

In preparation of STS Honours Thesis 2004

## **ISSCI Summer Scholarship Report**

Tentative Title

The Office of the Gene Technology Regulator and the  
Licencing of Australia's First Genetically Modified Food  
Crop: A case study in public (non) participation.

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## Introduction

The ISSCI Summer Scholarship has been extremely useful in allowing me time to explore my chosen topic in a broad manner before narrowing in on a particular area of interest. Initially my proposal outline was to look at Australian public policy regarding biotechnology in Agriculture. The case study for this research was the decision by the Office of the Gene Technology Regulator (OGTR) to grant a licence to Bayer CropScience for the commercial release of Australia's first genetically modified (GM) food crop, InVigor® canola. The focus at this point was to research the debate leading up to the decision in order to assess how this regulatory decision reflected the concerns of those who took part in the debate.

During the course of the Summer Scholarship my initial case study remained central, however it became obvious that the focus of my research had a few problems. Firstly, I realised that looking at the debate that led to the decision was a thesis in itself. It was a complex interaction of stakeholders and the debate was widespread in terms of avenues of communication. It took place not only in newspapers, on television, on the internet and in journals, it also became a traveling sideshow as industry, government and activist groups alike traveled to country areas to 'inform' farming communities. Secondly, I was unable to access key information from the OGTR. I had hoped to access a list of those who made public submissions to the OGTR during the decision-making process. This information did not appear on their website, nor in the final document that pertains to this decision.<sup>3</sup> I felt that an understanding of who made submissions, and their concerns, was crucial to providing a complete picture of the debate that took place. Unfortunately, the OGTR claimed that this information was restricted under the privacy act. This restriction is surprising given that this was a public consultation process and that details of previous public submissions about gene technology, both here and in New Zealand, are publicly available on the internet.

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<sup>3</sup> This document is the *Risk Assessment and Risk Management Plan (RARMP)* for DIR 021/20002 (this stands for 'dealing involving intentional release' with the number 021/2002 representing the application number and year of application).

The problems of breadth and accessibility of information were not the only reason for my shift in focus. During the research I realised that the Invigor® licencing debate in itself was not the major concern of my research rather, the difficulties of public participation in science and technology decision-making emerged as the central issue. As such, toward the end of the Summer Scholarship I began to research material that details the structure of the OGTR and its decision-making process to determine what sorts of provisions are in place to accommodate public participation, and conversely, what aspects of the decision-making process denied effective public participation. I also focussed more attention on secondary literature that details the issues surrounding public participation in science and technology decision-making. This area has proven to be a rich source of material both in terms of substance and theory. Despite the problems indicated above I did manage to obtain several public submissions that were made to the OGTR in response to the Bayer InVigor® decision, each of which was available on the website of key stakeholder groups. I expect to use them in my thesis to document the public participation process.

I have spent the major part of the Summer Scholarship accessing both primary and secondary resource material. I have identified the major areas of interest to my thesis and the following is a brief account of these areas and also some of the literature that I have looked at in depth.

## **Broad Background**

There has always been enormous pressure on government and industry to develop and adopt new technologies rapidly in order to reap the maximum economic benefit.<sup>4</sup> Despite the claim that a ‘free market’ will determine whether a new commodity fails or succeeds industry is increasingly aware that regulation can act to protect new technologies as they enter the marketplace.<sup>5</sup> The regulation of new or emerging technologies is difficult for

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<sup>4</sup> A good example in this case is, Commonwealth of Australia, *Australian Biotechnology: A National Strategy*, p 9, “Australia’s industrial competitiveness, and hence our standard of living, will be strongly influenced by whether we can grasp the opportunities presented by biotechnology”.

<sup>5</sup> See Lawson, ‘Risk Assessment in the Regulation of Gene Technology under the Gene Technology Act 2000 (Cth) and the Gene Technology Regulations 2001 (Cth)’, *Environmental and Planning Law Journal*,

governments. The impact of these new technologies is vast, sometimes global, and they are often adopted and regulated when a great deal of scientific uncertainty remains. Governments have sought to address these issues by adopting more technocratic models of decision-making in regulation. Not surprisingly, this reliance on technocratic models of decision-making has alienated the public<sup>6</sup> from the regulatory process. An alienated public has not been without repercussions for government and industry. Both are widely criticised and there is growing mistrust of their capacity to make decisions that are publicly accountable.<sup>7</sup>

As a result it is now recognised that public participation is crucial to legitimate decision-making outcomes.<sup>8</sup> The movement to develop strategies for public participation has intensified in the past decade with mixed results. One well known strategy is the Consensus Conference, which was developed in Denmark. This model has been adopted by several other countries, including Australia. The first Consensus Conference in this country was on the topic of this paper, gene technology in the food chain. At the time it was deemed a success and a number of key recommendations were made in the 1999 Lay Panel Report. Unfortunately though, they do not appear to have been adopted in the regulatory process for GM crops.<sup>9</sup>

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Vol 19, No 3, June 2002 p196, and Jackson. & Villinski, 'Reaping What We Sow: Emerging Issues and Policy Implications of Agricultural Biotechnology', *Review of Agricultural Economics*, Vol 24, No 1, 2002

<sup>6</sup> See Chin 'The Role of Public Participation in the Genetically Modified Organisms Debate', *Environmental and Planning Law Journal*, Vol 17, No 6, December 2000 and Rayner, 'Democracy in the age of assessment: reflections on the roles of expertise and democracy in public -sector decision making', *Science and Public Policy*, Vol 30, No 3, June 2003. The idea of a homogenous public is itself problematic and will be addressed in the thesis.

<sup>7</sup> See Dietrich & Schibeci, 'Beyond Public Perceptions of Gene Technology: Community Participation Public Policy in Australia', Paper presented at, *Towards Humane Technologies*, Conference, Ipswich, July 15-17, 2002, p 10, who argue that distrust of the regulatory process by the public is not an issue of public ignorance but rather a result of public awareness of institutional corruption and a realisation that science and technology cannot control their outcomes.

<sup>8</sup> This is widely acknowledged, see Dietrich, *Op Cit*, and Durant, 'Participatory technology assessment and the democratic model of public understanding of science', *Science and Public Policy*, Vol 26, No 5, Oct 1999 for example.

<sup>9</sup> McDonald, 'Mechanisms for Public Participation in Environmental Policy Development – Lessons from Australia's First Consensus Conference', *Environmental and Planning Law Journal*, Vol 16, No 3, June 1999. Applauds the concept but is concerned that the recommendations will be ignored because biotechnology policy in Australia is primarily driven by industry and political aims.

In order to look at public participation in science and technology decision-making in Australia I have chosen a single decision by the OGTR. It is apparent that this single decision exists in a much larger context, some of which I have outlined above. Yet although Australia has much in common with other countries that are grappling with these issues it is important to look at the local context of this decision also. The following points are not all unique to Australia, nonetheless they provide a framework in which to explore the significance of this decision and are useful issues to reflect upon during my research.

- 1) Invigor® canola is the first GM food crop to be licenced in Australia.
- 2) The agricultural industry in Australia is large, both spatially and economically.
- 3) GM canola is already approved as a food in Australia, which I suggest weakens the role of end use consumers in the current debate.
- 4) Australia has not suffered the type of food scares<sup>10</sup> that have plagued both the UK and to a lesser extent the US, which again explains why consumers/consumer groups have not played a particularly large role in this debate.
- 5) Stakeholder groups in Australia have benefited from an emerging body of literature that documents the problems associated with GM crops in the US.
- 6) There are a number of established and well-informed activist groups who have taken part in the debate.
- 7) There is a key stakeholder group (Network of Concerned Farmers) that developed in response to this particular issue, that is, applications to grow GM canola on a commercial basis. This group has members in all canola growing states in Australia and continues to maintain a high level of activity.

## **Canola and Genetic Modification**

An understanding of canola and genetic modification is essential to my thesis. The following documents and studies provide a useful insight into some of the issues

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<sup>10</sup> Although I recognise that Australia has experienced isolated episodes of food contamination we have not experienced anything like the political storm surrounding the BSE scare in the UK, or the public outrage over the Alar controversy and the Jack in the Box beef contamination in the US. In all of these cases, but particularly in the UK, public anger was not only directed toward the farmers or processors who were

surrounding GM canola. OGTR, *The biology and ecology of canola*, is a detailed history of canola; its uses, its characteristics, and its application as a food crop in Australia. The document is very comprehensive. However its usefulness as a source of information on GM canola is extremely limited as its whole focus is *conventional* canola. This document is important though, as it highlights a critical assumption of the OGTR, that GM canola is the same as conventional canola except for the inserted gene that expresses the desired characteristic.<sup>11</sup> This simplistic notion is dismantled in Murray, *Seeds of Concern*, a book that includes a chapter explaining the biology of plants and plant cells and a chapter on the methods of genetically manipulating plants. The detailed information provides an understanding of the many ways that GM crops can be produced. The book shows that each manipulation is unique and has the potential for unpredictable results, both in initial cropping or more particularly in gene transfer of next generation ‘volunteer’<sup>12</sup> plants. This is in stark contrast to industry and regulatory rhetoric that assumes genetic manipulation is a precise science in which the expression of the inserted gene is the only outcome. Murray details the use of ‘promotor’ genes in plant genetic modification and explains how and why these genes are unstable to such an extent that they are capable of mutating within the host organism to bring about unknown genetic changes. Worse still is the phenomenon known as ‘horizontal transfer’ in which unstable genes insert themselves into foreign organisms such as bacteria and viruses. As a result ‘promotor’ genes have the potential to cause unknown human health and environmental impacts both of which are relevant to the regulatory process as they fall within the confines of the OGTR *Risk Assessment Risk Management Plan (RARMP)*

Warwick & Meziani, *Seeds of Doubt: North American farmers’ experiences of GM crops*, was produced by the Soil Association of the UK in the lead up to the UK decision on growing GM crops. In its summary it is clear that this study is an attempt to counter the rhetoric of the US biotech industry in promoting the benefits of GM crops. The most

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responsible for the contamination, but also toward the government departments or politicians who were ultimately accountable for food safety and integrity.

<sup>11</sup> This is based on the notion of ‘substantial equivalence’, which is widely criticised in the literature. It appears to be a powerful tool in facilitating the regulation of GMOs and will be further exposed in the thesis.

serious concern in this study is the level of contamination of organic and conventional canola crops by GM canola. The study claims this has “undermined the viability of the whole North American farming industry”.<sup>13</sup> In this respect canola is by far the most dangerous of the current GM crops. The economic impact is also immense. Canada has lost its annual exports to the EU at a cost of \$300 million, and US government subsidies have increased dramatically to compensate for lost export markets, an estimated extra \$3 to \$5 billion dollars annually.<sup>14</sup> This study is significant because it documents environmental concerns that have emerged from the US experience with GM canola, concerns which *appear* to fall within the scope of the OGTR.<sup>15</sup> Additionally it addresses issues of importance to those who are arguably the most affected by GM crops, farmers. In this sense the study is a good outline of the impact this technology has on farmers and the agricultural industry in general.

Ho & Ching, *The Case for a GM-Free Sustainable World*, also looks at contamination and agrees that “*coexistence of GM farming and non-GM or organic farming would be impossible in many cases.*”<sup>16</sup> The report documents the flawed<sup>17</sup> regulatory process for GM crops in the US. The study also contains results of the limited studies on the safety of GM food for human consumption, finding that the transgenic process itself is cause for concern. There are a number of other human health issues highlighted, mostly in relation to the ‘horizontal transfer’ of genes into other organisms as mentioned by Murray. Another issue raised is the “...*misrepresentation and suppression of scientific evidence, especially on horizontal gene transfer.*”<sup>18</sup> which the authors (all of whom are scientists) claim is clouding the debate. These studies go some way toward exposing the ‘gap’

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<sup>12</sup> By ‘volunteer’ plants I refer to next generation canola plants that can radiate out from the initial crop, in some instances laying dormant for up to ten years before appearing.

<sup>13</sup> Warwick, H., & Meziani, G., *Seeds of Doubt: North American Farmers’ Experiences of GM Crops*, Soil Association, UK, 2002.

<sup>14</sup> *Ibid*, p 46.

<sup>15</sup> This is a grey area as the OGTR seems to have defined ‘environment’ extremely narrowly. I need to do some more reading on this, but according to a submission made by the Public Health Association of Australia to the OGTR re the Bayer InVigor canola decision, the OGTR has defined environment as “natural undisturbed ecosystems” which means that the vast majority of Australia is excluded from concern in this instance.

<sup>16</sup> Ho & Ching, Eds., *The Case for a GM-Free Sustainable World*, ISIS and Third World Network, 2003, p 12.

<sup>17</sup> Based on the notion of substantial equivalence.

between the reductionist scientific focus of the regulatory process and the everyday practices and reality of farming GM crops.

## **Office of the Gene Technology Regulator**

The OGTR is part of the Therapeutic Goods Administration within the Department of Health and Ageing. The Gene Technology Act 2000 (The Act )<sup>19</sup> established the OGTR, and its advisory bodies,<sup>20</sup> with a direction to make decisions under the Act. In effect, the role of the OGTR is to regulate all GMO dealings, and in the case of applications for intentional release into the environment, to assess the risk to human health and the environment.<sup>21</sup> The Gene Technology Regulator has “significant independence”<sup>22</sup> throughout this process although ostensibly any decisions must be based on “rigorous scientific assessment and extensive consultation with expert advisory committees, Government agencies and the public”<sup>23</sup>

The Act made a number of provisions that were not adopted by the OGTR in its decision-making process. These are crucial to my thesis as they include the capacity to address social and ethical concerns, guidelines for public participation, and the adoption of the precautionary principle when there is scientific uncertainty. I need to look more closely at these issues in order to assess what provisions were made for these issues in the Act and to what extent they were disregarded by the OGTR. Two articles in particular have been useful in alerting me to the existence of these issues. Lawson, ‘Risk Assessment in the Regulation of Gene Technology under the Gene Technology Act 2000 (Cth) and the Gene Technology Regulations 2001 (Cth)’,<sup>24</sup> details a number of provisions and guidelines under the Act that have been ignored or narrowly interpreted in the risk assessment process adopted by the OGTR. For example, the Regulator has the power to

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<sup>18</sup> Ho & Ching, *Op Cit*, p 49.

<sup>19</sup> The Act did not come into force till June 21 2001.

<sup>20</sup> The Gene Technology Technical Advisory Committee, (GTTAC), The Gene Technology Ethics Committee, (GTEC), and The Gene Technology Community Consultative Committee, (GTCCC)

<sup>21</sup> This process culminates in the RARMP.

<sup>22</sup> Office of the Gene Technology Regulator, *About the OGTR*, Commonwealth of Australia.

<sup>23</sup> *Ibid.*

<sup>24</sup> Lawson, *Op Cit*.

hold public hearings during the course of assessing a licence application.<sup>25</sup> It interprets low risk dealings as *no* risk dealings, and it fails to acknowledge the novelty of GMOs and so bases the RARMP on the non-modified parent plant. Similarly, Hain et al, 'Regulating Biosciences: the Gene Technology Act 2000',<sup>26</sup> are critical of the lack of direction imposed on the OGTR by the Act as it allows the OGTR too much independence in interpreting and implementing the licencing process. One of the more startling revelations in this article though relates to the Act itself and illustrates the level of industry bias throughout the whole regulatory process. When the OGTR does make a licencing decision only the licence applicant has a right to request a review, no other person or body has the right to challenge an OGTR decision.<sup>27</sup>

There are a number of issues relating to the OGTR that I need to research further. In doing so there is no doubt other avenues will open up but for the moment the following details must be addressed:

- 1) I need to detail the structure of the OGTR and its advisory bodies. Additionally, I need to examine their individual role in the regulatory process and look at the role they played in this instance.
- 2) What is the step by step licencing process for the intentional release of GMOs,? What was it in this instance?
- 3) How has the OGTR defined the two key elements of the RARMP? , that is, the environment and public health?
- 4) What are the avenues for public participation in this particular decision-making process?

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<sup>25</sup> I am fairly certain this did not happen in this case despite its significance, however, I can only be sure once I read the relevant policy documents.

<sup>26</sup> Hain, M., Cocklin, C., & Gibbs, D., 'Regulating Biosciences: the Gene Technology Act 2000', *Environmental and Planning Law Journal*, Vol 19, No 1, Feb, 2002.

<sup>27</sup> *Ibid*, p 171. This is quite amazing given that the applicant can call for a review of not only a negative decision, but of any conditions imposed on a positive licencing decision.

## Public Participation

As mentioned in the background, the need for developing strategies for public participation in science and technology decision-making has gained momentum, particularly in the past decade. However this process has been going on for some time, and one of the earlier models which is still cited in the literature is Arnstein's, 'Ladder of Citizen Participation'.<sup>28</sup> The article looks at urban planning issues in exploring a particular model of public participation, however the structure offered is applicable to any policy or decision making process in which the public is involved. Arnstein's ladder consists of 8 levels of public participation although this could be expanded depending upon the complexity of the situation. I don't agree with all of the ideas in this article, in particular the notion that the ultimate in public participation is 'citizen control' of decision-making. I don't think this could work in any practical sense, decision-making in science and technology is different from urban planning decision-making. Yet the ladder is a useful way of assessing the level of public participation in any one instance. Another good point Arnstein raises is that views of stakeholders within a debate are rarely polarized. More often there are any number of positions within a controversy and this is particularly so in science and technology issues. To this end Arnstein suggests the development of new institutions or bodies that can accommodate pluralistic views in order to reach a credible level of public participation.

Chin, 'The Role of Public Participation in the Genetically Modified Organisms Debate',<sup>29</sup> at one point critiques Arnstein's model, suggesting that governments should provide "improved public consultation mechanisms in the legislative process, rather than general models of public participation".<sup>30</sup> However, I would argue that this is what Arnstein is calling for given her recognition of the need to develop new mechanisms for public participation. Chin is looking at the Gene Technology Bill 2000 and Biotechnology Australia and is asking whether the establishment of these bodies incorporated public participation as defined by a 5 step consultative process. Whilst Chin sees, 'significant

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<sup>28</sup> Arnstein, S., 'A Ladder of Citizen Participation', *Journal of the American Institute of Planners*, Vol 35, July 1969.

<sup>29</sup> Chin, *Op Cit.*

<sup>30</sup> *Ibid*, p 524.

progress' in the way these bodies seek to expand public participation she also argues they are yet to be proven, "meaningful and welcomed by the community as sufficient consultative measures".<sup>31</sup> At this point I would argue that no amount of consultation can fully address issues of public participation if the decision-making process is technocratic and narrowly framed as in the OGTR decision. Chin then goes on to detail how the final policy abandons more democratic elements of the draft policy. This suggests that public consultation is ineffective if final policy or regulatory outcomes ignore the recommendations made. I plan to look at this more closely in the thesis, I have come across a number of instances, including the Australian Consensus Conference, in which public consultations are meaningless because there are no tangible outcomes.

Rayner, 'Democracy in the Age of Assessment: Reflections on the Roles of Expertise and Democracy in Public-Sector Decision Making',<sup>32</sup> is an interesting article that discusses the contradictory nature of modern government decision-making processes. These processes are increasingly reliant on expert assessments and technical/scientific data and yet at the same time governments are attempting to address the problem of public participation in decision-making processes. The article identifies three key areas that restrict the power of current models of public participation, noting that the flaws in the system relate not so much to the models themselves but to the overwhelming "political – cultural constraints" that frame them. The author rejects the boundaries of existing technocratic models of decision-making and suggests social scientists attempting to extend public participation would be better employed developing 'mobilisation' as a way of challenging the existing processes. Mobilisation would frame science and technology regulation with a social rather than remedial outcome and thus shift the decision-making concerns from one of process to one of outcome. Building on these themes is, Dietrich, & Schibeci, 'Beyond Public Perceptions of Gene Technology'.<sup>33</sup> The authors critique public policy assumptions about the public and their role in shaping technological development. The paper assesses recent Australian surveys on public perceptions of GM technologies with the suggestion that greater understanding of public attitudes to, and knowledge of,

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<sup>31</sup> *Ibid*, p 533.

<sup>32</sup> Rayner, *Op Cit*.

<sup>33</sup> Dietrich & Schibeci, *Op Cit*.

gene technologies is crucial to developing strategies to incorporate the public and legitimise the decision making process. The authors argue that the public would benefit by being viewed by policy makers as ‘citizens’ rather than consumers as this would strengthen their role in the decision-making process. The government surveys assume a knowledge deficit public, however the authors conducted their own research during the same period using qualitative methods in order to assess public perceptions. The conclusion of this research showed that interested publics who engage with the issues are a “valuable resource for continuing policy development with “the potential to play an important mediating role between researchers and decision makers on the one hand and the wider community on the other.”<sup>34</sup>

I recognise that the literature on public participation in science and technology decision-making is immense. To take advantage of this I expect to link theories and models of public participation to a theme. There are two themes that appear useful at this point although others may arise, firstly, public participation and democracy, and secondly, public participation and the expert vs lay knowledge divide.

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<sup>34</sup> *Ibid*, I intend to follow up this point in my thesis by looking at a recent article by Collins, (in bibliography) that in part details the need to develop and adopt strategies for identifying and involving key public participants in the decision-making process.

The following is tentative at best as I recognise that my thesis is in its early stages at this point and I may need to revise it any number of times during the coming months.

### **Thesis Title**

The Office of the Gene Technology Regulator and the Licencing of Australia's First GM Food Crop: A case study in public (non) participation.

### **Thesis Statement**

The role of the Office of the Gene Technology Regulator is to regulate the release of Genetically Modified Organisms in Australia. In this instance the OGTR assessed an application by Bayer CropScience to licence the release of Australia's first genetically modified food crop, InVigor® canola. The decision was based on a Risk Assessment and Risk Management Plan which invited widespread public consultation. Despite assurances of public accountability and opportunities for community involvement, the Office of the Gene Technology Regulatory failed to address legitimate concerns raised by key stakeholders.

### **Thesis Question**

Does the decision-making process of the Office of the Gene Technology Regulator foster genuine public participation?

## Thesis Chapters

### **Introduction**

General overview of topic of interest  
Framework of thesis  
Issues raised

### **Background**

Technocratic models of decision-making  
Growth of public participation techniques  
Australian context  
Canola characteristics  
What is genetic modification?  
GM canola

### **Office of the Gene Technology Regulator**

History of GMO regulation in Australia  
Structure of the OGTR  
Role of the OGTR  
The OGTR licencing process for dealings involving an intentional release  
The OGTR Risk assessment and risk management process  
The OGTR provisions for public participation  
According to the OGTR: definitions of environment and public health issues

### **Public participation in science and technology decision-making**

Models of public participation  
Successes and failures  
Theories of public participation  
What does genuine public participation look like?  
Theories of democracy *or* what is knowledge?, lay vs expert  
Risk assessment and public participation

### **Discussion**

Key stakeholders  
Issues of concern  
Public participation in practice  
Functions of the OGTR that limit public participation  
Outcome

### **Conclusion**

Public non participation  
Continuing unease

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