent for further investigation. Other long-term effects that may have been analysed are related to the proprietary nature of GM technology and the associated economic, social and legal risks to the non-GM farmers. GM seed manufacturers can hold Australian non-GM farmers liable for intellectual property infringement whose crops may be affected by the unintended cross contamination via pollen

¹⁴⁶ The Institute of Health and Environmental Research Inc. *Comments to the OGTR on the commercial release of InVigor® canola (DIR 021/2002)*, Accessed March 2015, <http://members.ozemail.com.au/~judycarman/Submission%20from%20IHER%20to%20OGTR%20re%20InVigor%20%20canola.htm>

¹⁴⁷ Shine, Richard. "The ecological impact of invasive cane toads (*Bufo marinus*) in Australia." *The Quarterly Review of Biology* 85, no. 3 (2010): 253-291; The Institute of Health and Environmental Research Inc., Comments to the OGTR.

¹⁴⁸ Shine, Ecological Impact of Invasive Toads, 255.

transfer.¹⁴⁹ For example, in 2001 a GM seed manufacturer indicted a non-GM Canadian farmer for copyright infringement for sowing contaminated canola seeds in his fields.¹⁵⁰ Furthermore, non-GM farmers can also be held liable under the *Gene Technology Act 2000* and the corresponding State legislation for an unauthorised use of a GM organism.¹⁵¹

Similar to Ross (2007), Schibeci et al., (2006) argued that the Regulator's understanding of 'risk' in this case was hinged on his interpretation rather than the limitations of the terminology of the statute. An appropriate interpretation of the statute would have guided the Regulator to consider all the risks, "including any risks to the health and safety of people or risks to the environment", as opposed to only health and safety risks.¹⁵²

Applying either of the two remedial measures discussed above (either the amendment of statute terminology or the broader interpretation of the current statute) could have potentially made the Australian gene technology regulation less ambiguous and more streamlined. For example, an immediate effect of this adjustment could have influenced the case of GM Canola commercialisation in 2003. Had the Regulator considered economic concerns, either due to the new mandate or personal interpretation, he/she would likely had given comparatively higher importance to cross contamination potential of GM Canola, and in-turn implemented effective buffer zones around the GM crop fields.¹⁵³ This action could have lain to rest the economic concerns of the non-GM Canola farmers and the NCF, as these concerns would have been automatically introduced to the RARMP process; and furthermore, avoided the controversy and the subsequent State moratoriums.

¹⁴⁹ Australian Government Department of Agriculture, Fisheries and Forestry. *Liability Issues Associated with GM Crops in Australia*, Accessed March 2015, http://www.daff.gov.au/SiteCollectionDocuments/ag-food/biotech/liability_issues_paper_final.doc. See page 6 to 9.

¹⁵⁰ v Schmeiser, Monsanto. "CASE LAW ANALYSIS." *Journal of Environmental Law* 17.1 (2005): 83-108. See page 102 to 104 for a summary.

¹⁵¹ Australian Government Department of Agriculture, Fisheries and Forestry, *Liability Issues with GM Crops*, 7.

¹⁵² Schibeci et al., *Community Involvement*, 439.

¹⁵³ McGrath, *A System Under Strain*, 37.

The second avenue for community participation in the Australian gene technology regulatory process is via the GTECCC. The GTECCC does not, however, offer direct involvement in the decision-making process to the lay public, as its membership requires specific skills and experiences.¹⁵⁴ It provides an opportunity for the non-scientific (mostly) experts to identify and analyse concerns of a social, ethical, cultural, and political nature. On paper, the provision to establish an expert committee with members of varied backgrounds and opinions looks promising. It is however the lack of importance given to GTECCC, under the Australian gene technology mandate, that renders it symbolic and toothless. For example, the GTECCC's recommendations regarding a given commercial GM application are non-binding on the Regulator. Furthermore, the Regulator is not obliged to seek assistance from the GTECCC, the way he/she would from the scientific consultative committee (the GTTAC). Australian gene technology formulators have attempted to separate the adjudication of 'risks' from the social, cultural, and economic concerns that surround gene technology. Since the GTECCC does not garner the same importance as the GTTAC, only health and safety judgments constitute the 'risk' analysis performed by the Regulator and social, cultural, and economic aspects remain established as public 'concerns'. Furthermore, the public's concern associated with gene technology does not neatly fit in to either of sections created by the Australian gene technology framework.¹⁵⁵ It is rather an amalgamation of social and scientific inquiry.¹⁵⁶ According to Salleh (2006),

“It should also be noted that GTTAC, GTCCC and GTEC are not representative of class, ethnic and gender interests in the citizen population. Plainly, the idealised

¹⁵⁴ *Gene Technology Act 2000*, § 108.3. The composition of GTECCC has been discussed in detail previously in the thesis.

¹⁵⁵ Wynne, *Creating Public Alienation*, 447.

¹⁵⁶ Wynne, *Creating Public Alienation*, 447.

science and ethics envisaged by those who framed the Act are disconnected from any grounding in lived social relations”.¹⁵⁷

The inherent limitations associated with the GTECCC are further compounded by the fact that its meetings are held in private and do not provide any option for direct public involvement. A community consultative committee without an avenue for public consultation seems ambiguous and may result in public distrust.

One of the avenues that the GTECCC has to influence Australian gene technology framework is via the development of GM policy principles and guidelines. The GT Forum, comprised mainly of ministerial heads from the Australian Commonwealth Government and all State and Territory governments, has the responsibility to prepare and issue policy guidelines and principles related to Australian gene technology framework. Prior to issuance of any policy principle, the GT Forum is required by mandate to consult with different arms of Australian gene technology framework, including the GTECCC.¹⁵⁸ Although this provision gives the GTECCC a say in decision-making process and provides an opportunity to voice social, ethical, cultural, and economic concerns, it too has its limitations. Firstly, this provision yet again fails to incorporate direct public participation, as the administration of the GTECCC lacks an avenue for the same. The input of Australian community in gene technology policy formulation hence remains equated to the personal views of a handful of experts, present in the ‘community’ consultative committee. Secondly, since the policy principles are drafted and finalised by the politicians comprising the GT Forum, the ruling party may end up introducing and finalising policies harbouring their own vested interests. Furthermore, the (token) act of consultation with the ‘community consultative community’ might provide the government with an arbitrary seal of public acceptance and assist in reconciling any associated arguments against gene technology.

¹⁵⁷ Salleh, *The Australian Government’s Strategy for GM Regulation*, 401.

¹⁵⁸ *Gene Technology Act 2000*, § 22.

In summary, although the Australian gene technology framework provides certain avenues for meaningful public participation, factors such as the terminology of the *Gene Technology Act 2000*, its susceptibility to inadvertent personal interpretations at various levels, the lack of importance given to GTECCC, the (need of and) unstable nature of the moratorium process and finally, and the lack of avenues for comprehensive direct public input, renders the public as inert participants in the process and places them at the receiving end of a top-down information dissemination system. According to Schibeci et al. (2006), “Australian policy makers have implicitly adopted the “cognitive deficit” model, which holds that citizens need to have their “deficit” remedied via one-way communication provided by authoritative experts”.¹⁵⁹ This deficit model assumes that the public is “deficient” in their understandings and acceptance of science can only be fulfilled via “sufficient” information flowing from the experts.¹⁶⁰ As a result, “knowledge alone is transferred” and “ethical and political concerns are ruled out as irrelevant”.¹⁶¹ Gross (1994), suggested that a more viable alternative to a deficit approach would be a contextual model, based on two way information flow between the promulgators of science and the public.¹⁶² This model treats the public as active contributors and aims to build trust by considering scientific, social, ethical and political concerns associated with the technology. Rather than only analysing scientific facts alone, the cognitive model aims to analyse case studies in a structured and focused manner, which includes the “situation of the public” as the central focus and not just the “state of science” alone.¹⁶³ Based on the above description by Gross and reconsidering the following details during the Australian gene technology risk assessment procedure, that is, the Regulator calls for public input towards the RARMP, and that the OGTR publishes other related information

¹⁵⁹ Schibeci et al., Community Involvement, 430.

¹⁶⁰ Gross, Alan G. "The roles of rhetoric in the public understanding of science." *Public understanding of science* 3, no. 1 (1994): 3-23. See pages 5-7.

¹⁶¹ Gross, The Roles of Rhetoric, 6.

¹⁶² Gross, The Roles of Rhetoric, 6.

¹⁶³ Gross, The Roles of Rhetoric, 10 - 11.

on its website, it is plausible to assume that the current framework exhibits certain traits of the cognitive model. It is however a different story altogether that neither the public submissions are binding on the Regulator nor have been observed to be implemented effectively (based on the previously discussed instances), which eventually renders these cognitive model traits as unconstructive.

Critics of the cognitive model may argue that a comprehensive public deliberation in Australian gene technology regulation may prove to be a waste of time and resources of the all the parties involved (as compared to current expert driven model), since it may take longer to assimilate different ideologies and opinions into quantifiable factors. As much as this may be true, on the other hand it has been observed that the current system has the potential to attract a moratorium state, due to public frustration. A moratorium state is convoluted, unpredictable, and even more time consuming as compared to an initial comprehensive public deliberation on new gene technology licenses. A way forward can be the inclusion of direct public participation in the GTTAC (scientific committee) and more specifically the GTECCC (community consultative committee). Specifics related to proprietary information may be withheld from public distribution if needed, to safeguard the interests of license applicants (as is now), and concerns may be discussed and deliberated. This may ensure that the Regulator does not suffer from time delay in his/her final judgement and is able to consider public opinion in a much more meaningful and organised manner. Furthermore, this inclusion has the potential to gather a much broader societal perspective and not just reflect the value judgements of handful of chosen experts. As Wickson (2006) noted,

“The notion of having committee meetings open to the public is not entirely without precedent, with the open board meetings of the British Food Standards Agency potentially serving as an example of how this could operate in practice”.¹⁶⁴

¹⁶⁴ Wickson, *From Risk to Uncertainty*, 177.

Chapter 5 - Contentions Between Decision Makers

Prior to the establishment of the *Gene Technology Act 2000*, the Australian government recognised the contentious nature of gene technology and proposed that,

“Given the high level of community interest in gene technology, it is important that both the GTR and the Ministerial Council remain “in touch” with community views on issues surrounding the regulation of gene technology. Both the GTR and Ministers will benefit from the community’s input into the development of the policy guidelines and codes of practice which will underpin the regulatory scheme”.¹⁶⁵

In other words, it acknowledged the potential for social contentions associated with gene technology and sought to resolve them using the help of the GTECCC (formerly the GTEC and the GTCCC). Similarly, GTTAC was established to provide “expert scientific advice” or simply, to analyse the scientific contentions associated with gene technology.¹⁶⁶ According to Sarewitz (2004), decision making on environmental issues mostly consists of conflict resolution “between competing values and interests embodied by competing disciplines”.¹⁶⁷ In the case of Australian gene technology committees, the GTTAC is primarily comprised of experts from the life sciences and biotechnology domain and the GTECCC is comprised of members mainly from outside of gene technology science domain, for example it may contain members with skill and experience in community consultation, risk communication, ethics, law, religion, human and animal health and welfare.¹⁶⁸ It can hence be construed that the final

¹⁶⁵ The Interim Office of the Gene Technology Regulator. *Explanatory Guide to the Commonwealth Gene Technology Bill 2000*, Accessed March 2015, [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/gtbill-3/\\$FILE/expguidebill.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/gtbill-3/$FILE/expguidebill.pdf) [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/gtbill-3/\\$FILE/expguidebill.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/gtbill-3/$FILE/expguidebill.pdf) . See page 53.

¹⁶⁶ The Interim Office of the Gene Technology Regulator. *Explanatory Guide to the Commonwealth Gene Technology Bill 2000*, Accessed March 2015, [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/gtbill-3/\\$FILE/expguidebill.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/gtbill-3/$FILE/expguidebill.pdf)

¹⁶⁷ Sarewitz, *Environmental Science and Policy*, 392.

¹⁶⁸ Office of the Gene Technology Regulator. *Gene Technology Committees*, Accessed March 2015, <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/committees-index-1>

deliberations associated with gene technology commercialisation in Australia are mainly an outcome of the competing social and scientific paradigms present during that period.

Sarewitz (2004) further suggested that the removal of “conflict of interests” and “ideological commitments” from environmental deliberations, and a pure focus on scientific facts, renders the whole process a “meaningless exercise”.¹⁶⁹ As each stakeholder may operate within different “bodies of contextually validated knowledge” hence either may stake claim to their interpretation.¹⁷⁰ This is because disciplinary orientation and knowledge has the potential to shape an expert’s worldview, which eventually may become more inclined to certain value systems than others.¹⁷¹ As a consequence, an expert’s definition of ‘environment’ and further, identification of ‘risk’, should largely become a reflection of his/her value judgements associated with the natural world.

In order to analyse the above-mentioned concept and reflect them in this thesis, interviews were sought from the members of the GTECCC and the GTTAC and the Australian gene technology Regulator.¹⁷² Similar approaches had been adopted by scholars such as Hendriks (2004), Schibeci et al. (2006), and Bovenkerk (2012).¹⁷³ A common theme observed in the works of the above scholars was that they aimed to obtain more contextualised opinions from the stakeholders rather than only scrutinising the official published information. As suggested by Schibeci et al. (2006), who sought to interview the members of the GTCCC, interviews would assist in elucidating the “political dynamics within the committee” and to gather the

¹⁶⁹ Sarewitz, Environmental Science and Policy, 392.

¹⁷⁰ Sarewitz, Environmental Science and Policy, 386.

¹⁷¹ Sarewitz, Environmental Science and Policy, 392.

¹⁷² Out of the original intended group of organisations, the Environmental Defenders Office, New South Wales (NSW) did not reply back to the interview request and the Greenpeace Australia, declined to undertake any interview requests for the remaining period of the 2014, via website based notice. The members from the GT Forum, and the GTSC could not be contacted due to a shortage of time.

¹⁷³ Hendriks, Carolyn M. “*Public deliberation and interest organisations: A study of responses to lay citizen engagement in public policy*, PhD thesis, Research School of Social Sciences, College of Arts & Social Sciences, Australian National University” (2004), Accessed March 2015, <http://hdl.handle.net/1885/6967> ; Schibeci et al., Community Involvement; Bovenkerk, Bernice. *The Biotechnology Debate: Democracy in the Face of Intractable Disagreement*. (Springer Science & Business Media, 2012).

“insights and experiences” of these stakeholders as compared to the formal information present within official communications.¹⁷⁴

Similarly using the medium of interviews, I wanted to elucidate whether disciplinary orientation, personal values, and ideologies, (and resulting worldview) shapes the opinions and judgements of Australian gene technology decision makers, and in doing so, highlight the contentions between the scientific and social paradigm surrounding gene technology in Australia. Furthermore, since the deliberation processes of both the GTECCC and the GTTAC are kept confidential and there were no avenues for the lay public to attend the meetings of these committees, hence, the interview process was considered to be a good avenue for procuring primary data.

After receiving the ethics clearance from the Macquarie University Human Research Ethics Committee (MUHREC), interview requests with a brief summary of the project were sent to the members of the GTECCC, the GTTAC and the Regulator via email. Over the course of four months (July 2014 to October 2014) a total of eleven interview requests were sent (the number of possible interviews was constrained by the time limitations of this project). The committee members were identified based on the information provided on the OGTR website and their contact details were obtained from the public domain, since most were affiliated to Australian institutions. A member of the GTECCC and another from the GTTAC were eventually interviewed via Internet-based interview sessions, respectively. Both of these interviewees were sent the interview questions, vetted prior by the MUHREC. I was mindful not to formulate the interview questions towards the disclosure of ‘committee business’ but rather to gauge the personal opinion of the committee members regarding gene technology regulation in Australia.¹⁷⁵ For example, Schibeci et al. (2006) were unsuccessful in procuring

¹⁷⁴ Schibeci et al., *Community Involvement*, 440.

¹⁷⁵ Please see the appendix for a copy of the interview questions.

any interviews with the GTCCC members and received the following reply from the chairperson of the GTCCC,

“A number of the interview questions relate to the conduct of Committee business. I have been asked to explain that the content and nature of GTCCC discussions are kept confidential. In order to allow members to feel free to express their opinions openly during meetings. Due to this agreement between members (as outlined in our Committee Operating Procedures), much of the information you seek cannot be disclosed. However, I would like to point out that the Committee issues a communiqué after each meeting, which is placed on the Office of Gene Technology Web site. In addition, I hope that the following information may be of some use to your investigation”.¹⁷⁶

As a part of the interview consent form and the initial invitation email, I also provided interviewees with the option of anonymity to avoid any future unwarranted disagreements with the rest of the members and to encourage an open response. After sending the initial invitation to all eleven intended interviewees, no responses were received from two members (also to the follow-up emails) and another member from the GTTAC replied as following:

“Sorry but I will not be able to participate in this research request. I wish you well in finding other suitably qualified scientists who can contribute. May I suggest that you search for contacts within the Institutional Biosafety Committees of Universities as potential people to also target”.¹⁷⁷

Further, this member from the GTTAC cited “obligations with GTTAC and time restrictions” as the primary reasons for non-participation in this project.¹⁷⁸ Although the suggestion to

¹⁷⁶ Schibeci et al., *Community Involvement*, 441.

¹⁷⁷ Reply received from the GTTAC member.

¹⁷⁸ Reply received from the GTTAC member.

consult other ‘suitably qualified scientists’ was encouraging towards this research, it showed that this member identified with certain stakeholders more than others, who are associated with gene technology regulation in Australia. The suggestion to consult other ‘qualified scientists’ indicates that this member may personally prioritise certain dimensions of gene technology. The current formulation of the Australian gene technology governance and scientific training may have guided the member to only identify with the scientific component (and risk) associated with gene technology. The reply was suggestive towards gathering more information from the scientific experts, although my introductory email of the research project did not mention my approach to be confined to the same, and included my intention to interview various stakeholders involved in the project, including the members from the GTECCC. In hindsight, it may also be possible that the reply received from the member from GTTAC was based on the member’s understanding of my invitation email and any shortfalls that may be present in the content of the brief summary.

It can be argued here that such a reply from a single member of the scientific committee may not be applied as an overarching judgement on the whole scientific lobby associated with the Australian gene technology regulation and that some of the members may also be considering social, economic, and ethical concerns in their deliberations (although privately). Hence, anticipating the above, during the inception stage of this project, I decided to incorporate interviews from multiple members in both the GTTAC and the GTECCC to obtain a broader set of data. However, had this reply been received from the Regulator, it would have had a considerably more elucidating effect towards the analysis associated with this research because of the final decision-making powers vested with him/her. Unfortunately, no reply was received from the Regulator towards this research, or from the OGTR, which was also copied in the invitation to the Regulator. As an alternative, for the scope of this research, an interview of the 2011 Regulator, Dr. Joe Smith conducted by the Australian Broadcasting

Corporation (ABC) in 2011 shall be referred to in order to gain insight into his personal opinions.¹⁷⁹ For example, throughout the length of the above-mentioned interview, the Regulator failed to mention/explain the role of GTECCC and mainly concentrated his explanation of the risk assessment process on his and GTTAC's role and the scientific robustness of the framework. Furthermore, he stated that his office does not "particularly care about the benefits" of gene technology and their "focus is very clearly on potential risks and making sure they are managed".¹⁸⁰ On the contrary, further along the length of the interview the Regulator appeared to be promulgating the benefits of gene technology science by suggesting that,

"...perhaps its something that people don't appreciate that Bt. Toxin is widely used as an agricultural chemical spray, quite separate to any genetic modification...it is actually recommended in a number places for use in organic agricultural as an alternative, if you like, to synthetic chemical treatment...Bt. Toxin is very well and thoroughly understood and so as part of our assessment we would have looked at all of that literature and accumulated science in concluding that there were no more than negligible risks associated with Bt. Toxin".¹⁸¹

Hence it may be plausible, that the Regulator's analysis of use of Bt. Toxin in GM plant agriculture could have been overshadowed by his pre-acknowledgement of the benefits of Bt. Toxin, and that may have led him to overlook other literature associated risk and uncertainty of this chemical.¹⁸² A scenario such as this convolutes the initial assertion made by the

¹⁷⁹ Smith, Joe. Interview by Catalyst, *Extended Interview - Gene Technology Regulator*, Australian Broadcasting Corporation, 2011, Web. Accessed March 2015
<http://www.abc.net.au/catalyst/gmfood/template.swf?revision=1>

¹⁸⁰ Smith, Joe. Interview by Catalyst, *Extended Interview - Gene Technology Regulator*, Australian Broadcasting Corporation, 2011, Web.

¹⁸¹ Smith, Joe. Interview by Catalyst, *Extended Interview - Gene Technology Regulator*, Australian Broadcasting Corporation, 2011, Web.

¹⁸² A vast body of data is available on the effects of Bt. Toxin, which analyse its long-term and short-term effects. For some highly cited examples, please see: Wolfenbarger, Laressa L., and Paul R. Phifer. "The

Regulator, that he and his team does not consider the intended benefits of the given technological product, whereas they may be doing the exact opposite due to their personal allegiance towards the type of science in discussion.

It should also be mentioned that the Regulator acknowledged the fact that “much of the information” that OGTR assesses during their risk assessment is provided by the applicant.¹⁸³ In regards to analysing published scholarly information, *Nature* editor Maxine Clarke observed that,

“...scientists with strong interests scrutinize published papers more intently than they would otherwise do for other types of papers because they are very motivated to find any flaws which can be used to undermine or support the conclusions of the paper”.¹⁸⁴

This further exhibits the vulnerability of the Australian gene technology risk assessment process and its openness to personal risk identification and assessment by the assessors, since the assessors may only be seeking for that additional information, which fits best with their scientific viewpoint, value systems, and worldview, which in some cases may be aligned with the goals of the gene technology proponent.

Out of the remaining seven interview requests, all intended interviewees showed interest in this research and requested further information. After receiving the interview questions, one

ecological risks and benefits of genetically engineered plants." *Science* 290, no. 5499 (2000): 2088-2093; Altieri, Miguel A. "The ecological impacts of transgenic crops on agroecosystem health." *Ecosystem Health* 6, no. 1 (2000): 13-23; Dale, Philip J., Belinda Clarke, and Eliana MG Fontes. "Potential for the environmental impact of transgenic crops." *Nature biotechnology* 20, no. 6 (2002): 567-574; Horrigan, Leo, Robert S. Lawrence, and Polly Walker. "How sustainable agriculture can address the environmental and human health harms of industrial agriculture." *Environmental health perspectives* 110, no. 5 (2002): 445; Altieri, Miguel A. "The myth of coexistence: why transgenic crops are not compatible with agroecologically based systems of production." *Bulletin of Science, Technology & Society* 25, no. 4 (2005): 361-371.

¹⁸³ Smith, John. Interview by Catalyst, *Extended Interview - Gene Technology Regulator*, Australian Broadcasting Corporation, 2011, Web.

¹⁸⁴ Lepkowski, Will, "Maize, genes, and peer review." *Perspectives - Consortium for Science, Policy & Outcomes* 14 (2002). Accessed March 2015 http://archive.cspo.org/library/perspectives/?item=lepkowski_oct02 ; Sarewitz, Environmental Science and Policy, 391. Sarewitz analysed the Clarke's observation in order to elucidate how scientists belonging to different areas of science can construe a single piece of literature in different ways.

member declined the interview request due to being unwell and further two did not respond. Follow-up emails were sent to these two members but to no avail. The remaining four members agreed for an interview but later two had to cancel due to time constraints. Finally two interviews were conducted, respectively, with a member from the GTECCC and another from the GTTAC.

As expected, (based on the rules given in the *Gene Technology Act 2000* regarding GTTAC membership) the member from the GTTAC had an academic background and research experience in plant biotechnology and was associated as a high level researcher with a leading agricultural research organisation of Australia.¹⁸⁵ The member from the GTECCC on the other hand was working at a high level academic position in one of Australia's premier universities and had an academic background and research experience in sociology of health and medicine, and science and technology studies including a keen interest in community participation associated with new and emerging technologies.¹⁸⁶

Both members had different motivations that led to their interest in gene technology. The GTTAC member became interested in gene technology because of prior academic training in life sciences and to explore the “technology side” of genetic modification. Further, the member's interest in gene technology regulation primarily arose through a desire to clarify false technical statements being made by many of the plant researchers in relation to the environmental safety of a particular GM crop; and attributed these statements to a lack of information on the subject, and false assumptions being made by these researches. As a result, the GTTAC member wanted to “understand the baseline by which regulators could then compare GM and non-GM plants”.¹⁸⁷ On the other hand the member from the GTECCC became interested in gene technology to enquire about the health as well as behavioural

¹⁸⁵ GTTAC Member, Personal interview. 29 August 2014.

¹⁸⁶ GTECCC Member, Personal interview, 08 August 2014.

¹⁸⁷ GTTAC Member, Personal interview. 29 August 2014.

aspects of gene technology and stated that “behaviours are always shaped by the social context and by history of particular culture in which one lives”. It was a mix of professional and scholarly interest that attracted the GTECCC member to gene technology and its various aspects.¹⁸⁸ This member considered gene technology to be a very speculative area and was concerned about the future benefits claimed by the scientists, which might lead to pernicious outcomes.

It can be noted that both of the interviewees were concerned about the risks associated with gene technology but had different identification of those risks, resulting approach, and mindset. Whereas the GTTAC member was concerned about the scientific risks posed by gene technology, the member of the GTECCC considered new technologies to be a co-product of the prevalent societal norms and scientific development and was concerned about broader outcomes (including human health). According to Sarewitz (2004), scientifically trained experts usually claim that uncertainty associated with complex environmental problems can only be reduced through more technical research and experimentation. However, in doing so, they fail to acknowledge the intrinsic uncertainties associated with nature, disciplinary science, or the “social and political context within which research is conducted”.¹⁸⁹ A similar observation can be noted in the reply from this GTTAC member, who firstly claimed that the findings of many other researchers on environmental safety of the given GM plant were false and secondly, attributed this ‘false’ knowledge to a ‘lack of information’.

When I enquired about the values (apart from scientific claims) that may influence deliberations on gene technology in their respective committees, both interviewees agreed that the committee members brought their own values and beliefs to the table. The GTTAC member did not have any philosophical opposition to GM technology and did not consider it

¹⁸⁸ GTECCC Member, Personal interview, 08 August 2014.

¹⁸⁹ Sarewitz, *Environmental Science and Policy*, 396.

to be either good or bad but rather was interested in “what GM for what purpose”.¹⁹⁰ This member also believed that the current “framework was set up to almost exclude all other values” apart from the scientific risks and that the “other values” were predominantly captured at the GTECCC level deliberations.¹⁹¹ Although this may be true in principle, the fact that recommendations from the GTECCC are not binding on the Regulator in effect sidelines the value based concerns under the Australian gene technology regulatory framework.

The member from the GTECCC believed that the GTECCC was more of a “reactive committee” and lacked innovation. The member further stated that the scope for reflecting on the ‘rights and wrongs’ associated with gene technology was limited, and was sceptical about the “optimistic claims” associated with new technologies. This member believed that the current decision makers of gene technology regulation in Australia undertook a very conservative and a “psychometric approach” to risk analysis which in turn did “not encourage reflection on broader implications of gene technology”.¹⁹²

Further, I noted that both the members had contrasting views about the propagation of gene technology science in Australia. The GTTAC member did not have any concerns related to propagation of gene technology science in Australia, although stated that there were economic bottlenecks present in Australia due to the high costs associated with regulation of gene technology and a comparably smaller market (as compared to the EU or the USA). The GTECCC member was concerned about the “enthusiasm” of the Australian government to adopt new technologies (including GM) without much reflection. This member also believed that the government departments entrusted with the responsibility to create policy around

¹⁹⁰ GTTAC Member, Personal interview. 29 August 2014.

¹⁹¹ GTTAC Member, Personal interview. 29 August 2014.

¹⁹² GTECCC Member, Personal interview, 08 August 2014.

gene technology were acting in “silos” by not providing effective avenues for public engagement.

The above discussion hence presents a very dismal picture of the amount of importance given to broader concerns associated with gene technology commercialisation under the current Australian gene technology technical committee level. Although, the GTTAC member acknowledged the broader value concerns associated with gene technology but believed that these concerns were mainly delegated to the GTECCC. On the other hand, the GTECCC member did not believe that the GTECCC provided a comprehensive platform for deliberations on these concerns, at least not an effective one. The GTECCC member was also concerned about the future of the community consultative committee, since the current GTECCC members had not convened for approximately one-year, when they had met following the change of the Australian government in 2013.

Out of the two interviewees, the member from the GTTAC was more aware of the intended use of gene technology to reduce green-house gas emissions and considered it to be in its early experimental stages in Australia.¹⁹³ He further stated that “the pertinent thing is that in the consumer studies that have been done, there seems to be greater acceptance of a genetically modified approach if there was an environmental outcome but the regulation was blind to end use”.¹⁹⁴ According to the member, the end use would only have a bearing if checks need to be performed on how GM products are transported, or if it created any additional risks, but the ‘purpose’ of the product was not important. On the other hand the

¹⁹³ Since January 2014 until April 2015, I was able to identify one commercial GMO license application, which was intended towards commercial release and was aimed towards improved cellulosic ethanol production from sugarcane biomass. Please see, The Office of the Gene Technology Regulator. *DIR 095*, Accessed April 2015, <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/DIR095>
In comparison, there were higher numbers of research proposals sent to OGTR at the laboratory level. Please see, The Office of the Gene Technology Regulator. “*List of Notifiable Low Risk Dealings (NLRDs)*”, Accessed April 2015, [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/1C59C053353D94A0CA257CD00009FD88/\\$File/nlrlistApril2015.xlsx](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/1C59C053353D94A0CA257CD00009FD88/$File/nlrlistApril2015.xlsx)

¹⁹⁴ GTTAC Member, Personal interview. 29 August 2014.

GTECCC member stated that the controversy around GM technology seemed to be fundamental and the regulation may not encompass how wider communities respond to issues. This member believed that the legislations could not properly capture these constructions of risk as perceived by the lay community.

The question of ‘purpose’ or the end use of a new technology hence becomes pertinent since firstly, the community may value varied risks (other than human and environmental health) that are associated with the use of the technology and secondly, the end use may be used as a façade by the gene technology promoter or the governments, in promoting its use, as the GTTAC member mentioned that there may be a better acceptance of gene technology use while guising it as a product for environmental upkeep. This was seen in the case of GM canola commercialisation in Australia in 2003, where, had the ‘end use’ been considered by the OGTR, it would have encompassed the economic concerns of non-GM canola farmers and assisted in reducing the controversy surrounding the matter.

Finally, both the interviewees were asked whether they wanted to propose any amendments to the current Australian gene technology regulation. Both commented on the ‘right of the public’ towards participation in gene technology regulation but had contrasting opinions. The GTECCC member felt that there was a need for a cultural change around public engagement in gene technology regulation whereby the interested public could act as active participants in the deliberation processes. In the opinion of this member, it would be worthwhile to enquire whether individuals and groups not currently involved in these deliberations should have the right to do so, since the “technology always has an impact”.¹⁹⁵ The member also gave an example of consensus based participation method, which in the member’s view was limited to only a select, highly interested public or public with a more direct impact from the use of such technology, rather than inviting participation from the lay public. The GTTAC member on the

¹⁹⁵ GTECCC Member, Personal interview, 08 August 2014.

other hand was content with the status quo and saw a bigger role for public participation prior to the establishment of the current law. In this member's opinion, it was the role of the erstwhile government's elected representatives to make sure there were avenues present for public participation and the current provisions were a reflection of that process. The member also stated that the current commercial gene technology proponents "should not be held hostage to unknowable things, from interest groups" since it may cost valuable time and resources to all stakeholders involved and that current form of legislation should be adhered to.¹⁹⁶ In addition the member wanted the regulatory process to become more streamlined, so that every new technical modification to the same GMO in question did not have to go through the same regulatory process again. In other words, once approved, a commercial GMO application need not undergo the same scrutiny as in the initial licensing process.

The above discussion illuminates the different perspectives of these members on the current regulatory processes as well as their hopes for the future. Through their different opinions we can see that while the scientific paradigm attached to gene technology and the social paradigm are both integral components of the regulatory process, there is a significant clash between them. Where the scientific committee member believed in status quo and had confidence in the current process and setup, the community consultative member desired a better integration of public opinion and more importance to broader issues associated with gene technology in Australia. The GTTAC member was not keen on outside influence in the way of interest group input and considered GTECCC to be apt for the role. The GTECCC member on the other hand acknowledged narrow approach of government officials and the GTTAC members, desired the GTECCC to become a more innovative and engaging body, and wanted a broader perspective on development of new technologies in Australia. These different stances reflect the different work that each of their committees perform. Since the objective of

¹⁹⁶ GTTAC Member, Personal interview. 29 August 2014.

the *Gene Technology 2000 Act* is to “protect the health and safety of people” and to “protect the environment”, a single committee which recognises the broader aspects associated with the Australian ‘environment’ can help in filling up the chasm experienced in the current setup.¹⁹⁷ Perhaps, a single committee comprised of members from both the GTECCC and the GTTAC with an effective public inclusion system would be more beneficial to achieve successful deliberations on the Australian gene technology commercialisation.

¹⁹⁷ *Gene Technology Act 2000*, § 3.

Chapter 6 - Summary and Conclusion

I began this thesis with a brief introduction of how gene technology science applications may be utilised in assisting with the reduction of the green-house gas emissions of Australian transportation and agricultural sectors. In doing so, I listed the expected outcomes of these applications and identified that this technology is still relatively new and investigated the relevance of other broader concerns associated with gene technology apart from human and environmental health concerns, for example social, cultural, economical and ethical. These concerns have grown in magnitude, along side the advances in this field. Furthermore, I demonstrated that the regulation associated with gene technology had changed from a technocratic self-regulatory model of the 1970's, to a more comprehensive model that included a mix of government policy underpinned by scientific assessment, currently being used in Australia. This in turn led to an increase of actors associated with this regulation.

Subsequently, I identified the core actors by briefly exhibiting the structure of the regulatory framework and analysing the *Gene Technology Act 2000*. Further, I categorised these core stakeholders based on their appointed work, responsibilities, composition, and professional backgrounds. The Regulator and the member of the GTTAC represented the scientific decision-making body. The GT forum represented a political policy- (or ideology-) based administrative body. The GTECCC represented a group of experts from the informed and educated Australian electorate. Lastly, there was the fourth category of 'general public' or 'electorate'. To analyse the interactions of these groups, I used the case study of GM Canola commercialisation decisions of 2003, which was the first GM food crop grown in Australia. I established that the Regulator could have avoided the ensuing controversies and the subsequent State moratoriums, had he considered the advice of the GTECCC and also taken into consideration broader concerns (for example economic and social) apart from human and environmental wellbeing.

Furthermore, the scientific experts involved in this assessment may have drawn their conclusions based on a set of values while deciding factors such as, what constitutes a risk, how to address risk and what in fact constitutes the human environment. The absence of in-house scientific experimental testing hence exposed the risk assessment procedure to the personal interpretations of scientists, at three separate levels. Firstly, by the researchers who set benchmarks (national and international) for risk quantities, secondly, by the researchers from the laboratories of GM manufacturer, who compare their data with the set benchmarks, and thirdly by the scientific experts associated with the OGTR, including the Regulator.

Further, the moratoriums placed on GM Canola by various jurisdictions of Australia, revealed the influence of political ideologies and interests (short term and long term). For example, these interests may have reflected the decisional sovereignty of the elected political party over matters related to the State's economic growth, and human and environmental welfare. Since the members of the GT Forum (or the government officials) held direct accountability to their voters, their decision may have been guided by the concerns of the interested and influential citizens (at that time).

By further analysis of scholarly literature, I was able to identify and establish that the Australian gene technology framework encompassed and contended with different ideologies, values, and personal interpretations. Such differences may ultimately lead, firstly, to contentions between the Australian general public and the gene technology decision-makers; and, secondly, to contentions between the different bodies constituted under the *Gene Technology Act 2000*. After analysing scholarship on the social and scientific paradigms associated with environmental issues, I was able to ascertain that the conflicts amongst the Australian public and the gene technology decision makers were therefore also contentions between the scientific and social paradigms associated with gene technology in Australia. Since the decision-making powers rested with the scientific experts, the current regulatory

model is a token platform to alleviate public concerns. This factor led to imposition of moratoriums of 2003, which can be viewed as an example of a secondary form of gene technology governance in Australia as it was independent (and opposite) to the OGTR's decision. However, the moratorium process had its own drawbacks since it is unstable and dependent on ruling government ideology towards gene technology and was contingent on the recognition of the environmental concern.

There are two other, more direct (as compared to the moratorium approach) avenues, incorporated in the *Gene Technology Act 2000* aimed at assisting with resolving the contentions between the Australian public and the decision makers. The first was the provision of public input process built within the statute, at different steps of the licensing process, and the second was through the GTECCC. Although the public input inclusion process had vast potential and can lead to citizen empowerment, in the case of Australian gene technology framework, its extent was found to be very limited and convoluted. Due to the preferences given to scientific concerns over social concerns under the statute, effective public involvement was left dependent on the Regulator's personal interpretation. Similarly, there were no direct public involvement opportunities in the deliberations of the GTECCC. Furthermore, if it is to be considered that the composition of the GTECCC represents the broader public concerns of Australia, even then, because of the statute, GTECCC's recommendations are non-binding on the Regulator. A way forward could be the inclusion of direct public participation in the GTTAC (scientific committee) and more importantly, the GTECCC (community consultative committee). This inclusion has the potential to gather a much broader societal perspective and not just reflect the value judgements of handful of chosen experts.

Out of all the intended stakeholders, I had planned to interview during the inception of this project, due to time limitations, potential participants declining interview requests or

withdrawing from participation, and schedule restrictions, I managed to interview one member each from the GTECCC and the GTTAC, respectively. In hindsight, it may be plausible that my initial goal to interview many of those involved in the regulatory process was over ambitious for a masters degree and is perhaps something more feasibly pursued at a doctorate level of study, which allows for a longer research project and time to develop relationships with participants.

Almost all of the replies received from both the interviewees were in contrast to each other. This helped to reveal the ways in which their respective disciplinary orientation and resulting worldview had shaped their judgements regarding gene technology. Although both agreed that all the stakeholders involved brought their own values and beliefs with them, the GTTAC member considered value judgements separate to scientific deliberations. This member agreed that the current system is shaped to exclude value judgements from the risk analysis conducted by their team and the regulator and privileges scientific approaches, which are viewed as value-neutral. The GTECCC member on the other hand believed in a holistic approach of deliberations related to new technologies and considered public opinion and social concerns to be a vital part of this process. Based upon my analysis of the scholarly literature, the GTTAC member's assumption that the scientific committee's deliberations were value-free, might not be entirely true. Although, scientific deliberations try to conceal value preferences, however this does not deny their presence. Inversely, scientists legitimise their value preference by citing factual information from their respective disciplines. This is because the choice of disciplinary interest and the formal intellectual framework used by a scientist is a product of his/her value preferences and how he/she prefers to see the world.¹⁹⁸

Whereas, the GTTAC member believed that the value judgements and broader concerns have been delegated to the GTECCC, the member of the GTECCC was of the opinion that the

¹⁹⁸ Jasanoff, *The Fifth Branch*, 14; Sarewitz, *Environmental Science and Policy*, 390-91, 397.

scope for reflecting on the ‘rights and wrongs’ associated with gene technology was limited to the GTECCC. The member considered the GTECCC to be a reactive committee, which lacked innovation. The GTECCC member’s observation was compounded by the fact that GTECCC’s deliberations were ultimately non-binding on the Regulator. Both of their views strengthened the observation made previously in this thesis that broader public concerns under the current gene technology regulation system have been sidelined.

In regards to the perceived use of gene technology for the reduction green house gases in Australia, as stated by the GTTAC member, the current regulatory process did not consider the ‘end use’ of gene technology. Yet, the question of ‘purpose’ or the ‘end use’ of a new technology is pertinent, since, firstly, the broader community may value varied risks (other than human and environmental health) associated with the end use; and secondly, the end use may be used as a façade by the gene technology promoter or the governments, in promoting its use. For example, as the GTTAC member mentioned, that there may be a better acceptance of gene technology use when intended as a product for environmental upkeep. Deliberations on the ‘end use’ can help in bringing these varied risks to foreground by providing scope for discussion on various values and ideologies, from the outset.¹⁹⁹ For example, had the ‘end use’ been considered by the OGTR in the case of GM canola commercialisation of 2003, it would have encompassed the economic concerns of non-GM canola farmers and assisted in reducing the controversy surrounding the matter.

It was evident from the analysis of the replies from both the interviews, that both the stakeholders held different views as to how Australia should govern gene technology. Where the technically trained GTTAC member defended the current legislation and disapproved of any outside influence, the GTECCC member trained in sociology, was sceptical about the ‘optimistic claims’ associated with new technologies believed that the current legislation

¹⁹⁹ Sarewitz, *Environmental Science and Policy*, 399.

could not properly capture the constructions of risk as perceived by the lay community. These different standpoints reflect the different work that each of their committees perform. Since the objective of the *Gene Technology 2000 Act* is to “protect the health and safety of people” and to “protect the environment”, a single committee comprised of members from both the GTECCC and the GTTAC with an effective public inclusion system would be more beneficial to achieve successful deliberations on the Australian gene technology commercialisation.

In summary, through this thesis, I have analysed the multidimensional aspects of Australia’s gene technology regulation associated with intended novel use of this technology. I demonstrated that the deliberations on the commercial gene technology licenses were an outcome of the competing social and scientific paradigms associated with gene technology in Australia. The contentions between the social and scientific paradigms were in-turn a result of the personal interpretations, values, ideologies, and disciplinary knowledge held by the actors who were involved in the regulation. Jasanoff (2006) suggested that “conventional risk assessment methods take little or no account of the social and ethical ramifications of technological systems”.²⁰⁰ By analysing the scholarly literature related to this transdisciplinary topic, I was able to demonstrate that Australian gene technology framework favoured the scientific concerns to broader social concerns by neglecting the opinions of the GTECCC and the public (both lay and informed). The contentions amongst the social and scientific paradigms were further analysed at the level of key stakeholders by interviewing two members from the GTECCC and the GTTAC, respectively. The resulting discussion reflected the deep chasm that lay between the working of these two integral committees by elucidating the personal opinions and values of these two members. In keeping with the aim set out by the Macquarie University regarding my current degree of Master of Research, this

²⁰⁰ Jasanoff, Sheila. "Biotechnology and Empire." *Osiris* 21, no. 1 (2006): 273-292. Please see page 288.

research project was intended to be the pilot study for a subsequent doctoral degree. If granted an admission to a doctoral degree, I plan to reflect on this research and further investigate the opinions of the remaining key stakeholders and explore in depth the social, ethical and cultural effects of gene technology applications in Australia.²⁰¹ Especially since the use of gene technology to mitigate climate change is still in its infancy stages in Australia, it would be beneficial to explore all the dimensions associated with this application prior to its deemed commercial use. A change of government or mindset may result in the sudden commercial proliferation of this new technology and result in unwarranted controversies.

²⁰¹ Including the Australian Pesticides and Veterinary Medicines Authority (APVMA), the Australian Quarantine and Inspection Service (AQIS), the Food Standards Australia New Zealand (FSANZ) and the Therapeutic Goods Administration (TGA). The gene technology applications intended for green-house gas reduction are currently at a research level in Australia. I would like to interview the scientists associated with the research on this topic, who should have requested for a clearance from their respective Institutional Biosafety Committees (IBCs) and are eventually recorded under the List of Notifiable Low Risk Dealings (NLRDs) by the OGTR.

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Appendix

Interview Questions

1. Could you please elaborate on what you do and your association with gene technology?
 - a. How did you become interested in gene technology?
2. What are your views about gene technology science and its application in Australia?
 - a. Do you have any concerns?
3. How are you currently involved with Australian gene technology regulation?
 - a. Apart from the scientific robustness of a given gene technology product, what other values, if any, influence your decision to approve or reject a new license.
4. Were you involved in drafting the current gene technology regulation?
 - a. If there was any, what aspect of the drafting process do you think was most neglected?
5. How familiar are you with Australia's green- house gas emissions and do you believe in climate change mitigation?
 - a. How familiar are you with application of gene technology to reduce green-house gas emissions? Do you think the current law is supportive or unsupportive of gene technology applications to mitigate climate change? (If familiar)
 - b. Do you think gene technology would be a good option for mitigating climate change? (If unfamiliar)
6. If any, what amendments would you like to propose to the current regulation?

Personal interview with GTTAC member – Transcript

- Sumit: Could you please elaborate on what you do and your association with gene technology? How did you become interested in gene technology?
- Interviewee: *[Information containing interviewee personal information has been redacted.]*
- So I got interested in it very much from a technology side, but then I became interested in the regulation of gene technology through my work with [GM Crop] where many of the researches in the area were making statements around the environmental safety of [GM Crop] based on a lack or false assumptions.
- Sumit: Right.
- Interviewee: So, it's important for me to explain something here.
- Sumit: Sure.
- Interviewee: A bit of a technical nature but [GM Crop] as you might well known is grown for its stalk, not a seed or a fruit or anything, and it's planted by that stalk. Understanding the sexual reproductive biology of [GM Crop] in the field wasn't anything necessary to know anything about it. Unlike wheat, canola, cotton where it's all about flaring the fruit and sexual reproduction.
- Sumit: Right.
- Interviewee: *[inaudible 00:01:26]* propagated crop like [GM Crop], there wasn't the information there. People were extrapolating from poor or lacking information, and so I got interested in trying to understand the baseline by which regulators could then compare GM and non-GM plants.
- Sumit: Right.
- Interviewee: That's how I got interested in it and then through that sort of work became in contact with the OGTR. We were in fact providing them the information and helping them update the Biology of [GM Crop] document. When the opportunity came up to apply to be on the Gene Technology Technical

Advisory Committee three years ago, I did that because the regulation was something that we became interested in.

Sumit: Ok.

Interviewee: Since then we've also had a look at what weediness looks like in a [GM Crop] relative. I spent five months in [City] looking at a relative of [GM Crop] that had been introduced and then became a very bad weed.

Sumit: Okay. Thank you. Moving further, what exactly are your broader views about gene technology science and this application in Australia? Do you have any concerns in terms of its propagation or in terms of how it's being perceived and how it's being tackled?

Interviewee: I personally don't have any concerns because I don't think of is GM good or is GM bad. I want to know what GM for what purpose, and would make a decision based on that. By decision, I mean a decision on this question rather than on a regulatory decision.

Interviewee: Yes, of course.

Sumit: I think the whole argument around GM is so polarized; it's either you're for it or you're against it. There are some things that blatantly wouldn't make sense and other things that because I don't have a philosophical opposition to it in a blanket sense, I'm neither for everything or against everything.

Interviewee: Just to drill into this a little bit more, in terms of your experience how would you say Australia is doing in terms of utilization of GM science?

Interviewee: I think the issue there is around cost for regulation and market size.

Sumit: Right, okay.

Interviewee: So the crops that have been put through that regular due process in Australia, either in the case of cotton there was a compelling case around the massive amount of insecticide that was being used.

Sumit: Okay.

Interviewee: The expenditure and ultimate market size was sufficiently large to do that. But even there it leveraged off technology that had already been developed.

Sumit: Right.

Interviewee: The canola is again leveraged from technology that has been developed from overseas. It is a barrier to entry because the regulatory costs are expensive. Events that have potential for application across many countries are likely to be developed rather than things specifically for a small market. That's a barrier there I think for some things. One of the things that was introduced in the US, papaya, was introduced long before there were very expensive regulatory processes. Some of the other things are a bit more [inaudible 00:06:47]. I'm not really sure about the economics of those but that's certainly an issue in Australia. For the commercialization is the expense of the regulatory steps.

Sumit: Okay. Thank you for that. Question number three. I'll skip the first part because I think I've clarified that now. The second part of question number three is in terms of scientific assessment of a given gene technology license application that would come up to the OGTR, in your opinion and in terms of the technical committee's opinion, whenever an assessment is done for a given gene technology product, apart from the scientific value or the scientific merits or the risks involved in a gene technology product, are there any other values, do you think, that might influence your decision or the committee's decision to probably approve or reject it?

Interviewee: So the first thing I need to clarify there is, that the technology does neither approve or reject, that the committee has only an advisory role.

Sumit: Right.

Interviewee: We're not in the business of approving or rejecting. We don't consider this in scientific robustness because that's not our remit, but maybe I'm not understanding what you mean by scientific robustness. For example, if a product claims to be tolerant to a herbicide for example, we do not assess the efficacy of that. We don't have to know whether it works or not. The APVMA also has to regulate that, cares very much about whether it works or not, but

that's not what the OGTR considers. The OGTR does not consider whether there are any benefits. It is only looking at risks and the level of those risks.

What values? Everybody who's on the committee or everybody who's a human has their own points of reference and their thoughts around particular things, but what happens in that process is, we always come back to, is there a plausible path to harm. If there is, what's the likelihood of that path to harm happening? Process, because the legislation is quite clear around what it is that you're assessing it against irrespective of what values or things people might raise because of their particular experiences or points of reference.

The question always then comes back to, "Okay. So that's your view on that. That's your concern. Is there a plausible path by which that can cause a harm? If there is, what's the likelihood of that happening?" I think the framework is set up to almost exclude other values.

Sumit: I see.

Interviewee: Other values come on in from the advice that the gene tech's committee, the ethical committee would have. I think that definitely probably captures other values more overtly than the gene technology technical advisory committee would.

Sumit: All right. Sounds good. That was actually quite interesting to know and it was very informative. Thank you. Question number 4: Were you involved in any way in the drafting of the current gene technology regulation that Australia has on board?

Interviewee: No.

Sumit: That will take to me to question number 5 then. In terms of application of gene technology to reduce greenhouse gas emissions, to give you an example, you might be aware for example, application of genetically modified crops for biofuels or to get biofuels out of genetically modified algae or if we were to use genetically modified feed crops to reduce and direct methane emissions. Are you familiar with this technology or do you have any experience that you may have worked on this field?

Interviewee: Just backing up, the third one that's obvious potential here is, reduction of nitrous oxide emission through better nitrogen use efficiency and things like that. The major components are CO₂ and nitrous oxides and methane as you've identified. In the past, not for the anti-methanogenic properties, but in the past there has been work around genetically modified approaches to increase digestibility for foragers. That would have potentially, the affect of reducing the amount of methane per kilogram of animal product reduced, but many of those in the early days were not done for that purpose. People have been looking at nitrogen use efficiency and there are experimental processes around that around the world.

The biofuels ... Well, I don't actually know how much canola in Australia ends up in biodiesel. That actually has come from a genetically modified canola, but if it has, it hasn't been modified specifically for reduction of greenhouse gas objectives. It's just a herbicide resistance trait. Whilst these things in Australia have occurred perhaps in an experimental sense, I'm not aware of any of them getting to be put up for commercial release and I'm struggling without going back and looking through all the records of OGTR. I think of too many that have come up even for field trials. There's been field trials of some pasture plants.

Some of those were against disease rather than increased digestibility though. I don't think there's been much. It's actually got very advanced very far. The pertinent thing here that you may or may not be aware of is, in the consumer studies that have been done, there seems to be a greater acceptance of a genetically modified approach if there was an environmental outcome such as reducing greenhouse gases. That's like I say, in terms of regulation, the regulation is blind to the end use because that's not what it's concerned about. It's concerned about being in code with the OGTR, the effect on the environment and it's the people that handle and come into contact with the gene.

Sumit: Your last statement would be probably an answer to the subpart of this question which was that, in your opinion, would the current law be of supportive or unsupportive of the gene technology applications to mitigate

climate change? As you are saying, the end use is probably not what the OGTR would consider?

Interviewee: That's right. The end use may have a bearing because it depends on how things are transported, where they're taken to, whether the processing itself might create any additional risks that the end use in terms of if it was for biodiesel. It's completely blind to that. How it was turned into biodiesel might have some bearing, but not the fact that it was biodiesel, if you know what I mean?

Sumit: Yeah.

Interviewee: If you're putting it through the same process and one of the bioproducts was a food additive or a paint stripper or some industrial product, you'd either have the same level of scrutiny. If it ended going into food, obviously it would also have the scrutiny of FSANZ, Food Standards Australia New Zealand. You're familiar with their role?

Sumit: Yes. Thank you for that. Last, but not the least, if any, in your experience, what amendments would you like to propose to the current regulatory scheme that Australia has for gene technology?

Interviewee: At the moment we have a system where every separate event which really, if you're not familiar with it, means every separate insertion into the DNA, has to go through the same level of scrutiny. We have cases of this now where we have the second or third examples of herbicide resistant cotton or herbicide resistant canola going through the system. It doesn't evoke any ... with the exception of environment which I'll come back to. It is going over the same territory that you've been over time and time again. You wonder whether in these particular cases the regulatory system is adding any value at all because it's just jumping through the same hoops that have been jumped through before.

You would think that you could explore opportunities to try and streamline that part of process because I don't think anybody gains any benefit out of that current activity. Many people spend a lot of time and effort, not just the developer of the product, but the committees, the OGTR. It just seems to me to

add very little value when you're doing yet another one of the same thing. The only caveat I would put on that is, that there will come a time when, if there are resistances to every single class of herbicide that we have available to us in the same crop, that then creates potentially a different and new challenge that we would have to then assess. The way we do it at the moment for those things, seems to waste an awful lot of time.

Sumit: Based on my previous interviews that I have done during the span of this research, I've had the opportunity to talk to certain members of the ethics committee as well and I wouldn't say layman as in members from the layman public, but for example, certain specific groups which have a potential say in how things can be governed in Australia. One thing that I have noticed is, the impact of public perception towards gene technology and public say towards gene technology and the role of the ethics committee in the approval or not approval of a given gene technology.

Do you think it's adequately represented considering that GTECCC, again as you said, it's a body that can give its opinion upon things, but it's not binding at the end of the regulator to consider those opinions on for example, economics or culture, ethics? Anything except the risks to human health or the risks to the environment.

Interviewee: Your question distilling from that is, should The Gene Technology Act be altered in some way to give interest groups a say in the process?

Sumit: Yes, interest groups and also maybe develop a way where concerns to economics or concerns related to culture or social impacts for example, can be included in the process a little bit more robustly than how things are currently?

Interviewee: From the current legislation's point of view, my answer to that which might not be very satisfactory is that, when we develop legislation of any kind, there is a debate amongst the elected representatives as to which components of those should be incorporated or not. I don't really see why any particular group should have a say into any legislation over and above everybody else. What I'm saying is, the argument is had and is made at the point that the legislation is

made. Anybody who wants to oppose amendments to that regulation, would need to argue their case in the democratic processes that we have.

Basically, otherwise what you're suggesting is, that we're going to give certain people vetoes and The Regulatory Act needs to have a level of certainty about it. It doesn't matter what it is. It can be anything from no GMOs ever to the case-by-case like we have now. What I think we need is, a level of certainty so that people who are proposing to do something know the ground rules and that that they can't be held hostage to something that's unknowable at the time of going into it because of a particular interest group's [crosstalk 00:17:07].

I think a more ... I'm being very philosophical now. This isn't CSIOA talking. This isn't Interviewee Bonnet, scientist talking. This is Interviewee Bonnet, individual talking.

Sumit: Right.

Interviewee: If the argument is around choice and things like that, then potentially it's a more fruitful debate about labeling and choice at the point of consumption. I think a lot of the debate then comes down to, at what point do you label? Could you get away with this product's not containing traces of GM, not containing traces of nuts being that as we know that nuts can kill people?

Sumit: No.

Interviewee: It does seem a bit ... Well, it depends. If you're coming at this from an ethical point of view that, "I don't want to eat them or have them in my body because I think they're going to do something dangerous to me," that's your view. The question then becomes about, how much does your view hinge upon the rights above us? That's a very different argument and I think we'd struggle probably, to enshrine that in legislation, whatever it is.

Sumit: Understood.

Interviewee: Part of the population would like everybody to be vaccinated. Part of the population doesn't want to go near it. We generally try as a society let people do what they want to do until it impinges upon other people's rights. It gets

trickier if people believe that because there is GM, that their rights are affected. I think that's fruitful sociological debate that, at the point of the legislation and the regulation, all of those debates need to be taken into account and distilled when the legislation is made.

Once the legislation is made, then I don't think giving other individuals or groups a right of veto is particularly helpful. That's what the legislation is for. That should happen at the legislative point. Like I said, if the legislation says no GMO, that's what it says. If the legislation doesn't, then you follow what the legislation says. I think what is good about the current legislation compared to many other places around the world is, that there is set timeline, that there are clear goalposts.

Sumit: Thank you. That concludes our interview.

Personal interview with GTECCC member – Transcript

Sumit: Could you please elaborate on what you do and your association with gene technology? How did you become interested in gene technology?

Interviewee: Sociologists have, I suppose, for a very long time been interested in issues around genes, genetics and the like often from the human health point of view but also from the behavioral point of view because I guess it fundamentally runs opposed to many of our propositions of sociology and many of the other social scientists where we believe that behaviors are always shaped by the social context and by history and a particular culture in which one lives. It's of intrinsic interest.

I guess I've been working in the area now for probably about 15 years and been interested in issues around construction of genetic based differences, sex and sexuality and the like, looking at scientific texts of one kind or another. Also, looking at popular cultural understandings of genes and genetics as portrayed through news media, for example. Some of my early work was looking at genetics and medicine in the print news media. That's how I got interested in it, but there are others interested.

I've had some sort of, I guess, professional interest in terms of being on these advisory committees as well as a scholarly interest.

Sumit: Interesting. Good to know. Thank you. Just a continuing question, I've had a look at your research profile on your web page it's mostly related to new and emerging technology if I'm correct.

Interviewee: That's right.

Interviewee: Look at the area of say stem cell science, it's a field which is driven very much by high optimism, promise and optimism. I think that in terms of the market, the biotech sector, very much relies on optimism.

In fact, I was just recently reading that Janet Yellen who is the US Reserve Bank CEO has been warning about a bubble in the technology, particularly she mentioned biotechnology sector especially where the price-earnings ratio was such that it was creating a bubble type scenario where there was no real earnings. It was all based upon, I suppose she wasn't [captured in 00:08:03] these languages, but all based upon a great expectation, a future. It's a very speculative area in others words is what I'm saying.

It's a bubble of expectation and hope which is really driving the whole field. I suppose scientists at the outset of their work often tend to over claim, if you like, the significance of their work, that it's going to have various [pernicious 00:08:27] outcomes. We can see that in stem cell field where we've had a lot of fraudulent research practice. There was a [inaudible 00:08:37] the other day. I don't know if you read it. Japanese co-author of that article which was written by Obokata in Japan, and the co-author who was head of the Riken Research Institute committed suicide only about 4 days ago.

This fraudulent research practices and also in some cases, ruin lives, I think, has been very much related to this incredible pressure to make the next breakthrough and to be ahead of the field and compete with other groups who are under similar pressure.

Interviewee: Since 2000, of course, and the announcement of the mapping of the human genome, there's been [critical 00:10:24] expectation about translating that basic research into technologies, moving into what they call functional genomic stage, trying to figure out what genes do and to actually develop innovations on the back of that. I think there has been so much investment in that, so much promise and hope attached to that that the last 10 or 15 years or so, 14, 15 years has been this incredible exuberance around biotechnology. I suppose nanotech leads into that as well, which was increasingly likened to stem cell field, not a stem cell [inaudible 00:11:05]. We are talking about employing nanotech to provide the scaffolds for a lot of these new treatments.

Of course, we hear a lot about convergence of technologies. It's a discussion we've had a lot of actually in this other group that I was involved with, the [Governmental Consultative group]. That was under the previous federal

government where a lot of the discussion was around convergence between bio, nano, digital technologies, etcetera.

Sumit: Okay. Thank you for that.

Going to the second question, what would be your views about gene technology science and its application in Australia per se? Elaborating on that, would you have any concerns regarding gene technology science as being utilized in Australia?

Interviewee: Are you talking about in the agricultural sector or in the medical sector?

Sumit: If you're comfortable, we can generalize it. In agricultural sector, I have seen the work that has happened on GM canola and other related plants as well. Whatever you're comfortable with.

Interviewee: It's very interesting. I think that the sort of scenarios that these technologies play out differently, I think, somewhat differently in the different sectors. We've had a great wave of excitement about biomass and ethanol and all that in the wake of the global financial crisis when there was food and energy security. Efforts around the world to find new forms of energy.

In the food security system and the energy security system are tightly intertwined as people became very aware of those food rights, you might remember around about 2008, 2009 in the wake of the financial crisis and massive disparities which were becoming apparent when the markets froze. Especially in Australia, I think, it has gone a little bit cool. We hear a lot about energy crisis, etcetera. I think, of course, the liberal government has taken the foot off the pedal in regard to initiatives in relation to climate change [crosstalk 00:13:56] alternative energy sources and things like that.

I think in the REDD technology sector with which I'm most familiar, there is still optimistic claims being made about how this is going to transform healthcare in the future. I think governments and I think even the current conservative government in terms of its announcement in the budget about this new biotechnology future fund, medical research future fund, there's implicitly even if it's not a very sophisticated theory about how a lot of these

technologies are going to solve health problems associated with degenerative diseases of aging populations which many governments are grappling with.

I'm skeptical about it because I think most of the world's health problems are not related to these new high tech interventions but rather to basic things like clean water and shelter and things like that which affect the bulk of the population. Even if a lot of these medicines become available and new devices, there is a question about who is going to gain access and be able to afford it because most of them will be tied up in payments which will mean they'll be very expensive. I think it's not easy to come up with a [inaudible 00:15:16] genes generally.

Sumit: The part first of the next question is your current involvement in cell and gene technology regulation, which I think I've gotten a handle on now. The second part of the question was in terms of assessment of any new gene technology, product, or innovation, there is scientific robustness of a given product which is based on scientific testing and then which is analysed both at the technical committee and the ethics committee and eventually at the regulators level. In terms of evaluation, apart from the scientific robustness, what other values as a person yourself would you look into a given license that has come through? How would it influence your decision to probably say approve or disapprove of a given technology?

Interviewee: That committee in a way is sort of a response to things that come up. Like [Company] might come up with a proposal to develop a genetically modified crop of some kind, weed resistant or something like that. Some innovation where the gene technology regulator has to make sure that there is no risk involved. It's a bit of a reactive committee in that sense. It's not particularly innovative. The scope for reflecting on the rights or wrongs of that are quite limited because the gene technology regulator and its history was set up and it really merged out of concerns about regulating the risks.

I was involved, for example, in the last year in a working party trying to develop a risk analysis framework, which I thought was quite a conservative document in the language it used because I know a little about the risk literature, and I thought the literature was drawing on very psychometric

approach to risk. It didn't really encourage reflection upon the broader implications of these new technologies. In fact, there wasn't the scope. When you talk to people who are involved in these government departments, they say they're in this silo and they're just dealing with issues as they come up. They've got no scope for actually shaping these broader value questions.

On the committee, we looked at things like [*Gene Technology applications*], which might be seem very science fiction, but discussions have been had about these things. We had [decision 00:19:04] papers on it, and I suppose, discussed within the context of GTECCC whether or not there was something there which needed to be taken into consideration in our deliberations. The case of synthetic biology is such a [inaudible 00:19:18] defined area, we felt there was nothing there that was particularly unique that could be regulated under the existing legislation.

That's a very long way of getting around to your question, I guess. I suppose as a member of that committee I bring my own particular values and sensibility. I'm very interested in what might mean by the democratization of science and technology which is often top down policy driven. I think it's very difficult to democratize science and technology. This needs so many efforts, not so much in this country. I think Australia is really behind what's happening say in the UK, in Europe where there is quite a bit of discussion about what that might mean, funded research through the EU and various initiatives, which you don't see in this country.

I think we fit somewhere between the US, which is very gung ho about new technologies and Europe, which has broadly speaking a precautionary approach to new technologies. Precautionary approaches are very broad too, but I think Australia somewhere fits in between pretty. I think Australians and Australian governments are very keen to adopt new technologies generally of all kinds and hasn't been until relatively recently much consideration given to public engagement, what that might mean in practice.

Going to the [*country*] and then coming back, I've come back with this thinking about things which I found, mixing with people, being on committees where there wasn't a great deal of receptivity to some of these issues. The

National Enabling Technology Strategy did have a public awareness community engagement and community ... They call it Public Awareness and Community Engagement Program, which they developed, which I think is now being shelved effective because the liberals don't seem to be much interested in these things.

Sumit: Would you agree that these community development programs work with information dissemination approach? Information dissemination in terms of reports, online media rather than having the public to come up with, how should I put it, in terms of their opinions and actually utilizing those opinions in terms of formation of policy. Would you agree with that kind of scenario that's currently happening?

Interviewee: I think so. I've written a couple of papers which are really the premises that many of these public engagement efforts are really about gendering consent or engineering consent rather than trying to allow space for broad-based deliberation on the issues at stake. Often it happens at a stage where the technology has already been decided upon like with UK Biobank. There was no scope there really for publics to be involved at the outset of deliberations. Decision was pretty much made behind closed doors.

I believe BAT, British American Tobacco were one of the key players in that. They were very keen as have others been to prove that there is a genetic basis to lung cancer. That might seem pretty bizarre, but GeneWatch had done some research on this and looked at some of the various players. There was a collusion of interest decided that was necessarily a good research program to be had. Later, they decided to have a consultation. It was a stakeholder driven series of consultation involving groups who had been involved in other forms of consultation about things unrelated to genetics. I thought it was a very staged, very constrained form of deliberation. That often happens with a lot of these projects.

That's happened with the early nanotech public engagement in this country. There has been, I think, a lot of these efforts, they have failed. They may fail because it was never set up to be successful in terms of a broader public

deliberation because the people who were involved don't really understand what that might entail in practice.

Sumit: Digging a little bit deeper into this aspect, in your opinion in terms of the gene technology ethics committee, a person's background in terms of analyzing a given gene technology or let's just say a new technology product, how would you think the innate values of a person or have you ever noticed that because you do have a consensus-based approval method in GTECCC I believe. For example, someone from a scientific background, how the development of a person in terms of his social values may affect the analysis of a given report, which could be a risk analysis report. Do you think that actually affects in any way in terms of assessment of a given gene technology product while you were deliberating on a given product?

Interviewee: People always bring their personal values so it's hard to know to what extent that has an ultimate impact, [the few 00:24:59] ones deliberating on. If I look at the other committee, the National Enabling Technology Strategy Stakeholders Advisory Council, that is a group which involve business groups, consumer groups, Trades Hall, there are some academics on it. It is a very diverse group. I found one of the problems was that it became bogged down in interest group politics, you might say, where particular groups are trying to push something which is a concern.

I think it became so dominant because, for example, Friends of the Earth and Trades Hall had a particular issue, set of issues they wanted to push. They saw a window of opportunity to put them on the agenda whereas I didn't think that was necessarily the big issue. I didn't think it was the only issue to be spending time on.

Groups obviously do as they would in any forum, bring their own perspectives. I've seen it operate under these committees that have been involved in where, I think, the relationship between, because there is lot of things which shape policies and the alternate outcomes of policies so it's not necessarily one committee that shapes it. That committee and its values can have an impact on a particular decision or a set of decisions. In terms of the overall frame, how these things are dealt with, there is a history of things happening there. I think

policy makers themselves are involved in the political process even though they pretend not to be. They shape the way things are done, the approaches that are made to particular issues, the sort of expertise they muster, etcetera.

Sumit: Moving further, were you involved in any way in terms of the drafting of the current gene technology regulation over the course of the years?

Interviewee: I was only on the committee [X] years, which is not a long time. I suppose my influence has been in relation to this risk analysis framework. I'm just trying to think what else we're involved in now. Responding to particular policies, I guess, which pertain to how to respond to certain things as I just mentioned like the synthetic biology and things like that. Indirectly, there has been influence on policy. It's hard to tell what the overall impact is. I think it's just one element in the mix of things along with the [inaudible 00:29:14] group's input as well.

I'm not sure if the current government is even interested in this sort of engagement. That's probably why I haven't heard. They're probably either not interested in reappointing people or this is not a priority. I'm not quite sure what's behind it. I envisaged that this is what would happen. I've been told whenever liberals get in. I've got a colleague in [low 00:29:38], who's been involved. He is quite prominent in the environmental science area. I've been doing some work with him for the now department of industry. He was saying the last time liberals got in in 1996, a lot of these communities just disappeared and no one ever heard any more about it. Didn't even send a thank you letter to the people who were on the committee. I'm not expecting to hear anything from them.

Sumit: I'll add on to the last question. I think it's relevant that it can be tagged along here. In terms of current gene technology regulation, what do you think are the certain areas that would have been neglected in terms of the regulation itself? What amendments do you think, in your personal opinion, can be brought forward to make it a more robust mechanism?

Interviewee: I have to think about that one. I suppose the difficulty really, and I suppose this is a limitation with the way government departments operate generally is they

tend to operate in silos. For example, I discovered during my time in the GTECCC that there are certain things that cross over between the National Health and Medical Research Council and GTECCC around regulation of medicines for example. I think there is some degree of interaction between these bodies, but for historical reasons, they deal with quite a specific domain. Sometimes it's to do with risk management. It's dealing with issues downstream rather than upstream where technologies are developed and investments start to occur, and I guess active networks begin to evolve around particular issues.

I don't know what can be done about that because it's the way the [inaudible 00:31:56] process operates. That would be one of my, I suppose, comments on your question. I'm not sure what you can do about it really. I think even public engagement type efforts are quite limited too because they're often stakeholder-driven, time-limited initiatives whereas what you want to do is change the culture, and I suppose, create a context where people are engaged and have some genuine involvement in deciding on the path of technologies.

Interviewee: [X] was a public forum where public would come in and have a vote on various things. There was a series of propositions put to them and then people would talk on the panel and then they would vote afterwards. It was a very crude way of seeing where the people's views were changing as a consequence. It was developed by [inaudible 00:33:09], a group called [inaudible 00:33:11] that was funded through the National Enabling Technology Strategy.

So often, these events are ways to try and involve publics, but often, they're quite educated groups, the sort of people that would go out to hear academics largely talk about these issues. There is a whole section of the population who aren't involved that wish to be involved. It's a question about whether or not people have a right not to be involved if they don't want to be. I suppose ideally, it would be better if people were involved because technologies always affect, always have some impact. There are always winners and losers from technologies. Many people just respond to them and say like they do with new

mobile phones or other things which come on to the marketplace. It's consumers rather than as active participants in deciding on the path of technological development.

That's how I'd like things changed. It may be a very idealized view of things.

Sumit: Last but not the least, How familiar are you with Australia's green- house gas emissions and do you believe in climate change mitigation?

Interviewee: I think in your earlier question you sent me you wanted to know something about make a link with genes or genetics.

Sumit: That's correct. The second part of this would be are you familiar with the utilization of gene technology to actually mitigate climate change, certain gene technology applications that are currently being used around the globe to do that?

Interviewee: I'm only thinking about the biomass and I suppose trying to intervene into the agriculture productive space, which would mitigate the carbon emissions in some way, moving towards so called greener forms of energy. I'm sure there are others, but that's the main one I guess.

Sumit: Talking on that, how would you think that the current gene technology regulation and the fact that we have the GTECCC the technical committee because when we talk about utilization of gene technology for mitigation of climate change, there are two separate aspects to it.

Would you think the current gene technology regulation in Australia is either supportive or unsupportive of this assessment? If a product were to be introduced, for example, genetically modified feed for Australian agriculture and husbandry. Do you think the current law is supportive or unsupportive of gene technology applications to mitigate climate change?

Interviewee: It may not be. Whenever you introduce anything into food, there is always public concerns about it. I think that's a large part of the controversy around GM crops and food. It seems to be fundamental, anything to do with our fundamental subsistence of human populations in altering the so called natural.

What the natural is always disputable anyway. Some would argue that there's always been intervention in the food crops even in terms of applying Mendel's fundamental principles to shape the food chain in simple ways or whether it's more recent efforts to change in other ways.

There has been concerns around the impact that nano carbon tubes, for example, and how that is used in food processing and things like that. There has been concerns about that. The regulations may not really, I haven't looked closely yet, but may not adequately encompass and often don't encompass the ways in which lay communities respond to issues, how they construct risk for example. The popular everyday understandings of health issues, and this cuts through lots of things, when you start tampering with the food chain, I think that's a source of great concern to a lot of people.

One of the areas I'm interested in is around food. I do read quite a bit about it. There is a lot of popular cultural imagery concerns, constructions of risk, etcetera, which don't always fit alongside expert constructions. Legislation, of course, can't probably capture these lay constructions.

Sumit:

Understood. That's the end of this interview. Thank you

Ethics Approval Letter

Dear Dr O’Gorman

RE: Ethics project entitled: "Governing Genes for Climate Change: Analysing values and ideologies in Australia’s Gene Technology regulation”

Ref number: 5201400423

The Faculty of Science Human Research Ethics Sub-Committee has reviewed your application and granted final approval, effective 4th June 2014. You may now commence your research.

This research meets the requirements of the National Statement on Ethical Conduct in Human Research (2007). The National Statement is available at the following web site:

http://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/e72.pdf.

The following personnel are authorised to conduct this research:

Dr Emily O’Gorman

Mr Sumit Salaria

NB. STUDENTS: IT IS YOUR RESPONSIBILITY TO KEEP A COPY OF THIS APPROVAL EMAIL TO SUBMIT WITH YOUR THESIS.

Please note the following standard requirements of approval:

1. The approval of this project is conditional upon your continuing compliance with the National Statement on Ethical Conduct in Human Research (2007).
2. Approval will be for a period of five (5) years subject to the provision of annual reports.

Progress Report 1 Due: 3rd June 2015

Progress Report 2 Due: 3rd June 2016

Progress Report 3 Due: 3rd June 2017

Progress Report 4 Due: 3rd June 2018

Final Report Due: 3rd June 2019

NB. If you complete the work earlier than you had planned you must submit a Final Report as soon as the work is completed. If the project has been discontinued or not commenced for any reason, you are also required to submit a Final Report for the project.

Progress reports and Final Reports are available at the following website:

http://www.research.mq.edu.au/for/researchers/how_to_obtain_ethics_approval/human_research_ethics/forms

3. If the project has run for more than five (5) years you cannot renew approval for the project. You will need to complete and submit a Final Report and submit a new application for the project. (The five year limit on renewal of approvals allows the Committee to fully re-review research in an environment where legislation, guidelines and requirements are continually changing, for example, new child protection and privacy laws).

4. All amendments to the project must be reviewed and approved by the Committee before implementation. Please complete and submit a Request for Amendment Form available at the following website:

http://www.research.mq.edu.au/for/researchers/how_to_obtain_ethics_approval/human_research_ethics/forms

5. Please notify the Committee immediately in the event of any adverse effects on participants or of any unforeseen events that affect the continued ethical acceptability of the project.

6. At all times you are responsible for the ethical conduct of your research in accordance with the guidelines established by the University. This information is available at the following websites:

<http://www.mq.edu.au/policy/>

http://www.research.mq.edu.au/for/researchers/how_to_obtain_ethics_approval/human_research_ethics/policy

If you will be applying for or have applied for internal or external funding for the above project it is your responsibility to provide the Macquarie University's Research Grants Management Assistant with a copy of this email as soon as possible. Internal and External funding agencies will not be informed that you have final approval for your project and funds will not be released until the Research Grants Management Assistant has received a copy of this email.

If you need to provide a hard copy letter of Final Approval to an external organisation as evidence that you have Final Approval, please do not hesitate to contact the Ethics Secretariat at the address below.

Please retain a copy of this email as this is your official notification of final ethics approval.

Yours sincerely,
Richie Howitt, Chair
Faculty of Science Human Research Ethics Sub-Committee
Macquarie University
NSW 2109