From risk to uncertainty: Australia's environmental regulation of genetically modified crops

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From Risk to Uncertainty: Australia's Environmental Regulation of Genetically Modified Crops

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ABSTRACT

In this thesis I present a critical appraisal of Australia's environmental regulation of genetically modified (GM) crops. I begin by suggesting that, although realist risk analysis currently dominates environmental decision-making on recombinant DNA technologies, the existence of contested values and widespread scientific uncertainty challenge the adequacy of this approach. What an appropriate approach to regulatory decision-making under these conditions would involve is then used as a guiding question to survey literature on risk and uncertainty from a range of social science disciplines. Through this survey, a theoretical framework is synthesised where the ends of a spectrum of stances taken towards environmental decision-making are contrastingly described as traditional 'science/risk' and emerging 'precaution/uncertainty' based approaches.

After describing the important components of precaution/uncertainty based approaches and suggesting that they represent a more appropriate way to orient environmental decision-making on GM crops, I then analyse Australia's regulatory framework in terms of where it can be positioned along the science/risk - precaution/uncertainty spectrum. Exploring the key distinguishing themes of the discourse of decision-making, the role awarded science, the avenues for public participation, the requirements for ongoing research and monitoring, and the range of policy options considered, I argue that Australia's environmental regulation of GM crops currently represents a predominantly science/risk based approach to decision-making.

With the process of 'objective' scientific risk assessment shown to be central in Australia's environmental regulation of GM crops, I then perform a detailed deconstruction of a case study risk assessment - the impact of Bt cotton on non-target organisms. Using criteria developed to explore the analytical themes of the reliability of cited scientific studies, how scientific information was used and the adequacy/appropriateness of the conclusions drawn, the thesis provides a detailed example of 'extended peer review'. This review challenges the objectivity of the risk assessment process, demonstrates the value of social science analyses of science for policy and offers a framework to help advance these forms of investigation.

Through this research, I critically appraise Australia's environmental regulation of GM crops, present recommendations for how it could be improved, and provide practical and theoretical frameworks to assist the development of robust processes for environmental decision-making.

CERTIFICATION

I, Fern Wickson, declare that this thesis, submitted in fulfilment of the requirements for the award of Doctor of Philosophy, in the School of Biological Sciences and Science, Technology and Society, University of Wollongong, is wholly my own work unless otherwise referenced or acknowledged. The document has not been submitted for qualifications at any other academic institution.

Fern Wickson

(Date)

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ABBREVIATIONS

ANZFA Australia New Zealand Food Authority

APVMA Australian Pesticides and Veterinary Medicines Authority

AQIS Australian Quarantine and Inspection Service

COGENE Committee on Genetic Experimentation

CRC Cooperative Research Centre

CSCG Commonwealth State Consultative Group on Gene Technology

CSIRO Commonwealth Scientific and Industrial Research Organisation

DNA Deoxyribonucleic acid

EPA Environmental Protection Agency

ESD Environmentally Sustainable Development

FSANZ Food Standards Australia New Zealand

GM Genetically Modified

GMAC Genetic Manipulation Advisory Committee

GMO Genetically Modified Organism

GTCCC Gene technology Community Consultative Committee

GTEC Gene Technology Ethics Committee

GTTAC Gene Technology Technical Advisory Committee

IOGTR Interim Office of the Gene Technology Regulator

ISAAA International Service for the Acquisition of Agri-Biotech Applications

IUCN The World Conservation Union

NAS United States National Academy of Sciences

NICNAS National Industrial Chemicals Notification and Assessment Scheme

NIH National Institute of Health

NRA National Registration Authority

OGTR Office of the Gene Technology Regulator

RAF Risk Analysis Framework

RARMP Risk Assessment and Risk Management Plan

rDNA Recombinant Deoxyribonucleic acid

TGA Therapeutic Goods Administration

UK United Kingdom

US United States of America

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INTRODUCTION:
A TRANSDISCIPLINARY RESEARCH PROBLEM

In this introduction I begin by articulating the research problem addressed in this thesis. Suggesting that this problem will benefit from a transdisciplinary approach to research, I then describe what I mean by transdisciplinarity, and importantly, how the quality of this type of research endeavour may be judged. Finally, I use this introduction to foreshadow the content of the thesis by providing a brief summary of each chapter.

1. THE RESEARCH PROBLEM

My interest in this research project began with a rather informal concern about the potential environmental impacts of genetically modified (GM) crops. While conducting preliminary research on this topic, I realised that there was a debate occurring that involved contested environmental values and widespread scientific uncertainty. This saw my interest shift toward understanding how Australia went about making regulatory decisions on the potential environmental impacts of GM crops in the face of the challenges posed by competing values and scientific uncertainty. However, rather than simply being interested in how Australia regulates GM crops (a question that could be satisfied with a descriptive answer), I was interested in how regulatory decisions should be made under these conditions and how well our system measured up against a theoretical ideal[1]. Therefore, the research problem I selected for this thesis was to critically appraise Australia's environmental regulation of GM crops.

The selection of this particular research problem was also motivated in part by the fact that in 2005/2006, an independent review of the operation of the Act governing Australia's regulation of gene technologies would take place[2]. In selecting the research problem of providing Australia with a critical appraisal of its environmental regulation of GM crops, one of my aims was to contribute to this planned review. I wanted to produce research that not only represented a reflection on Australia's regulatory system in light of a range of theoretical literature on environmental decision-making, but also, to produce research outcomes that represented practical recommendations for how the regulatory system could be improved. While a critical appraisal could be structured around other themes or performed using alternative methodologies than those I have adopted, my research does offer an informed and engaged perspective on Australia's environmental regulation of GM crops.

Critically evaluating Australia's environmental regulation of GM crops is a complex research problem because it is embedded in a very real social context; a context within which there are not only contested values and widespread uncertainties but within which the issues of importance are not just scientific, but also political, social and ethical. Rather than being an abstract problem that exists only in the mind, the question of how we regulate GM crops for their potential environmental impacts is a practical problem that exists 'out there' in a social world that is complex and heterogenous and therefore, where the boundaries that structure disciplinary knowledge become blurred. As a contextualised problem, disciplinary based approaches to research will necessarily have severe limitations.

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[1] A more detailed description of how I came to be interested in this topic is provided in the 'Preface' section of the Appendix.

For example, to understand the potential environmental impact of GM crops, knowledge from a range of scientific disciplines (e.g. molecular biology, ecology, toxicology) becomes important. When focussed on the issue of regulation in relation to environmental impacts, dealing with the research problem also requires an ability to engage with knowledge from social science disciplines such as politics, sociology and philosophy. This means that my research problem requires an engagement with disciplinary knowledge from across both the natural and social sciences. While one could choose to perform a critical appraisal of the regulatory system using the frameworks, tools and methods provided within a single discipline, any use of a strict disciplinary approach would fail to capture the complexity that is involved in the particular research problem I have selected.

The provision of a critical appraisal of Australia's environmental regulation of GM crops is therefore a contextualised research problem located at an interface between natural and social systems. As such, I argue that it is a problem that requires a 'transdisciplinary' approach to research.

2. TRANSDISCIPLINARITY[3]

Although disciplinary approaches to knowledge production have traditionally dominated the tertiary research environment, various forms of cross-disciplinary[4] research have been undertaken for some time (Dogan & Pahre

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[2] The requirement for this review is described in section 194 of the Gene Technology Act 2000 (Commonwealth of Australia 2000a).

[3] The general ideas on transdisciplinarity presented in this section were developed during collaborative research work with Drs. A. L. Carew and A. W. Russell, more detail of which is recorded in Wickson et al. (in press). In acknowledging this joint effort, I would highlight that collaboration is an important component of transdisciplinary research, as described in section 2.1.3 of this chapter.

[4] Cross-disciplinary (like 'supra-disciplinary' (Balsiger 2004) and 'pan-disciplinary' (Ramadier 2004)) is used as an umbrella term for the various approaches to crossing disciplinary borders, including interdisciplinarity, multidisciplinarity and transdisciplinarity.

1990). In fact, cross-disciplinarity has arguably been an essential part of the development, evolution and rearrangement of disciplines. Transdisciplinarity can however be regarded as a 'new' form of cross-disciplinarity by virtue of the substantial efforts that have been devoted to theorising this approach in recent years. In this section, I review the emerging theoretical literature on transdisciplinarity to develop a description of the characteristic concerns, processes and challenges of this research approach and to discuss how the quality of transdisciplinary investigations may be judged.

2.1 CHARACTERISTICS

Having surveyed the theoretical literature on transdisciplinarity, I describe three key themes that can be used to characterise a transdisciplinary approach to research. These themes are problem focus, evolving methodology, and collaboration[5].

2.1.1 PROBLEM FOCUS

One of the broadly agreed characteristics of what constitutes transdisciplinary research is that it is performed with the explicit intent to solve problems that are complex and multidimensional, particularly those at an interface of human and natural systems (Costanza 1990; Gibbons et al. 1994; Hammer and Soderqvist 2001; Balsiger 2004; Lawrence & Despres 2004; Thompson-Klein 2004). The fundamental idea here is that society is facing problems manifest in the real world that are complex, multidimensional and not confined by the boundaries of a single disciplinary framework. Transdisciplinary research is then characterised by its willingness to engage with these types of societal problems.

[5] In Wickson et al. (in press) these characteristics of transdisciplinarity are described specifically in terms of how they serve to demarcate transdisciplinarity from multi- and inter-disciplinary research. As my aim here is simply to describe transdisciplinarity rather than distinguish it

The research problem I have selected and described in section one of this chapter (providing a critical appraisal of Australia's environmental regulation of GM crops) clearly falls within this characterisation of the types of problems amenable to transdisciplinary research.

Implicit in this understanding that a focus on 'real world' problems characterises transdisciplinary research is the notion of creating change. In focussing on problems that exist in society, solutions to these problems will not simply be answers to conceptual puzzles, but rather, they will represent practical outcomes that can be applied in a social or environmental context and which will therefore bring about some degree of change in those contexts. As my research aims to contribute to the planned review of the operation of Australia's gene technology legislation, this idea of creating change is indeed central to my research endeavour.

2.1.2 EVOLVING METHODOLOGY

There is broad agreement in the literature that there can be no single prescribed methodology for transdisciplinary research as the particular methodologies employed will need to respond to and reflect the problem and context under investigation. Authors who describe transdisciplinarity do, however, suggest that the dissolution of disciplinary boundaries is key for the construction of novel or unique methodologies tailored to a particular problem and its context. Horlick-Jones & Sime (2004) suggested that, in transdisciplinary research, "elements of methodologies drawn from different disciplines are combined within a single approach…an evolved methodology" and that "In epistemological terms, transdisciplinary involves an integration of

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from other cross-disciplinary approaches, I refer those interested in these comparisons to the collaborative paper.

knowledges". The integration of different epistemologies is also emphasised in the description of transdisciplinarity provided by Gibbons et al. (1994) – "Transdisciplinarity…must be accompanied by a mutual interpenetration of disciplinary epistemologies". These quotes illustrate transdisciplinary research being characterised as involving an integration of different disciplinary methodologies, and ideally, epistemologies.

The idea implied by the term 'evolved' methodology is that once developed, methodologies are complete and remain static throughout the research process. Alternatively, the characteristic feature of transdisciplinary methodology could be more appropriately viewed as the way in which it continues to evolve in an iterative relationship with the research problem and processes. The implication here is that transdisciplinary researchers go beyond developing an 'evolved' methodology that remains static, to an 'evolving' or dynamic/responsive methodology that continues to develop in response to the research, its context and the learning and changing perspectives of the researcher and/or stakeholders in the research. A detailed description of how different disciplinary methods and epistemologies are combined in my approach to research is presented in the methods chapter of this thesis.

2.1.3 COLLABORATION

If transdisciplinary research is focussed on complex and multidimensional problems and involves an evolving methodology that fuses different disciplinary approaches and epistemologies, the importance of collaboration becomes obvious. While the notion of collaboration can be viewed in terms of working to bring knowledge from different disciplines together, Thompson-Klein (1994) extends this to suggest that a distinguishing characteristic of transdisciplinary research is that it includes the "intentional involvement of stakeholders in the definition of problems and those criteria, objectives and

resources used to analyse and resolve them". This means that collaboration between not only different disciplinary knowledge bases but also between the researcher and the broader community becomes an important characteristic of transdisciplinarity.

Understood in this way, the foregrounding of collaboration as a distinguishing feature need not preclude individuals from researching in a transdisciplinary manner. If the importance of collaboration for transdisciplinary research is understood as referring to the importance of the ability to fuse knowledge generated in a number of different disciplines and to engage with stakeholders and members of the public in the process of defining the problem and generating knowledge, then individuals are clearly able to adopt this type of approach to research. A discussion of the role collaboration has played in this thesis is presented in the conclusions and recommendations chapter.

While this section has focussed on characteristics defining transdisciplinarity, in the coming section I further develop the concept by presenting some of its important challenges. I discuss these challenges here because both the distinguishing characteristics of transdisciplinarity and the unique challenges associated with this research approach can be used to structure frameworks for conceptualising and judging quality.

2.2 CHALLENGES

2.2.1 INTEGRATION

Transdisciplinary research offers the potential for many different dimensions/scales of integration, each posing unique conceptual and practical challenges (Somerville & Rapport 2003). The two dimensions of integration I

discuss here relate to integrating disciplinary knowledges and epistemologies, and the integration of researcher and research context.

On one level, transdisciplinary researchers are required to integrate knowledge from different disciplines. In doing this across the natural and social sciences there will be a particularly obvious need to integrate different epistemologies. Some theorists of transdisciplinarity have developed concepts to help tame challenges involved with this integrative exercise. For example, Ramadier (2004) talks about the need to move away from a search for a unity of knowledge towards a search for coherence. Thompson-Klein (2004) draws attention to the way in which Nicolescu calls transdisciplinarity "the science and art of discovering ridges between different areas of knowledge and different beings". Henagulph (2000) cites the ideas of Morin to suggest that transdisciplinary researchers need to focus on finding and developing "knots of communication". What these ideas collectively suggest is that in trying to integrate different knowledges and epistemologies, the transdisciplinary researcher does not need to aim towards the development of a single unified 'truth', but rather, can seek to integrate different knowledges by looking for coherence, correspondences and 'ridges' across the differences, generating knowledge by finding, identifying and communicating patterns across diverse disciplines and discourses.

In the theory chapter of this thesis, I am particularly focussed on the task of identifying patterns and ridges of correspondence across diverse social science disciplines. The most challenging integrative task, however, involves working across the divide between the natural and social sciences. For example, in the final empirical part of the thesis, I review a case study risk assessment document using a combination of natural and social science perspectives. By

conducting this task without specialist scientific training, my research approach may attract criticism. As I argue in section 1.2 of the methods chapter, however, when science is used in a policy setting for issues involving high degrees of uncertainty and disputed values, the assurance of quality and reliability requires review by an extended community of peers and the inclusion of more social forms of analysis becomes valid, and indeed, vital (Funtowicz & Ravetz 1992a & 1993; Ravetz 1999; van Zwanenberg & Millstone 2000; Jasanoff 2003). In my case study deconstruction of a risk assessment, I integrate scientific and social scientific forms of analysis specifically because I view the environmental regulation of GM crops as a situation involving contested values and widespread scientific uncertainty.

A second dimension of integration required in transdisciplinary scholarship relates to the notion of being an embedded or engaged researcher. Rather than simply being an outside observer, being an embedded or engaged researcher means that issues of practice are in some sense directly experienced. The idea here is that the transdisciplinary researcher develops a deeper understanding of the problem they are investigating if they can manage to not only fuse different theoretical and lay knowledges, but also to engage with the problem in context directly and experience the practice first hand. In this thesis, I have worked as an engaged researcher by actively participating in regulatory decision making on a number of occasions. I made written submissions on the draft risk assessment and risk management plan developed for my case study crop Bt cotton, I submitted written comments on the regulatory agency's risk analysis framework when it was under review in 2004, and I presented my research findings to the committee established to review the operation of Australia's gene technology legislation in 2005. An inherent challenge associated with this dimension of integration is how to maintain some critical distance while

working as an embedded researcher. One way to address this challenge is to nurture reflective research habits.

2.2.2 REFLECTION

Having suggested that transdisciplinary researchers benefit from being engaged with the problem they are investigating, it subsequently becomes imperative to highlight the importance of reflection for transdisciplinary research processes. When researchers become engaged in the problem they are investigating, assumptions of objectivity inevitably come into question. It becomes important for the researcher to reflect on how their own frames of reference/values/beliefs/assumptions etc have shaped the conceptualisation of the problem, as well as the development of the method of investigation and the solution. Exactly how this reflective process proceeds and the way in which it influences the research outcomes is a challenge that transdisciplinary researchers need to consider.

For this thesis, I chose to actively undertake a reflective process at two key stages. Early in my research, I wrote a "preface" to the thesis that reflected on the experiences and environments of my life that were important influences on how I had defined my research problem. When the research was complete, I wrote an "epilogue" reflecting on how my own values and assumptions could be seen to have influenced my methods and results. Both the preface and epilogue detailing these reflections are contained in the appendix.

2.3 QUALITY

For disciplinary research, the evaluation of quality is traditionally performed by peer review. This relies on the existence of an established community of peers who judge research using quality criteria that are often implicit in disciplinary knowledge frameworks. As transdisciplinarity is a nascent approach to

research, there is not yet a well established community of peers experienced in reviewing the quality of these endeavors. Additionally, because transdisciplinary research is broad, diffuse, evolving and context specific, the criteria for quality assessment will arguably be implicit in the research context rather than in particular disciplinary frameworks. The lack of an established peer community and the contextualized nature of transdisciplinary research mean that critically robust ways to discuss and evaluate the quality of transdisciplinary endeavours are currently underdeveloped and insufficient (Häberli et al. 2001; Somerville & Rapport 2003). The synthesis of transdisciplinarity's characteristics and challenges presented in this chapter can, however, be viewed as useful for shaping quality assessment tools.

One way in which the synthesised characteristics and challenges might be utilised is in the development of a series of strategic (Peavey 1995) or reflective (Schön 1987) questions. Evaluators of transdisciplinary quality could ask how well the characteristic features (problem focus, evolving methodology, collaboration) and challenges (integration and reflection) have been accounted for. For example:

- How was the research problem formulated?
- How have competing epistemologies been reconciled?
- How has collaboration featured in the project?
- How well have knots of communication between different bodies of knowledge been created? Is the weave informative, useful, compelling?
- How has the researcher reflected on, recognised and/or accounted for the limitations and subjectivities involved?

A second approach to evaluating transdisciplinary research might be to use the synthesised characteristics and challenges to reinterpret aspects of an already

established approach to quality assessment. One such established approach is that developed by Glassick et al. (1997). This schema for evaluating the quality of scholarship has been widely adopted because it offers a formal yet flexible process for evaluating academic endeavour. According to this schema, the work of academics can be evaluated using the following six criteria:

- Clear goals – the scholar identifies important questions in the field, clearly articulates the purpose of the work and defines realistic objectives.
- Adequate preparation – the scholar demonstrates an understanding of existing knowledge in the field and brings the necessary skills and resources to the project.
- Appropriate method – the scholar selects and effectively applies methods appropriate to the goals and modifies these methods in response to changing circumstances.
- Significant results – the scholar achieves set goals, makes an important contribution to the field and highlights new areas for exploration.
- Effective presentation – the scholar employs appropriate means (style, medium, forums etc) to clearly communicate the work to its intended audience.
- Reflective critique – the scholar uses a breadth of evidence to critically evaluate their work and through this process improves the quality of future endeavours.

As originally formulated, this schema was purposefully generic, designed to evaluate a range of scholarly activities. While this means that these generic criteria could be adopted to evaluate transdisciplinary research, some could

also be refined to specifically relate to transdisciplinarity's characteristics and challenges[6]. For example:

- Responsive goals – in transdisciplinary research, the scholar defines goals through ongoing consultation with the problem context. Goals may therefore shift in response to developments over the course of the project.
- Broad preparation – in transdisciplinary research, 'adequate preparation' would require accessing and integrating literature and theory across a broad range of disciplines.
- Evolving methodology – An 'appropriate method' for transdisciplinary research is ideally epistemologically integrative and capable of evolving in response to a changing research context.
- Significant outcome – The outcome of transdisciplinary research should contribute to the solution of a manifest problem.

In presenting this type of schema for quality evaluation, the suggestion is not that transdisciplinary researchers necessarily have to satisfy all criteria equally to produce work of quality. What is important, however, is an appreciation of the significance of each and an awareness and acknowledgement of any limitations.

In this section I have sought to describe transdisciplinarity as a research approach through synthesising distinguishing characteristics and challenges and to indicate how my research aligns with these distinguishing features. I have also commented on how assessing the quality of transdisciplinary research can be informed and guided by these synthesised characteristics and

[6] In presenting these refinements, it is important to note that the aim is not to supplant the original criteria but rather to supplement them so that they specifically relate to transdisciplinary research.

challenges. By providing a clear description of transdisciplinary research and some of the ways in which the task of quality assessment can proceed, my aim has been to clarify the research approach adopted in this thesis and provide some guidelines for quality assessment that can be used to assist both the process of thesis examination and my own reflection on this issue.

3. THESIS CONTENT SUMMARY

Following this introduction is a context chapter, which provides some background information to the thesis by describing important elements of the social context within which my research problem is located. In that chapter, I discuss three key contextual issues - the development of recombinant DNA (rDNA) technology, modern environmentalism and the regulatory discourse of risk. The chapter therefore begins with a description of rDNA technology and the history of its development, specifically highlighting the debate that has surrounded this technology from its inception. In the second section dealing with modern environmentalism I describe how rDNA technology has developed within a social context where, although concern for the environment is widespread, environmental values and beliefs remain contested. Specifically, the section describes competing environmental paradigms to highlight how contested values complicate the process of environmental decision-making. Finally, the context chapter discusses how a discourse of risk currently dominates the regulation of controversial technologies, particularly in relation to their environmental impacts, and emphasises the problem of scientific uncertainty for adopting this discourse in relation to GMOs.

Through describing rDNA technology, modern environmentalism and the regulatory discourse of risk, the context chapter highlights the existence of contested values and widespread scientific uncertainty as a key problem facing

Australia's environmental regulation of GM crops. As my aim is to critically appraise our regulatory system, I need to then develop an understanding of what an appropriate way to approach environmental decision-making under these difficult conditions might involve. To develop this understanding, the next chapter of the thesis details my survey of theoretical literature on risk and uncertainty in environmental decision-making.

The theory chapter begins with a description of the realist approach to risk that is traditionally adopted in policy settings. I then survey and synthesise literature on risk and uncertainty from a range of social science disciplines, including psychology, anthropology, sociology and science and technology studies. Through this survey, I demonstrate how social science theories on risk represent a serious challenge to the appropriateness of employing realist discourses, particularly in the environmental regulation of GMOs. By identifying patterns across the different theories and disciplines as to what is important for regulatory decision-making under the conditions of contested values and uncertainty, I synthesise an approach to decision-making that balances the quantification of risk with the negotiation of uncertainty. I refer to this as a 'precaution/uncertainty' based approach to environmental decision-making in opposition to the 'science/risk' based approach that has traditionally dominated policy settings. Having developed this theoretical framework through a synthesis of the literature, in the following chapter I explain the methods I employ to explore Australia's environmental regulation of GMOs according to this framework.

The methods chapter is divided into three sections. In the first section I describe my method for analysing where Australia's regulatory system for GMOs can be positioned along the 'science/risk' - 'precaution/uncertainty' spectrum of

approaches to environmental decision-making. This method is based around an analysis of the key distinguishing themes detailed in the theory chapter - the discourse of decision-making, the role awarded science, the avenues available for public participation, the range of policy options considered, and the requirements for ongoing research and monitoring. In the second section of the methods chapter I discuss how I explore a case study scientific risk assessment conducted by Australia's regulatory agency. The method I describe for deconstructing this case study risk assessment involves criteria developed for three broad questions: What is the reliability of the cited scientific information? How has science been used in the assessment? and How adequate and appropriate are the conclusions drawn? In the final section of the methods chapter I provide background information on my case study GM crop, Bt cotton. This includes information on what it is, how it was developed and why it was selected as a case study.

Following the chapters on context, theory and method are the two key empirical chapters of this thesis. The first of these contains an analysis of the framework for the environmental regulation of GMOs in Australia. This chapter is particularly concerned with how legislation has framed Australia's regulatory system for GMOs and whether it can be more accurately characterised as a 'science/risk' or 'precaution/uncertainty' based approach to environmental decision-making. Through analysing the regulatory framework according to the key themes I describe as distinguishing these approaches, this chapter argues that Australia has adopted a largely technocratic 'science/risk' based approach to environmental decision-making. According to my analysis, 'scientific risk assessment' forms the basis of the decision-making process. In the following chapter then, I engage in a detailed deconstruction of a particular risk assessment.

The particular risk assessment I use as a case study is that conducted by Australia's regulatory body (the Office of the Gene Technology Regulator (OGTR)) on the impacts of Bt cotton on non-target organisms. I review this risk assessment and its use of scientific information as a member of an 'extended peer community', as called for by Funtowicz & Ravetz (1993 & 1994). This involves exploring both the reliability of the scientific information and the way it has been used through a range of criteria and questions I detail in the methods chapter. Through this review, I challenge the objectivity of the risk assessment process, demonstrate the value of social science analysis of science for policy and develop a framework that others wishing to engage in a similar process of review could use to structure their investigations. I refer to this framework as Reliability Rating and Reflective Questioning.

Following the chapters that document my analysis of the regulatory framework and the practice of risk assessment is a final Conclusions and Recommendations chapter. In this chapter I draw together the information from across the thesis and make recommendations for both further research and the future evolution of Australia's environmental regulation of GM crops. While this can be viewed as the final 'formal' element of the thesis, it is followed by an appendix that records my reflections on the PhD research project.

In summary then, this thesis begins with a description of the context surrounding my research project that depicts the existence of contested values and scientific uncertainty as a key problem facing Australia's environmental regulation of GM crops. I then survey theoretical literature to uncover what an ideal approach to decision-making under these difficult conditions might involve. After synthesising a theoretical framework that contrasts traditional

'science/risk' with emerging 'precaution/uncertainty' based approaches to environmental decision-making, I analyse which of these best characterises the Australian regulatory framework. Through this analysis, scientific risk assessment emerges as a key element of the current decision-making process. This leads me to deconstruct a case study risk assessment to explore exactly how science, uncertainty and contested values have been handled in the decision-making process. Finally, I draw the research together and make recommendations for both future research and how Australia's environmental regulation of GM crops can continue to evolve.

CONTEXT:
RECOMBINANT DNA, ENVIRONMENTALISM & RISK

CHAPTER OUTLINE

To contextualise my research project on Australia's environmental regulation of GM crops, this chapter sketches the development of recombinant DNA (rDNA) technology, modern environmentalism and the dominance of a regulatory discourse of risk. In the first section of this chapter I briefly outline the history of the rDNA controversy and highlight how concerns have shifted from a focus on the risks associated with genetically modified organisms (GMOs) escaping from laboratories to the risks associated with their deliberate environmental release. I emphasise how GM crops are currently the most widely commercialised form of GMO and conclude the section by suggesting that social concerns and debate over rDNA technology have created pressure on governments to regulate the deliberate release of GM crops so as to minimise potential adverse effects.

In the second section of this chapter, I discuss the growth of modern environmentalism and how increased concern for the environment means that (in addition to impacts on human health) the potential for adverse environmental impacts is an important political consideration for technological decision-making. The discussion then focuses on one of the key problems associated with incorporating concerns for the environment into political decision-making, namely, the diverse range of environmental beliefs and values that exist in modern societies. In discussing this problem, I present the theoretical stance often adopted in green political thought that debate over environmental issues can be understood as existing across a paradigmatic divide. The conclusion of this section is that although the environment has become a key political concern,

the existence of paradigmatic differences makes incorporating concerns for the environment into technological decision-making particularly challenging.

In the final section of this context chapter, I discuss the increasing dominance of a discourse of risk in technological decision-making, particularly in relation to environmental impacts. I present the technical definition of risk used in regulatory settings and briefly highlight some problems facing a technocratic approach to ecological risk assessment for GMOs. Through concluding that contested environmental values and widespread ecological uncertainties complicate the process of using risk analysis for regulatory decision-making on GM crops, I introduce the important questions that frame the following chapter's survey of the theoretical landscape on risk and uncertainty in environmental decision-making.

1. RECOMBINANT DNA TECHNOLOGY

Biotechnology can be defined as "the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services" (Beier et al. 1985 p. 16). Recombinant DNA (rDNA) technology is one form of biotechnology, which in popular terms has come to be called 'genetic engineering' or 'genetic modification'[7]. Recombinant DNA technology refers to the recently developed ability for human beings to cut and splice DNA from different sources to create 'recombinant DNA' and the ability to then transfer and integrate this rDNA into an organism's genetic makeup so that it is replicated by that organism. In other words, "Recombinant DNA technology is the name given to the combination of *in vitro* genetic recombination techniques with techniques for the insertion, replication and expression of recombinant DNA inside living cells" (Wheale & McNally 1988, p.29). An organism that has been modified through the use of rDNA technology is referred to as a 'genetically modified organism' or a GMO.

The first successful example of rDNA technology combined the DNA of two different plasmids from one species of bacteria - *Escherichia coli* (*E. coli)* (Cohen et al. 1973). The technology progressed when the ability to work across species boundaries was demonstrated with the successful combination of DNA from two different species of bacteria (*Staphylococcus aureus* and *Escherichia coli*) (Chang & Cohen 1974). An ability to combine DNA from across biological kingdoms was then demonstrated when genetic information from the toad *Xenopus laevis* was successfully transferred into the bacterium *Escherichia coli* (Morrow et al. 1974).

[7] In this thesis I preference the term genetic modification over genetic engineering and use it to specifically refer to the manipulation of genetic material through the use of rDNA technology.

As the science and techniques of recombining genetic information advanced during the 1970s, debates began to arise about the potential hazards of this technological development[8]. Concerns about potential health hazards began to surface because many of the early experiments into rDNA technology used a bacterium (*E. coli)* with the potential to be a human pathogen (Wheale & McNally 1988, p.42). Questions were also raised as to whether the technology could inadvertently create new pathogens, which as novel life forms could have disastrous effects because other organisms (including humans) would be unlikely to have the required defences and immune responses (Wheale &McNally 1988, p.46). Concerns were also raised about the use of plasmids conferring antibiotic resistance and the potential for rDNA experiments to spread resistance to antibiotics within bacterial communities (Wheale & McNally 1988, p.43).

Originally, concerns about the potential hazards of rDNA technology were expressed by scientists working in the field and primarily focussed on the possibility that GMOs may escape from the laboratory, survive and have an adverse impact, particularly on human health[9]. The scientists' discussion of these potential hazards began in earnest in 1973 at a Gordon research conference, where the results of experiments by Cohen et al. (1973) were presented. At the conclusion of this conference, the chairs sent a letter[10] to the US National Academy of Sciences (NAS) calling for a committee to be established to examine the potential problems involved with rDNA research and to suggest guidelines for future activities (Wheale & McNally 1988, p.46; Wright 1994, pp.130, 136). The NAS responded by recruiting scientist Paul Berg

[8] For a more detailed account of the history of the rDNA scientific controversy than is presented here see Krimsky (1982), Wright (1994) and Wheale & McNally (1988).
[9] There were also concerns about the potential health impacts GMOs may have on the scientists engaged in the research.
[10] Called the "Singer-Soll letter" after the chairs Maxine Singer and Dieter Soll.

to establish the requested committee[11] and the recommendations of this committee were published in what came to be known as the "Berg letter" (Wright 1994, p.137). This letter was widely understood as having proposed a temporary, voluntary moratorium on rDNA experimentation (Wright 1994, p. 138).

A voluntary moratorium on rDNA research was largely adhered to until the Asilomar conference in 1975. At this conference, the invited scientists reached a consensus to end the moratorium and continue rDNA research using self-imposed regulations (Wright 1994, pp. 148-157). Reasons suggested for why scientists chose to develop self-imposed regulations for rDNA work at Asilomar were to control the issues of debate and to avoid regulations being set from outside (Wheale and McNally 1988, p.47; Hindmarsh 1998). By focussing on technical concerns, scientists at Asilomar suggested that the research could continue with minimal risks to human health if different types of experiments were classified on the basis of degrees of risk and relevant containment measures then applied. The proposed containment measures were two fold; biological containment through the use of organisms that would have little ability to live or multiply outside the laboratory, and physical containment measures that involved laboratory equipment and procedures designed to stop the organism escaping from that controlled environment (Wheale & McNally 1988, p. 47; Wright 1994, pp.152-157). These self-imposed regulations on rDNA research were soon supplemented by governmental guidelines as the Asilomar recommendations for biological and physical containment measures were adopted and expanded upon in the development of National Institute of Health

[11] It is worth noting that all members of this early advisory committee were scientists.

(NIH) guidelines for rDNA work in the USA and in the proposals of the Genetic Manipulation Advisory Group (GMAG) in the UK[12].

As rDNA research resumed after the Asilomar conference, public apprehension about the technology began to rise. Concerns were expressed over the adequacy of the proposed containment approaches, the conflict of interests involved in self-regulation, the limited force and scope of the guidelines for hazard control and the lack of public participation in the decision-making processes (Wheale & McNally 1988, p.56-59). As the controversy intensified and regulations tightened around what was permissible, the scientists involved in the research began to argue that the potential hazards from rDNA technology had previously been overemphasised (Wright 1986). Through meetings held at Bethesda, Falmouth and Ascot and through the establishment of the scientists' pressure group COGENE (Committee on Genetic Experimentation) to promote the benefits of rDNA research, a new consensus between scientists working in the field began to emerge that the hazards of rDNA research would in fact be minimal (Wheale & McNally 1988, p.60; Wright 1994, p.228).

Interestingly, approximately 20 years after the development of this consensus, the potential hazards of GMOs are no longer conceptualised primarily in relation to the ability of these organisms to *escape* from laboratories, survive and have a negative impact on human health. The original controversy over scientific research has developed into a technological controversy as approvals are now routinely sought for the *deliberate* environmental release of GMOs for the purposes of commercial production. While it might be suggested that the controversy that now surrounds GMOs is simply a debate between the ignorant and the scientifically informed, or between irrational luddites and rational

[12] A description of the implications of this conference in the Australian context is provided in section 1 of chapter five analysing the regulatory framework.

progressives, there is in fact extensive debate within the scientific community (particularly between ecologists and molecular biologists) about the potential risks, benefits and appropriate regulatory responses for GMOs (Krimsky & Wrubel 1996; Regal 1996; Barratt & Abergel 2000; Snow et al. 2005). This means that in relation to the issue of deliberate environmental release, there is both a social and scientific debate about the potential hazards involved.

Genetically modified (GM) crop plants are the most common form of GMO currently entering commercial production. The commercialisation of GM crops is occurring at an astoundingly rapid rate. For example, during the nine year period between 1996 and 2004, the global area of GM crops increased 47 fold from 1.7 million hectares to 81 million hectares, and the increase from 67.7 million hectares in 2003 to 81 million hectares in 2004 was the second highest on record (ISAAA 2005). The debate surrounding the commercialisation of GM crops has been described as growing "increasingly complex, intense and emotional" (Poppy 2000) and this debate has dramatically increased pressure on governments to regulate the release of GM crops in a way that is capable of minimising any potential adverse effects. Interestingly, the nature of the current social context has meant that this pressure for the regulation of GM crops is demanding decision-making processes that are able to evaluate not only potential adverse impacts on human health, but also potential adverse impacts on the environment.

2. MODERN ENVIRONMENTALISM

The development of a social movement that has used concern for 'the environment' as a core motivating force has raised social and political awareness about the importance of considering impacts on non-human systems when making decisions. This new social movement has been given various labels, including the environmental movement, the green movement and the

ecology movement[13]. While modern environmentalism[14] certainly draws inspiration from older traditions of environmental thought including other earth embracing movements like Romanticism, religions such as Buddhism, Hinduism and Taoism and the environmental beliefs of indigenous cultures, what is arguably unique about the growth of contemporary concern for the environment is that it has developed in response to the adverse environmental impacts of industrialisation. As a social movement it can therefore be viewed as a reaction to some of the problems generated by modernity; a movement characterised by a link between concern for the environment and a critique of modern industrial practices.

In seeking to identify a defining moment that marks the birth of this distinctively 'modern' form of environmentalism, emphasis could be placed on Rachael Carson's seminal 1962 work, *Silent Spring*[15]. *Silent Spring* spoke, in the authoritative voice of science and yet with a markedly feminine engagement with emotion, of the negative effects of liberally and indiscriminately using synthetic chemicals (in the form of pesticides, herbicides and fungicides). The broad message of social resonance from this work was that modern industrial practices were having unintended adverse impacts on both human and non-human systems. Since the publication of *Silent Spring,* social awareness has increased about the potential for modern technologies to have unintended adverse impacts, particularly on non-human systems, and this increased awareness has developed into what can be understood as the social movement of 'modern' environmentalism.

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[13] See Hay (2002, p.1-3) for a discussion of some of the distinctions made between these terms.
[14] This is a term also used, but not necessarily clearly defined, by Pepper (1996), Eder (1996) and Hindmarsh & Hulsman (2004).
[15] It is important to reiterate that I am not suggesting that environmental thought began with the publication of Carson's *Silent Spring,* but rather, that it was a highly influential piece of work encouraging the development of the critique of industrialisation that is characteristic of 'modern' environmentalism.

Modern environmentalism has been growing and diversifying for over forty years and we have now reached a point where 'the environment' has become a mainstream concern (Eder 1996, pp.163-5; Szerszynski et al. 1996 p.19; Lanthier & Olivier 1999). While people may care about environmental issues in different ways and to different degrees, the environment *as an* issue has certainly been embraced by the entire political spectrum in contemporary Australia[16] and there is now explicit political recognition that impacts on the environment need to be considered when making decisions about new developments and technologies. One of the key problems of incorporating environmental concerns into political decision-making, however, is the serious challenge posed by the existence of a diverse range of environmental beliefs and values.

Rather than representing a uniformly shared set of beliefs and assumptions, modern environmentalism is actually a movement characterised by its diversity (Doyle & Kellow 1995, p.87; Eder 1996, p.163). Indeed, it is this diversity of beliefs that makes environmental politics such a rich field of research. The divergent beliefs about the environment within the movement of modern environmentalism can be usefully conceptualised as existing along a spectrum of thought. At one end of the spectrum, the critique of industrialisation is a shallow one in which only minor changes to current social systems are seen as required for the amelioration of environmental degradation. This end of the spectrum has been described as representing a reformist approach to environmental issues (Porritt 1984, p.5; Doyle & Kellow 1995, pp. 66-70; Pepper 1996, p.7). At the other end of the spectrum, the critique of modernity goes much deeper to suggest that radically different beliefs and organising principles need to be adopted if environmental decline is to be avoided. In contrast to the

reformist approach, this deep green critique of industrial modernity is often described as representing a revolutionary or radical approach to environmental problems (Doyle and Kellow 1995, pp.71-83; Pepper 1996, p.7). The existence of markedly different beliefs within modern environmentalism has led to the suggestion (particularly from within the revolutionary or deep green critique itself) that the defining ends of modern environmentalism's spectrum of thought represent competing paradigms.

The term 'paradigm' stems from the 1962 work of Thomas Kuhn, who used it to discuss the development of scientific knowledge. In his book *The Structure of Scientific Revolutions,* Kuhn used the term to refer to a constellation of beliefs, values, concepts and techniques that are shared by a scientific community and used to define legitimate problems and solutions (Kuhn 1962 p.175). Kuhn suggested that the development of scientific knowledge involved revolutionary paradigm shifts where, through being presented with anomalies which are not explainable under the dominant constellation of achievements, a new set of commitments and beliefs about what entities exist in the world and how those entities behave is gradually developed into an alternative paradigm of thought. For Kuhn, an alternative paradigm develops either to provide a better framework for explaining anomalies or for solving previously intractable problems. When scientific knowledge passes through these revolutionary periods or paradigms shifts, while the natural world itself is unchanged, the frameworks of observation and understanding have been altered and through these new frameworks, a different image of the world is created. It is the way the scientist views the world, what it consists of, how it behaves, what problems are significant and what constitutes an acceptable explanation, that have all been altered during the paradigm shift of a scientific revolution.

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[16] For a detailed examination of environmental politics in Australia see Doyle & Kellow (1995);

Kuhn's suggestion that scientific knowledge develops through revolutionary paradigm shifts has gone on to influence a wide variety of intellectual fields and the term paradigm is now often used in a much broader sense. For example, Fritjof Capra (1997) has generalised Kuhn's definition of a scientific paradigm to define a 'social paradigm'. For Capra, the term social paradigm is used to describe "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 community organises itself" (Capra 1997, p. 5-6). This concept of a social paradigm enlarges the notion of a 'community' so that the theory of a paradigm is applied beyond scientific communities to communities existing within society more broadly. So while Kuhn originally employed the term paradigm to refer to the way in which a constellation of achievements and beliefs informs how a scientific community defines legitimate problems and solutions, the concept of a paradigm is now often applied in a broader sense to illuminate how the visions of reality within non-scientific communities are also informed and shaped by particular constellations of beliefs and achievements[17].

A number of critical writers and analysts of environmental issues have used the theoretical framework of competing paradigms to describe the radically divergent approaches to environmental issues existing within western societies (Drengson 1980 & 1989; Capra 1983 & 1997; Porritt 1984; Devall & Sessions 1985; Merchant 1992 & 1994; Callicott 1994). In environmental scholarship, this

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Hay et al. (1989); Hutton (1987) and Walker (1992).

[17] 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. It should, however, be noted that questions remain about whether the significance and operation of paradigms is identical between scientific and non-scientific communities.

framework of competing paradigms has been applied to various spheres, including: the concept of nature (where a mechanistic approach to the natural world is contrasted against an ecological vision), knowledge generation (where the paradigmatic divide is described as reductionism vs holism), environmental ethics (with the radical divide described as existing between anthropocentrism and ecocentrism) and how to deal with environmental problems (where a technocentric approach is contrasted against a more ecocentric approach)[18].

While the notion of competing paradigms can be applied to these different spheres individually (e.g. concept of nature, knowledge generation, environmental ethics etc), I would suggest that an *environmental* paradigm is better described as constituted by a constellation of beliefs from across all of these different fields[19]. In the construction of a constellation of beliefs about the environment and the human relationship to it (a constellation that I am describing as an environmental paradigm), particular beliefs held in one of the above described spheres will be more compatible with certain beliefs in another. For example, a mechanistic concept of nature is compatible with a reductionist approach to knowledge. If I believe that the natural world is composed of atomised and interchangeable parts that are inanimate until acted upon by universal laws (a mechanistic concept of nature) then my approach to knowledge generation is likely to be one in which I begin by reducing the object of study to its most basic component parts (a reductionist approach to knowledge). An environmental paradigm can therefore be seen as composed, not of isolated beliefs, but rather, of a set of attuned commitments, or a

[18] It is important to realise that in discussing this notion of competing paradigms, the suggestion is not that these represent clear black and white positions in environmental thought, as even within these paradigms there are shades of difference, the suggestion is rather that these paradigmatic differences represent the defining ends of a spectrum of western thinking about the environment.

[19] In using the term environmental paradigm, I would also suggest that overarching views of the environment are the result of a co-production of social and scientific beliefs.

constellation of compatible beliefs from across a range of different fields that are brought together to build a coherent image of the world.

The currently dominant environmental paradigm within modern industrial societies can be described as containing the following constellation of beliefs about the environment and the human relationship to it: a mechanistic concept of nature (where the natural world is viewed through the analogy of a machine)(Merchant 1980 & 1992; Tokar 1987; Soper 1995; Pepper 1996), a reductionist approach to knowledge generation (where an understanding of the natural world is sought through reducing phenomena to their most basic component parts)(Pepper 1996, p.140), an anthropocentric approach to the value of nonhuman nature (where the environment only has value in the sense that it provides essential systems and processes for human survival)(Fox 1992) and a technocentric approach to dealing with environmental problems (where technological fixes are thought to be sufficient to ameliorate environmental problems).

This constellation of beliefs about the environment and the human relationship to it has allowed human beings to see themselves as separate and superior to the rest of the natural world[20]. This has been complemented by an instrumental view of the rest of the natural world where a relationship of control and domination over nature is pursued as a way of eliminating scarcity and

[20] This separation of humanity from the rest of the natural world is a legacy often attributed to the importance granted to the thinking of Rene Descartes. Essentially, the legacy of Descartes' thinking is the belief that the human mind and our capacity for self-awareness and conscious rational thought make us unique in the natural world and more than just a collection of parts animated by natural laws. This postulated separation has become known as the Cartesian dualism, a dualism between mind and body or mind and matter, and this dualism has been extended to a belief in the separation of humanity from nature and subject from object.

providing for human needs and desires[21]. The shallow critique of modernity within modern environmentalism can be seen to operate from within this currently dominant and established paradigm of environmental thought. This critique essentially accepts that modernity has created a host of environmental problems that need to be addressed, but it espouses solutions that do not serve to challenge the constellation of beliefs that make up the dominant paradigm.

When the deeper green critique of modern environmentalism claims to represent a challenge to the currently dominant paradigm of environmental thought, a radically different constellation of beliefs about the environment is espoused. Informed by the science of ecology and systems thinking more broadly, modern environmentalists advocating this deeper green critique generally appeal to an ecological concept of nature, where the natural world is seen to be composed of interconnected and dynamic systems with the ability to display emergent properties through levels of organisation. The idea here is that when parts are integrated, the whole develops characteristics and properties that are not possessed by the parts but which emerge through the organisation and operation of the systemic whole. The appropriate approach to knowledge generation then becomes a more holistic or systems based approach capable of viewing an entity or phenomenon in its entirety as an integrated system embedded within a particular context.

A systems based approach to knowledge generation is where explanations of complex natural phenomena are sought through an increased focus on examining the relationships, interactions and interconnections between the

[21] Francis Bacon was one intellectual of the Enlightenment who was graphically explicit about how the natural world should be exploited to meet human needs and desires. With the growth in experimental science, Bacon saw the opportunity for humanity to recover the dominion over the natural world that was lost in the fall from the Garden of Eden (Merchant 1992; Hindmarsh & Lawrence 2004).

parts. Through focussing on relational dynamics and presenting a systems based view of the world, ecological science has challenged the adequacy of the reductionist approach to knowledge which has traditionally dominated scientific disciplines[22] and because of this, has sometimes been called 'the subversive science' (Hay 2002, p. 131)[23].

The deeper green critique usually criticises science and technology for reductionist approaches and applications. The belief is often that science and technology have arisen from within a particular socio-economic context and therefore, if technological applications are resulting in environmental degradation, what is needed is not newer and better applications, but rather a shift in the socio-economic organisation and structure within which science and technology are developed. This approach does not necessarily reject science and technology outright; it simply does not adhere to the belief that environmental problems can be overcome by technological fixes alone. For the ecocentric deep green critic, environmental problems will only be adequately addressed by an altered relationship between humanity and the rest of the natural world, and the application of science and technologies constructed through this altered relationship.

Within this alternative constellation of beliefs, rather than being separate and superior, human beings are seen as just another species within an

[22] For a more nuanced discussion of the role holism and reductionism play in the science of ecology, see Trepl (1994) and the reply to this article from Levins & Lewontin (1994).

[23] While this ecological model for knowledge generation can still be seen as existing within a positivist epistemology, it should be highlighted that although ecological science is important, it is not the only form of knowledge that is seen as being valid within the deeper shades of modern environmentalism's spectrum. In the way that the scientific knowledge of ecology, spiritual beliefs and support for indigenous knowledge systems are combined within the deeper shades of modern environmentalism, it can be suggested that a type of epistemological pluralism exists that represents a radically different approach to knowledge generation than is currently dominant within modern western societies.

interconnected web of life on earth. The suggestion that follows is that we need to adopt a far more humble position in relation to our role in the biotic community and surrender our quest for total domination. The catchcry is often that we need to relearn how to live in harmony with nature rather than trying to assert control over it. This type of relationship can be viewed as being similar to the Taoist notion of wu wei, which is a form of doing that is neither coercive nor assertive, a way of doing that aims to respect the myriad life paths being pursued in one's surroundings to achieve a creative, harmonious and mutually beneficial result.

As a paradigm of thought that is developing in opposition to an established and institutionalised position, there remains a degree of diversity in beliefs that has not been well communicated by the simplified and generalised description I have provided above. As a way of highlighting some of this diversity, I would like to consider the issue of the value of non-human nature and describe some of the different positions taken on this matter within the alternative environmental paradigm I have described. While all of the different positions I discuss suggest that the natural world has some degree of intrinsic value (and thereby contrast with the purely anthropocentric, instrumental approach of the dominant paradigm) this discussion specifically aims to draw attention to the shades of green that can exist within environmental paradigms, specifically in relation to exactly what entities are viewed as possessing inherent or intrinsic value.

Within an animal rights or animal liberation based approach, the key feature of awarding nonhuman systems value is whether or not they are sentient, i.e. whether or not they are capable of experiencing pleasure and pain. This view was famously espoused by Jeremy Bentham (1970, first published in 1823)

when he suggested that the key question for granting an organism value beyond instrumentalism was not "Can they reason?" nor "Can they talk?" but rather, "Can they suffer?". This represents a shift away from the Cartesian implication that the capacity for rational thought was what made an organism capable of being considered as an end in itself. Peter Singer (1975) and Tom Regan (1976; 1982) have been two of the most influential proponents of an individual rights based approach that awards to nonhuman systems a value beyond mere instrumentalism. One of the primary concerns about adopting this approach within an alternative environmental paradigm, however, is that it represents an environmental ethic that is restricted to individuals and therefore arguably does not represent a truly ecological approach to the notion of value in the natural world (Hay 2002, p. 28).

Aldo Leopold (1968) presented an environmental ethic that awards value to nonhuman systems through extending the notion of a community. Leopold described a 'land ethic' where the boundary around what is considered a community is extended to include the soil, rivers, plants and animals – or, in Leopold's terms, the land. This extension of the community boundary was then taken to imply that the respect and obligations normally awarded within a community now need to be extended to the land, or to the environment as a whole. Leopold (1968, p. 224-25) describes his land ethic as "a thing is right when it tends to preserve the integrity, stability and beauty of the biotic community. It is wrong when it tends otherwise".

For Leopold, extending the community boundary in this way means that human beings should not see themselves as controllers of the community but rather as simply members or citizens of it. Through enlarging the idea of what constitutes a moral community, Leopold's land ethic allows value to be

awarded to nonhuman systems beyond instrumentalism or individualism and challenges the belief that the most appropriate relationship between humanity and the rest of the natural world is one of domination and control. While the animal rights approach to valuing nature has been criticised as being too individualistic, Leopold's community approach has been criticised for not allowing individual organisms to be granted any value in and of themselves (Eckersley 1992, p. 61).

In a slightly different manner, the philosophical school of deep ecology sees no clear boundary between the human and non-human realms and suggests that all things in the biosphere are equal in their right to "live and blossom and to reach their own individual forms of unfolding and self-realisation" (Duvall & Sessions 1985, p.67). For deep ecologists, the perceived boundary between humanity and the rest of the natural world is collapsed and value is awarded to the natural world through the realisation of an expanded sense of self. The idea here is that we cannot survive without other natural systems and so if we go through a process of 'Self-realisation', where these natural systems and other beings are increasingly embraced as part of our own identity, as part of our self, then a new environmental ethic will naturally develop. In deep ecological thought, an environmental ethic is not something which must be prescribed, for in recognising other beings as part of our self, it is suggested that compassion and empathy would naturally flow as part of an individual's way of being in the world rather than being a duty or obligation (Eckersley 1992, p. 62).

While this position may not appear that different to the anthropocentric position that values non-human nature only for its ability to support human life, the difference has best been described by John Seed. Implying that our beliefs about the natural world and our relationship to it change as we

internalise what the science of ecology and evolution are postulating, Seed suggests that we move through a cognitive process akin to the shift from "I am protecting the rainforest" to "I am part of the rainforest protecting myself. I am that part of the rainforest recently emerged into thinking" (Seed cited in Fox 1990, p. 239). In deep ecological thought we therefore do not protect the rainforest because it is useful to our survival, or because it is part of our community, we protect the rainforest as part of an expanded sense of self.

Another approach to awarding value to nonhuman systems beyond mere instrumentalism is based on the notion of autopoietic systems (Fox 1990; Eckersley 1992). An autopoietic approach to the value of nonhuman nature attributes intrinsic value to all entities that display the property of autopoiesis, which means 'self-production' or 'self-renewal' (from the Greek autos, 'self' and poiein 'to produce'). Autopoietic entities are entities that are "primarily and continuously concerned with the regeneration of their own organisational activity and structure" (Eckersely 1992, p.60). Under autopoietic value theory, the capacity for regeneration makes that entity an end in itself and therefore, this entity can be seen to possess intrinsic value (Fox 1990, p. 172).

This autopoietic approach to intrinsic value allows individual plants and animals to be awarded value but it also enables broader communities such as ecosystems and even the entire ecosphere to be granted intrinsic value. This means that this position on what can legitimately be seen to possess intrinsic value is not as vulnerable to either the objections associated with extreme atomism or the objections associated with extreme holism. An autopoietic approach to the value of nonhuman nature recognises the value of "process-structures that continuously strive to produce and sustain their own organisational activity and structure" (Eckersley 1992, p. 61).

In presenting these varying positions on how the value of nonhuman nature can be conceptualised, some of the shades of green that exist within what I have described as an alternative environmental paradigm become clear. This is important because in describing the variance in modern environmentalism as two competing paradigms and providing only a brief and general description of what this means, some of the more subtle diversities existing within each body of thought have been sacrificed. While I hope the above discussion has drawn attention to the existence of this diversity, I have chosen to focus on a more general description of paradigms of thought in this section to simply demonstrate how different first principles generate different environmental beliefs and radically divergent approaches to environmental issues. In doing this, my aim has been to highlight how competing environmental beliefs and values exist in western societies and therefore, how one might reasonably expect that the appropriate way to incorporate environmental concerns into political decision-making will be contested.

Analysts of the social and scientific debate surrounding the environmental release of GMOs have variously characterised it as a debate over values, attitudes and ideological beliefs (Kershen 1999 & 2003), a disagreement in underlying value assumptions (Clark & Lehman 2001), a debate involving philosophical ideas, ideology and politics (Regal 1996), a quarrel about dogmas (Rehmann-Sutter 1993), and a debate involving deeper concerns related to alternative visions of reality (Bruce 2002). In all of these instances, the debate over the environmental release GMOs can be understood as involving competing paradigms of thought about the natural world and the human relationship to it. This suggests that while we all might wish to minimise 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 alternative visions of reality about what constitutes environmental harm and how we could set about avoiding it.

As the contemporary environmental movement has gained increasing social support and political influence, acceptance has clearly spread that impacts on the environment must be considered when making decisions about new developments and technological applications. The incorporation of environmental concerns into technological decision-making is, however, complicated by the existence of diverse environmental beliefs and values. My aim in this section has been to not only highlight the importance of the environment in the modern social context but also to demonstrate the lack of a shared understanding through a description of competing environmental paradigms. The existence of contested values and competing beliefs make the field of environmental decision-making particularly challenging and complex. When a controversial new technology emerges, the idea that environmental impacts need to be considered in any regulatory decision-making processes may receive some degree of general agreement but the different discourses that flow from alternative environmental paradigms can be expected to clash and compete for dominance in both public and political arenas.

3. THE REGULATORY DISCOURSE OF RISK

As concerns for the environmental impact of new technologies have increased in modern industrial societies, there has been an accompanying increase in demand for tools and methods capable of assessing potential environmental impacts that can be used in aid of the difficult process of decision-making. This demand has seen the development of such processes as life cycle analysis,

environmental impact assessment, risk analysis and environmental modelling (Harding 1998, p.133). In the consideration of technological developments, the concept of risk has increasingly come to dominate decision-making processes (Winner 1986). This dominance of a discourse of risk is particularly prominent in public policy deliberations relating to the environmental impact of new technological developments (Jasanoff 1999; Rosa 2000).

Risk is a term that can be ascribed a number of different definitions, depending on the context within which it is used[24]. A general distinction can be made between a definition of risk that encompasses both the potential for harm *and* the potential for benefit, and a definition of risk that is more particularly focussed on the potential for harm. For example, I can describe skydiving as being a 'risky' activity in the sense that this is an activity in which the potential for enjoyment is accompanied by the possibility of injury. Alternatively, I could say that skydiving is an activity that involves risks and use the term risk to refer more specifically to the dangers involved and the possibility of injury. Botterill and Mazur (2004) suggest that in modern societies there has been a shift away from a traditional view of risk taking as a positive activity associated with rewards, towards an understanding of risk that is solely focussed on the potential for harm.

Harding (1998, p.167) suggests that risk has a technical definition for environmental decision-making (as distinct from its use in everyday language) and this is one focused on the notion of potential for harm. For Harding (1998, p. 167), the technical definition of risk refers to:

[24] See Botterill & Mazur (2004) for particular definitional variations.

> *a combination of the probability, or frequency, of occurrence of a defined hazard and the magnitude of the consequences of the occurrence. In other words, how often is a particular potentially harmful event going to occur and what are the consequences of this occurrence?*[25]

The definition of risk as one focussed on the potential for harm is also echoed in the definition given by Australia's risk analysis framework for GMOs. In this framework, risk is defined as "the chance of something happening that will have an undesired impact on objectives" (OGTR 2004, p.7). This definition is expanded by the statement that "Risk is measured in terms of a combination of the likelihood that a hazard gives rise to an undesired outcome and the seriousness of that undesired outcome" (OGTR 2004, p.7). These two definitions support Botterill & Mazur's (2004) suggestion and indicate that, particularly in terms of its use in Australia's environmental decision-making, risk is understood as the potential for harm or the potential for an undesired outcome. Furthermore, this potential can be calculated as the probability that a hazard will occur multiplied by the magnitude of the consequences of its occurrence. In this sense, the technical definition of risk = the probability of a hazard occurring x the magnitude of its impact[26].

The current public and political focus on issues of risk has led to the claim that not only is risk a central concept in environmental regulation, it is now the dominant organising principle of modern western societies (Beck 1992). In a widely cited social science thesis, Ulrich Beck (1992) has suggested that new

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[25] Harding (1998, p. 167) quotes Standards Australia/Standards New Zealand (1995) to define a hazard as a "source of potential harm".

[26] Understandings of the concept of risk beyond that portrayed in this technical definition are further explored in the following chapter surveying social science theory on risk and uncertainty.

social movements, such as modern environmentalism (as well as the experiential knowledge gleaned from living in an industrial society) have made us increasingly aware of how the application of science and technology can be accompanied by unintended negative impacts on human and environmental health, or in Beck's words, an awareness that "the sources of wealth are 'polluted' by growing 'hazardous side effects'" (Beck 1992, p.20). This awareness of the hazards involved in the application of science and technology has resulted in western societies becoming increasingly concerned with how to predict, distribute and manage the risks arising from modern industrial development. Beck (1992, pp.19-20) describes this as representing a new phase of modernity, a phase in which the primary concern is no longer with the production and distribution of goods, but rather with the production and distribution of 'bads' conceptualised as risks.

According to Beck's influential thesis, we are now living within a society dominated by concerns with the 'risks' of modern industrial development – a "Risk Society". The general idea here is that as basic needs and excessive desires have largely been catered for in modern western societies, scarcity has subsided as an issue of primary social concern and we are no longer solely concerned with controlling nature for the production of useful goods; instead, we are becoming increasingly concerned with how to handle the problems resulting from technological and economic development (Beck 1992, p. 19). What the development of the contemporary environmental movement and Beck's thesis of the Risk Society suggest is that the current social context is one in which technological developments are increasingly scrutinised for their potential impacts on social and biological environments and this scrutiny is increasingly structured around the notion of risk.

For Adams (1995, p. 192), the most notable feature of risk in modern societies is that large corporations or governmental agencies now seek to manage it far more than they did in the past. Adams (1995, p.192) argues that the increased involvement by the state and other institutions is primarily due to the scale of modern technological risks, a scale which places them beyond the ability of individuals to control through self regulation. The idea that modern risks differ in the way that they are subject to regulation by collective bodies rather than by individuals is an idea that has been lent empirical support by a comparative study performed by Edwards & von Winterfeldt (1986). In their study, Edwards and von Winterfeldt compared past debates over technologies to modern ones and concluded that the existence of regulatory arenas for risk and the ability of these arenas to become the locus of debate is a distinctively modern feature. Importantly for this research project, Edwards and von Winterfeldt (1986) also found that a significant difference between past debates over technologies and more modern ones is that ecological or environmental concerns are now a key factor, as are concerns for future generations. This suggests that two distinctive features of modern technology debates are the degree to which the environment has become a key concern and the way in which debate can become focussed in regulatory arenas using a discourse of risk.

Langdon Winner (1986, p.138) has proposed that the dominance of a discourse of risk in regulatory arenas is not a neutral development. Winner (1986, p. 145) suggests that the term risk is currently associated with a scientifically quantifiable danger. This means that when resistance to a particular technological development is based on ethical concerns or concerns for the socio-political implications of the technology, the discourse of risk allows these types of concerns to be marginalised during the decision-making process. For Winner (1986, p. 148), the discourse of risk also serves to limit engagement in a debate and evaluation of the conditions of modern life itself and therefore tends

to maintain the status quo of production and consumption in modern industrial societies. This is because industrial practices that have been accepted in the past effectively function as a baseline of comparison for what is an 'acceptable' degree of risk. Any desire to alter current industrial practices or impose moral or political limits on technological developments is therefore placed at a disadvantage by engaging in a discourse of risk. Winner's argument is that it is precisely because of the way in which a discourse of risk tends to draw debates in a particular direction (e.g. towards a discussion of scientifically quantifiable dangers that may be tolerated if the degree of harm is perceived to be no greater than that associated with current production practices) that the concept of risk has become the dominant principle guiding technological decision-making.

This argument from Winner (1986) suggests that risk analysis can be viewed as an example of a technocratic approach to decision making. Under a technocratic approach, it is believed that a clear distinction can be drawn between facts and values; or expressed in another way, between ends (defined according to values) and means (decided according to facts) (Fay 1975). It is then espoused that for rational decision making, there must be a focus on facts. This desire to focus on facts is coupled with the positivist belief that scientific knowledge represents absolute truth (Elliott & Elliott 1976). A technocratic approach therefore suggests that by relying on scientific experts, rational, objective and politically neutral decisions can be made. What this approach to decision making does, however, is limit the issues of concern to technical matters only and sideline the importance of public discussion and debate (Habermas 1971; Fay 1975). While it is claimed that a reliance on scientific expertise allows for value-neutral decision making, the technocratic approach has been criticised for using this as a 'front' to hide the interests and values it actually serves.

Criticisms of technocratic approaches to decision making have suggested that by focussing on means and ignoring ends, current social relations and structures are taken as given and undebatable. Without debate on ends and values, the technocratic approach effectively serves existing ends and dominant values, working to maintain the status quo and reinforce existing social and economic organisation (Elliott & Elliott 1976). Since the technocratic approach to decision making has only arisen in the context of industrial society (Habermas 1971; Fay 1975), the argument is that it works to support capitalist socio-economic organisation (Elliott & Elliott 1976). It has also been suggested that the distinction between ends and means or facts and values is invalid because means are inevitably infused with particular beliefs in relation to what is permissible (Fay 1975) and represent the prior acceptance of particular political perspectives (Wynne 1974).

This means that while there is power and appeal in claiming that decisions made by scientific experts are objective, it has been argued that it is actually highly misleading because it conceals the ways in which science is infused with particular values and by eliminating debate on broader issues of goals and socio-economic relations, it works to maintain the status quo of industrial society and thereby serves the interests of a capitalist elite. The way in which risk analysis as a decision making tool privileges the knowledge of scientific experts and tends to limit discussion and debate around broader, non-technical, social and ethical concerns certainly suggests that it can be seen to represent an example of a technocratic approach to decision making[27].

[27] The extent to which this is the case and whether or not risk analysis in the context of Australia's GM crop regulation hides value judgements and serves to maintain the status quo of industrial agriculture are issues that will be explored in depth in the empirical chapters of this thesis.

Traditionally, the notion of risk has been applied to the area of human health, where risk was typically measured in relation to the number of human deaths that might occur given a particular time frame or degree of exposure to an identified hazard. Since the rise of contemporary environmentalism and an increased concern for the environmental impacts of technological developments, however, a new type of risk has emerged for consideration – the notion of an environmental or ecological risk[28]. Generally, an ecological risk can be seen to relate to the risk of a negative environmental impact, rather than a negative impact on human health (although the distinction between the two will not always be clear). The understanding and assessment of environmental risks creates a number of unique challenges.

As discussed above, the discourse of risk used in regulatory arenas for the management of new technologies has tended to use a technical definition of risk. This has institutionalised a particularly technocratic approach to decision-making where scientific knowledge and expertise have been awarded monopoly authority. The 'invisible' character of many modern technological risks, requiring what Beck refers to as the "sensory organs of science" (Beck 1992, p.27), is one important factor in why scientific knowledge and expertise have been awarded a privileged position in risk analyses. Another, however, is that the technical definition of risk emphasises the calculation of probabilities and magnitudes of potential adverse impacts and this definition also favours a reliance on specialised scientific knowledge.

[28] Risks *to the environment* as opposed to risks *to human health from environmental factors* have in some cases been distinguished by being termed ecological (rather than environmental) risks. In this thesis, however, I use the terms ecological and environmental risk interchangeably to refer to risks to the environment.

Scientific assessments of the risks posed to the environment by particular technologies are, however, complicated by the fact that while a negative impact on human health can almost uncontestedly be structured around illness or death, it is much harder to gain consensus on exactly what a negative environmental impact entails. Even if a traditional scientific assessment of risk is capable of calculating the likelihood of a potential impact occurring, whether that impact and the probability associated with its occurrence represent an 'acceptable' level of risk or not is indisputably a question of value. As I have already discussed, there is a diverse range of beliefs within modern western societies about what constitutes 'the environment' and what is of value within non-human nature and this means that the issue of what is a socially acceptable environmental risk will inevitably be complicated by competing environmental beliefs and values.

It is not, however, only when we reach the question of whether a scientifically determined risk is acceptable or not that issues of value can be seen to enter the risk analysis process. Constructivist approaches to scientific knowledge have developed to challenge the idea that science is capable of simply revealing objective insights about the natural world that can then unproblematically guide decision-making. According to a constructivist approach, scientific knowledge is (in either a strong or a weak sense) shaped and constructed by social factors (e.g. cultural beliefs, political persuasions, economic constraints). If we accept that the development of scientific knowledge is shaped and negotiated by social factors, then issues of value can be seen to enter the process of scientific risk assessment itself. This may occur through the types of scientific studies that are performed or cited in the risk assessment, how those scientific studies were undertaken, what questions were asked, what is deemed to constitute acceptable evidence, and/or how particular results are interpreted. A

constructivist approach would suggest that while we might be reliant on scientific methods and experiments to perceive the hazards of modern technology and calculate the risks, these experiments and methods can be variously constructed depending on social and political commitments[29].

Another key problem for technical risk assessment as a decision-making tool is the way in which environmental issues invariably span various scientific disciplines. Achieving effective communication and interaction across disciplinary boundaries will therefore always be a challenge associated with performing an assessment of the environmental risks a particular technology may pose. Additionally, the complexity of environmental systems challenges our ability to identify all potential hazards and makes calculating the probabilities associated with identified hazards particularly difficult. In modern societies there is an increased awareness of the limitation of scientific knowledge to accurately predict and control all the potential adverse impacts of a new technology in the face of complex and interconnecting biological systems; an awareness that has been described as a crisis of public confidence in science (Slovic 1992; Lofstedt & Frewer 1998; House of Lords Select Committee 2000; Wynne 2001). A situation therefore exists where we are both reliant on science to identify potential hazards and propose effective management techniques for controlling technological risks and yet also painfully aware of the inadequate nature of scientific knowledge for predicting and managing all potential negative impacts.

[29] The constructivist approach to risk raises a host of important questions about the role for science in policy and environmental decision-making and both the constructivist approach and the questions it raises for policy are examined in more detail in the following chapter.

Our ability to perform accurate and comprehensive ecological risk assessments is particularly challenged when the technology under investigation represents a novel development. For example, the novel nature of GM crops and the lack of experience and data on their potential ecological interactions means that the impact these crops will have on the environment is an area with a high degree of scientific uncertainty (Kloppenburg 1988; Webster 1991; Regal 1996; Wolfenbarger & Phifer 2000; Snow et al. 2005;). In fact, there has been widespread agreement among ecologists that the current body of knowledge is insufficient to enable an accurate prediction of the impact GM crops may have on the environment (Kolata 1985; Käppeli & Auberson 1997; Beringer 2000; Johnson & Hope 2000; Wolfenbarger & Phifer 2000). Additionally, the difficulty of assessing the ecological risks of GM crops is complicated by the fact that GMOs are living organisms with the capacity to reproduce, cross-breed and spread throughout the environment. This means that their relationship with the environment is dynamic in a way that is not shared by other technologies where environmental risk assessments have been applied (e.g. mining and nuclear power generation).

Although it represents the currently dominant approach to decision-making, adopting a discourse of risk for the environmental regulation of GMOs therefore faces a number of serious problems. Notably, with the existence of varying environmental values and beliefs within modern societies, the notion of what constitutes environmental harm will inevitably be contested. Widespread uncertainty only extends the space for these diverse values and beliefs to shape divergent assessments of risk and constructions of scientific knowledge. This means that although there may be broad agreement on the need to regulate the release of GMOs to minimise negative impacts on the environment, the existence of competing environmental values and widespread scientific

uncertainties represent a serious challenge to the currently dominant discourse of risk for the decision-making process.

4. Chapter Conclusion

Since its early beginnings in the 1970s, rDNA technology has created controversy. While concerns were originally voiced by scientists working in the field and related to the possibility that GMOs would escape from laboratories and have undesired impacts, the debate has now shifted as various groups within the community express concerns over the deliberate environmental release of GMOs for the purposes of commercial production. As the state of the environment has increasingly become a concern in modern industrial societies, the concerns about GMOs relate not only to their potential impacts on human health, but also to the effects they may have on the environment. These concerns and the intense social debate within which they are being expressed have created pressure on governments to regulate the release of GMOs to minimise potential adverse impacts on social and biological environments.

The dominant approach to technological decision-making, specifically in relation to environmental impacts, is structured around a technical discourse of risk. However, using technocratic risk assessment approaches to making regulatory decisions about the environmental impact of GMOs is seriously complicated by the existence of contested environmental beliefs and values and widespread scientific uncertainties. This raises the question of how decision-making processes for the environmental regulation of GM crops should be structured given the challenges posed by contested values, scientific uncertainties and widespread social debate. With the aim of developing an understanding of what an ideal process of decision-making under these circumstances might involve, in the following chapter I survey and synthesise

theoretical literature from the social sciences on risk and uncertainty in environmental decision-making.

THEORY:
RISK AND UNCERTAINTY IN DECISION-MAKING

CHAPTER OUTLINE

In the previous chapter I established that rDNA technologies have emerged within a social context where the environment is an important political concern and the discourse of risk dominates environmental decision-making for controversial technologies. I outlined some of the problems involved in using a risk based approach to environmental decision-making and specifically highlighted the challenges posed by competing environmental beliefs and values and widespread scientific uncertainty. In this chapter I survey and synthesise the theoretical landscape on risk and uncertainty, both in a general sense and specifically in relation to environmental decision-making for rDNA technology. The enormity of the literature on risk and uncertainty precludes a complete overview as part of this thesis. Instead, I focus on identifying key issues and bodies of work, as well as tensions and debates within the literature, that are specifically relevant for my research into Australia's environmental regulation of GM crops.

This chapter begins by presenting the 'realist' approach to risk and outlining, in general terms, the dominant process for analysing risk as a decision-making tool. The chapter then focuses on contrasting social science approaches to risk with the realist position that currently dominates regulatory settings. I begin by presenting the findings and associated criticisms of both psychometric and cultural theories of risk perception. Discussing constructivist approaches to risk more generally, I then ask what constructivism means in a practical sense for the role of science in environmental decision-making. Finding this role linked to the conceptualisation and handling of uncertainty, I synthesise some of the

different typologies of incertitude available in the literature and discuss what it means for decision-making to be 'precautionary'.

In the previous chapter I argued that the debate over the environmental impact of GM crops was one involving pervasive uncertainty and conflicting values, therefore, this chapter surveys the theoretical landscape to identify what is required for decision-making under these conditions. The identified patterns are then synthesised into the theoretical ideal I contrast with traditional 'science/risk' based approaches and describe as 'precaution/uncertainty' based decision-making. The theoretical framework developed in this chapter is therefore one in which these represent two ends of a spectrum of possible approaches to environmental decision-making.

1. Risk Analysis as a Regulatory Decision-making Tool

The dominant approach to risk taken by state organisations (and featuring in the literature on risk generally) is one based around the notion of actual or objective risk (Adams 1995, p.10; Robins 2002; Stirling 1999a). This is an approach that is structured around the belief that risk is a real phenomenon that exists "out there" as a property of a technology or system under investigation and which can therefore be measured and calculated in an objective manner by an appropriate set of experts. This can be referred to as a 'realist' approach to risk and is a position that is particularly prominent in the natural sciences. According to this dominant approach to risk, the process of performing risk analysis as a decision-making tool generally consists of the following key stages: risk assessment, risk evaluation, risk management and risk communication.

As traditionally performed by corporations and government agencies, the initial stage of risk analysis (referred to here as risk assessment) involves a process of hazard identification and risk calculation. As mentioned in the previous chapter, for regulatory decision-making processes, a hazard is usually defined as a potential source of harm and risk is seen as a function of the probability of the hazard occurring multiplied by the magnitude of its impact. This process of risk assessment (hazard identification and risk calculation) has traditionally been understood as the objective component of risk analysis. By using experts who apply scientific knowledge to arrive at a figure, ranking or categorisation that describes the risks associated with any particular activity or technology, the risk assessment process is claimed to be a value free activity.

Under the traditional approach to risk analysis, the subsequent stages of risk evaluation and management are the parts of the decision-making process that

are seen to entail subjective judgements and values. In the risk evaluation stage, the 'objective' results of the assessment process are considered in terms of what constitutes 'acceptable risk'. While the risk assessment process might arrive at a figure or category (such as high, low etc) to describe the risks involved, there will be different perceptions of what types and degrees of risk are acceptable. The consideration of these different positions and the extent to which they will influence what is deemed an acceptable risk are considered in the risk evaluation stage. Having decided what constitutes an acceptable degree of risk, this evaluative stage is followed by a process of risk management.

In the risk management phase, decisions are made about the management strategies that will be put in place to ensure that all the potential risks revealed through the risk assessment process can be kept within tolerable bounds. Deciding what an acceptable degree of risk is and what action should be taken to manage potential hazards is a part of the risk analysis process seen to involve value judgements and political decisions and therefore, it has traditionally been very important for regulatory bodies using a realist view of risk to conceptually separate what is seen as the objective process of risk assessment from the political process of risk evaluation and management (Douglas & Wildavsky 1982, p.65; Adams 1995, p.8; Jasanoff 1992).

The process of risk communication can occur following any of the above described stages but is usually associated with communicating the results of the risk assessment process and/or risk management strategies. As traditionally performed, this has been viewed as a one way process of communication where those performing the risk analysis are seen to possess knowledge that needs to be communicated to members of the general public. This model of communication has been referred to as the 'deficit model' (Durant 1999; Frewer

et al. 2003; Irwin & Michael 2003) because it assumes that the public is ignorant and therefore the role of risk communication is to address this knowledge deficit through a one way passage of information. This model of communication is justified by the assumption that risks are 'real' and objectively quantifiable. This communication stage of the risk analysis process became an important addition when the public was considered to be reacting 'irrationally' to the risks posed by particular technologies.

2. Risk Perception

Throughout the period of modern industrial development, lifespans have increased, infant mortality rates have plummeted and a litany of diseases have been brought under control. While the lives of those living within modern societies could be viewed as markedly improved by industrial advances, it has been proposed that despite modern advances in health and security, people's perception of risk has increased in industrial societies to the point where they believe that they face more risk today than in the past (Douglas & Wildavsky 1982, p.15; Covello & Johnson 1987; Slovic 1987 & 1999; Rosa 2000). This counter-intuitive development in the perception of risk in industrial societies has raised a number of questions about what is driving public concerns and why public risk perceptions often differ from expert analyses.

In the late 1970s, the persistence of public fears over certain technologies (such as nuclear power plants) that had been assessed by experts as being safe, or posing only a small and acceptable degree of risk, became a source of confusion for regulators and industrialists (Slovic 1987). As experts were seen as having performed an objective and rational assessment of the risks posed by a particular technology, the conclusion often drawn was that the public's fears represented a false perception of risk, an 'irrational' response to the technology

arising from ignorance (Douglas & Wildavsky 1982, p.75; Turner 1984; Shrader-Frechette 1998). The suggestion that followed was that strategies were needed to communicate risk information to the public in a way that was able to overcome the persistence of these 'irrational' fears. One suggestion was that the public needed an index of risk that would present risk information in a comparative sense, so that the public could see how the risks associated with certain feared technologies (e.g. nuclear power plants) were assessed as being particularly low in contrast to the high risks associated with other well accepted technologies (e.g. motor vehicles) (Rothschild 1979).

For risk communication strategies to successfully alleviate public concerns over particular technologies, however, it became increasingly important to try and understand exactly why the public perceived risks in the way they did. For example, why were the comparatively low risks from nuclear power plants an issue of fierce contention and widespread social rejection, while the high risks associated with driving a motor vehicle were generally well accepted? What was driving this difference in risk perception? This intriguing and politically relevant question opened the way for explorations of the social dimensions of risk (Krimsky 1992) and a wealth of social science studies into public risk perceptions developed across a number of different disciplines, including geography, political science, sociology, psychology and anthropology (Slovic 1987; Wildavsky & Dake 1998).

The following discussion explores two of the important bodies of social science theory on risk perception: the psychometric approach that was developed within the field of psychology and the sociological and anthropological approach of cultural theory. These two distinct social science approaches to risk primarily differ in the sense that one body of theory is focussed on individuals

(psychometric theory) while the other is directed more towards group explanations and analysis (cultural theory) (Krimsky 1992).

2.1 The Psychometric Approach

Particular impetus for the development of the psychometric approach to risk perception has been linked to a seminal essay by Chauncey Starr (1969) (Slovic et al. 1982; Slovic 1987). In this essay, Starr was interested in the evaluative question of "how safe is safe enough?" and explored the social acceptability of risks by examining patterns of risk/benefit tradeoffs that had been taken in society. Starr (1969) suggested that the issue of whether a risk was voluntarily taken or involuntarily imposed was an important distinction affecting risk/benefit weightings. Concerned with some of the assumptions in Starr's approach, Fischhoff et al. (1978) began to develop what is now known as the psychometric approach.

The psychometric approach to risk perception represents a body of research grounded in cognitive psychology that seeks to identify factors shaping risk perceptions beyond those that have been traditionally used to calculate or rank levels of risk. It is research that aims to illuminate the psychology behind why members of the public may choose to reject some risks that, by expert analysis, represent an acceptable level of danger if calculated according to the levels of risk that are accepted in other areas of day-to-day life. Psychometric studies on risk perception apply psychophysical scaling methods and multivariate analysis to examine the opinions expressed when individuals are asked to characterise and evaluate various hazardous activities and technologies (Slovic et al. 1982).

2.1.1 Important Findings of the Psychometric Approach

The most widely cited finding to emerge from psychometric studies of expressed preferences was that, in addition to voluntariness, other factors or characteristics of the risk in question were important for how it was perceived by members of the public. The characteristics revealed to be of importance include: familiarity, reversibility, controllability, catastrophic potential, equity and potential to impact on future generations (Slovic et al. 1982; Slovic 1987 & 1991). Psychometric approaches have suggested that all of these factors play an important role in how risks are ranked and whether or not particular risks are deemed to be acceptable by the broader public.

In addition to demonstrating the importance of these various characteristics to how risks are perceived, psychometric research has also highlighted how many of these qualitative characteristics are strongly linked with one another. For example, a risk that is seen to be voluntarily undertaken also tends to be viewed as controllable. This suggested that the identified characteristics could conceivably be reduced to a smaller set of higher order characteristics. In collating their psychometric studies, Slovic et al. (1982) mapped various hazards in relation to the two factors of "dread risk" (defined by a perceived lack of control, catastrophic potential, inequitable distribution and threat to future generations) and "unknown risk" (where hazards are judged in accordance with whether they can be observed, whether they are familiar and whether the effect is delayed or immediate). Psychometric research suggested that public risk perceptions were closely related to where the hazard was judged as lying within the factor space presented in this model, with the horizontal axis of dread risk being the most influential on lay risk perceptions (Slovic 1987).

Through highlighting the importance of risk characteristics on public perceptions, psychometric research has suggested that the provision of an index of risk or a set of risk comparisons would not necessarily ameliorate public concerns about particular technologies. This is because experts tend to assess risks solely on a statistical basis in relation to probabilities and mortality rates while the public uses a broader conception of risk and incorporates a consideration of characteristics such as familiarity, controllability, voluntariness etc in their evaluation of risks and their acceptability. This point is highlighted well by Slovic (1991, p.62) where he states that:

> *To many persons, statements such as 'the annual risk from living near a nuclear power plant is equivalent to the risk of riding an extra three miles in an automobile' give inadequate consideration to the important differences in the nature of the risks from these two technologies.*

Psychometric approaches to risk perception have therefore served to highlight how the public is capable of sensitivity to non-statistical considerations in their assessments and how they tend to perform a more holistic or contextual assessment of the risks posed by a particular technology (Slovic et al. 1982, Slovic 1987, Otway 1987).

Another interesting finding to emerge from the psychometric approach is that, while experts tend to judge risk in relation to statistical information on the probability of a hazard occurring and the magnitude of an impact, when there is a lack of data on these elements, expert assessments are also influenced by the types of characteristics that influence lay assessments (Slovic et al. 1982; Slovic 1987). This is not necessarily a surprising finding given that experts are only

human and when there is a lack of information, they too will inevitably rely on intuition, past experiences and value judgements, just as lay members of the public do. This finding does, however, have important implications for the monopoly authority of expert risk assessments in data deficient contexts – a point that will be returned to later in this chapter when I discuss the issue of uncertainty.

Recent studies using a psychometric approach to risk perception have shown that factors such as gender, race, political worldview and trust can also all affect risk judgements (Davidson & Freudenburg 1996; Peters & Slovic 1996; Siegrist 1998 & 2000; Slovic 1999). The issue of trust, both in the institutions promoting and regulating emerging technologies and in the information that is provided to the public by these institutions, has recently become an issue of particular interest in this field (Slovic 1998 & 1999; Siegrist 2000; Frewer et al. 2003). While some analysts have suggested that public perceptions of risk are strongly influenced by the level of trust that is held in governing institutions and the information provided by different sources (Frewer et al. 2003 cites McGuire 1985 and Worcester 1999 as examples), the alternative view is that trust is a consequence rather than a cause of risk perceptions (Frewer et al. 2003). This position suggests that risk perceptions are influenced by socio-political attitudes and that it is these attitudes that determine the degree of trust awarded to institutions and information sources (Frewer et al. 2003). Empirical research on the role of trust in risk perceptions has provided mixed results (Frewer et al. 2003) and trust is therefore an issue that requires additional research to uncover its implications for decision-making processes.

2.1.2 Implications of Psychometric Findings for Decision-making

The findings of psychometric research have potentially important implications for how risk analysis should be performed for technological decision-making.

The finding that the public generally employs a broader or more holistic conception of risk than that used by experts suggests that there are important characteristics of technological risk not currently captured by formal processes of risk assessment. This has led to the proposition that these broader elements of risk need to be incorporated into decision-making processes (Otway 1980 & 1987; Slovic 1998). This means that it would be pertinent for decision makers to consider and take into account the nature of the risks associated with a particular technological application during their assessment, particularly in relation to whether the risks can be considered familiar, controllable, reversible and whether they have the potential for catastrophic impacts or impacts on future generations.

The ability to incorporate these broader elements of risk into decision-making processes is seen to be dependent on a reconceptualisation of the role of expertise in risk assessments (Otway 1987), the establishment of a two way path of communication between the public and experts (Otway 1987) and the encouragement of increased public participation and deliberative decision-making during the assessment of technological risks and their acceptability (Slovic 1998). As long as experts maintain a monopoly on authority in risk assessment and communicate with the public only according to a knowledge deficit model, the broader and more contextual elements of risk that are deemed important by members of the public will continue to remain outside the scope of formal risk assessment processes and debates over the risks associated with contested technologies will be likely to continue.

2.1.3 The Psychometric Approach, rDNA Technology and Ecological Risk

As a demonstration of the insights available through psychometric research, in their 1982 paper, Slovic and colleagues warned that rDNA technology shares

many risk characteristics with nuclear power (characteristics such as a lack of familiarity, controllability and reversibility and the potential to have catastrophic effects and impact on future generations), and that these characteristics may make rDNA technology equally unacceptable to many in the community if the technology was ever able to capture public attention. Now that rDNA technology has captured the public's attention and debate over the risks of rDNA technology has become increasingly intense, we can see the merit of this claim and the potential predictive power of the research.

Research has indicated that the acceptance of gene technologies is strongly correlated with both the nature of the application (particularly in terms of whether it involves crossing species boundaries) and the organisms that are involved (Hoban et al. 1992; Frewer et al. 1997; Siegrist 2000; Grice & Lawrence 2004). These findings have been supported by surveys conducted in Australia where the acceptability of genetically modified products was also shown to vary according to the type of gene transfer and the organisms involved; with the genetic engineering of plants more accepted than that of animals or humans and cross-kingdom transfers of more concern than those performed within a species or between closely related organisms (Norton et al. 1998; Parkinson & Hindmarsh 2003). Medical applications of gene technology have also been found to be perceived differently to the technology's application for food production (Frewer et al. 1997; Siegrist 2000). In food applications, perceptions of 'naturalness' have been shown as particularly important for acceptance of the technology (Hoban et al. 1992; Frewer et al. 1997). Other factors such as ethical or moral concerns (Hoban et al. 1992) and the perceived need for or benefits from the technology (Frewer et al. 1997) have also been indicated as important factors influencing public risk perceptions of rDNA technologies.

This body of research suggests that, in addition to factors such familiarity, controllability, reversibility etc., public risk perceptions of rDNA technology are also influenced by issues such as the type of application, the organisms involved, ethical concerns and what the perceived need for or benefits from the technology are. If these are important factors for members of the public, the implication is that to overcome debates over this controversial technology, regulatory decision makers would do well to formally incorporate a consideration of these types of characteristics into their assessments.

Psychometric research has also begun to be specifically applied to understanding perceptions of ecological risk (McDaniels et al. 1995; Lazo et al. 2000). In the study performed by Lazo et al. (2000), it was found that in perceptions of ecological risk there was as much variation in expert responses as in lay responses. However, lay people generally perceived risks to ecosystems to have greater impacts than those perceived by experts, while experts perceived a wider range of potential impacts from ecological risks. Interestingly, in contrast to these differences in ecological risk perceptions, both experts and lay people perceived the same ecological risks as having the largest and smallest impacts, with the loss of plant and animal species being the least acceptable ecological risk of the 25 used in the studies.

In the psychometric studies on ecological risk perception performed by McDaniels et al. (1995), the aim was to clarify what factors influenced an individual's perception of ecological risks and their acceptability. The five most significant factors identified were: impact on species, benefits for humans, impact on humans, avoidability and knowledge of impacts. Nuclear war, loss of animal species, ozone depletion, and loss of plant species were rated by the study participants as posing the highest risks to natural environments

(McDaniels et al. 1995). Biotechnology was selected as one of the items where ecological impacts were perceived as being relatively unknown (McDaniels et al. 1995). The authors also chose to highlight how there is a fundamental difference between human health and ecological risks, stemming from the greater complexity involved in ecological risk judgments. This complexity was linked to a number of factors, such as "the wider range of possible end states of interest" in perceptions of ecological risk, the fact that ecological health has a wider range of meanings than human health, the greater degree of influence that worldviews/values etc may have on ecological risk perceptions and how the issue of natural forces creating ecological change will impact on perceptions of what constitutes an ecological risk (McDaniels et al. 1995).

Willis et al. (2004) conducted an exercise in ecological risk ranking and found that the environmental concerns of participants were primarily based on large-scale disruptions of ecological functioning rather than on more specific effects and that agreement among the participants about the relative weight and importance of different ecological risks increased over the course of the deliberations involved in the exercise. This suggests that differences in perceptions of ecological risk that are the result of different knowledge or competing values can be negotiated through deliberative processes towards increased agreement and potentially, a consensus position.

While further research is still required in this nascent field of ecological risk perception (McDaniels et al. 1995; Lazo et al. 2000), based on the available information, I would suggest that regulators of rDNA technologies would do well to consider how different groups perceive ecological risks and the types of factors and characteristics impacting on these perceptions. As understandings of what the environment is and what is of value in the environment differ

within society and even within expert groups, it becomes important for any decision-making process based on ecological or environmental risk analysis to clearly define the system of concern (see Hatfield & Hipel 2002; Stave 2002) or the environmental endpoints for the assessment process. That is, it is important to clearly define the system being considered in the risk assessment and what it is specifically within 'the environment' that is seen to be of value and therefore, what it is exactly that the risk assessment process is aiming to protect. This is an inherently normative exercise as the identification of the relevant system and what are seen to be the most important and relevant environmental endpoints for the risk assessment process will invariably differ within the community. As such, the articulation of these would ideally be achieved through a deliberative dialogue between experts, stakeholders and lay members of the public.

2.1.4 Criticisms of the Psychometric Approach to Risk

While the psychometric approach has made an important and influential contribution to social science understandings of risk, it has not escaped criticism. The primary criticism directed at psychometric research is that rather than challenging the idea that lay perceptions of technological risks are irrational, it has lent itself to being used as a way of explaining the irrationality. While it may not be the intention of psychometric research to perpetuate a divide between actual (real) and perceived (false) risk, the reported characteristics can be held up as explaining why the public responds irrationally to particular technologies and the potential risks associated with them - their perceptions have been wrongly influenced by characteristics of the risks other than the probability of their occurrence and the magnitude of their impact.

Associated criticisms of the psychometric approach include the way in which it aims towards objectivity (Horlick-Jones & Sime 2004), seeks generalisable

answers for explaining public risk perceptions (Otway & Thomas 1982), advances a realist ontology of risk (Krimsky 1992), and implies that there is one 'correct' view of risk (Otway & Thomas 1982; Jasanoff & Wynne 1998). For example, emphasising the importance of the characteristics associated with dread and unknown risk tends to imply that their importance is generalisable for all perceptions of risk related to new technologies. Otway & Thomas (1982) argue, in contrast, that the findings associated with the psychometric approach are limited in their generalisability to the particular hazards and technologies that were directly involved in the studies conducted. Indeed whether the findings of psychometric approaches on risk perception are applicable to risks not related to technological developments remains largely unanswered, as does the question of why some people will choose to focus on the dangers associated with technology over other forms of risk (Douglas & Wildavsky 1982, p.194). Frewer et al. (1997) have also criticised the psychometric approach for the way in which the characteristics have been selected by the researcher rather than by participants and the lack of information available on the reasons why participants responded in the way they did.

Another criticism of the psychometric approach is that the characteristics or factors identified as important in risk perception are not actually objective or inherent in the technology itself, but rather, these factors are themselves influenced by social and historical experience (Jasanoff & Wynne 1998; Douglas & Wildavsky 1982, p.17). According to this criticism, the psychometric approach takes the factors themselves as being static and real and does not place enough emphasis or importance on the way society and culture will influence not only the perception of risk but also the perception of the characteristics identified in psychometric approaches.

Otway & Thomas (1982) and Covello & Johnson (1987) have also suggested that the lack of attention given to the way socio-political factors shape risk assessments is an important limitation of the psychometric approach. Wynne (1983) has emphasised the importance of a socio-political dimension to risk perception through his presentation of the idea of a 'social risk', which he defines as the potential for a technology to substantially alter social structures or basic moral tenets. While highlighting the importance potential 'social risks' may have on public perceptions of controversial technologies, Wynne (1983) takes the argument one step further to suggest that technology should not be viewed as simply a tool (with potential physical and social risks associated with it) but rather as a social system that through its very existence can threaten particular social structures or moral tenets. The notion of social risks and the importance of socio-political factors for public risk perceptions of particular technologies are issues not addressed by the psychometric approach.

Some of these limitations of the psychometric approach to risk perception have been countered through the development of sociological and anthropological approaches to risk perception, most notably through the development of what is now referred to as the cultural theory of risk.

2.2 Cultural Theory

The basic premise of cultural theories of risk is that perceptions of risk are influenced by cultural factors. While this general statement is supported by a range of social science theorists on risk, the title of 'cultural theory' has been co-opted by a much smaller group of researchers with a far more particular theory on how cultural influences can be conceptualised. In this section I will outline this more specific cultural theory approach and discuss some of the criticisms that have been directed at it.

2.2.1 IMPORTANT FINDINGS OF THE CULTURAL THEORY APPROACH

The key distinguishing feature of the body of social science theory on risk that has come to be known as "cultural theory" is the belief that commitment to a particular preferred form of social organisation implies common values and will therefore lead to common fears. The perception of risk and the selection of particular risks for attention is therefore seen to stem from a preferred form of social organisation. While the literature contains some variation in the number of different social groupings used by cultural theorists to understand the influence of social organisation on risk perception (Rayner 1992; Renn 1992), the most widely referred to analytical tool for cultural theorists is a four fold typology (or 'grid/group').

In the first instance, this typology relates to human nature and describes four different cultural biases about preferred forms of organising social relations. As developed by Douglas & Wildavsky (1982, p.138) the horizontal axis of *group* is used to describe the boundary that is erected between people and the outside world, while the vertical axis of *grid* refers to all other social distinctions and delegations of authority that are used to limit how people behave towards one another. More concretely, the horizontal axis of group runs from a belief in social organisation that is individualistic to a more collective approach, while the vertical axis can be described as running from belief in the importance of hierarchical social relations to a prescription of equality (Schwarz & Thompson 1990; Thompson et al. 1990). Using this 'grid/group', cultural theory characterises beliefs in preferred forms of social organisation as being individualist, hierarchist, egalitarian or fatalist[30].

[30] Rayner (1992) refers to this final group as stratified individuals rather than fatalists. Douglas and Wildavsky (1992) give this characterisation little attention, potentially because those within it do not actively pursue participation in decision-making, due to either apathy or inability (Rayner 1992).

Following Adams & Thompson (2002), a description of these different classifications and how they affect perceptions of risk is outlined below[31].

The **individualist** (weak group, weak grid position) classifies those who believe in freedom from outside constraints but who may try to exert control over others. Individualists support the notion of freedom of opportunity and believe in the free market rationale that the selfish behaviour of individuals leads to improvements for society as a whole. A good example of the type of person within this individualist category would be a venture capitalist (Adams & Thompson 2002). According to this position, risks to the economy and the loss of resources in the market would be viewed as primary (Douglas & Wildavsky 1982, p.188).

A **hierarchist** (strong group, strong grid position) will generally belong to groups with binding prescriptions and be prepared to submit to hierarchical social organisation. A good example of a hierarchist would be a soldier (Adams & Thompson 2002). For a hierarchist it is the risks to the organisation and its hierarchical structure which can be expected to be of central importance, particularly the risks associated with war (Douglas & Wildavsky 1982, p.188)

Egalitarians (strong group, weak grid position) have strong group loyalties but unlike hierarchists, do not support externally imposed rules. Equality is an important principle for them and group decisions are sought through participation, deliberation and cooperation. Members of environmental pressure groups can be seen to be good examples of those falling within this category (Adams & Thompson 2002). Technological risks are said to be the primary focus of concern for egalitarians (Douglas &Wildavsky 1982, p.188).

Fatalists (weak group, strong grid position) are those people within society who choose not to belong to organised groups but who, unlike the individualist, believe they exercise little control over their own lives. They are

[31] The typology is also represented in Figure 1.

resigned to their fate and are hence given the title of fatalists. The untouchables of the Indian caste system are given as an example of those classifiable as fatalists (Adams & Thompson 2002). As fatalists are resigned to their fate, they will not necessarily actively select particular risks to focus management strategies on.

When applying cultural theory to an understanding of environmental risk perception, it is suggested that another fourfold typology can be laid over this one dealing with social relations. Holling (1979 & 1986) distilled what he saw as different patterns of beliefs about nature; beliefs about the behaviour of nature that had implications for how decisions were made in areas where information was deficient. Schwarz & Thompson (1990) adopted and added to Holling's description to create the second typology that can be used in cultural theory analysis, a typology that describes four "myths of nature": nature benign, nature ephemeral, nature perverse/tolerant and nature capricious. This typology has been usefully represented as the way a ball may behave in varying landscapes (as described below and represented in figure 1).

In the **nature benign** category, nature is seen as "predictable, bountiful, robust, stable and forgiving of any insults humankind might inflict upon it" (Adams & Thompson 2002). The accompanying diagram is of a ball in a cup and this is to suggest that no matter what perturbation is encountered, the ball will always return to rest safely at the bottom of the cup. **Nature ephemeral** is essentially the diametrically opposed view that nature is "fragile, precarious and unforgiving" (Adams & Thompson 2002) and is therefore easily threatened by human activity. In the diagram given for this category, the ball rests precariously atop an overturned cup to indicate that the ball's balance can be easily disturbed. The **nature perverse/tolerant** category is essentially a

combination of the two myths already described. The idea being that nature is predictable and stable in the face of perturbations, but only within certain limits (Adams & Thompson 2002). The representative diagram is a wave with two peaks and a single trough, with the ball resting in the trough. This is used to imply that the ball will remain within the trough given only modest disturbance, but any major perturbation will send it over the edge. The final myth is **nature capricious** and within this myth, nature is viewed as entirely unpredictable and essentially uncontrollable (Adams & Thompson 2002). The illustrative diagram is a ball sitting on a straight line, indicating the belief that if disturbed, the ball's (nature's) behaviour will not be predictable.

When this typology of different myths of nature is laid over the typology of human behaviour, the suggestion is that the nature benign view corresponds with individualist category, nature ephemeral with the egalitarian, nature perverse/tolerant with the hierarchist and nature capricious with the fatalist (see figure 1).

These typologies of cultural theory are suggested as having particular implications for how the management of environmental risks will be approached. Adams & Thompson (2002) describe the different approaches in the following way. The risk management style associated with the nature benign/individualist classification is essentially laissez faire. Nature is to be commanded for human benefit and the free market is thought to be capable of providing any guidance necessary for environmental risk management. Regulation is strongly opposed in this view as individualists will not support externally applied restraints. The risk management style of the nature ephemeral/egalitarian group is said to be one ruled by the precautionary principle. Nature in this view is to be obeyed and as it is fragile and unforgiving, humanity must use caution in its management of any potential

environmental risks. Under the nature perverse/hierarchist view, the risk management style is interventionist. As nature is only robust within limits there needs to be intervention and regulation to ensure that environmental risks are contained within tolerable levels. For the nature capricious/fatalist, there is essentially no sense in trying to apply risk management strategies as nature is viewed as unpredictable and what will be will be.

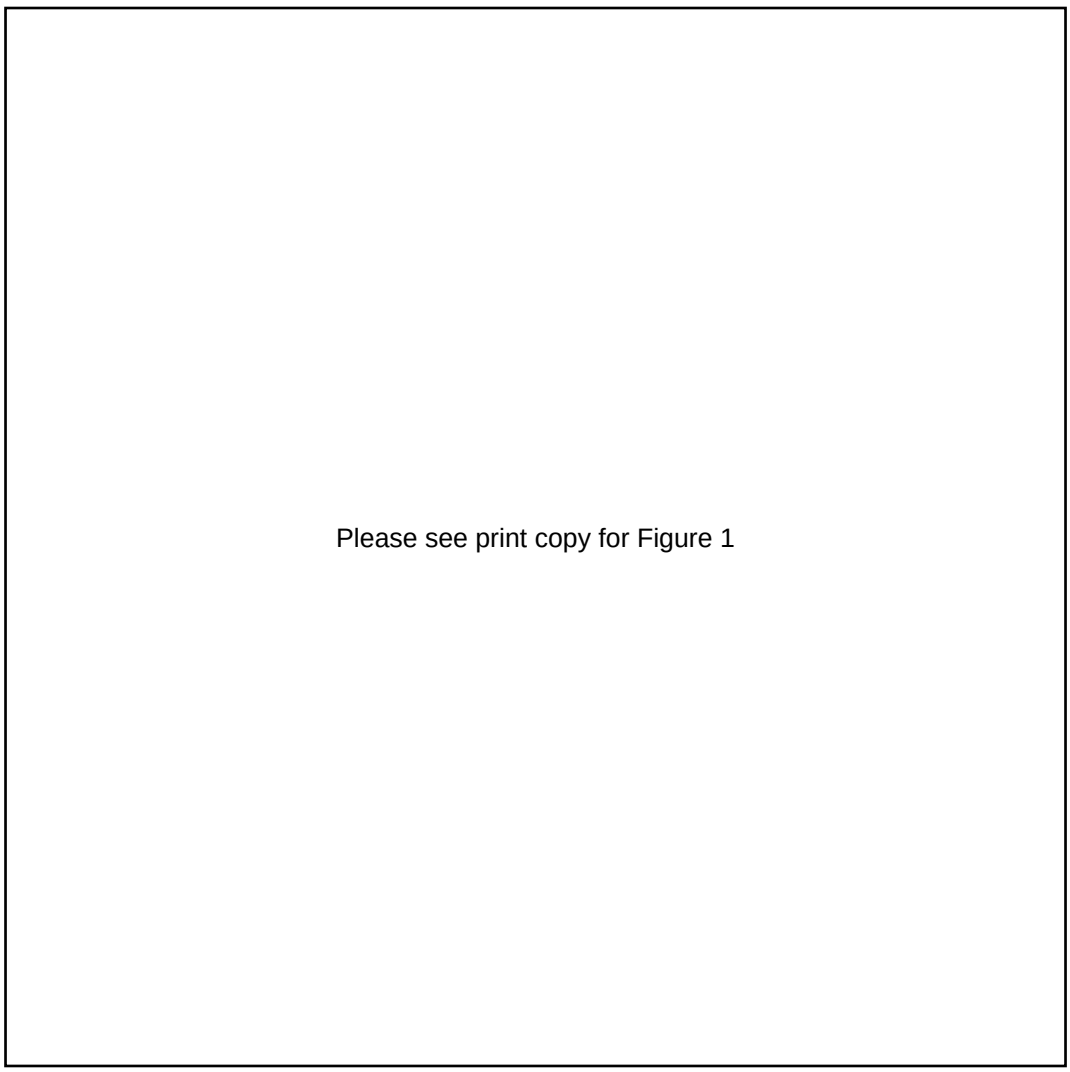

Figure 1: Cultural Theory Typologies (Adams & Thompson 2002)

By proposing that different cultural biases and beliefs about nature are key to understanding divergent perceptions of risk, cultural theory suggests that certain technological debates may not be about risk at all, but rather, may represent much broader ideological debates occurring through a discourse of risk (Slovic 1987). In any debate centred on physical risks, cultural theory suggests that people will be found to be arguing from different premises, premises that stem from their commitment to preferred forms of social organisation and beliefs about nature. This serves to imply that divergent risk perceptions are best explained not by a lack of rationality or by the characteristics of the hazard involved, but rather, by the disparity in the perceptual filters adopted by different social actors. Rather than a rational and an irrational position in relation to risk then, a plurality of rationalities begins to emerge in which risk debates are seen to be occurring between people operating from different premises. Through the provision of typologies that can be used to characterise different positions on risk, the aim of cultural theory is to allow the premises underlying divergent positions to be made explicit (Douglas & Wildavsky 1982, p.195).

2.2.2 Implications of Cultural Theory Findings for Decision-making

What does the existence of plural rationalities in risk debates mean for how decision-making on particular technologies should proceed? For Adams & Thompson (2002), the importance of perceptual filters in risk debates means that a new set of policy tools that allows for the negotiation of competing values need to be employed. A plurality of rationalities implies that rather than simply appealing to 'objective' scientific expertise for decision-making on contested technologies, broader participation from the public needs to occur. The belief that decision-making in risk debates involves negotiation between competing sets of values implies that public participation needs to occur in a way that

brings those operating within competing worldviews to the decision-making table.

Here we can see a pattern beginning to emerge. In spite of the differences in understanding risk perceptions between the psychological approach of the psychometric paradigm and the anthropological and sociological position of cultural theory, both approaches essentially call for increased public participation in decision-making processes.

2.2.3 Cultural Theory, rDNA technology and Ecological Risk

In their 2002 paper, Adams & Thompson apply cultural theory's typologies to the issue of the ecological risks from GM crops. Using quotes from various people involved in the debate, the varying positions on the technology and its risks are described in relation to the different perceptual filters described by cultural theory. What follows is a presentation of the different positions in this debate as provided by Adams & Thompson's (2002) cultural theory analysis.

For the individualist, rDNA technology and GM plants are viewed positively. GM plants are not seen as novel organisms but rather as just the latest development in a string of biotechnological applications that began with the making of bread and cheese and the brewing of beer. Without any evidence that GM crops pose a danger to the environment, the assumption is that they are safe. For an individualist, the technology is viewed as familiar, containing the potential for widespread benefits and unless proven otherwise, the risks to the environment from this technology are viewed as minimal.

In contrast, the egalitarian is said to view rDNA technology not as something familiar but as something novel and 'unnatural'. This belief in the novelty of the

technology means that the impacts it will have on the environment are viewed as unpredictable. In contrast to the individualist position of, 'unless it is proven dangerous we should assume it is safe', the egalitarian posits that 'unless you can prove that this new technology is safe, we should assume that it is dangerous'. In the descriptions given by Adams & Thompson (2002), the egalitarian is not only concerned with the impacts GM plants will have on the environment but also with the socio-economic consequences of the technology; particularly the way ownership of the technology is concentrated in the hands of a select few multinational corporations.

The hierarchist is presented by Adams & Thompson (2002) as not supporting the suggestion that GM plants pose no risk for the environment, or the position that the risks are unpredictable and so large as to require that the technology be abandoned. For the hierarchist, GM plants present a management problem that can be handled through regulation and the application of scientific knowledge. The hierarchist view is that there are risks involved with the application of rDNA technology but science is capable of identifying and managing these risks to keep them within tolerable bounds.

The fatalist approach to the issue of the environmental risks of GM plants is presented by Adams & Thompson (2002) as being, quite simply, that there are risks involved but there is very little that can be done to control them. In the view of the fatalist, GM crops are the product of powerful profit driven corporations and as such, nothing can be done to control either their release or their impacts on biological or social environments. The actions of large multinational corporations are seen as being beyond control and therefore there is a need to accept that rDNA technologies will become part of our lives, whether we like it or not.

In classifying different positions on the environmental risks of GM crops, Adams and Thompson (2002) aim to demonstrate how the different worldviews described by cultural theory can be used to organise different risk perceptions in the rDNA technological controversy. Suggesting that there are 'social solidarities' as represented by the typology of bias, cultural theory proposes that an understanding of these cultural biases can be used for understanding, organising and even predicting divergent perceptions of technological risk.

2.2.4 Criticisms of the Cultural Theory Approach to Risk

The first criticism that can be directed at cultural theory's approach to explaining risk perception is whether the typologies that form the cornerstone of the theory are accurate or adequate (Renn 1992). Related criticisms include whether individuals and groups can be classified using the grid/group model and how the model can be practically applied when individuals and groups can in fact possess and exercise multiple identities across different contexts (Johnson 1987). It certainly seems a simplification to suggest that the diverse range of beliefs within society can be accurately characterised by four ideal types or that the description given for the four types is adequate for capturing the full range of beliefs that can be held by an individual or group. Cultural theorists are, however, aware of this criticism and have developed a response to it.

Adams & Thompson (2002) draw attention to the fact that the classifications given by cultural theory are indeed caricatures lacking the complexity of real people; however, this does not necessarily mean that they are not useful caricatures. If the different cultural biases outlined by cultural theorists are useful for understanding, organising or explaining divergent risk perceptions

within society, then the typologies and the types they describe can be viewed as simplifications of a complex reality (as all models inevitably are), but functionally useful simplifications. If the typologies are viewed as functionally useful simplifications, the question then has to be asked whether the usefulness of these simplifications has been extensively supported by evidence or whether we are simply expected to accept the logic or intuitive appeal of the explanations. Indeed, one of the main criticisms of cultural theory is that it has been supported by very few empirical studies (Kasperson 1992; Rayner 1992; Renn 1992).

Another criticism that has been directed at cultural theory is that it encourages a slide towards relativism, where every view of risk becomes equally valid and no distinctions can be made between the quality of different assessments (Mayo 1991; Schrader-Frechette 1991; Rosa 2000; Garvin 2001). Douglas & Wildavsky (1982, p.193) reject this criticism by suggesting that a relativist position would undermine the very conditions that the theory has established for risk analyses. That is, rather than supporting a relativist notion of an infinite diversity of risk perceptions, cultural theory is based on a reduction of the range of cultural variation to three (or four) ideal types. Schrader-Frechette (1991, p. 228) criticises this position presented by Douglas & Wildavsky (1982) by proposing that believing all risk perceptions to be simply a product of cultural factors such as social structures and political beliefs represents a reductionist approach to the issue of risk perception. Mayo (1991) and Rosa (2000) also criticise cultural theory as a form of social reductionism because of the way in which it suggests that all risk assessments can be reduced to social or moral judgements.

A further question that can be asked about the cultural theory approach to explaining risk perception is: When do the different worldviews come into

play? Adams (1995) suggests that cultural biases become important for risk perception when there is scientific uncertainty. This implies that cultural biases are important in risk perceptions only when a lack of scientific data creates a space for some interpretive flexibility. Assuming that cultural influences on understandings of risk only occur when there are gaps in scientific knowledge tends to 'black box' the generation of scientific knowledge itself. In this way, cultural theory fails to consider the ways in which cultural biases may influence not only the assessment of risk in data deficient contexts, but also the way in which scientific assessments of risk are themselves framed.

While Douglas & Wildavsky (1982) do not explicitly limit the influence of cultural biases to areas where there is scientific uncertainty (as Adams (1995) does) and do state that all perceptions of risk, expert and lay, will be influenced by preferred forms of social organisation, they do not directly and explicitly address the way in which cultural biases influence scientific assessments of risk. This lack of engagement with the literature on the sociology of scientific knowledge and lack of clarity on how the theory relates to the generation of scientific knowledge on risk is in my view a serious limitation of the cultural theory approach.

In presenting the psychometric and cultural theory approaches to risk, I have discussed an important tension in social science theories of risk - the tension between an approach that focuses on individuals and an approach that focuses on social organisation and cultural context. Deciding whether a focus on individuals or cultural context should hold primacy in social understandings of risk has been described as a 'chicken and egg' type of problem (Krimsky 1992); and one that becomes irrelevant if we view each of these approaches as shedding light on a different dimension of the multifaceted concept of risk. There is, however, another important tension in the theoretical literature on risk

that is worth further exploration. At the beginning of this section, I mentioned that cultural theory sits within a broader set of literature that adopts a constructivist as opposed to an objectivist position on risk. I will now explore some of the diversity in this broader set of literature, particularly as it relates to the extent to which social factors influence risk assessments and what adopting a constructivist position means for the role of science in environmental decision-making on controversial technological developments.

3. CONSTRUCTIVIST APPROACHES TO RISK

A constructivist account of scientific knowledge challenges the positivist position that science is objective and describes the natural world as it 'really' is, uninfluenced by values or cultural biases. Mayo (1991) suggested that challenges to the positivist position were sparked by Kuhn's (1962) description of how scientific knowledge develops and were extended through research conducted in the sociology of scientific knowledge (e.g. Latour & Woolgar 1979). Examining science and technology from a constructivist position means that importance is granted to the "role of human agency and cognition, cultural discourses and practices and social goals and norms in the making of scientific knowledge and technological products" (Jasanoff & Wynne 1998). A constructivist approach to risk seeks to explore the importance of these various social factors in both lay and expert understandings and assessments of technological risks (Jasanoff 1998) and is essentially an approach that considers how social commitments frame alternative accounts of risk (Robins 2001). Additionally, a constructivist understanding suggests that the relationship of science to policy as one of 'speaking truth to power' (Price 1965) needs to be reconceptualised.

Jasanoff (1998 & 1999) describes three different approaches to risk, contrasting positivist and constructivist approaches and introducing a third approach that is described as discursive. In the positivist view, there are actual risks that are real and objectively quantifiable by experts and there are perceived risks which are seen to be false understandings of risk (usually held by lay members of the public) that have been influenced by ignorance, prior beliefs or values. This positivist approach currently dominates the way the concept of risk is used in environmental decision-making. In comparison, under a constructivist approach to risk, the divide between actual (real) and perceived (false) risk is collapsed as social and cultural values are seen to permeate all assessments of risk, not just those of the public (Jasanoff 1998). The third discursive approach to risk is described by Jasanoff (1999) as being inspired by the constructivist position but an approach that focuses on how risk mediates between knowledge and power.

According to the social analysis of risk that Jasanoff (1999) describes as discursive, risk analysis is viewed as a discourse that implicitly empowers some people as experts while excluding others. Because of the way in which risk analysis uses a highly specialised and technical language and operates through particular procedures, adopting a discourse of risk for environmental decision-making will work to exclude those people who lack these language and procedural knowledge and skills. Adopting a discourse of risk can therefore be seen to channel power in society by excluding certain people from participating fully in decision-making deliberations. The discourse of risk can also be seen to mediate between knowledge and power in the way it structures the notion of harm in a limited and specifically, technical way. According to this discursive approach, the discourse of risk is essentially analysed as an example of technocratic decision-making with its attendant criticisms. As I view this

discursive approach as a derivative of constructivist approaches to risk, and Jasanoff (1999) herself describes it as inspired by constructivist understandings, I will now focus on describing constructivism more broadly[32].

3.1 CONSTRUCTIVISM

In suggesting that there is a divide between positivist (or realist) and constructivist approaches to risk, there is a tendency to see this as a divide between the belief in the existence of objective knowledge and the belief that all knowledge is mediated by social and cultural beliefs and is therefore entirely subjective. Certainly for some social science analysts of risk, a belief in the influence of social factors on understandings of risk does lead to an espousal of the position that risk is entirely a social construct and therefore that varying assessments of risk can not be distinguished on the basis of quality or truth[33]. According to this extreme or 'strong' constructivist view, there is no way to distinguish a form of knowledge that is more reliable or robust than others (van Zwanenberg & Millstone 2000).

According to a 'strong' constructivist position then, risk is not something 'out there' that is real and objective, but rather it is a mental construct shaped *entirely* by social values and cultural beliefs. While this position on risk could be described as relativist, it is important to note the distinction between relativism in an epistemological sense and ontological relativism. To say that risk is a mental construct shaped entirely by social values and cultural beliefs does not necessarily equate with the position that physical risks (such as that of dying in

[32] I would like to highlight at this point that although the type of discursive analysis (focussed on the interests served by a risk discourse) as described by Jasanoff (1999), would be a relevant and highly informative approach to take in a critical examination of Australia's environmental regulation of GM crops, it is outside the scope of this particular research project. My analysis is conducted using the approach Jasanoff (1999) describes as constructivist, although I certainly highlight discursive or interests-based analysis as an area worthy of further investigation.
[33] Rosa (2000), Mayo (1991) and Scrader-Frechette (1991) all cite the work of Douglas & Wildavsky (1982) as an example of this type of approach to risk.

a car accident) do not really exist. In contrast to an ontological form of relativism that would essentially deny the existence of social or physical risks, a 'strong' constructivist position on risk could be seen as relativist in an epistemological sense if it refers to the way in which social values and cultural beliefs will always influence our ability to know, understand and calculate the risk involved with any activity or technology. The strong constructivist position that our ability to understand risk is shaped *entirely* by social values and cultural beliefs certainly challenges the usefulness of the traditional approach to risk assessment as a decision-making tool but it has been criticised for having nothing practical to offer in terms of guidance for how policy making should proceed. It has been suggested that without some practical outcome, this position on the nature of risk is unlikely to have any real influence on decision-making processes (Rayner 1987).

In contrast to both this strong form of constructivism and a realist notion of risk, however, there are a number of 'in between' positions that suggest that while all assessments of risk are invariably influenced by social, cultural and political factors, the degree to which these factors construct assessments of risk is to some extent limited by the material agency of nature (van Zwanenberg & Millstone 2000). This approach to risk analysis highlights the importance of social factors in shaping understandings of risk but also acknowledges that the natural world operates, to some degree, as a constraining factor. Rayner (1987 & 1992) has described nature's constraining role as "natural feedback" and suggests that:

> *The combination of natural feedback with cultural constraints on the organisation of information combine to form a total knowledge system, parts of which may be overdetermined by either natural or cultural*

constraints at different times and places. However, both types of constraint are always present in the knowledge process.

According to this more moderate constructivist position, assessments of risk are variable but not infinitely so[34]. Scientific knowledge may be unavoidably value-laden but this does not necessarily mean that it is entirely relative (Schrader-Frechette 1998).

While a strong form of constructivism may tend to dismiss science as just one form of knowledge among a plurality of equally valid positions, the more moderate position would suggest that the way in which natural feedback is an important part of science makes it a useful and important contributor to the decision-making process. However, rather than simply being accepted as objective truth, scientific knowledge and expert advice should be subject to critical scrutiny for the way in which it will inevitably be infused with particular social values or shaped by political influences. This moderate constructivist approach to risk would therefore suggest that science can help inform decision-making but there needs to be critical reflection on the assumptions and beliefs which have underpinned its development (Jasanoff 1996).

Adopting this type of constructivist stance, Beck (1992, p.155) suggests that as science is not just one of the causes of modern risks but also the medium of definition and source of solutions, it should not be simply dismissed, but rather, should seek to develop in such a way as to be a source of knowledge that

[34] The assertion that natural and cultural factors intertwine in the generation of human knowledge forms the essence of how I interpret and apply the term constructivism throughout the later parts of this thesis.

reflects on its own process of generation[35]. For Beck, adopting a constructivist position in relation to scientific knowledge and risk represents an opportunity for the further development of a new phase of modernisation (a phase that he refers to as reflexive modernisation), in which a classically scientific scepticism is extended to "the foundations and hazards of scientific work" itself (Beck 1992 p.14)[36]. This approach suggests that science should not be abandoned in environmental decision-making but rather, should itself be subjected to methodological scepticism. Unfortunately, how this scepticism would be applied in practice in a policy setting is an issue that Beck does not address in any substantial detail. The basic idea, however, is that the belief in realism in science as a basis for decision-making would be replaced by a more reflexive approach that would attempt to understand and draw out the assumptions, subjective elements and social factors that have influenced the generation of scientific knowledge or advice.

This constructivist position suggests that critical reflection on scientific knowledge can positively contribute to public policy decisions by enabling the exposure of previously hidden assumptions and values. While critical reflection on the scientific knowledge and expert advice offered in a regulatory risk analysis process would certainly seem an admirable pursuit, exactly how this would operate in practice is still unclear. How exactly could regulators go about drawing out the assumptions, subjective elements and social factors influencing

[35] While some commentators on risk have chosen to highlight the realist tendencies within Beck's (1992) 'Risk Society' thesis (e.g. Rosa 2000; Wynne 1996), the description of constructivism adopted in this thesis allows me to present him as a theorist espousing a constructivist stance towards risk.

[36] In his recent work Beck has highlighted how his use of the term 'reflexive modernisation' should be seen as characterised as much by 'reflex' as by 'reflection', i.e. "a *reflex*-like transition from industrial to risk society" (Beck 1996). Reflexive modernisation can therefore be viewed as a form of modernity that is a reflex response to the challenges and inadequacies of industrial society, bringing about self-confrontation and through this, the potential for reflection.

scientific knowledge and advice in regulatory risk analysis and how should they proceed once this information has been attained?

3.2 Applying Constructivist Understandings to Risk Analysis

Adopting a constructivist stance, Shrader-Frechette (1991) claims that some risk judgements are more warranted than others, even though none can be seen as being value free. Through providing a differentiation of the types of value judgements that can enter science for policy, Shrader-Frechette (1991) suggests one way in which constructivism and a critical reflection on scientific knowledge can be applied in a policy setting.

The first set of value judgements described by Shrader-Frechette (1991) is "Bias Values", said to occur whenever anyone misinterprets or omits information consciously as a way of furthering their own interests. These are presented as both the easiest value judgements to identify and the most important to exclude from risk assessments. "Contextual Values" are described as being more difficult to avoid as they are present whenever personal, social, cultural or philosophical emphases are used in the provision of risk judgements and are said to often play a role when limited data is available. The final category of "Constitutive Values" are described as present whenever a particular method is chosen over another. As perception will always be framed by the beliefs and theories already held, constitutive values are said to be impossible to eliminate entirely from science and risk assessment.

According to Shrader-Frechette (1991, p.237), what is needed is a risk assessment framework that encourages the development of alternative risk judgements that can then be compared and criticised, not in relation to which assessment is value neutral, but according to which judgements are normative

in a way that is not "misleading, incoherent, incomplete, question begging or implausible". The typology of value judgements is presented as a tool to aid this imagined scrutiny of different risk assessments. It is also important to emphasise that Shrader–Frechette (1991) envisages that the critical reflection on risk assessments demanded by constructivist approaches would involve review by both scientists and lay members of the community where all judgements would be open to debate and criticism. This demonstrates a recurring pattern - the importance of public participation and deliberation for enabling critical reflection in regulatory decision-making.

By differentiating between the different types of values that can enter risk assessment processes and emphasising the importance of having alternative risk assessments, Shrader-Frechette (1991) provides one useful way of applying constructivist understandings to policy problems. Funtowicz & Ravetz (1993) have, however, developed a particularly influential model for understanding how and when critical reflection and public deliberation on scientific knowledge becomes important for policy problems. The model they propose for conceptualising the different ways in which science can be applied and judged for its quality in varying contexts is titled the 'postnormal science' model.

3.2.1 Postnormal Science

Funtowicz & Ravetz (1993 & 1994) have suggested that in modern issues of risk and the environment (such as rDNA technologies) there are often extensive scientific uncertainties, high decision stakes, disputed values and a pressing need for decisions. From this position, they suggest that although science will be an important contributor to policy decisions in these contexts, it can no longer claim monopoly authority. Funtowicz & Ravetz (1993) propose that the challenges associated with modern issues of risk and the environment are

seeing a new type of science emerge with a re-imagined role in the policy process. Through the provision of their heuristic model, Funtowicz & Ravetz (1993 & 1994) suggest that different contexts require different problem solving strategies and that these strategies have varying roles for scientific inputs and for assuring the quality of these inputs for policy.

In the postnormal science model (see figure 2) Funtowicz & Ravetz (1993) use the attributes of decision stakes and systems uncertainties to characterise the different problem solving strategies required. They term these different strategies 'applied science', 'professional consultancy' and 'postnormal science'. In this model, decision stakes are said to involve "all the various costs, benefits, and value commitments that are involved in the issue through the various stakeholders" and systems uncertainties relate to the way in which "the problem is not concerned with the discovery of a particular fact but with the comprehension or management of an inherently complex reality" (Funtowicz & Ravetz 1993).

The postnormal science model suggests that when decision stakes and systems uncertainties are low, the familiar strategy of applied science is appropriate[37]. A low characterisation of uncertainties occurs when uncertainties are largely technical, manageable by standard routines and procedures, i.e. practices such as instrument calibration and statistical analyses. The decision stakes are deemed to be low when research is 'mission oriented' with a well defined and straightforward end use. In this situation where the applied science strategy of

[37] Rayner (1987 & 1992) has noted that Funtowicz & Ravetz's use of the term 'applied science' does not exactly correlate with the way in which this term is commonly used to refer to scientific activities directed towards practical and technical outcomes and because of this, I agree with Rayner's suggestion that the use of a term such as 'consensual science' in the model may help to avoid confusion on this matter.

problem solving is appropriate, the quality of the scientific information is said to be aptly managed in the traditional way through peer review and appraisal by the relevant community of specialists.

As systems uncertainties and decision stakes increase, the appropriate problem solving strategy shifts into what the authors term 'professional consultancy'. In this case, the degree of uncertainty involved in the research problem goes beyond technical issues to include questions about the reliability of particular theories and information as well as what the relevant methodologies are. With uncertainty having increased from the technical to the methodological, a degree of personal judgement is seen to become involved. Higher decision stakes emerge as the research becomes 'client serving' rather than 'mission oriented'. This means that when an academic researcher with an established reputation from their performance in applied science problem solving is asked to give advice on a policy issue, the researcher is serving a client and offering their personal judgement on a situation and is therefore engaged in a 'professional consultancy' role. Of course, where there is methodological uncertainty, different individuals may make different judgements of a given situation and the client then becomes an important contributor to the evaluation of what constitutes quality.

The unique part of the model that specifically relates to the new problem solving strategy needed to address modern issues of risk and the environment (where both systems uncertainties and decision stakes are high) is titled postnormal science. This strategy is seen to be 'issue driven' and involves uncertainties that are of an epistemological or ethical variety and decision stakes that involve conflicting values and new stakeholders such as future generations and other species. In this type of issue where decision stakes and systems uncertainties are high, the process of quality assurance is said to

require extension to the broader community, a process entitled 'extended peer review'. The justification for this extension is best phrased by Funtowicz and Ravetz (1993):

> *When problems lack neat solutions, when environmental and ethical aspects of the issues are prominent, when the phenomena themselves are ambiguous, and when all research techniques are open to criticism, then the debates on quality are not enhanced by the exclusion of all but the specialist researchers and official experts. The extension of the peer community is not merely an ethical or political act; it can positively enrich the processes of scientific investigation.*

What this heuristic model provides then is both a way to conceptualise some of the different roles that science can play in policy decisions (using the problem attributes of decision stakes and systems uncertainties) and different ways in which the quality assurance of science for policy can proceed (according to types of uncertainty and the intended function of the information). For the particular issue of political decision-making on the environmental impact of rDNA technologies, the model suggests that due to the contested values, high decision stakes and systems uncertainties involved, the postnormal science problem solving strategy would be the most appropriate. This means that while science will be important for the decision-making process, the quality of this information should be assured through a process of extended peer review, where the broader community is able to assess and debate the scientific claims in relation to knowledge generated through other means, as well as in relation to value sets and social priorities. Through exposure to this critical reflection, the idea is that the hidden assumptions and values that may have influenced particular scientific assessments or advice can be exposed and opened to

deliberation. This resonates with the pattern already identified in this survey of the theoretical landscape that increased public participation, deliberation and critical reflection are required in regulatory decision-making processes for issues such as the environmental impact of rDNA technologies. Additionally, it draws specific attention to the importance of the management of uncertainty in environmental decision-making.

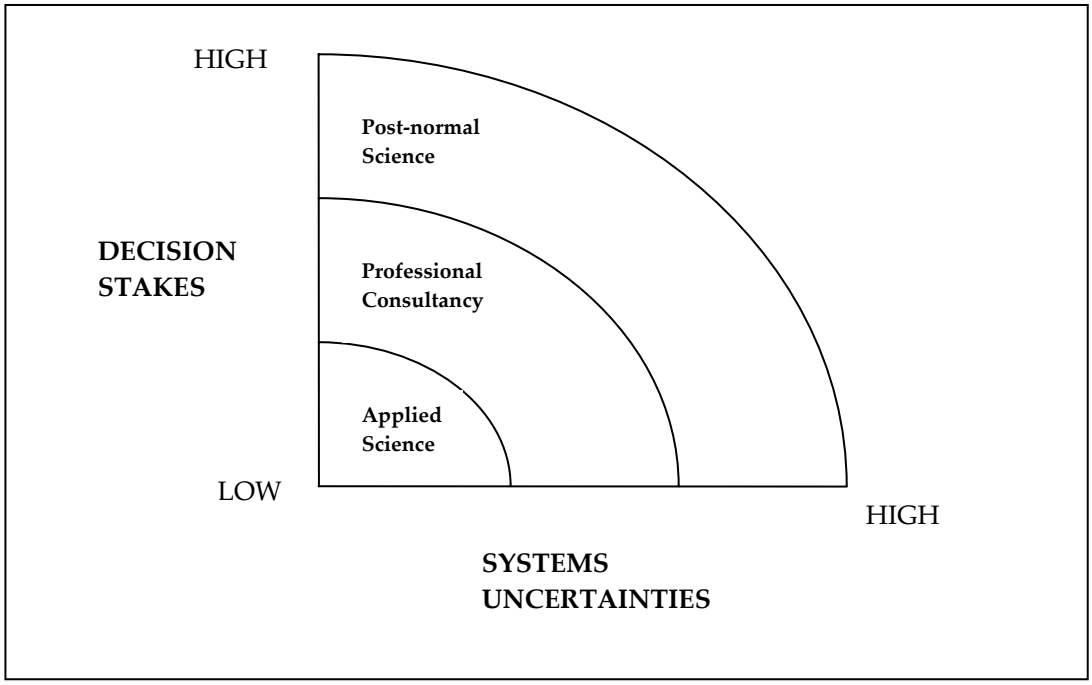

Figure 2: The Postnormal Science Model

3.2.2 Criticisms of the Postnormal Science Model

Jasanoff & Wynne (1998) and Yearley (2000) have criticised the postnormal science model for the way in which it either assumes that the axes of systems uncertainties and decision stakes are independent of each other or the assumption that the reduction of uncertainty will always simultaneously reduce decision stakes. The model has also been criticised for the way in which it fails

to account for divergent constructions of uncertainty between individual stakeholders (Jasanoff & Wynne 1998) and how these constructions of uncertainty may shift during a decision-making process (Yearley 2000). Wynne (1992) has particularly criticised the model for purveying a sense of uncertainty existing on an objective scale, rather than as a function of the social commitments or decision stakes invested in the knowledge being accurate.

Carew (2004, pp.105-108) has proposed that rather than being an inherent quality of a particular problem, the degree of uncertainty can be seen as more related to the extent to which a problem has been 'decontextualised' (removed from its surrounding context). Additionally, Carew (2004, p.109) questions the assumption that any change in a problem will always be towards resolution and suggests that the model does not convey an understanding of the way in which a problem may become increasingly uncertain or intractable when exposed to the type of democratised debate espoused by the postnormal science strategy. Carew (2004, p.111) effectively turns the postnormal science model 'inside out' to suggest that, in practice, it is often less the problem dictating the appropriate decision-making strategy and more a case of decision makers shaping the problem and choosing an approach based on particular real-world constraints. In this case, the model becomes useful as a way of raising awareness about the assumptions and challenges associated with the choice of a particular problem solving strategy, rather than as a way of choosing an appropriate strategy for a statically defined problem.

Despite these criticisms of the accuracy and adequacy of the postnormal science model, the work conducted by Funtowicz & Ravetz (1990a&b; 1993 & 1994) has been important for highlighting how different types of uncertainty influence what can be seen as the most appropriate role for scientific knowledge in policy

settings. In the literature on decision-making regarding the environmental impact of new technological developments, the notion of uncertainty has now become key and I would suggest that there is an emerging shift in the intellectual climate away from a focus on quantifying the environmental risk of new technologies, to an increasing concern with how uncertainties are to be managed and negotiated. While risk and uncertainty are inherently related concepts, in the past, the focus of environmental decision-making theory has arguably been on how to quantify the risk associated with an activity or technology, whereas now, there is increasing attention being paid to how the inherent uncertainties can be most appropriately handled. An important development for understanding this emerging shift from risk to uncertainty based processes for environmental decision-making has been the articulation of a number of different typologies of uncertainty.

4. TYPOLOGIES OF UNCERTAINTY

In section 3.2.1, I discussed the way in which Funtowicz & Ravetz (1993) have classified uncertainty as being technical, methodological or epistemological and how they suggest that these different types of uncertainty have implications for the role of science in policy, as well as for the way in which the quality assurance process for scientific inputs is conducted. Another influential contribution to the conceptualisation of different types of uncertainty in environmental decision-making has been presented by Brian Wynne (1992).

According to Wynne's (1992) typology, "risk" can only be authentically talked about when the behaviour of a system is believed to be well characterised and therefore, when the probabilities associated with different outcomes can be reasonably calculated – i.e. we can talk about risk when we 'know the odds'. Wynne's second category is that of "uncertainty", which is used to describe

situations where important system parameters are known but probability distributions are not – i.e. uncertainty occurs when we 'don't know the odds' involved. Uncertainty, as presented by Wynne (1992), relates to a lack of knowledge and is therefore something that can conceptually be reduced through further research.

Wynne (1992) labels his third type of uncertainty "ignorance" and suggests that this title refers to those situations where 'we don't know what we don't know'. Ignorance in this sense refers more to ignorance in relation to relevant questions rather than ignorance about the answers. For example, in testing the environmental impact of chemicals 30 years ago, we were 'ignorant' about the potential risks of endocrine disruption. Rather than simply not having enough information to make a judgement and therefore being 'uncertain', we were ignorant that disruption of endocrine systems was a potential risk, and we didn't know that we didn't know about it.

Wynne (1992) suggests that this type of ignorance is endemic to scientific knowledge as science necessarily reduces complex systems and the multitude of potential problem formulations to those that are applicable to particular disciplinary models and methods. This means that social judgements become implicit in the generation of scientific knowledge through how problems are formulated and approached. Value judgements in terms of the relevant endpoints and pragmatic considerations in terms of what is possible within a particular paradigm of thought, timeframe or financial position all structure what develops as scientific knowledge and this excludes other potential ways of framing a problem or research approach. For Wynne (1992), this endemic ignorance in the way scientific knowledge develops really only becomes

problematic when science is applied to policy making without a clear recognition of the limitations involved.

The fourth category of uncertainty described by Wynne (1992) is that of "indeterminacy", which arises because of the open-ended nature of causal chains and the way in which outcomes are dependent on the behaviour of various agents engaged in interconnecting systems. Indeterminacy is a type of uncertainty that relates to the way in which behaviour can vary across different contexts and through time and how different actions taken by humans will affect processes causing environmental impacts. Recognition of the element of indeterminacy makes it important to consider potential social interactions in risk analyses (Wynne 1992). An example of indeterminacy is our inability to determine the behaviour of farmers and rural communities across different contexts and time when trying to assess the environmental risks of genetically modified (GM) crops. What other crops, plants, animals, chemicals etc GM plants may be exposed to over their lifetimes and how this will vary in different locations and times represents an element of indeterminacy for decision makers.

Wynne (1992) highlights how processes of risk analysis were originally developed in application to technological artefacts, where system behaviour could be well characterised and the probabilities associated with particular outcomes reasonably well calculated. When being applied to environmental systems, however, the process of risk analysis as it is traditionally understood fails to take account of the new types of uncertainty that become important. When policy deliberations use a traditional language of risk to consider the potential environmental impacts posed by technological developments, the full range of the different forms of uncertainty involved is generally reduced so that

only uncertainty as incomplete knowledge is considered in the analysis (Wynne 1992). This failure of traditional approaches to acknowledge the existence and importance of ignorance and indeterminacy in environmental risk assessment fails to consider the way in which ignorance and indeterminacy can be sources of risk in themselves (Wynne 1992).

This conceptualisation of the different types of uncertainty affecting environmental risk assessment leads Wynne (1992) to suggest that to understand environmental harm we need "not only intense and open examination of the scientific evidence and competing interpretations in an area of interest" but also "reflexive learning…about the nature and inherent limitations in principle of that knowledge". To make our ignorance 'useable' (Ravetz 1987), Wynne (1992) suggests that the issues of ignorance and indeterminacy need to be embraced in broader social debate about the commitment to particular technological trajectories. To achieve this, regulatory cultures need to recognise the importance of these forms of uncertainty and develop in a way that actively encourages public debate on not only the costs and benefits involved with particular technological developments, but also on the indeterminacies involved. Scientific research that is used in a policy setting should be opened to debate (or deconstructed) and then 'renegotiated' through engagement with various stakeholders and the different values and epistemological commitments they bring to the process (Wynne 1992).

This notion of negotiation and critical reflection on the scientific knowledge applied to modern issues of risk and the environment has also been espoused by Carr & Levidow (1999) in their description of a process they call 'Negotiated Science'. Carr & Levidow (1999) attach importance to the way environmental questions can be differentially framed and the way natural and social systems

intertwine in issues of environmental risk. Emphasis is placed on the importance of 'unknowns' in the anticipation of environmental impacts and the suggestion is that these unknowns (or different forms of uncertainty) require a new approach to risk assessment. The suggestion that follows is once again that the challenges associated with different types of uncertainty require a democratisation of the risk assessment process through the encouragement of active public engagement with the process and a broad based scrutiny of scientific evidence and expertise. The idea is that to adequately address the different types of uncertainty involved in environmental risk decisions, scientific knowledge needs to be 'negotiated' through deliberations including relevant stakeholders and the public (Carr & Levidow 1999). The authors argue that this 'negotiated science' approach to policy is particularly important for the issue of regulating the environmental impact of rDNA technologies.

In addition to Wynne's (1992) typology, Stirling (1999a&b) and Stirling & Gee (2002) have also presented a characterisation of different forms of uncertainty relevant to environmental decision-making for new technological developments. As uncertainty is a term that is given a specific meaning in the typology, however, Stirling (1999a&b) and Stirling & Gee (2002) use 'incertitude' rather than 'uncertainty' as the collective term for describing what the typology characterises. The criteria used to classify different forms of incertitude in this typology are knowledge about likelihoods and knowledge about outcomes. According to this typology (and echoing Wynne's (1992) description), "Risk" refers to situations where outcomes are well defined and there is some basis for assigning probabilities (Stirling 1999a&b; Stirling & Gee 2002). "Uncertainty" is the title given to the type of incertitude where outcomes are well defined but there is no concrete basis for assigning probabilities to those outcomes (Stirling 1999a&b; Stirling & Gee 2002). Again, this

understanding of what constitutes 'uncertainty' is analogous to that presented by Wynne (1992).

Where the characterisation of outcomes is poorly defined but there is some basis for assigning probabilities, this type of incertitude is referred to as "Ambiguity" (Stirling 1999a&b; Stirling & Gee 2002). Elaborating on the factors that lead to this category of incertitude, Stirling & Gee (2002, p.525) state that:

> *The multidimensionality, complexity and scope of the different forms of environmental risk and the different ways of framing and prioritising these risks can easily render the characterisation of outcomes ambiguous.*

Stirling & Gee (2002) go on to suggest that defining what constitutes environmental harm for assessments of the deliberate environmental release of GM crops is an issue where ambiguity is a particularly important element of the incertitude faced by regulatory decision makers. This characterisation of ambiguity supports Carr & Levidow's (1999) emphasis on the important impact divergent framing assumptions can play and is analogous to Klinke & Renn's (2002) description of ambiguity as the "variability of (legitimate) interpretations" stemming from "differences in interpreting factual statements about the world or from differences in applying normative rules to evaluate a state of the world".

The final type of incertitude in the typology of Stirling (1999) and Stirling & Gee (2002) is entitled "Ignorance". Ignorance is said to represent the type of incertitude that is present when outcomes are poorly defined and there is no basis for assigning probabilities. In the sense that this idea of ignorance relates

to 'the things we don't know we don't know', it can be seen to mirror the characterisation provided by Wynne (1992). Stirling (1999a, p.122), however, states that ignorance:

> *arises from many familiar sources, including incomplete knowledge, contradictory information, conceptual imprecision, divergent frames of reference and the intrinsic complexity or indeterminacy of many natural and social processes.*

This description of what gives rise to a state of ignorance seems to conflate elements of what Wynne (1992) separates as uncertainty (incomplete knowledge), indeterminacy (particularly in relation to the interactions between natural and social processes) and ignorance. This description of what gives rise to ignorance also seems to encompass what Klinke & Renn (2002) would perhaps separate as ambiguity (arising from contradictory information and divergent frames of reference).

While these typologies differ in how they draw boundaries of distinction and define the different forms of incertitude relevant to environmental decision-making, I believe some patterns can be extracted and developed into useful categories for this research project. Firstly, there appears to be agreement that the term risk is specifically relevant to situations where both potential outcomes and the probabilities associated with those outcomes can be reasonably well characterised. Uncertainty appears a term best applied to those situations where there is some agreement about the potential outcomes but the basis for assigning relevant probabilities is not strong. I would suggest that this state of 'uncertainty' stems primarily from a perceived lack of relevant information or incomplete knowledge. In this sense, uncertainty is a form of incertitude that can conceptually be reduced by further research. These understandings of risk

and uncertainty are those that have traditionally been employed in risk analyses.

When attempting to assess the environmental impacts of new technologies and their acceptability, new types of incertitude arise that are not well addressed by traditional approaches to risk analysis and the notion of uncertainty they have adopted. These types of incertitude can be titled ambiguity, indeterminacy and ignorance. I would suggest that ambiguity results from contradictory information and/or the existence of divergent framing assumptions and values. I would describe indeterminacy as the type of incertitude that exists because of the intrinsic complexity associated with predicting the outcomes (and probabilities) associated with the interaction of various open-ended social and natural systems, while ignorance can perhaps best be used to describe our inability to conceptualise, articulate and therefore consider the outcomes and causal relationships that lie beyond current frameworks of understanding - the 'things we don't know we don't know'.

In my search for different typologies of incertitude that are relevant to environmental policy decisions, I also uncovered the notion of 'linguistic uncertainty'. This notion of 'linguistic uncertainty' was specifically discussed in relation to qualitative risk assessment processes (Hayes 2004). When risk assessments are performed in a qualitative rather than a quantitative sense, descriptions such as 'low risk' or 'high risk' are often used. Hayes (2004) suggests that this raises the problem of 'linguistic uncertainty' because the terms themselves are vague, ambiguous, lack a degree of specificity and fail to convey the context within which a particular proposition is made. The way particular words or phrases can be interpreted differently in various contexts or through divergent framing assumptions and values, seems to suggest that

'linguistic uncertainty' can perhaps be viewed as a subcategory of what I have described as ambiguity.

Additionally, Stirling (1999b) talks about the problem of incommensurability for processes of technological risk assessment and I would also consider this a form of ambiguity according to my classificatory scheme. As discussed by Stirling (1999b), incommensurability refers to the problem of comparing, weighing and prioritising different aspects and dimensions of technological risk during an assessment. For example, to what extent should economic and ethical concerns be incorporated into a risk assessment and how can they be compared when they have no common unit of measure? I view incommensurability as a problem that is intrinsically connected to the existence of divergent framing assumptions and values and therefore, classify it as a problem linked to ambiguity.

By providing a way to conceptualise new forms of uncertainty that arise in attempts to assess the environmental impacts associated with new technologies, these typologies highlight some of the limitations associated with traditional risk assessment processes. More specifically, these typologies highlight the way in which traditional risk assessment processes generally fail to take account of incertitude in the forms of ambiguity, indeterminacy, ignorance, and even uncertainty in some cases (Jasanoff 2003; Stirling & Gee 2002; Wynne 1992). Recognising this inadequacy of traditional risk assessment processes, particularly when applied to the environmental impacts of new technologies, is said to represent "the real justification and imperative for adopting newly emerging precautionary approaches" (Stirling & Gee 2002).

5. PRECAUTION

5.1 THE PRECAUTIONARY PRINCIPLE

While applying precaution in environmental decision-making may seem like common sense, the development of a formal precautionary principle for policy making was a modification of the German "Vorsorgeprinzip" (Boehmer-Christiansen 1994; Sand 2000; Fairbrother & Bennett 2003). This principle was articulated to justify regulatory restrictions placed on marine discharges into the North Sea despite the lack of scientific consensus about the causal relationships between these discharges and environmental harm (Wynne 1992). The precautionary principle has now been widely adopted in both national and international environmental legislation and is particularly prevalent in debates over regulating the environmental risks of new technologies (O'Riordan & Cameron 1994; Sand 2000; Stirling 2002; Stirling & Gee 2002).

An early definition of the principle that is commonly cited is from the 1990 Bergen Declaration of European Ministers, which states that "Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation" (cited in Levidow 2001). When the principle was formulated in the Rio Declaration that emerged from the 1992 United Nations Conference on Environment and Development (UNCED), the term "measures" was changed to "cost-effective measures" (Levidow 2001). The term "cost-effective" was added as an 'oral correction' by conference delegates from the US and received formal objections from both the European Union and Japan (Sand 2000).

While specific definitions of the precautionary principle differ between countries and pieces of environmental legislation (e.g. see Lofstedt et al. 2002; Sand 2000), common elements of what constitutes the principle can be

identified. Firstly, the precautionary principle demonstrates a proactive, preventive or anticipatory approach to controlling environmental harm, rather than a defensive or reactionary approach that seeks to remedy environmental harm only after it has occurred (Tait & Levidow 1992; Dovers & Handmer 1995). This can be viewed as a shift of environmental decision-making 'upstream' (Wynne 1992) where policy is aimed at identifying and avoiding potential sources of environmental harm before they occur rather than remedying the damage once it has already taken place. Additionally, a precautionary approach to environmental decision-making sees a shift in the burden of proof relating to environmental harm (Dovers & Handmer 1995; Fairbrother & Bennett 1999). Rather than the onus of proof resting with those claiming an action is environmentally harmful, it becomes the responsibility of those promoting a potentially damaging activity or technology to show that the degree of environmental change will be within tolerable bounds.

For the purposes of this chapter, it is the relationship between precaution and scientific uncertainty that is most pertinent. The precautionary principle represents a clear recognition of the existence of scientific uncertainty and suggests that it is important for decision makers to actively consider the limitations of scientific knowledge when making decisions about activities and technologies that are potentially harmful to the environment. When the precautionary principle is adopted as a guide for environmental policies, it becomes important to not only consider the weight of scientific knowledge when making a decision but also the limitations associated with that knowledge, the degrees of uncertainty involved and the implications of this uncertainty for preventing environmental harm.

5.1.1 Criticisms of the Precautionary Principle

While the precautionary principle can be seen to represent a shift in the basis for environmental decision-making, the extent to which it enables engagement with the full range of incertitude is debateable. Wynne (1992) suggests that some of the existing interpretations of the precautionary principle, although acknowledging the importance of uncertainty for environmental decision-making, do not necessarily dictate an engagement with the types of incertitude described in this chapter as ambiguity, indeterminacy and ignorance. This is because the understanding of 'a lack of scientific certainty' often adopted in application of the principle is one in which the only type of incertitude involved is conceptually reducible through further research. While the principle has therefore developed to provide guidance for what should happen under situations of scientific 'uncertainty', the criticism is that it does not necessarily enable or encourage an engagement with the important challenges associated with ignorance, indeterminacy and ambiguity.

Levidow (2001) suggests that while the precautionary principle certainly offers policy makers greater scope to acknowledge, clarify and engage with scientific uncertainty, this can also be problematic because full scientific certainty is rarely, if ever, claimed in relation to judgements of safety and therefore the degree of uncertainty involved with any decision can be viewed as ambiguous. Additionally, Levidow (2001) questions the usefulness of the "cost-effective" criterion in relation to environmental protection measures because this necessarily implies that there is adequate knowledge to predict the degree of potential damage and therefore enable an assessment of what a "cost-effective" measure for avoidance might be. Stirling (2002) also makes similar criticisms of the formulaic version of the principle suggesting that the idea of what counts as a threat, the criteria for judging seriousness or irreversibility, how the degree of

uncertainty is gauged and the yardstick for judging what is cost effective, are all issues for which no objective or single rational answer exists. This means that applying the notion of precaution as a dogmatic principle or rule is problematic at least and paralysing at worst.

The precautionary principle may represent a desire to shift the burden of proof but the issue of how far along the axis of 'guilty until proven innocent' decision makers need to slide is also problematic. Does adoption of the principle as a policy guide mean that decision makers are required to avoid an activity at the slightest hint of danger? What does it take to 'prove' innocence? What will constitute acceptable evidence? How will the inevitable tradeoffs between safety and costs be decided when weighing the available information against potential avoidance measures? These questions suggest that while the precautionary principle may be seen to represent admirable sentiments for environmental protection, important questions remain about how it is to be practically applied in political decision-making.

The questions and criticisms of the precautionary principle presented here are just the tip of the iceberg in relation to the debates over the principle's practical usefulness and how it can be translated into concrete decision-making processes[38]. The combined weight of the criticisms directed at the precautionary principle is driving an emerging theoretical shift away from discussions of how a specific 'precautionary principle' can be applied, towards a description of what a 'precautionary approach' to decision-making might entail. In this sense, the notion of precaution moves away from being a formulaic decision-making rule towards representing a particular approach to the process of dealing with certain types of problems.

[38] For a more detailed discussion of these debates see O'Riordan & Cameron (1994).

5.2 Precautionary Approaches to Environmental Decision-making

Based on an explicit recognition of the importance of scientific uncertainty for environmental decision-making, the precautionary principle has been influential in enabling an acknowledgement of the limitations of scientific knowledge for assessing the future environmental impacts of certain activities or technologies. In a precautionary *approach* to environmental decision-making, this translates into the requirement for a greater degree of humility about scientific knowledge in the face of various types of incertitude (Stirling 1999b; Stirling 2002; Stirling & Gee 2002). Associated with this need for a greater degree of humility about scientific knowledge is the requirement for a more reflective approach to science that enables the knowledge to be examined, reflected upon and considered in terms of the uncertainties, underlying assumptions and subjective judgements involved. This reflective approach to scientific knowledge can be undertaken by not only exposing particular knowledge claims to the scrutiny of various other scientific disciplines but also to stakeholders and the public more broadly (Stirling 2002) – i.e. to the type of 'extended peer review' described by Funtowicz & Ravetz (1993 & 1994) or the 'negotiated science' approach presented by Carr & Levidow (1999). This means that a precautionary approach broadens the notion of expertise and expands the evidence-base to include public views (Oreszczyn 2005).

The suggestion that precautionary approaches require humility and reflection on scientific knowledge supports constructivist understandings of risk and reiterates the already identified pattern of social science risk analyses calling for broad based participation and critical reflection in decision-making processes. Broad based participation in decision deliberations is certainly justified when

decisions involve value judgements and widespread uncertainties, but it is also said to be important for encouraging an engagement with the ambiguities involved in how science for policy is framed (Stirling & Gee 2002). In emphasising the importance of broad-based participation in precautionary decision-making processes, it is also important to note that the aim is not necessarily to achieve a consensus view, but rather, to create opportunities and processes that encourage transformative social learning for all parties involved (Stirling 1999b).

In addition to a reflective approach to scientific knowledge and the encouragement of broad based participation in decision-making processes, precautionary approaches are also said to require detailed consideration of the benefits and potential adverse effects associated with a *range* of alternative options (Fairbrother & Bennett 1999; Stirling 1999b; Willis & Rose 2000; Stirling 2002; Stirling & Gee 2002; Hindmarsh & Hulsman 2004). This means that a range of policy options for delivering a particular good or service need to be considered when a particular activity or technology is considered in a regulatory arena (Dovers & Handmer 1995; Willis & Rose 2000; Stirling 2002; Stirling & Gee 2002; Hindmarsh & Hulsman 2004; Levidow et al. 2005). This requirement suggests that decisions need not necessarily focus on what is the 'best option' but perhaps also on how to maintain diversity, resilience, flexibility and adaptability across a range of options (Klinke & Renn 2002; Stirling 2002). This represents not only a way to handle ambiguity (diversification offering a way to accommodate different values and interests) but also a way to approach the challenges associated with ignorance (when there are things we don't know we don't know, the best approach might be one focussed on flexibility and adaptability, or in other words, 'not putting all our eggs in one basket') (Stirling & Gee 2002). While the idea of making decisions to

encourage flexibility and minimise error costs may not be a new idea in itself, it does represent an important point of difference between what the precautionary principle says is important for decision-making and what is seen to constitute a precautionary approach.

Another important element of a proposed precautionary approach to environmental decision-making is the requirement for ongoing research and dedicated monitoring efforts (Klinke & Renn 2002; Stirling 2002; Stirling & Gee 2002; Hindmarsh & Hulsman 2004; Oreszczyn 2005). Through a commitment to ongoing research and environmental monitoring, the idea is that uncertainty can continue to be reduced and our degree of exposure to surprises that may arise due to our ignorance can be minimised (Stirling 2002; Stirling & Gee 2002).

In summary, then, important elements of what represents a precautionary approach to environmental decision-making are:

1. A recognition of the limitations of scientific knowledge and a willingness to expose scientific claims to critical reflection and 'extended peer review'.
2. A commitment to reducing uncertainties and minimising surprises generated by ignorance through ongoing research and monitoring.
3. A transparent handling of ambiguity and indeterminacy through broad based public participation and the consideration and implementation of a range of policy options.

In general, a precautionary approach represents a more inclusive and reflective process for decision-making than is currently used in conventional technocratic approaches to risk assessment.

5.3 Science/Risk vs Precaution/Uncertainty Based Approaches to Environmental Decision-making

Critics of using the notion of precaution in environmental decision-making will often emphasise the concept's vagueness and ambiguity, although this is usually done specifically in relation to the precautionary principle rather than the process based approach to precaution outlined above. These critics of decision-making approaches based around precaution often hold up 'science-based' assessment as being the preferred alternative. The traditional approach to risk analysis that has been described in this chapter as realist or positivist is that referred to when the term 'science-based' assessment is used. The claim that regulation should be 'science-based' as opposed to 'precaution-based' appeals to the traditional image of science as providing certain and objective knowledge, revealing the real world as it exists outside of social and cultural frameworks. The presentation of precaution- and science-based approaches as representing mutually exclusive decision-making strategies serves to suggest that precaution based approaches result in decisions that are not based on a rigorous scientific assessment of the 'facts'.

Of course, a constructivist understanding of scientific knowledge suggests that the 'facts' are always influenced by social factors and subjective framing assumptions. As a precaution based approach accepts this and attempts to provide a process for dealing with the various types of incertitude involved in environmental decision-making, this approach will usually be favoured by those adopting constructivist positions on the nature of scientific knowledge. It has, however, been argued that science-based and precaution-based approaches to environmental decision-making do not have to be conceptually separated on this basis and that, in fact, the type of precautionary approach outlined above holds a more authentic claim to what it means to be "science-based" than the

traditional narrowly framed approaches to risk analysis (Stirling 1999b; Stirling 2002; Stirling & Gee 2002).

The argument in this case is that denying the existence or relevance of the challenges associated with ambiguity, indeterminacy and ignorance for decisions involving the prediction of impacts in complex, interacting and open-ended systems does not really represent a rational or scientific approach to decision-making (Meyer et al. 2005; Stirling 1999b; Stirling & Gee 2002). As stated by Stirling & Gee (2002, p.530):

> *a precautionary approach's greater breadth of scope and attention to a greater diversity of information and knowledge could be considered more scientifically robust than the relatively narrow and uncertainty-suppressing tendencies of so-called science-based approaches like cost-benefit analysis and risk assessment*.

Risk analyses have traditionally proceeded under the belief that scientific knowledge is objective and certain. The challenges associated with applying this approach to decision-making to the environmental impact of new technologies have been made visible through social theories of risk and the conceptualisation of different types of incertitude involved. These challenges seem to require a new approach to decision-making that is better able to recognise social dimensions of risk, negotiate value differences and acknowledge and handle the different types of incertitude involved; an approach that recognises the limitations of scientific knowledge, engages the public and a range of different stakeholders in decision deliberations, assesses a range of different policy options and focuses on the fostering of diversity,

resilience, flexibility and adaptability. This type of approach can be characterised as 'precaution' rather than 'science' based[39].

In discussing the distinction between 'science' and 'precaution' based approaches to decision-making, I do not mean to imply that approaches using scientific information cannot involve the adoption of a position of caution or that precautionary approaches do not involve the use of scientific knowledge or experts. Rather, the important distinction is in the role and degree of influence awarded to scientific knowledge and expertise. In science or risk-based approaches to decision-making, science has traditionally held a monopoly on authority, whereas in precaution-based approaches, science is recognised as having limitations and this enables a plurality of rationalities and value sets and a broader range of concerns to be recognised and embraced in the decision-making process.

Calling these different approaches to decision-making 'science' and 'precaution' based may be misleading and therefore we might better conceptualise the key differences existing between these approaches as differences between a technocratic and a democratic approach to decision-making, or between an approach based primarily on analysis of risk and an approach that balances this with the deliberative negotiation of incertitude. With this in mind, I will refer to the two ends of the spectrum created by these contrasting alternatives as 'science/risk' and 'precaution/uncertainty' based approaches to environmental

[39] Some decision-making processes that claim to represent a more 'precaution-based' approach to environmental decision-making include multi-criteria mapping (see Stirling 1997; Stirling & Mayer 1999) and alternatives assessment (see O'Brien 2000).

decision-making[40]. Presenting these approaches as ends of a spectrum does not mean that I necessarily see precaution/uncertainty based approaches as something completely separate from those based on science/risk. Science-risk based approaches to decision-making can be conceptualised as a starting point to which various layers (such as critical review and public participation) may be added until a different approach (described here as precaution/uncertainty based) is created. The variety of layers and ways in which they can be applied creates shades of difference between the two approaches that allows them to be conceptualised as defining ends of a spectrum. The type of decision-making that is favoured in any given situation will depend to a substantial degree on the nature of the problem at hand, the extent to which a regulatory body adheres to a realist or a constructivist position on scientific knowledge and risk, and/or the degree to which technocratic politics and ideology have become entrenched.

6. CHAPTER CONCLUSION

In this chapter, I have broadly surveyed the theoretical literature on risk and uncertainty in environmental decision-making and have identified a number of key tensions and debates. In the first instance, I identified the tension between realist and constructivist approaches to risk. In discussing how these different approaches frame how public risk assessments are understood, I presented the findings and criticisms of both the psychometric and cultural theory literature.

[40] Adopting this terminology allows me to engage in debates currently using the language of science vs precaution based decision-making, while at the same time emphasising the distinction between a focus on quantifying risk and negotiating uncertainty that I personally prefer. I would, however, like to reemphasise that I do not see quantifying risk and negotiating uncertainty as mutually exclusive approaches to decision-making, in fact, I consider it imperative that they be integrated. In adopting the framework of a spectrum of approaches ranging from science/risk to precaution/uncertainty based, I simply mean to distinguish between those approaches to environmental decision-making that are structured solely around a scientific quantification of risk, and those that build on this scientific basis by actively seeking to balance it with a deliberative negotiation of incertitude.

For my research project on Australia's regulation of GM crops, I highlight the following points from the psychometric theory as particularly important:

- The public often demonstrates sensitivity to non-statistical factors in their assessments of technological risks.
- To minimise ongoing technological controversies, regulators would do well to consider and be transparent about how factors such as controllability, reversibility, familiarity, catastrophic potential, potential to impact on future generations etc. influence decisions on risk acceptability.
- In relation to GM crops and the question of environmental or ecological risks, regulators would be well advised to consider the factors that have been identified as important in public risk assessments. These include factors such as the nature of the application, the species involved, ethical questions and the potential benefits for humans.
- For environmental risks, it is important that regulators clearly identify the system under investigation and the environmental endpoints for the assessment process.
- To incorporate the broader, more contextual and holistic factors that are of concern in public risk assessments, formal risk assessment processes would need to reimagine the role for expertise, provide for a two way system of communication with members of the public and encourage increased public participation and deliberative decision-making processes during the assessment of technological risks and their acceptability.

The important considerations for regulatory decision-making that I draw from the cultural theory body of work include:

- The notion that risk debates may be influenced by cultural biases and different beliefs about nature, and
- Decision-making should allow for different ideologies and worldviews to be included in deliberations and this objective would be supported if avenues for broad-based public participation were available.

After presenting the findings and criticisms of psychometric and cultural theories of risk, I went on to discuss some of the degrees of difference within the constructivist camp and raised questions about how constructivist approaches to science and risk can positively and practically contribute to the policy process. From this discussion I note the following points of importance for regulatory decision-making on the environmental impact of GM crops:

- Scientific knowledge and advice used in formal risk assessments should be exposed to critical reflection to reveal hidden assumptions and value judgements.
- Analytic and deliberative processes need to be integrated for decision-making.
- Deciding the most appropriate role for science and the way in which analysis and deliberation can be integrated will be assisted by the consideration of the different types of incertitude involved in decision-making.

As this final point suggests, it is important for policy makers to recognise different types of incertitude. In this chapter I outlined different typologies of incertitude and highlighted the types of incertitude that can arise in assessing the environmental impacts of new technologies, specifically those of ambiguity, ignorance and indeterminacy. I then introduced the notion of a process based approach to precautionary decision-making (as opposed to the simple

application of a single precautionary principle) as an approach that seeks to directly engage with the challenges associated with uncertainty and the types of incertitude I described as ignorance, indeterminacy and ambiguity.

I suggested that a process-based approach to what it means for decision-making to be precautionary would include:

- A recognition of the limitations of scientific knowledge and a willingness to expose scientific knowledge to critical reflection and a process of 'extended peer review'
- A commitment to reducing uncertainties and minimising surprises generated by ignorance through ongoing research and monitoring
- A transparent handling of ambiguity and indeterminacy through broad based public participation and the consideration and implementation of a range of policy options.

From the survey of the theoretical landscape on risk and uncertainty in environmental decision-making presented in this chapter, I therefore distinguish two ends of a spectrum of approaches that can be adopted towards environmental decision-making – a traditional technocratic approach that is solely focussed on a scientific quantification of risk, and an emerging approach that seeks to balance scientific analysis with broad-based negotiations of incertitude. I describe these as 'science/risk' and 'precaution/uncertainty' based approaches to environmental decision-making. The key themes that can be used to distinguish these approaches include: the discourse employed for decision-making, the authority granted scientific knowledge, the avenues available for public participation, the requirements for ongoing research and monitoring, and the range of policy options considered. According to this synthesised theoretical framework, the precaution/uncertainty based approach represents

the most appropriate way to structure decision-making processes for the environmental regulation of GMOs. This is because this approach seeks to directly engage the problems identified in the context chapter as facing environmental decision-making on GM crops – the existence of contested values and widespread scientific uncertainty. Exactly how I use this theoretical framework to structure my analysis and critical appraisal of Australia's environmental regulation of GM crops is outlined in the following chapter describing my research methods.

METHODS:
ANALYSING AUSTRALIA'S REGULATION OF GM CROPS

CHAPTER OUTLINE

This chapters details the particular research methods I have developed to structure my investigation into Australia's environmental regulation of GM crops. It is divided into three key sections. In the first section, I describe my method for analysing how Australia's environmental regulation of GM crops has been framed by legislation. This method is informed by the theoretical framework developed in the previous chapter that 'precaution/uncertainty' based approaches, that balance scientific analysis with means for negotiating incertitude, are more appropriate for environmental decision-making on GM crops. This section describes how the key themes I identify as characterising a 'precaution/uncertainty' based approach to environmental decision-making are used to structure my investigation into the framework of Australia's regulatory system.

The second part of this chapter describes the method I have developed for my analysis of the practice of Australia's environmental decision-making on GM crops. This analysis proceeds through a detailed deconstruction of a case study scientific risk assessment. The risk assessment I have selected for this detailed analysis is that conducted by the Office of the Gene Technology Regulator on the GM crop Bt cotton, and specifically, the assessment related to its impacts on non-target organisms. The second section of this chapter therefore describes and justifies the criteria and questions I use to guide my deconstruction of the scientific risk assessment of Bt cotton's impact on non-target organisms.

As I use Bt cotton as a case study for the final empirical part of this thesis, the third key section of this chapter provides more information on this GM crop. This involves a description of what Bt cotton is, how it operates, why it was developed, why I selected it as a case study crop and why I have chosen to focus on the issue of non-target impacts. This chapter therefore describes the methods I have developed for my analysis of Australia's environmental regulation of GM crops (organised around my two key analytical themes of the regulatory framework and the practice of decision-making) and concludes with the provision of background information on my case study crop of Bt cotton.

1. METHODS

In this section I describe the particular research methods I have developed to structure my investigation into Australia's environmental regulation of GM crops. While the presentation of these methods may indicate that they were simply developed and then applied, in actual fact, the articulation of method provided here represents the culmination of an iterative process. Therefore, while I present a rather static image of research methods in the below description, it is important to highlight that both my research problem and the way I went about investigating it have developed and evolved throughout the life of the research project and in response to it.

1.1 THE REGULATORY FRAMEWORK

My examination of the framework for the environmental regulation of GM crops begins with a description of the history of gene technology regulation in Australia and a discussion of the impetus and development of the current system. I then provide a general description of the current regulatory system and in doing so, focus on the decision-making process established for the deliberate environmental release of GMOs. Having provided some background detail on the history of the regulatory system and its general structure, I then go on to analyse the framework for decision-making in detail through a process of policy analysis. As I am particularly interested in having my research contribute to the planned review of Australia's current gene technology legislation and its operation, the focus of my analysis is the current system and specifically, the piece of legislation that created it, the Gene Technology Act 2000 (the Act).

My analysis of the Act and the regulatory system it established is predominantly structured around the theoretical framework developed in the

previous chapter through my survey of the literature on risk and uncertainty in environmental decision-making. Specifically, I am interested in whether Australia's regulatory framework can be more accurately characterised as a 'science/risk' or 'precaution/uncertainty' based approach to environmental decision-making. Through my review of the theoretical literature, I identified a number of key themes that distinguish these different approaches to decision-making. These include:

1. The discourse employed for decision-making,
2. The authority granted scientific knowledge,
3. The avenues available for public participation,
4. The requirements for ongoing research and monitoring, and
5. Whether or not a range of policy options is considered.

In my chapter on the regulatory framework, I therefore analyse the current regulatory system and the legislation that established it in relation to these key themes. I also question the independence of the key decision maker as an additional important issue.

In addition to using this theoretical framework to analyse the Act and the regulatory system it established, I also consider the Gene Technology Bill (the Bill) that preceded the Act and give particular consideration to a Senate inquiry conducted into the Bill. In drawing on the Senate inquiry, I am particularly interested in how the debates and recommendations arising from this inquiry relate to the themes listed above as distinguishing science/risk and precaution/uncertainty based approaches to decision-making. This means that where the issues raised in the inquiry connect with my key analytical themes, I consider how these issues were debated before the Act was finalised, what recommendations were made by the Senate committee on these matters and

how the debates and recommendations were addressed in the development of the Act. This provides my analysis with some historical depth as it allows me to consider the development of the regulatory system in relation to my theoretical framework.

It is also worth noting that, while my research is primarily structured around an analysis of the regulatory framework as created by the Act, I do draw on additional sources when I feel they are important to the key themes of investigation. For example, in addition to the Act and the Senate inquiry into the Bill, another important document framing regulatory decision-making is the Risk Analysis Framework developed and used by the Office of the Gene Technology Regulator (OGTR). I particularly draw on this document in my discussion of the discourse of decision-making and the authority granted scientific knowledge. Additionally, I refer to documents such as the consensus conference lay panel report, communiqués released by advisory committees to the regulator and sections of risk assessment and risk management plans as appropriate and relevant to the analysis. These additional documents are primarily used to supplement my analysis with the core of my research concern remaining how the Gene Technology Act 2000 has framed Australia's current regulatory system for the deliberate environmental release of GMOs.

1.2 The Practice of Decision-making – A Case Study of Scientific Risk Assessment

In the final empirical chapter of my thesis, I explore the practice of decision-making through a detailed deconstruction of a case study scientific risk assessment. The risk assessment I use as a case study is that conducted by the OGTR on Bt cotton and non-target organisms. This case study deconstruction represents what I see as a form of 'extended peer review'.

The term 'extended peer review' has been taken from Funtowicz & Ravetz (1992a&b; 1993; 1994) who suggest that when policy problems involve disputed values, high levels of uncertainty and high decision stakes, the exercise of quality assurance requires review not just by a scientific community of peers, but by an 'extended peer community'. In other words, when science is used in a policy setting for issues involving high degrees of uncertainty and disputed values, the assurance of quality and reliability requires review by a broader or extended community of peers (Jasanoff 2003). The survey of social science literature presented in the previous chapter offered extensive support for this notion of exposing policy science to critical reflection, deconstruction, negotiation and review by those outside the scientific community, especially when contested values and widespread uncertainty are involved. In this thesis, I have described the existence of contested values and scientific uncertainty as conditions under which Australia must make regulatory decisions about the deliberate environmental release of GM crops. This means that it is a policy problem where review by an extended community of peers becomes important for ensuring quality and reliability in the way science is used in decision-making.

In using the term 'extended peer review', I mean to refer to a process where science used in a policy setting is reviewed by those not traditionally seen as 'peers'; those who may not be specialists in the scientific discipline involved, but who bring other relevant knowledge and skills to the process of review. In adopting the term I am suggesting that when science is used in a policy setting involving contested values and widespread scientific uncertainty, the process of reviewing the quality and reliability of this information and its use, will benefit from a peer community that is broader than simply other disciplinary

specialists. Specifically, it will benefit from review by scientists working outside the field in question, by social scientists interested in science, technology and policy, and by interested members of the community who may have experiential or interactional expertise[41] or a good generalist understanding of scientific knowledge and processes. To draw out hidden values and assumptions, the process of extended peer review will particularly benefit from the involvement of people holding a different set of values to those represented in the research and exercised during the assessment[42].

While these groups of people are not those traditionally understood as 'peers' capable of reviewing scientific information, the argument being made here is that when science is used for policy decisions involving contested values and uncertainty, the types of knowledge and experience relevant to the review process can legitimately be expanded. It is because the process of critical reflection in these cases requires consideration of issues beyond technical concerns that this broader community of people can engage in the review process as 'peers'.

Seeing myself as a member of this extended peer community (based on my education and training as a generalist scientist and policy analyst[43]), I therefore review Australia's regulatory assessment of the risk Bt cotton poses to non-

[41] For an explanation of this form of expertise see Collins & Evans (2002).
[42] Although I don't limit it to a particular discipline, I do imply that to conduct the type of extended peer review I describe and undertake in this thesis requires some form of education, training or relevant experience. While I would certainly argue that laypeople with no particular education and/or training have an important role to play in technology policy debates, I would suggest that rather than engaging in the process of review I propose in this thesis, their participation may be better directed towards engagement in broader debates over environmental endpoints, future visions and the relevant criteria for assessment and review. This said, should an interested member of the public wish to engage in the form of review I describe in this thesis, I would certainly not advocate their exclusion based on a lack of qualifications.
[43] For more information on this background see the 'Preface' section of the Appendix.

target organisms with a particular view to questions of quality and reliability in how science has been used in the practice of risk assessment.

My primary aims in conducting this extended peer review of a particular risk assessment are:

1. To challenge the claim that risk assessment is an objective process (OGTR 2002a, p. 15),
2. To highlight the contribution social science analysis of scientific risk assessment can make to regulatory decision-making and
3. To develop a framework for deconstructing expert risk assessments that others can use as a tool to operationalise the notion of extended peer review.

In conducting this extended peer review that deconstructs a particular risk assessment, I adopt a position of moderate constructivism as a way of fusing realist and constructivist epistemologies. As described by van Zwanenberg & Millstone (2000), a position of moderate constructivism suggests that although all scientific studies and assessments of risk are constructed, these constructions can be judged as more or less reliable and robust. Van Zwanenberg & Millstone (2000) suggest that policy analysts can make judgements about this relative reliability by examining the extent to which scientific studies and risk assessment practices are consistent with the standards and beliefs that are held (both individually and collectively) to be the most coherent. Through exploring how well or poorly knowledge claims have been constructed according to these standards and beliefs, van Zwanenberg & Millstone (2000) propose that social science analysts can make a positive and critical contribution to science, sociology and policy.

In conducting my extended peer review of the OGTR's assessment of the risk Bt cotton poses to non-target organisms I will consider the risk assessment document and all of the scientific studies cited within it and will be particularly focussed on three broad questions:

1. What is the reliability of the cited scientific sources?
2. How has the scientific information been used? and
3. How adequate and appropriate are the conclusions drawn?

This means that, in the first instance, my review is concerned with evaluating the reliability of the scientific studies cited in the risk assessment. To do this, I have created a list of criteria for the evaluation process that have been shaped by traditional (collective) standards and beliefs about what constitutes quality in scientific studies; collective standards originating from within the scientific community. The first criterion relates to the independence of the scientific researchers, the second, third and fourth can be interpreted as relating to the relevance of the study for the risk assessment, while the fifth, sixth and seventh are concerned with evaluating the study's rigour.

The information given in brackets for each of these criteria listed below represents a scale of increasing strength of the evidence. This notion of the strength of evidence increasing with peer review status and fit to ecological reality is one supported by Australia's regulatory body, the Office of the Gene Technology Regulator (OGTR). In describing different types of evidence and their strength, the OGTR's Risk Analysis Framework (2004) places "unsubstantiated statements" at the bottom as the weakest type of evidence, "commissioned research" a little higher, "peer-reviewed experimental data on the parent organism, modified traits or ecology" higher again and "peer-reviewed experimental data on the GMO in the Australian environment" at the

top as the strongest type of evidence available. This means that the criteria informing the first level of my analysis are based on standards and beliefs that are collectively accepted as coherent by both the scientific community and our current regulatory agency.

The criteria developed for the first level of my review relating to the reliability of cited scientific studies are as follows:

1. **Who performed the study?** - (applicant, unreviewed data; applicant sponsored researchers, unreviewed data; independent researchers, unreviewed data; applicant, peer-reviewed data; and independent researchers, peer-reviewed data).
2. **Where was the study conducted?** (in controlled laboratory conditions; in field trials outside Australia; in commercial production outside Australia; in field trials in Australia; in commercial production in Australia).
3. **What was the test material?** (insecticide formulation; purified toxin (not Cry1Ac); Bt plant (not Cry1Ac); purified toxin (Cry1Ac); Bt plant (with Cry1Ac); Bt cotton (with Cry1Ac)).
4. **What was the exposure pathway?** (increasing in strength with fit to pathway of actual ecological exposure experienced by an organism)
5. **What was the length of the study?** (days, weeks, months, multiple growing seasons/generations, years – considered in context of the organism and its lifespan)
6. **What was the size of the study?** (relates to sample size and the diversity of organisms tested (strength generally increasing with numbers[44]) and

[44] It is important to highlight that what makes an adequate sample size relates to the degree of variability observed in the experiment. An experiment with results showing a high degree of variability requires a larger sample size to give confidence in the mean.

also to size of field plots and number of different locations when performed outside a laboratory)

7. **How many repetitions were made?** (relates to whether the results have been corroborated by other experiments, either by the same group of researchers or by others (strength increasing with number of repetitions and diversity in researchers performing repetitions))

Following my review of the risk assessment in terms of these kinds of traditional scientific criteria for reliability assessment, I go on to consider how science has been used in the assessment process. In this level of analysis I am primarily concerned with exploring the risk assessment in terms of the broadly accepted quality criteria of: accuracy in representation, consistency in treatment and comprehensiveness of information. The types of issues and illustrative questions I use to structure this level of my review include:

1. **Depth of Critique** (e.g. Have the methods used in the cited studies been subject to critical scrutiny in the risk assessment? Has the same depth of critique been applied to all studies?)
2. **Interpretation** (e.g. Does the interpretation of the studies given in the risk assessment match that provided by the authors? Is information from the studies selectively used? Is any uncertainty or need for further research identified in the study also communicated in the risk assessment?)
3. **Assumptions** (e.g. What assumptions are made in the studies and the risk assessment's interpretation of them? Are assumptions consistently applied in the risk assessment? Have the assumptions been tested for reasonableness?)

4. **Values** (e.g. What values are revealed by problem definitions and research frameworks? What values are evidenced in the way inferences are made?)
5. **Comprehensiveness** (e.g. Are there other peer-reviewed and publicly available studies that could also have been used in the risk assessment?)

This second level of my review adopts a more constructivist position on the nature of scientific knowledge and the process of risk assessment and as the criteria demonstrate[45], is concerned with highlighting any assumptions and/or values embedded in the risk analysis and exploring how broader issues of incertitude (such as ambiguity, indeterminacy and ignorance) have been addressed. In reviewing the risk assessment in light of this set of criteria, I am particularly focussed on my second broad question, namely the way in which science has been used in regulatory decision-making.

To explore my third broad question of how appropriate and adequate are the conclusions drawn from the risk assessment, I combine the more objectivist and constructivist elements of my review. This involves pulling together my analysis of the reliability of the cited scientific studies and how they have been used in the construction of the assessment to question the conclusions that have been drawn and to critically consider whether alternative or additional conclusions could be supported.

[45] It is worth noting that some of these more constructivist type criteria would also be viewed as important by objectivist scientists. For example, scientists would undoubtedly support the notion that policy decisions should be based on comprehensive information and that all information should be subject to critique. I have chosen to separate these criteria from the more traditional ones relating to scientific quality because, in my review, I use these criteria primarily to discuss the way in which science has been used, rather than to evaluate the reliability of the scientific studies *per se*.

The analysis presented in this part of my thesis really highlights the transdisciplinary nature of my research project, and particularly, the way it works across the boundary between biological science and science and technology studies (STS). For example, in the first part of my review I am concerned with the reliability of the cited scientific sources and conduct my analysis as a generalist scientist. In the second level of analysis where I am more concerned with the way in which science has been used in the assessment, I am drawing on STS theory and conducting the analysis primarily as a social scientist. Through combining these analyses in my discussion of the adequacy and appropriateness of the assessment's conclusions, my research serves to demonstrate the constructed nature of the divide between science and STS and highlights the value of the boundary crossing implicit in transdisciplinary research.

2. CASE STUDY DESCRIPTION: BT COTTON

As I have already indicated, my review of the practice of regulatory decision-making uses a particular GM crop, Bt cotton, as a case study. In this section, I provide some background information on this crop and the reason why I selected it as a case study.

2.1 WHAT IS BT?

Bt is an acronym referring to the bacterium *Bacillus thuringiensis*, which is commonly found in the soil and insect-rich environments such as grain storage facilities (Lambert & Peferoen 1992). This bacterium is Gram-positive, rod-shaped and spore forming. During sporulation, Bt produces insecticidal crystal proteins within the cell, which are released into the environment when the cell wall of the spore degrades (Lambert & Peferoen 1992). These insecticidal crystal proteins vary in shape and size according to the subspecies of Bt that produces

them (Goldburg & Tjaden 1990) and the different proteins produced have a toxic effect on the larvae of different insect orders (Hofte & Whitely 1989, Lambert & Peferoen 1992). The subspecies that has been most widely used in agriculture, *Bacillus thuringiensis* var. *kurstaki* (*B.t.k*) (Salleh 1998), produces bipyramidal crystals consisting of what are known as 'delta-endotoxin' proteins (Goldburg & Tjaden 1990). There are three types of delta-endotoxins that have been used against insects, the Cry toxins, the Cyt toxins and the recently characterised binary toxins (Frutos 2002). The Cry toxins comprise 32 families and 202 members and are of specific interest to this thesis because they are the only Bt toxins currently found in commercialised GM crops (Frutos 2002).

Microbial formulations of *B.t.k* have been used as biopesticides for over 40 years (Perlak et al. 1990) with the first Bt preparation registered as an insecticide in the United States in 1961 (Goldburg & Tjaden 1990). These Bt formulations are one of the very few sprays permitted within certified organic farming. Bt formulations have been viewed as a relatively environmentally benign way of controlling insects (Frutos 2002; Lambert & Peferoen 1992) because the toxic compounds are seen to have a narrow range of activity, primarily limited to certain insect orders, and because the toxic compounds degrade within days when exposed to UV light (Salleh 1998). While these characteristics have seen substantial attention directed towards understanding Bt toxins, their mode of activity and developing novel delivery systems such as GM plants, it has been suggested that far less research has been conducted into more fundamental questions of the distribution and ecology of *Bacillus thuringiensis* (Lambert & Peferoen 1992; Glare & O'Callaghan 2000, p.19). The ecology of Bt in soils and their natural environments has been indicated as a particular area requiring more fundamental research (Lambert & Peferoen 1992).

2.2 The Mode of Action of Bt Toxins

While some uncertainty remains about the mode of action of Bt toxins (Adang et al. 2002; Heckel 2002; Clark et al. 2005), there is a level of understanding that currently has broad agreement (Heckel 2002). The crystal protein inclusions contained within Bt spores are protoxins, or toxin precursors, that require degradation to become toxic to the insects (Heckel 2002). When an insect ingests a Bt spore, the highly alkaline environment of the insect midgut (8-10 pH) dissolves the crystal and releases the proteins from the inclusion (Heckel 2002; Murphy 2003). In the midgut, digestive proteases work to break down the protoxin until only a protease resistant core remains (Heckel 2002). This core represents the active toxin. When released from the protoxin form, Cry proteins move through the peritrophic sheath (a membrane contained within the midgut of insects) to the microvilli of the midgut epithelial cells (Heckel 2002). The midgut epithelium is a sheet of tightly bound cells lining the surface of the midgut and the microvilli are thin foldings of the cell surface which form brush borders. On these brush borders, there are believed to be sites and molecules capable of binding Cry1 toxins (Adang et al. 2002). These are referred to as receptors. Three different molecules have so far been identified as capable of binding Cry1 proteins: Aminopeptidases, Cadherins and other Glycoconjugates (Adang et al. 2002; Clark et al. 2005). The role and importance of these different molecules in binding Cry1 proteins is said to require further investigation (Adang et al. 2002; Angelucci 2002).

After binding to receptors on the midgut brush border membrane, the toxin molecules undergo a conformational change that allows them to insert themselves into the lipid bilayer of the gut (Adang et al. 2002; Heckel 2002). This is followed by a process of oligomerisation (or joining together of several molecules) that causes pores to form in the membrane (Adang et al. 2002).

These pores increase the permeability of the membrane (Adang et al. 2002) and the epithelial cells start to swell and break open in a process known as cell lysis. Cell lysis is thought to be due to the increased flow of water and solutes through the pores (Heckel 2002). At this point, the insect larvae stop feeding and starvation and/or the damage done to the midgut epithelium results in death (Heckel 2002). It is worth noting that other life processes are negatively affected by the ingestion of Cry proteins (e.g. the blocking of amino acid transport) but, at this stage, it is unclear whether these changes contribute to the death of the insect larvae (Heckel 2002).

2.3 WHAT IS BT COTTON?

Bt cotton refers to cotton plants that have been genetically modified to express delta-endotoxins from the soil bacterium *Bacillus thuringiensis* var. *kurstaki.* In Australia, there are essentially two different types of Bt cotton. The first generation Bt cotton has been marketed in Australia under the name INGARD®. INGARD® cotton has been genetically modified to express the Cry1Ac protein from Bt that is toxic to Lepidoptera (the order of insects commonly known as moths and butterflies). The other type of Bt cotton that has been approved for commercial release in Australia is a second generation development modified to express the Cry2Ab as well as the Cry1Ac toxin. This Bt cotton has been marketed in Australia under the name Bollgard II® and has been designed to give increased control over Lepidopteran pests by expressing higher levels of toxin over longer time periods (OGTR 2002b, p.13). This second generation Bt cotton has also been combined with cotton varieties resistant to the herbicide Roundup® to create what is known as Bollgard/Roundup Ready® varieties. In this thesis, I focus on the INGARD® variety and am primarily concerned with examining how the application for the commercial release of this crop was handled by the Australian regulatory system (as opposed to

applications for initial developments and field trial testing). In the following paragraphs I describe the process used to create this particular Bt cotton variety.

While it is often stated that INGARD® cotton has been modified by the insertion of the Cry1Ac gene from Bt, this is in fact a misleading statement that simplifies the actual process involved. Transformation events using the Cry1Ac gene from Bt, or what is referred to as the "wild-type *B.t.k.* insect control protein gene", resulted in low levels of toxin expression in the cotton plants that were insufficient to control insect pest attack (Perlak et al. 1990). This lead to the development of a number of modifications in the genetic material used in the transformation process and how it was transferred so as to increase the toxin expression levels in the plants and create commercially viable varieties of Bt cotton.

One of the means used to increase the expression of the Bt toxin in the modified cotton plant was the use of an "improved" promoter (a sequence that 'promotes' the expression of the gene) in the form of the 35S promoter from the cauliflower mosaic virus with a duplicated enhancer region (Perlak et al. 1990). The other significant factor used to improve expression levels in the modified plants was "modifications of the truncated structural gene" (Perlak et al. 1990). It was found that the genes expressing the *B.t.k.* insect control protein at the highest level in cotton plants were ones that were "significantly altered and retained less than 80% DNA homology to the wild-type sequence" (Perlak et al. 1990). In the effective, highly modified, truncated variant of the Cry1Ac gene, the first 453 amino acids are the same as an analogous region of the Cry1Ab protein, while the remaining amino acids (from 454-615) are from the coding sequence of Cry1Ac (Perlak et al. 1990).

What this means is that, to create cotton plants capable of expressing the desired levels of Cry1Ac protein, biotechnologists created a synthetic version of the Cry1Ac gene that was shortened (or truncated) and which had DNA sequence modifications involving both Cry1Ab and Cry1Ac genes. Despite these differences between the wildtype gene for Cry1Ac production and the chimeric, truncated, synthetic version used to create Bt cotton plants, both are said to create the same active form of the Cry1Ac toxin (Murphy 2003). While the modified cotton plant produces a protoxin that is derived from both Cry1Ab and Cry1Ac (Murphy 2003), when this protoxin is cleaved or degraded in the midguts of susceptible insects it is said to result in an active Cry1Ac toxin that is identical to that produced by ingestion of the bacterial spores (Murphy 2003). While the active toxin released in the insect midguts may be the same, it is important to realise that the creation of Bt cotton has not occurred through the simple insertion of a Bt gene for Cry1Ac production into cotton plants. The inserted gene is in fact a synthetic and highly modified version of the wildtype gene. This constructed gene is patented property of the Monsanto corporation.

In addition to this synthetic, modified, truncated gene for Cry1Ac production, there are a number of other pieces of DNA (combined in what is called a gene cassette) used in the creation of INGARD® cotton. These include two antibiotic resistance genes taken from *Escherichia coli*: neomycin phosphotransferase II (nptII), which confers resistance to the antibiotics kanamycin and neomycin, and aminoglycoside adenylyltransferase (aad), which confers resistance to spectinomycin and streptomycin (OGTR 2003a, p.13; OGTR 2003b, p.53). The nptII gene is also followed by a nopaline synthase 3' region that has been taken from the bacterium *Agrobacterium tumefaciens* (OGTR 2003b, p.53). These antibiotic resistance genes have been transferred into the cotton plants to function as selectable markers, i.e. they allow successful transformation events

to be tested for because when antibiotics are used in the growing medium only those cells containing the transferred DNA are able to resist the effects of the antibiotics and survive.

As gene expression in plants relies on different regulatory sequences than those used by bacteria, the regulatory regions of the wildtype Cry genes have been replaced during the creation of INGARD® cotton by sequences taken from another plant and a virus (Murphy 2003). The gene cassette used in the creation of Bt cotton contains a modified (enhanced) 35S promoter from the cauliflower mosaic virus that works to 'turn on' the expression of the transferred genes (OGTR 2003a, p.14; OGTR 2003b, p.53). There is also a sequence of DNA that works to terminate transcription (referred to as 7S 3') that has been taken from a soybean. The diverse package of DNA contained in the gene cassette was transferred into the genome of cotton plants using *Agrobacterium tumefaciens* as a vector. In Australia, the patented gene construct was transferred into varieties of cotton developed to be particularly suited to Australian conditions and this process involved collaboration between Monsanto and the primary public research institute of Australia, the Commonwealth Scientific and Industrial Research Organisation (CSIRO) (CSIRO 2004; Salleh 1998).

2.4 Motivation for Development

Cotton represents one of Australia's most important rural exports, contributing around $(Aus)1.7 billion per annum to the economy (CSIRO 2004). Despite this substantial contribution to the Australian economy, the practice of farming cotton is not free from public criticism. While one of the major concerns relates to the amount of water used to irrigate cotton fields during production, the cotton community has also become increasingly aware of public concerns over their extensive use of synthetic chemicals (Cotton Research and Development

Corporation 2001, p.31). Cotton is one of the most heavily sprayed crops in Australian agriculture (Salleh 1998) and public concerns over the extensive use of agricultural chemicals do not just relate to issues of human health, but also to the potential environmental impacts of synthetic chemicals.

Many of the sprays used in Australian cotton fields are pesticides, synthetic chemicals applied to control the organisms that feed on cotton plants and decrease production levels. In fact, the cotton industry is currently spending around $(Aus)250 million a year on pesticides (CSIRO 2004). The most dominant and problematic insect pests of cotton in Australia are the larvae of *Helicoverpa armigera* and *Helicoverpa punctigera* (Fitt & Wilson 2002). *Helicoverpa armigera* has proved to be a particularly difficult pest to handle in recent years as it has successfully developed resistance to a broad range of the synthetic chemicals applied for its control (Akhurst et al. 2002). Genetically modified Bt cotton has largely been developed and adopted as a way of addressing these dual problems of the widespread pesticide resistance within *Helicoverpa armigera* populations and increasing public concerns over the environmental impact of synthetic chemical use. Bt cotton can therefore be seen to have been developed to serve the dual purpose of maintaining pest control in monocultural cotton crops but doing so in a way that is seen to be more environmentally friendly.

2.5 Reason for Selecting Bt cotton as a Case Study Crop

Bt cotton, specifically the INGARD® variety, was the first broadacre GM crop to be grown commercially in Australia, with the first round of commercial plantings beginning in 1996 (CSIRO 2004; Salleh 1998). At this time there was only a voluntary regulatory system in place and the Genetic Manipulation Advisory Committee (GMAC), the non-statutory body that was overseeing the

environmental release of GMOs at the time, advised a limited commercial release. The commercial release was limited to those parts of Australia where native cotton varieties are not found, i.e. south of 22 degrees latitude. At this time, Bt cotton was registered with the National Registration Authority (NRA) as a pesticide and as part of a program to control the spread of insect resistance to the Bt toxin, the NRA (in consultation with scientists and stakeholders) limited INGARD® plantings to no more than 30% of acreage planted with cotton. When the current regulatory system for GMOs commenced in 2001, INGARD® was granted a deemed licence, to be revised after 2 years. In June 2003, Monsanto submitted an application to the OGTR for the continued commercial release of INGARD® cotton.

My interest in using INGARD® as a case study crop was motivated by a number of factors. When I began this thesis in mid-2002, INGARD® was the only broadacre GM crop being grown commercially in Australia. This made it an obvious choice for a case study. Importantly though, it was also a GM crop that would pass through the newly developed regulatory system during the early stages of my PhD research as the deemed license expired and a license application had to be submitted for continued commercial production. This meant that I would be able to observe and participate in the regulatory decision-making process for this particular crop from beginning to end during my thesis research and this also made it an appealing case study choice.

As the first GM crop grown in Australia and one which was given a deemed licence by the current regulatory system for 2 years, it was also arguably the crop for which one might expect the most extensive research on environmental impacts to exist. The licence application for INGARD® that was submitted in 2003 should represent the most comprehensive information available in

Australia on the environmental impacts of a GM crop because not only had it completed a period of field trials at the time the licence application was submitted, it had also had 7 years of commercial production during which information on environmental impacts could be gathered. Other licence applications for commercial release that could now be examined have not had this same opportunity for data collection. I therefore decided that the licence application for Bt cotton would be the one for which the most extensive environmental information would be available and therefore it would be one in which the degree of scientific uncertainty could be expected to be at a minimum.

The third reason for selecting Bt cotton as an interesting case study was the fact that it featured prominently in debates over the environmental impacts of GM crops. The perceived ability of Bt cotton to reduce the application of synthetic pesticides makes it a regular feature in the arguments of biotechnology proponents for the potential environmental benefits of GM crops. It is often touted as the perfect example of how biotechnology generally, and GM crops more specifically, have the potential to improve environmental conditions. While opponents of agricultural biotechnologies do construct arguments against this claim, the fact that it is a crop regularly featuring in environmental debates was another factor making it an appealing case study crop.

2.6 Reason for Focusing on Risk to Non-target Organisms

In using this case study crop, I have chosen to focus on the OGTR's assessment of the risk Bt cotton poses to non-target organisms. My selection of this particular risk assessment was motivated by a number of factors. Firstly, the literature on ecological risk perception that I reviewed in my theory chapter (see chapter three, section 2.1.3) suggested that impacts on plant and animal

species are seen as particularly important and Jepson et al. (1994) specifically define ecological risk as adverse effects on non-target organisms. Secondly, the sheer diversity of 'non-target organisms' and the complexity of the ecological systems they inhabit means that assessing the risks a GM crop poses to these organisms will inevitably confront issues of incertitude. This makes it a perfect example to explore how issues of incertitude are handled in the practice of risk assessment and regulatory decision-making. Finally, while the consultation version of the OGTR's risk assessment did not list impacts on non-target organisms as a potential hazard of Bt cotton, the final version did and this discrepancy made it an interesting example to explore in depth.

3. Chapter Conclusion

This chapter has outlined the methods I have developed to conduct my critical appraisal of Australia's environmental regulation of GM crops. These methods relate to two key analytical themes – the regulatory framework and the practice of decision-making. As I use Bt cotton as a case study crop for my analysis (particularly in relation to the practice of decision-making), this chapter has also provided some background information on this crop. This means that this thesis has now provided a description of the context of my research problem (detailed in chapter two), surveyed the theoretical landscape and synthesised a theoretical framework for this problem (chapter three) and outlined the transdisciplinary methods developed for my research on this problem. In the following chapters, I go on to detail my critical appraisal of Australia's environmental regulation of GM crops, beginning with the first key analytical theme – the regulatory framework.

THE REGULATORY FRAMEWORK: SCIENCE/RISK – PRECAUTION/UNCERTAINTY

CHAPTER OUTLINE

In the survey of theoretical literature presented in chapter three, I discussed a range of social science theories on risk and uncertainty in environmental decision-making. This survey sketched an emerging theoretical shift for environmental decision-making away from a simple focus on an 'objective' quantification of risk, towards the development of decision-making approaches where the negotiation of various forms of incertitude is central. In contrasting emerging precaution/uncertainty based approaches with traditional science/risk based approaches, I have described two poles of a spectrum of attitudes that can be adopted towards environmental decision-making.

In chapter three I described precaution/uncertainty based approaches to environmental decision-making as differing from science/risk based approaches in the discourse adopted for decision-making, the degree of authority that is awarded scientific knowledge, the avenues available for public participation, the commitment to ongoing research and monitoring and the willingness to consider and implement a range of policy options. By highlighting the limitations associated with science/risk based approaches and the technical discourse they employ, I presented the emerging precaution/uncertainty based approaches as more appropriate for the environmental regulation of GM crops.

This chapter begins with a brief overview of the history of gene technology regulation in Australia and outlines the system currently in operation. This is then followed by a detailed analysis of Australia's regulatory framework for whether it can be more accurately characterised as a science/risk or

precaution/uncertainty based approach to environmental decision-making. Specifically, the framework is analysed in relation to the key differentiating themes of my theoretical framework as reiterated above. In this chapter, I also question the independence of the key decision maker as an additional important theme. From this analysis, I conclude that although Australia's regulatory system does contain some elements of a precautionary approach, these are positioned within a largely technocratic framework that can be more accurately characterised as a science/risk based approach to environmental decision-making.

1. THE HISTORY OF GENE TECHNOLOGY REGULATION IN AUSTRALIA

In 1975 following the Asilomar conference[46], an Australian Academy of Science on Recombinant DNA was established. This was followed in 1981 by the Commonwealth government's Recombinant DNA Monitoring Committee. These two bodies were then replaced in 1987 by the Genetic Manipulation Advisory Committee (GMAC), which operated as the cornerstone of gene technology regulation in Australia prior to the implementation of the current regulatory system in 2001[47]. GMAC was initially a committee of scientists and its primary role was to make recommendations in relation to the types of safety and containment concerns that dominated the period following the Asilomar conference. This was a voluntary system of regulation, so both the submission of applications to GMAC and compliance with its guidelines were not mandatory or enforceable[48].

In addition to the voluntary regulatory system administered by GMAC, a number of other established agencies regulated spheres within which particular GM products fell. These agencies were:

- the National Registration Authority (NRA) (now the Australian Pesticides and Veterinary Medicines Authority (APVMA)), responsible for regulating Agricultural and Veterinary Chemicals.
- the Australia New Zealand Food Authority (ANZFA) (now Food Standards Australia New Zealand (FSANZ)), responsible for regulating food stuffs.

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[46] For a more detailed discussion of this conference and its consequences refer back to chapter two.

[47] For a detailed discussion of the Australian regulatory context in the period between Asilomar and the establishment of GMAC, see Hindmarsh (1998). For information on the development of the Australian biotechnology industry during this period see Hindmarsh et al. (1998).

[48] While it was generally accepted that compliance with the voluntary system was high, the detection of breaches during the transition to a statutory system suggested that non-compliance had gone undetected (Salleh 2001).

- the Therapeutic Goods Administration (TGA), responsible for regulating therapeutic products
- the National Industrial Chemicals Notification and Assessment Scheme (NICNAS), responsible for regulating the use of industrial chemicals
- the Australian Quarantine and Inspection Service (AQIS), responsible for ensuring the safety of imported goods

This meant that if a GM product was imported, for example, it had to go through the regulatory system administered by AQIS. Likewise, if a GM product was to be sold as a consumable in Australia, then it would have to pass the regulatory requirements of the agency now known as FSANZ. In addition to its role in considering safety and containment concerns, GMAC was also expected to provide advice to these other regulatory bodies on issues relating to GM products that they encountered.

Two key concerns that arose over this regulatory system for gene technology were that:

1. Without the backing of legislation, the voluntary system administered by GMAC had no legal power to enforce or monitor compliance (IOGTR 2000, p.9-10).
2. The range of applications of gene technology was expanding and this meant that certain dealings did not clearly fall within the mandate of any of the existing regulatory bodies listed above. For example, while the existing regulatory bodies potentially regulated most GM products (GM stockfeed being a significant exception), live viable GMOs (such as GM crops) fell through the gaps of this system and were not covered by mandatory regulatory requirements (IOGTR 2000, p.9-10).

These concerns over the lack of a comprehensive and mandatory regulatory regime for all gene technologies in Australia, particularly in relation to live viable GMOs, lead to pressure for the development of a new system of biotechnology oversight and regulation. This pressure was heightened in 1992 when a report from the House of Representatives Committee on Industry, Science and Technology ("Genetic Manipulation: The Threat or the Glory?") recommended that the government develop legislation to regulate GMOs, particularly in relation to their deliberate environmental release (Senate Committee 2000, pt 1.7). While extensive debate occurred on this issue between both Commonwealth and State governments between 1992 and 1995, the issue was abandoned when agreement on an appropriate model for regulation could not be reached (Senate Committee 2000, pt 1.7).

In 1997, the Commonwealth government announced its intention to introduce a new national regulatory system for gene technology and in October of that year a committee of government officials from all States and Territories and the Commonwealth (called the Commonwealth State Consultative Group on Gene Technology (CSCG)), was formed. In 1998 CSCG began a consultative process to develop a set of broad policy principles to assist the development of proposals for a national legislative regulatory system for gene technology. In May 1999, the Interim Office of the Gene Technology Regulator (IOGTR) was established within the Therapeutic Goods Administration in the Commonwealth government health portfolio to assist with the development and implementation of the new national regulatory system for gene technology. Members of the IOGTR all had scientific expertise, which was seen as required to supplement the government officials on CSCG. Upon the creation of the IOGTR, GMAC became subsumed but retained an advisory role on gene technology research and field trials.

In October 1999, a discussion paper developed by the CSCG in consultation with the IOGTR (entitled "Proposed national regulatory system for genetically modified organisms – how should it work?") was released for public consultation and received 200 written submissions (OGTR 2005). Targeted consultations were also held in all States and Territories during November and December of 1999, as were discussions with relevant State, Territory and Commonwealth agencies. In 1999 Australia also held its first consensus conference on gene technology in the food chain. The lay panel involved in this consensus conference generated a report that detailed a number of recommendations, including how the issue of regulation should be approached (Lay Panel 1999)[49].

Following these consultative processes, a draft Gene Technology Bill (and an explanatory guide) were released in December 1999 and these too were made available for comment and discussed in public forums around the nation[50]. Following this consultation process, the draft bill was amended to reflect what were deemed to be pertinent concerns raised by the community[51]. The Gene Technology Bill and related legislation (Gene Technology (Consequential Amendments) Bill and Gene Technology (Licence Charges) Bill) were then introduced into Federal parliament on June 22 2000[52].

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[49] While a detailed analysis of this conference and its impact on regulatory framing is outside the scope of this thesis, more information on this issue can be found in Russell (1999), Mohr (2002a & 2002b), Dietrich & Schibeci (2003) and Einsiedel et al. (2001).

[50] It is pertinent to point out that while public forums were held in all capital cities around Australia, as well as in three major rural centres, the collective total of participants at these forums was under 1000 (OGTR 2005, p.12).

[51] See the Explanatory Memorandum Gene Technology Bill 2000 (Commonwealth of Australia 2000c) for a summary of those concerns that helped shape the draft Bill.

[52] While the bill entered parliament with an unprecedented level of agreement between the States, Territories and the Commonwealth on a regulatory system for gene technology, it is worth highlighting that the State of Tasmania was an exception, not endorsing all aspects of the proposed system (Senate Committee 2000, pt 1.16).

The Gene Technology Bill (and related Bills) were debated in the House of Representatives before being passed and submitted to the Senate. On the 28th of June 2000, the provisions of the Gene Technology Bill were referred to the Senate Community Affairs References Committee for an inquiry into the legislation. This inquiry received 125 submissions from the public and interested stakeholders, although consistent reference was made to the difficulty of assessing the Bill when details on how the system would operate would be contained in the Gene Technology Regulations, which had not been developed at that time (Senate Committee 2000, pt 1.17)[53]. The submissions made and the recommendations of the inquiry were detailed in the Senate Committee report entitled "A Cautionary Tale: Fish don't lay tomatoes" (Senate Committee 2000). Following these discussions, some amendments were made to the Bill and the Federal government passed the Gene Technology Act (and associated legislation) in December 2000. The legislation came into force on the 21st of June 2001.

2. THE REGULATORY SYSTEM ESTABLISHED BY THE GENE TECHNOLOGY ACT 2000

The Gene Technology Act 2000 established a national regulatory system that would support the existing regulatory bodies for GM products (as listed in section 1 above) and cover the perceived regulatory gap for living organisms. In this section, I provide a general overview of the system for regulatory decision-making established by the Act. More detail on the established system will then be given in the following sections, which present my analysis of the framework in relation to the theoretical ideal of precaution/uncertainty based approaches to decision-making.

[53] Consultations on the draft Gene Technology Regulations and an accompanying explanatory guide began in August 2000.

The agency responsible for gene technology regulation in Australia is the Office of the Gene Technology Regulator (OGTR), positioned within the Federal Department of Health and Ageing. The Gene Technology Act 2000 decreed that the Governor General would appoint a single statutory officer, known as the Gene Technology Regulator, (the Regulator), with responsibility for administering the legislation and making decisions. The Act gives the Regulator a large degree of independence, clearly stating that in relation to whether or not a licence is issued and what conditions are placed on a licence, the Regulator has the power to make these decisions independent of outside direction (Commonwealth of Australia 2000a, section 30)[54]. The Act also established three groups to provide advice to the Regulator and the Ministerial council[55]. These are: The Gene Technology Technical Advisory Committee (GTTAC), The Gene Technology Ethics Committee (GTEC) and The Gene Technology Community Consultative Committee (GTCCC). Members of the three advisory groups are appointed by the Minister for Health and more information on their makeup, function and operation is provided in the latter parts of this chapter.

Through the Regulator and the three advisory committees, the system established by the Act revolves around a series of prohibitions and approvals. All people wishing to deal with GMOs and their progeny (including all aspects of what it means to 'deal', such as research, manufacture, importation, field

[54] The Act does, however, permit the Regulator to delegate any of their powers or functions to other employees of the Department of Health and Aging or other Commonwealth or State departments and agencies dealing with GMOs and GM products (Commonwealth of Australia 2000a, section 29).

[55] The Ministerial Council on gene technology contains a minister from the Commonwealth and all States and Territories and is responsible for issuing enforceable policy principles that the Regulator must follow when making decisions, suggesting policy guidelines to assist the Regulator in their decision-making and developing ideal codes of practice for those engaging in gene technology activities.

trials and commercial release) are essentially prohibited from doing so unless the dealing is:

a) Exempt from regulation (a dealing is deemed exempt if the Regulator is satisfied that it involves a very low risk, for example, contained research that involves a well understood process. No release of a GMO into the environment can be classified as exempt.)
b) A 'notifiable low risk dealing' (i.e. those dealings categorized in the Gene Technology Regulations as representing a minimal degree of risk, e.g. research work contained within certified facilities. Again, no environmental release of a GMO can be classified as a notifiable low risk dealing)
c) Listed on the Register of GMOs (dealings may be listed on the GMO Register after substantial licensed operation has convinced the Regulator that the dealing is sufficiently safe to no longer require oversight by a licence holder. No GMOs are currently listed on this Register).
d) Licensed by the Regulator

The Act therefore effectively established a system with a sliding scale of regulation depending on the perceived degree of risk (Lawson 2002). However, unless a dealing with a GMO is classifiable as exempt, a notifiable low risk dealing or listed on the GMO Register, the person or organization wishing to undertake the dealing will be prohibited from doing so unless they gain approval from the Regulator in the form of a licence.

For the specific issue of deliberate environmental release that this thesis is concerned with, the licensing system established by the Act contains the following key stages:

Stage 1: The person or organization wishing to release a GMO into the environment (for field trials or commercial production) submits an application for licence to the Regulator with all the information listed in the Gene Technology Regulations (2001) as required – e.g. information about the parent organism, the characteristics of the GMO, the receiving environment, the potential impacts on health and the environment, proposed monitoring and containment mechanisms etc.

Stage 2: The Regulator reviews the information submitted by the applicant to ensure its comprehensiveness and makes an initial assessment as to whether it is consistent with any issued policy principles[56] and whether it may have a significant impact on the environment. If the Regulator considers the dealing to have the potential for significant environmental impacts, a notice about the application must be published that invites public submissions on the application (Commonwealth of Australia 2000a, section 49).

Stage 3: The Regulator must then prepare a Risk Assessment and Risk Management Plan (RARMP) for the application. In preparing this RARMP, the Regulator must seek advice from the Commonwealth Environment Minister and relevant Commonwealth agencies, the Gene Technology Technical Advisory Committee, the States and any relevant local councils (Commonwealth of Australia 2000a, section 50). In preparing this RARMP, the Regulator may also commission independent research on certain issues (Commonwealth of Australia 2000a, section 27 (h)).

Stage 4: After completing a draft RARMP on environmental releases, the Regulator is required to seek public comment on this draft document and the decisions contained therein (Commonwealth of Australia 2000a, section 52 (2c)).

[56] Policy principles are disallowable instruments that can be issued by the Ministerial Council. These principles can relate to matters other than those specifically concerned with the health and safety of people or the environment, i.e. policy principles can be issued in relation to ethical or marketing concerns (Commonwealth of Australia 2000a, section 21).

In addition to calling for written submissions from the general public on the draft RARMP, the regulator must again seek the advice of the Commonwealth Environment Minister and relevant Commonwealth agencies, The Gene Technology Technical Advisory Committee, the States and any relevant local councils on this draft RARMP (Commonwealth of Australia 2000a, section 52 (3)). The Regulator is also permitted to undertake any other actions deemed necessary for making a decision on the application, including holding a public hearing[57] (Commonwealth of Australia 2000a, section 53).

Stage 5: After comments on the draft RARMP have been received, the Regulator makes a decision on the application. If a licence is approved, conditions on this licence may be applied to manage any potentially significant risks (Commonwealth of Australia 2000a, section 62). The Regulator must not issue a licence if it would be inconsistent with an issued policy principle (Commonwealth of Australia 2000a, section 57) or if the Regulator believes that the applicant is not suitable to hold the licence (taking into account any relevant convictions, whether other licences held have been revoked or suspended, and/or whether the applicant is capable of meeting licence conditions) (Commonwealth of Australia 2000a, section 58).

As a basic outline then, for the deliberate environmental release of GM crops in Australia, the Act established a regulatory system to be administered by a single statutory officer, supported by three advisory committees and the Office. All environmental releases are prohibited unless the Regulator issues a licence for the release. To obtain a licence, an application must be submitted to the Regulator. Based on this application and the information and advice received

[57] Whether a public hearing should be held or not is a decision that only the Regulator has the power to make in Australia. This contrasts markedly with the situation in New Zealand where the regulatory authority is obligated to hold a public hearing should any member of the community express within a written submission the desire to be heard (New Zealand Government 1996, section 60(c)).

from interested parties, the Regulator is required to go through a process of performing a risk assessment and developing a risk management plan. This RARMP must then be released for public comment before the final decision on the application can be made. A licence will be granted if the potential risks are considered acceptable and conditions on the licence may be applied to manage any significant risks that the release may pose to human health or the environment.

3. Analysis of the Regulatory Framework

3.1 Discourse of Decision-making

The objective of the Gene Technology Act 2000 is stated thus:

> *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 GMOs*
>
> (Commonwealth of Australia 2000a, section 3).

This objective clearly establishes a discourse of risk for the regulation of GMOs in Australia. In the original risk analysis framework developed and used by the OGTR, it is stated that the regulatory office views risk assessment as "a scientific process that does not take political or other non-scientific aspects of an application to use a GMO into account" (OGTR 2002a, p. 12) and that "risk assessment will be transparent, objective and scientifically based" (OGTR 2002a, p. 15). These quotations indicate that within the discourse established by the Act, the OGTR has adopted a realist position on the nature of risk and risk assessment.

In both the context and theory chapters of this thesis, I discussed some of the potential problems associated with adopting a realist discourse of risk for the regulation of GMOs. One of the issues I highlighted was how a discourse of risk tends to imply that the potential for benefits permits some degree of harm to be tolerated. Some of the submissions made to the Senate inquiry into the Gene Technology Bill, which preceded the Act, expressed concern over the way in which the objective of the legislation is stated as one of risk management rather than risk prevention (Senate Committee 2000, pt 3.74). While the terms risk prevention and risk management could be interpreted to hold an identical meaning, the term prevention does tend to imply that the aim is to avoid danger altogether, while management suggests that a potential for harm may be tolerated within certain limits. Through establishing a discourse of risk management, the Act arguably implies that a certain degree of harm will indeed be tolerated.

The objective of the legislation also clearly confines the potential undesired effects of the technology to physical harm to human beings or the environment. This works to exclude the consideration of potentially undesirable social, political, or ethical impacts from the decision-making process. In the process of developing the Act, the public is said to have expressed a desire not to have economic considerations enter regulatory deliberations (Senate Committee 2000, pt 6.38) due to a concern that incorporating economic considerations in decision-making may lead to safety concerns being outweighed by the prospect of economic benefit. While some members of the public did not want economic considerations overriding safety concerns, this does not mean that the public did not wish the regulatory system to be sensitive to social, political and ethical concerns. The final lay panel report from the consensus conference on gene technology did in fact specifically emphasise the importance of having a

regulatory body that took more than just science into account when making decisions (Lay Panel 1999) and indeed, the incorporation of an ethics committee and a community consultative committee are testament to the public's pressure not to have non-scientific issues excluded from regulatory decision-making. Limiting the objective of the legislation to managing physical harm to humans and the environment does, however, serve to marginalise non-scientific concerns related to social, ethical and political factors[58].

Renn (1992) has suggested that drawing debates in the direction of a discussion of scientifically quantifiable dangers and excluding social, ethical or political concerns from decision deliberations is a characteristic feature of technical discourses of risk. The argument that a technical discourse of risk has been employed in Australia's gene technology regulation can be further explored by considering how the term "the environment" has been defined in the Act.

3.1.1 Definition of "the environment"

Since one of the stated objectives of the Act is "to protect the environment", how the environment is defined is particularly important for understanding what it is exactly that the legislation is aiming to protect. One might reasonably expect that the definition of the environment would be the same as other pieces of Australian legislation designed to protect the environment, particularly the Environment Protection and Biodiversity Conservation (EPBC) Act of 1999. Interestingly, the Gene Technology Act's definition of the environment is less comprehensive than that used in the EPBC Act, not explicitly referring to what might be construed as social or cultural aspects of what "the environment" means. It is worth highlighting this point by reproducing the definitions in their

[58] Hindmarsh (1998) has suggested that there has been a long history of ethical and other non-technical concerns being excluded from the gene technology regulatory agenda in Australia.

entirety here.

The Gene Technology Act 2000 (section 10) defines 'the environment' to include:

(a)ecosystems and their constituent parts; and

(b)natural and physical resources; and

(c) the qualities and characteristics of locations, places and areas.

Commonwealth of Australia (2000a)

The Environment Protection and Biodiversity Conservation Act of 1999 (EPBC) (Section 528), defines the environment as including:

(a) ecosystems and their constituent parts, including people and communities; and

(b) natural and physical resources; and

(c) the qualities and characteristics of locations, places and areas; and

(d) heritage values of places; and

(e) the social, economic and cultural aspects of a thing mentioned in paragraph (a), (b) or (c).

Commonwealth of Australia (1999)

While it may be argued that point (c) of the Gene Technology Act's definition may understood as referring to broader social and ethical aspects of what is defined as "the environment", the explanatory memorandum to the Bill suggests otherwise (Vanclay 2003). In the explanatory memorandum it is stated that, "It is intended that the definition of environment include all animals (including insects, fish and mammals), plants, soils and ecosystems (both aquatic and terrestrial)" (Commonwealth of Australia 2000c). In failing to mention people or the social, economic, aesthetic and cultural aspects of what

"the environment" can be taken to mean, the explanatory memorandum does indeed seem to support the suggestion that point (c) of the Act's definition is not meant to refer to social and/or ethical factors. Vanclay (2003) highlights how the definition given in the EPBC is one that is widely used around the world, often adopted by State and Local governments and is also the one used in State and Federal "State of the Environment" reporting. This raises the question as to why a narrower definition of "the environment" has been employed in the Gene Technology Act. I would suggest that this narrow definition of the environment has been employed in the Act because it complements and enforces a technical discourse of risk.

How the environment is defined effectively sets the scope for what issues can be considered in any decision-making process that considers 'risks to the environment'. In this section I have reemphasised the argument that employing a discourse of risk can work to exclude socio-political and ethical concerns from decision-making deliberations. In the case of Australia's GMO regulation, the inclusion of the less comprehensive definition of the environment in the Act is an element of regulatory framing that demonstrates a realist concept of "the environment". The environment is presented as existing 'out there' in a real and objective sense, rather than as something that is defined and valued through cultural beliefs and frameworks. This realist approach to "the environment" maintains a technical discourse for decision-making that effectively denies any consideration of social and ethical factors from entering the risk assessment process as performed by the OGTR.

The realist concept of "the environment" demonstrated by the definition provided in the Act is further evidenced by the lack of a provision of clear environmental endpoints for the assessment process; a lack of "explicit

definitions of the environmental values that are to be protected by an assessment" (Suter II 1994). This oversight serves to imply that environmental endpoints[59] exist in an objective sense, determinable by the appropriate set of experts. This hides an important element of ambiguity. What "the environment" is, and what it is specifically we should be trying to protect when we aim to 'protect the environment', are questions for which the answers will inevitably vary within community because the notion of undesirable environmental impact is socially defined (Kasperson 1992; Renn 1992). For example, in aiming to 'protect the environment', are we aiming to protect all species or just some (the cute fluffy ones or keystone species for example)? Are we trying to protect them from any change whatsoever or just from a change that might lead to their extinction? Are we aiming to protect ecosystems rather than species, and if so, is that agricultural ecosystems or natural ecosystems, or both? What it is exactly that we should be trying to protect is not simply a scientific question, it is a question of value, with no single right and rational answer. Therefore, a lack of explicit environmental endpoints creates an important element of ambiguity for the decision-making process.

In discussing the ecological risk perception literature in chapter three section 2.1.3, I emphasised the importance for any decision-making process based on ecological or environmental risk analysis to clearly define environmental endpoints for the assessment process and suggested that due to the normative nature of this exercise, this process of identification and definition would ideally be performed through a deliberative dialogue between experts, stakeholders and lay members of the public. Without this deliberative approach to defining environmental endpoints, this important element of ambiguity in

[59] Or what are referred to as "assessment endpoints" in the ecotoxicology literature (Suter II 1994, 1998 & 2000)

the decision-making process remains unacknowledged, unrecognised and unaddressed.

Without a clear statement of endpoints to guide environmental risk assessment processes, the Regulator is essentially being asked to protect all animals, plants, soils and ecosystems from the risks associated with gene technologies. Even if we adopt a realist concept of risk and the environment, performing an assessment that is capable of considering the risks to every single organism and ecosystem in a scientifically robust manner is arguably an impossible feat, particularly when the information required to perform this task is deficient and there is a limited timeframe within which the assessment can be performed[60].

While the definition of the environment provided in the Act can therefore be considered limited in the sense that it excludes social and cultural aspects of an understanding of what 'the environment' is, on the other hand, it can be viewed as so broad as to make the process of comprehensive risk assessment an impossible task. Without clearly delimiting what it is exactly that the assessment process should be aimed at protecting, i.e. those elements of the environment that can serve as operational endpoints for the risk assessment process, this important aspect of how assessments are framed is left to the discretion of individual evaluators.

In Australia's environmental regulation of GM crops, there is no recognition of the importance of having clear, operational and deliberatively decided

[60] The timeframe within which the OGTR must reach a decision on deliberate environmental release applications is a 170 working days (Gene Technology Regulations 2001, reg. 8). This contrasts markedly with the 18 months permissible for the registration of new agricultural chemicals (APVMA 2005a).

environmental endpoints or the practical limitations involved with asking a regulatory body to scientifically assess the risks gene technologies will pose to every single organism and ecosystem. The definition of the environment used in the Act works to exclude social and ethical concerns and effectively denies the ambiguity associated with defining environmental harm. This supports the suggestion that a realist discourse of risk dominates environmental decision-making in Australia's regulation of GM crops.

3.2 The Role Awarded Science

So far in this chapter I have argued that a realist discourse of risk has been adopted for regulatory decision-making. I have also indicated how elements of the regulatory framework, such as a narrow concept of 'the environment', have marginalised social and ethical concerns from decision deliberations. This framing of regulation implies that scientific knowledge will be awarded a privileged position in the decision-making process. In this section, I discuss the advisory committees to the Regulator and the risk analysis framework to explore the understanding of scientific knowledge that has been adopted and the degree of authority this form of knowledge has been granted over the decision-making process.

The Risk Analysis Framework (RAF) employed by the OGTR demonstrates that a positivist approach to scientific knowledge has been adopted and that this form of knowledge has consequentially been granted a privileged position in regulatory decision-making. As I have already stated, the original version of the RAF states that risk assessment is viewed as "a scientific process that does not take political or other non-scientific aspects of an application to use a GMO into account" (OGTR 2002a, p. 12) and that "risk assessment will be transparent, objective and scientifically based" (OGTR 2002a, p. 15). In a revised

consultation version of this framework released in August 2004 it is stated that "the licensing system is centred on a rigorous process of risk analysis based on scientific evidence and extensive consultation with experts" (OGTR 2004, p. 11). This version also claims "the process of assessing risks requires a systematic approach that is based on scientific evidence" and that "the requirement to focus on objective scientific information is evident in the matters specified by the Act that the Regulator must have regard to when considering risks" (OGTR 2004, p. 14). Through consistent emphasis on the importance of science and the objectivity of scientific knowledge, these quotes indicate that science is given authority in the decision-making process and that a positivist understanding of this form of knowledge has been adopted.

In listing the characteristics identified as integral to the regulatory system for GMOs in Australia, the original version of the RAF presents the first of these as "that it should be focused on science-based risk assessment". The final two characteristics are identified as "public input should be part of the decision-making process; and broader issues such as ethical concerns should be taken into account". What this arguably indicates is that a science-based process of risk assessment is seen as the primary component of the regulatory system but public participation and the consideration of ethical concerns must also be involved. While this may appear to mitigate the authority of scientific knowledge, the way in which the consideration of ethical concerns and public participation have been framed by the Act actually provides further evidence for scientific knowledge holding a privileged position in the decision-making process.

For example, while the Act did establish an ethics committee to consider ethical concerns, interestingly, the Act has legislated that it is only the committee of

scientific experts (the GTTAC) that *must* be consulted during the risk assessment process and whose advice *must* be taken into account when making a decision. As outlined in section 2 of this chapter, when preparing a draft RARMP, the Regulator is required by the legislation to seek advice from the GTTAC (Commonwealth of Australia 2000a, section 50).There is, however, no legal requirement that advice from the non-scientific committees be sought. It is also clearly stated in the Act that "the Regulator must take into account…any advice in relation to the risk assessment provided by the Gene Technology Technical Advisory Committee" (Commonwealth of Australia 2000a, section 51), while the Regulator is not required by legislation to take into account any advice offered by the GTEC or GTCCC.

Of course, the Regulator *may* take the advice of the non-scientific committees into account, but under current legislation there is no requirement that this advice be routinely sought on individual applications or taken into account when offered. While all three committees must be consulted by the Ministerial Council during the development of policy principles (Commonwealth of Australia 2000a, section 22), the fact that the GTEC and the GTCCC do not have to be consulted on individual applications and that their advice does not have to be taken into account by the Regulator when it is made, is a factor of the regulatory framework that severely limits the influence these non-scientific committees have over decision-making processes.

This lack of influence that the regulatory framework grants the non-scientific advisory committees has been clearly demonstrated in practice. Before approval was given for the commercial release of GM canola in 2003, the GTCCC chose to advise the Regulator that "a state of unreadiness exists concerning the risks to the environment of the commercial release of GM canola, so significant that the

applications should be declined at this time" (GTCCC 2003). As evidence of a lack of influence, this advice was not taken and the crop received regulatory approval. The lack of influence held by the non-scientific advisory committees has been further evidenced by the fact that transkingdom GM crops have been approved for commercial release before the GTEC has completed its investigation into the ethics of transkingdom crosses (GTEC 2003). The approval of transkingdom crops before the GTEC has completed its investigations suggests that the regulatory decision-making process has adopted an implicit ethical position in relation to this form of technological development. With the Regulator granting approval to GM crops before investigations from the non-scientific advisory committees have been completed and not acting on advice given when those investigations are complete, it becomes obvious that even though community consultative and ethics committees exist within Australia's regulatory system, their degree of influence over the decision-making process has been severely limited.

The Senate committee inquiry made particular note of the fact that the non-scientific committees were not required to give advice to the Regulator on individual licence applications and made recommendations that this be changed in the Act. The recommended changes were not, however, adopted and so there remains no legal requirement that the advice of these committees be sought and/or considered in relation to licence applications. It is also worth noting that in contrast to the GTTAC, the non-scientific committees are not even given the title of 'advisory' committees. The fact that the non-scientific committees are not seen as 'advisory' committees and have not been granted the same degree of authority over the decision-making process as the committee of technical experts is an element of the regulatory framework that

supports the argument that a realist discourse of risk privileging scientific knowledge dominates Australia's regulatory decision-making on GMOs.

3.2.1 Range of Scientific Expertise

In relation to the technical advisory committee, the Senate inquiry recommended that "the Bill be amended to require the Minister, in appointing members of the GTTAC, appoint members representative of a range of scientific disciplines and a diverse and broad range of scientific views" (Senate Committee 2000). This recommendation was made because during the inquiry, concerns were raised about the narrow range of proposed experts for appointment to the GTTAC and how this committee could be dominated by gene technologists, who by virtue of their interests in the field, would arguably not be impartial (Senate Committee 2000, pt 5.11). The incorporation of experts from environmental science on the GTTAC was emphasised as particularly important (Senate Committee 2000, pt 5.11). The recommendation for a balanced representation of views was also made in the lay panel report from Australia's consensus conference on gene technology (Lay Panel 1999).

In the Act it is stated that "In appointing the members of the [technical] Committee, the Minister must ensure, as far as practicable, that among the members as a whole there is a broad range of skills and experience in the areas mentioned in subsection (5)" (Commonwealth of Australia 2000a, section 100 (7)). Subsection (5) states that the Minister can only appoint members to the technical committee who have skills or experience in one or more of the following areas: molecular biology, ecology, plant, microbial, animal or human genetics, virology, entomology, agricultural or aquacultural systems, biosafety engineering, public health, occupational health and safety, risk assessment,

clinical medicine, biochemistry, pharmacology, plant or animal pathology, botany, microbiology, animal biology, immunology, toxicology.

The Minister for Health and Ageing appointed only eighteen members to the first GTTAC[61], despite 20 being permitted in the legislation (Commonwealth of Australia 2000a, section 100 (2)). Two of these advisors are what are called "cross members", which are members from one of the other two committees[62]. One of the cross members in the original GTTAC was an adjunct professor of cellular and molecular biology, the other a lecturer in law. Of the remaining sixteen members, five worked specifically in the field of human health. Four of these scientists were specifically concerned with health at the molecular or genetic level. The remaining eleven members of the committee can therefore be seen as the scientists, who during the risk assessment process, could offer informed advice or "expertise" on the issue of the *environmental* impact of GM crops.

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[61] Members of GTTAC are appointed for a three year term and in December 2004, the second round of appointments to this committee was announced. In this thesis I have chosen to focus on the first GTTAC because this was the committee that reviewed the licence application for my case study crop of INGARD® cotton. Also, because the second committee had only recently been appointed at the time of writing, the way membership affects decision-making remained to be seen. It is, however, worth making note of the expertise on this second committee and how it differs from the first. In the second GTTAC, there are nineteen members, six of which can be considered experts in issues of human health with four of these six specialising in health at the level of the cell or below. Of the remaining thirteen members capable of commenting on risks to the environment in an expert capacity, nine of the members have specialised expertise in agricultural systems, two of which hold ecological or systems based expertise. Of the remaining committee members, three are specifically involved in biotechnology research while the other member works in the field of plant functional genomics. While systems based environmental expertise remains limited, perhaps the most obvious difference between this second committee and the first round of appointments is the prominence of agricultural expertise. Hindmarsh and Hulsman (2004) have suggested that in the assessment of GM canola, consideration was primarily given to the potential for agronomic over ecological impacts. I would argue that this new round of appointments to the GTTAC indicates that this trend is likely to continue.

[62] The provision that there be cross members on the technical committee was only adopted in the Act after the Senate inquiry recommended that this be the case. In the Bill, it was only the non-scientific committees that were required to have cross-members.

Of the eleven scientists able to comment on environmental impacts in an expert capacity, two taught biotechnology at the university level and another two headed research programs in biotechnology. Of the remaining seven, four specialised in biological research in fields at the level of the cell or below (i.e. molecular science, molecular genetics, and microbiology). The remaining three scientists worked in the fields of entomology, weed ecology and herbicide resistance. What this brief break-down of specialisations reveals is that through the first round of appointments, the GTTAC was numerically dominated by scientists who were experts in cellular and molecular levels of biological science. This means that the first technical advisory committee to the Regulator was dominated by disciplines of biological science that tend to adopt a reductionist approach to knowledge.

Having a committee of scientific experts dominated by disciplines that represent a reductionist approach to knowledge may provide expertise on detailed mechanisms, but it will arguably not provide an adequate understanding of consequences within higher levels of organisation. Understanding the environmental impact of GM crops requires an approach to knowledge that is capable of considering multiple levels of organisation and interactions between numerous biological systems. The dominance of the GTTAC by scientists who are experts at a cellular or molecular level of biological analysis suggests that when considering the question of the environmental impact of GM crops, the majority of experts on the GTTAC are really being asked to answer a question that extends beyond the boundaries of their specialised "expertise".

As Funtowicz & Ravetz (1992a) argued, the specialised disciplinary training of scientists does not always equip them with the skills required to solve the problems arising from their work. For example, molecular biologists and biotechnologists may be able to create GMOs, but their specialist training does not really equip them to understand and assess the impacts these organisms may then have on wider ecological communities because they are essentially unfamiliar with the fields of knowledge required. Funtowicz & Ravetz (1992a) suggested that scientists trying to cope with problems created by their work end up working outside their disciplinary paradigm and therefore "in important aspects of the problem, they are as amateurs". Having a scientific advisory committee dominated by cellular and molecular biologists means that in relation to understanding and assessing the risks GMOs may pose to the environment, the committee contains limited expertise. The paucity of ecologists on this committee offering advice on environmental risks is of particular concern. The need for a truly multidisciplinary technical committee, particularly in terms of *levels* of biological analysis, would seem vital if the risk assessment process is to be capable of adequately and impartially considering all the potential risks GM crops may pose to the environment.

Tarr & Jacobson (1987) suggest that experts from different disciplines working on the same problem may disagree because of the different values imparted by their disciplinary training. Shapiro (1990) has supported this suggestion by specifically highlighting some of the documented differences between molecular biologists and ecologists in relation to environmental risks of biotechnological applications; discussing how molecular biologists tend to view the technology in a positive light while ecologists tend to be more concerned about how the technology will interact with complex social and natural systems. The predominance of scientists working at a cellular or molecular level

of analysis and the appointment of a number of scientists with a direct interest in gene technologies therefore arguably creates an advisory committee that is likely to view the technology in a positive light. The potential for different positions on the environmental risks of biotechnologies between scientists from different disciplines suggests that ideally, there should be some degree of balance on the GTTAC (particularly between ecologists and molecular biologists) if potential bias in decision-making is to be avoided. The dominance of biotechnologists and scientists working at a molecular or cellular level of analysis is particularly significant because GTTAC is required to make decisions by a majority vote[63].

The lack of experts in systems-based approaches to the environment on this technical advisory committee may stem from the curious fact that skills and experience in environmental systems are listed as a relevant field of expertise for the ethics committee but not for GTTAC. This failure to mention environmental systems as a relevant field of expertise might be viewed as particularly curious in light of the fact that skills and experience in agricultural and aquacultural systems are listed as relevant. If the listing of ecology or agricultural and aquacultural systems as a relevant field of expertise for GTTAC was meant to cover skills and experience in environmental systems, questions still remain about why there is a lack of consistency in language across the requirements for all committees.

What I have argued in this section is that the regulatory framework has adopted a positivist view of scientific knowledge and that this knowledge has

[63] The committee must act according to the Gene Technology Regulations (2001) and these Regulations clearly state that "A decision of the Gene Technology Technical Advisory Committee is made by a majority of the members present, and voting for the decision, at a Committee meeting" (Commonwealth of Australia 2001, Regulation 28 (1)).

subsequently been granted a privileged position in the decision-making process. I have suggested that the privileged position of science is particularly well demonstrated by the divergent degrees of authority awarded the GTTAC, GTEC and GTCCC. Additionally, I have argued that through appointments to the GTTAC, scientific knowledge from within a reductionist paradigm has been favoured and that this has been to the detriment of an incorporation of a broad range of views and specifically, to the detriment of the incorporation of systems based approaches to understanding the environmental risks posed by GMOs. This means that not only has scientific knowledge been granted authority over the decision-making process, but that reductionist sciences that tend to view the technology in a more positive light have been privileged over more systems based approaches.

3.2.2 THE POSITION OF PRECAUTION

The objective of the Gene Technology Act (2000) is directly followed by the statement that:

> *The object of this Act is to be achieved through a regulatory framework which:*
>
> *(aa) provides that where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation; and*
>
> *(a) provides an efficient and effective system for the application of gene technologies; and*
>
> *(b) operates in conjunction with other Commonwealth and State regulatory schemes relevant to GMOs and GM products.*
>
> (Commonwealth of Australia 2000a, section 4).

Although it is not referred to as such, section (aa) of this statement clearly represents the declaration of a precautionary principle. Interestingly, this statement of the precautionary principle was added at the very last minute in terms of the Act's development as it was not in the original Bill. When the Gene Technology Bill was the subject of a Senate inquiry, the issue of whether or not the Act should contain explicit reference to a precautionary principle was an issue of extensive debate. While the majority of those involved in the inquiry supported the notion of employing caution in decision-making, debate occurred over whether this would be best served by incorporating an explicit reference to a precautionary principle (Senate Committee 2000, pt 3.57). Some submitters expressed concern that explicitly incorporating a precautionary principle into the legislation would stifle innovation and/or introduce uncertainty into the regulatory process (Senate Committee 2000, pt 3.42, 3.48). Others involved in the inquiry expressed the opinion that it was an important principle for achieving the objective of environmental protection and one that was already well supported through its widespread adoption in both national and international environmental legislation (Senate Committee 2000, pt 3.51, 3.56).

The IOGTR informed the Senate committee that similar debates regarding the inclusion of a precautionary principle had occurred during the development of the Bill but that all jurisdictions had agreed that the regulatory system framed by the Bill represented a "precautionary approach" without directly stating so (Senate Committee 2000, pt 3.48). It was considered to represent a "precautionary approach" to decision-making because the regulator was required to perform a risk assessment using the best available scientific evidence, refuse a dealing if the risks were deemed unmanageable and establish

a system to monitor and enforce compliance (Senate Committee 2000, pt 3.48)[64]. The conclusion that the regulatory system proposed by the Bill represented a precautionary approach to decision-making and therefore, that explicit reference to a precautionary principle was not required in the legislation, was not supported by the Senate committee inquiry. One of the recommendations of the committee was that "the Object of the Bill contain the same words that appear in the *Environment Protection and Biodiversity Conservation Act 1999* in relation to the Precautionary Principle" (Senate Committee 2000).

While the Act was amended so that a statement representing a precautionary principle was provided for how the object of the Act is to be achieved, the recommendation made by the Senate committee was not followed in its entirety because the wording of the precautionary principle is not identical to that used in the EPBC Act. One of the objects of the EPBC Act is to promote ecologically sustainable development (ESD) (Commonwealth of Australia 1999, section 3) and a statement of a precautionary principle is listed in section 3A as a principle of ESD. As a principle of ESD in the EPBC Act, the precautionary principle is worded thus:

> *If there are threats of serious or irreversible environmental damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation*
>
> (Commonwealth of Australia 1999, section 3A(b)).

While the incorporation of the phrase "cost-effective measures" in the Gene Technology Act may seem like a minor variation on the definition provided

[64] This understanding of what constitutes a precautionary approach to decision-making clearly differs from the characterisation I have developed and adopted in this thesis.

above, I would argue that the difference is significant. The primary reason for the Senate committee recommending that the principle be phrased in the same way as in the EPBC Act was to minimise uncertainty about the implications of the principle for decision-making (Senate Committee 2000, pt 3.49). Inserting the term "cost-effective" into the Gene Technology Act's phrasing not only adds another area where diverse interpretations can operate, it also suggests a weakening of the principle's sentiment. Measures to prevent environmental degradation must now meet the criterion of being "cost-effective" while how cost effectiveness is weighed and determined remains open to interpretation. The incorporation of the term "cost-effective" therefore introduces an additional element of uncertainty or ambiguity into the decision-making process.

In chapter three, section 5.1, I highlighted how the term "cost-effective" was used in the phrasing of the precautionary principle for the Rio Declaration and this demonstrates that the phrasing used in the Act is not unique. However, it is interesting that the phrasing of the principle selected for the Act was not that recommended by the Senate committee and is not the same as that used in the primary legislative document governing environmental protection in Australia (the EPBC Act). It is also interesting to note that in the EPBC Act, the precautionary principle is presented as one the principles of ESD while in the Gene Technology Act, attempts to incorporate the notion of ecologically sustainable development and the other principles associated with this were expressly rejected (Lawson 2002). Additionally, it is pertinent to mention that no guidelines were provided for how the principle should be applied in practice or how the well recognised ambiguities associated with it should be handled during decision-making.

In the Bill that preceded the Act, there was no reference to a precautionary principle, it was simply stated that the object of the Act was to be achieved through a regulatory framework that "provides an efficient and effective system for the application of gene technologies" (Commonwealth of Australia 2000b, section 4(a)). This statement suggests that rather than aiming to provide an efficient and effective regulatory system, the current framework's aim is to provide a regulatory system that is efficient and effective in fostering the application of gene technologies. This is highly significant because, as it currently stands, the statement about how the objective of the Act will be achieved frames the regulatory system as primarily focussed on enabling the application of gene technologies (Tranter 2003a & 2003b). The fact that in the Act a precautionary principle was simply tacked onto this statement raises questions about the extent to which the principle will actually affect decision-making and how the potentially competing objectives of precaution and an efficient and effective application of gene technologies might be balanced.

The original resistance to incorporating a precautionary principle in the gene technology legislation, and the fact that it was only adopted during the final stages, suggest that the sentiments of this principle did not guide the development of the Act and its framework for regulatory decision-making. The lack of guidance on how the well recognised ambiguities associated with the principle will be handled in practice also indicates a lack of commitment to making the sentiments of the principle operational. The coupling of the principle with the idea that the regulatory framework will provide an efficient and effective system for the application of gene technologies also raises questions about how the notion of precaution will be interpreted in practice. All of these factors serve to suggest that while the Act clearly includes a statement of a precautionary principle, this does not necessarily negate the argument that

the regulatory system is more representative of a science/risk based approach to environmental decision-making.

3.3 Avenues for Public Participation

While it may be argued that extensive public consultation was involved in the development of Australia's gene technology legislation, this thesis is concerned with the avenues available for public participation in the actual decision-making processes for the environmental release of GM crops. While public participation in environmental decision-making has arguably become commonplace (Ravetz & Funtowicz 1999; Gregory et al. 2001; Stave 2002), there is widespread acknowledgement in the literature that empirical evaluation of the various mechanisms employed for public participation is limited (Fiorino 1990; Chess 2000; Rowe & Frewer 2000; Buchy & Race 2001).

Approaches to evaluating public participation in environmental decision-making vary according to the reasons why public involvement is considered important. Fiorino (1990) has outlined three different arguments for why public participation in environmental decision-making can be viewed as important. The first of these is a substantive argument suggesting that lay judgements about risk are as sound, or more so, than those of experts, particularly because of the way in which lay risk judgements can exhibit sensitivity to social and political factors as well as issues of incertitude (Fiorino 1990). The second argument for public participation in environmental decision-making is described by Fiorio (1990) as a normative argument – that a technocratic orientation to decision-making contradicts democratic ideals. The third type of argument is an instrumental one that claims public participation is important for risk decisions to be viewed as legitimate. Another argument presented by Rowe & Frewer (2000) is that because values are involved at each stage of a risk analysis process, participation from the public is necessary and desirable. This

argument aligns with constructivist positions on science and risk and is one that I will therefore refer to as a constructivist argument for public participation.

While Fiorino (1990) evaluated various participatory mechanisms in accordance with the normative argument using criteria developed from democratic theory, he suggests that evaluations using criteria developed from other types of arguments are also important. As the substantive and constructivist arguments are those connecting most directly to the arguments presented in my theoretical survey of risk and uncertainty, I have chosen to develop a set of criteria for evaluation that derive from these types of arguments for why public participation in environmental decision-making is important.

The first question for my critical appraisal of the avenues available for public participation in Australia's GMO regulation is that of who can be involved. Fiorino (1990) claims that the ability for direct participation by amateurs is important and I propose that this criterion is relevant for substantive, constructivist and instrumental arguments for public participation[65]. For social and political impacts and influences to be considered at each stage and for decisions to hold legitimacy, the opportunity for lay members of the public to be involved is vital. In addition to the question of who is involved, the issue of when they become involved in the decision-making process is a relevant question for analysis. There is consistent emphasis in the public participation literature on the importance of involving the public in decision-making at an early stage so that rather than simply reacting to agency proposals, they have the ability to engage in the formulation of problems, objectives and alternatives (Laird 1993; Stern & Fineberg 1996; Chess & Purcell 1999; Gregory et al. 2001).

A third important question for analysis is that of how participants are involved in the decision-making process. According to the substantive and constructivist arguments for participation, it is important that the mechanisms used for participation permit social and political factors to be raised and that the values involved in competing risk positions and assessments become the subject of deliberative discussions. By describing a process of decision aiding rather than dispute resolution, Gregory et al. (2001) suggest that exploring and clarifying the values involved in decision disputes needs to be a first step for decision-making involving public participation. Rowe & Frewer (2000) also emphasise the importance of having participants engage in a discussion of what they value. This means that how participants are engaged in the decision-making process and whether the mechanisms for participation permit social and political concerns to be raised and encourage the clarification of value disputes is an important question for my critical appraisal.

The final question for my appraisal of the framing of public participation relates to whether or not the mechanisms put in place create an opportunity for two-way transformative learning. The opportunity for this type of transformative social learning to arise from participatory mechanisms has been emphasised as important by a number of theorists writing on evaluating public participation (Fiorino 1990; Laird 1993; Chess & Purcell 1999) and I would suggest that when basing public participation on substantive or constructivist arguments, social learning is perhaps the only way to approach the evaluation of outcomes. When using participation as a way to encourage contextual factors to be incorporated in decision-making deliberations and to assist with the clarification of value disputes for the negotiation of alternatives, there will be no way to evaluate a

[65] I do not specifically include the normative argument in this list because if a pluralistic view on democracy is adopted, participation by amateurs may not be regarded as vital.

decision outcome in terms of whether it is 'correct' or not, but an evaluation of outcome in terms of whether transformative learning was able to occur does become relevant.

In this section, then, I have used the literature on evaluating public participation in environmental decision-making to generate a set of questions for my appraisal of how participation has been framed in Australia's regulation of GMOs. These questions have been primarily based on substantive and constructive arguments for why public participation is important. Other arguments outlining the reasons why the public should be involved in environmental decision-making would perhaps generate a slightly different set of questions or evaluative criteria. To reiterate, the evaluative questions I have developed in this section are:

- Who can participate in the decision-making process?
- When are they able to participate?
- How is their participation is structured?
- Is transformative social learning a potential outcome of participation?

For Australia's regulation of GMOs, the Act essentially established two potential avenues for public participation in the decision-making process. These avenues are the non-scientific advisory committees and written submissions on individual applications. The non-scientific advisory committees do not, however, provide an avenue for lay members of the public to participate in decision-making. This is because to be appointed to these committees you need

to demonstrate skills or experience in one of the fields listed by the Act[66]. This requirement for relevant skills and experience works to exclude laypeople from using this as an avenue for participating in decision-making processes.

These requirements mean that the GTEC and the GTCCC are essentially made up of non-scientific experts, which in turn frames social, ethical and political concerns as matters best represented in the decision-making process by experts. This element of the regulatory framework highlights how, in the regulation of biotechnology, the state has attempted to separate judgements of risk from ethical issues and assigned both of these realms to specialists (Levidow & Carr 1997; Carr & Levidow 2000). Wynne (2001) refers to this as an 'institutionalised divorce' between issues of risk and ethics in biotechnology regulation; a divorce that serves to inhibit an awareness of how these issues are intertwined and works against the development of a policy culture encouraging reflection on the social dimensions of scientific knowledge.

Wynne (2001) focuses on the implications of a classificatory divide between risk and ethics for regulation. In establishing three separate committees, Australia has actually added another questionable dimension to this conceptual divide by attempting to separate not only risk and ethics but also both of these spheres from general issues of public concern. Through the establishment of three separate expert committees, Australia's regulatory framework fails to recognise

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[66] For the GTCCC, members must demonstrate skills or experience of relevance to gene technology in relation to one or more of the following: (a) environmental issues, (b)consumer issues, (c) the impact of gene technology on the community, (d) issues relevant to the biotechnology industry, (e) issues relevant to gene technology research, (f) public health issues, (g) issues relevant to primary production, (h) issues relevant to local government. (Commonwealth of Australia 2000a, section 109(3)). To be appointed to the GTEC, members must demonstrate skills or experience in one or more of the following areas: (a) ethics and the environment, (b) health ethics, (c) applied ethics, (d) law, (e) religious practices, (f) population health, (g) agricultural practices, (h) animal health and welfare, (i) issues of concern to consumers in relation to gene technology, (j) environmental systems. (Commonwealth of Australia 2000a, section 111 (5)).

the inherent entanglement of these issues, manages to maintain an objectivist and privileged discourse of risk and scientific knowledge and effectively works to exclude lay members of the public from participating in decision-making through the avenue of advisory committees.

Lay people are further excluded from this avenue of participation through the way in which the meetings of the committees are not open to the public. The notion of having a "community consultative committee" whose meetings are not open to members of the public seems misleading at least and laughable at worst. Several submissions to the Senate inquiry into the legislation argued that committee meetings should be held in public (with commercial in confidence information excluded where necessary) and that these meetings should be held around the country to facilitate the incorporation of a broad range of views (Senate Committee 2000, pt 5.34). Having open committee meetings would create an avenue through which lay members of the public could participate and raise their social and political concerns. It would also arguably encourage deliberation between various worldviews and ideologies, and as argued during the Senate inquiry, would allow the workings of the committees to be truly transparent (Senate Committee 2000, pt 5.34). 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 (British Food Standards Agency 2005)[67].

[67] Another area in which the approach of the British Food Standards Agency could inform the practice of Australia's regulatory system for GMOs and assist with public transparency is in relation to the declared interests of committee members. The British Food Standards Agency publishes the registered interests of board members on its website (British Food Standards Agency 2005). To increase transparency in Australia's regulatory system for GMOs, the declared interests of all committee members could likewise be made freely available in the public domain.

The current framework for regulation has no requirement that committee meetings be open to the public and this combined with the fact that expertise is required for appointment, severely limits the ability of the general public to participate in decision-making through this avenue. I have, however, already discussed how the non-scientific committees are not consulted on individual applications for the environmental release of GMOs and how this limits the power they have over decision-making processes. This means that, even if these meetings were to be held in public, under current requirements there would be no guarantee that public views and opinions would be granted any real access to decision-making processes through this avenue.

It is, however, important to note that while the legislation does not contain any provision that the GTEC or GTCCC be consulted on individual licence applications, these committees have another avenue through which they can influence decision-making - during the development of policy principles issued by the Ministerial Council (Commonwealth of Australia 2000a, section 22). The ability of the Ministerial Council to issue policy principles that the Regulator must heed in decision-making and the requirement that these are generated in consultation with the non-scientific committees represents an avenue through which ethical and more general community concerns can shape decision-making processes. As there is no provision that lay members of the public can be involved in policy principle deliberations, however, this provides further evidence for non-scientific concerns being framed as appropriate subject matter for expert committee negotiations. McGinty & Atherley (1977) have suggested that expert advisory committees tend to work as a substitute for more open and democratic forums. The way in which lay members of the public are excluded from participating in the advisory committees of Australia's regulatory framework certainly appears to lend support to this argument.

Another provision of the Act worth mentioning in this discussion is that the GTTAC must contain a layperson as a member (Commonwealth of Australia 2000a, section 100 (6)). During the Senate inquiry, concerns were raised that incorporating a single layperson on the technical committee would achieve very little and this indeed seems to be a valid concern, particularly considering that the decisions of this committee are made by a majority vote. Interestingly though, while this requirement is quite separate from the Act's requirement for GTTAC to have cross members from the other committees (Commonwealth of Australia 2000a, section 100 (7A)), the role of layperson in both the first and second GTTAC was deemed to be satisfied by one of the cross members. Through being appointed as a member of one of the other advisory committees, the person serving as a cross-member on GTTAC has arguably been recognised as possessing skills and experience relevant to the regulation of gene technologies. The fact that this cross member has then been used as a surrogate layperson raises questions about what the Act was aiming to achieve by requiring a layperson on the committee and whether this is satisfied by using another committee member to function in this regard.

The other avenue available for public participation in decision-making is written submissions on draft risk assessment and risk management plans (RARMPs) developed by the OGTR[68]. As an avenue for public participation this approach has a number of limitations. Firstly, in calling for public submissions on RARMPs, the public is being invited to react to an agency developed document. This means that the public is being invited to participate in the final

[68] While the Regulator is required to call for public submissions before developing a RARMP if the dealing is considered to have the potential for significant environmental impacts (see section 2 of this chapter), this early call for submissions has not yet been made for any application submitted to the OGTR (Tranter 2003a). It is for this reason that I discuss the avenue of public submissions only in relation to draft RARMPs.

stages of the process, without the ability to frame the problem, objectives or alternatives for decision-making. Additionally, in its call for submissions, the OGTR uses bold print to clearly state that comments made in submissions must relate to potential risks to human health and safety and the environment and that "issues such as food labelling, the safety of insecticides and herbicides and trade implications do NOT fall within the scope of the evaluations conducted under the Act" (OGTR 2003, p. VI). This means that the public is only invited to participate in the final stages of decision-making and the types of concerns they are able to raise have been narrowly framed in terms of physical risks to human health or the environment as posed by the GMO in isolation[69].

When the public does raise social, economic or political concerns in written submissions, the Regulator deems them to be "OSA" or outside the scope of the assessment. The types of issues raised by the public in relation to Bollgard II®[70] cotton that were deemed OSA by the Regulator provide further evidence for how written submissions can only contribute in very limited ways due to the narrow framing of public participation in the regulatory system.

Some of the issues raised in public submissions on the RARMP for Bollgard II®

[69] While the Regulator states that issues related to chemical usage, for example, are the responsibility of another agency (e.g. the APVMA is responsible for assessing the safety of chemicals) it is worth highlighting that these regulatory agencies do not have avenues for public participation so members of the community with concerns relating to these types of issues do not have an avenue to raise these concerns and participate in decision-making processes relating to them.

[70] The RARMP developed for Bollgard II® cotton received a much larger number of public submissions than INGARD®, primarily because this crop was not already in widespread use at the time of the assessment and was seeking approval for expansion into the tropical savannah areas of the northern states of Australia where INGARD® was prohibited.

but deemed OSA include[71]:

1. The intensive water and chemical usage associated with cotton cropping (e.g. submission 3 & 12 cited in OGTR 2002b),
2. The impacts of cotton cropping on the unique tropical savannah ecosystems of northern Australia (e.g. submission 10 & 13 cited in OGTR 2002b)
3. The specific impacts of cotton cropping on river health (e.g. submission 10, 12, & 18 cited in OGTR 2002b)
4. Issues relating to the potential for contamination of neighbouring farms, affecting their ability to claim 'GE Free' status (e.g. submission 23, cited in OGTR 2002b)
5. The lack of ecological research performed in the unique environments of northern Australia (e.g. submission 13 cited in OGTR 2002b).

All of these concerns relate to the practice of broadacre cotton cropping in general and its suitability to the environment of northern Australia. While one submission called on the Regulator to address these types of concerns by looking "at the big picture in your assessment" (submission 13, cited in OGTR 2002b), the fact that this request too was deemed OSA by the Regulator clearly demonstrates the narrow framework for regulatory decision-making.

The way in which this narrow regulatory framework excludes consideration of how the GM crop and the farming practices associated with it will impact on the unique environments present in northern Australia suggests that not only

[71] It is worth noting at this point that the OGTR only releases a summarised version of the content of submissions and the details of those making the submissions remain anonymous. Some of the problems with this include the way in which the summarised statements are presented outside of the context within which they were embedded in the actual submission and by not presenting the submission in its entirety, the OGTR can exclude some of the issues of importance that may have been raised.

does the framing of the regulatory system exclude the consideration of social and political impacts, it also does not permit all potential environmental risks to be considered. The GM crop is essentially assessed in isolation rather than contextually in relation to how and where it will be grown in practice. This arguably represents a fragmented and particularly reductionist approach to risk assessment because it is an approach that fails to capture all of the more holistic or contextual concerns that public submissions demonstrate exist in the community.

Additional concerns that were raised in public submissions and listed as 'Noted', without a reference to where they had specifically been considered in the RARMP, included concerns about the trustworthiness of the organisation submitting the application - Monsanto (submission 3 & 23 cited in OGTR 2002b) and concerns relating to the lack of evidence and information for the assessment process, particularly peer-reviewed and publicly available information (submissions 1, 11, 13, 16, 17, 24, 29, 30, 31, 37 & 48 cited in OGTR 2002b). These concerns can be seen to indicate the importance of issues such as trust and familiarity for public risks assessments, issues that are clearly recognised as important in the risk perception literature.

What these public submissions and the way they have been handled suggest is that, while the public has been granted an avenue for participating in decision-making, the avenue of written submissions has been framed in such a narrow way as to exclude the types of concerns that predominate in the community; concerns that go beyond scientifically quantifiable dangers and relate to characteristics of the technology, the context within which it will operate, the quality of information and its public availability and the reputation of the organisation applying for a licence. The current framework for regulation

simply does not allow these types of concerns to enter the decision-making process and one might argue that so long as social and political impacts and more holistic or contextual factors such as familiarity, controllability and trust are excluded from decision-making processes, public discord over decisions made by the OGTR can be expected to continue.

While I have demonstrated that regulatory framing has placed limitations on how the public can be involved, there are other limitations associated with the avenue of written submissions that I became particularly aware of through my own attempts to engage with regulatory decision-making through this avenue. The first of these is the effort required to read both the application for licence and the RARMP. These are very large documents with particularly dense language that is prohibitive for anyone without scientific training. Assessing the quality of the quoted scientific information was also particularly problematic since most of the studies quoted were not publicly available. When I requested a copy of these studies from the Regulator, I was informed that I would have to pay to gain access to these documents (Cleland 2004). Then after I had paid the required fee I was informed that some of the cited studies I requested a copy of could not be found (Cleland 2005). Public access to information has been cited as an "important cornerstone of public participation" in GMO regulatory decision-making (IUCN 2004). The lack of free and complete public access to the scientific studies quoted as supporting evidence for decisions taken raises serious questions about the degree to which the public can effectively participate in Australia's regulatory system and particularly, the degree to which they can critically reflect on the cited scientific knowledge.

Not only does the lack of peer-reviewed information raise questions about the quality of scientific information used in assessments, the lack of public

transparency in cited scientific studies also severely inhibits the ability of members of the public to engage in any kind of extended peer review process. This means that exploration and exposure of the impact that value judgements have on risk analyses is inhibited. While the following chapter of this thesis does engage in a case study extended peer review of the risk assessment process for INGARD® cotton, it is important to note that this is not an option that is readily available to others because of the lack of free and complete access to the scientific studies used in assessment processes.

In the only evaluative study conducted on public participation in OGTR decision-making that I am aware of, Ross (2004)[72] describes how all respondents believed that their concerns were ignored and not addressed by the OGTR. All respondents answered that their participation in the process had not been worthwhile, with one indicating that it had been "a total waste of time" (Ross 2004). All respondents also answered that their experience and expertise had not been valued by the OGTR. The majority of respondents did not receive a reply to their submission, although when one had been specifically requested, the OGTR did send a standardised reply that did not respond to the submission directly. While I did receive a reply from the OGTR for my submission on the RARMP for INGARD®, this was potentially because of the very limited number of submissions that were made on this application and because I focussed exclusively on concerns relating to scientifically quantifiable dangers[73].

The avenue of written submissions as a way of including the public in decision-making is limited on its own, but when submitters fail to receive a response

[72] Ross (2004) surveyed individuals and organizations that made public submissions on the OGTR RARMP for the commercial release of herbicide resistant canola.
[73] Interestingly, the one concern that I raised in my submission that was not referred to in the reply I received related to the evidence that GM Bt crops demonstrate unintended impacts on soil communities – an issue that I explore further in the following chapter.

from the Regulator that addresses their concerns directly, then the opportunity for transformative social learning completely disappears. Efremenko (2003) defines the essence of social learning as "a reflexive synthesis of visions, values and purposes of actors and affected groups". Without allowing for a process of two-way communication and the shift in positions that this kind of interaction can generate, the avenue of written submissions as a way of engaging the public in decision-making processes becomes particularly limited and arguably ineffectual. While two-way processes of communication that create an opportunity for transformative social learning could potentially be available through committee meetings, the fact that these meetings are not open to members of the public means that opportunities for transformative social learning arguably do not currently exist in Australia's environmental regulation of GM crops.

What this discussion indicates is that a narrow framing of the avenues for participation excludes the more holistic and contextual types of concerns held by members of the public and fails to encourage open discussions and deliberations about environmental values. This means that while public participation was recognised as necessary, the avenues created for it were so narrowly framed as to allow a largely technocratic approach to decision making to remain dominate. While the non-scientific committees and the requirement for an invitation for public comment on draft RARMPs do represent avenues for participation, they both have severe limitations that inhibit the full engagement of the public in decision-making processes. The general public can only participate through making written submissions on completed agency documents and these submissions can only raise a narrow range of concerns, specifically those relating to scientifically quantifiable dangers. Additionally, submissions raising concerns over scientifically quantifiable dangers can only

refer to the crop in isolation rather than how the crop will interact with farming and management practices or broader social and political systems. As the avenue of written submissions fails to create opportunities for reflexive face-to-face social learning, this also makes it a particularly limited approach to what it means to engage the public and their diverse views in decision-making processes.

3.4 Ongoing Research and Monitoring

During the Senate inquiry into the Gene Technology Bill, concerns were raised about the idea that licences would essentially be granted in perpetuity because the Bill did not establish any requirements for licences reviews or renewals (Senate Committee 2000, pt. 4.115). Additionally, concerns were expressed over the lack of legislative requirements for ongoing monitoring or regular testing for unintended environmental impacts (Senate Committee 2000, pt. 4.121). While the Bill did state that licence holders would be required to report any unintended impacts they observed (Commonwealth of Australia 2000b, section 65), the committee concluded that the provisions for regular monitoring and testing should be strengthened. The Senate committee recommended that "the Bill be amended to include provisions for the mandatory review or renewal of all licences granted by the Regulator; and that this review or renewal take place at intervals of not more than three years" (Senate Committee 2000, pt. 4.115).

The Act currently contains no provisions for reviewing licences or the decisions contained therein. What it does contain is the statement that the Regulator may suspend or cancel a licence if:

> *the Regulator becomes aware of risks associated with the continuation of the dealing authorised by the licence, and is satisfied that the licence*

holder has not proposed, or is not in a position to implement, adaquate measures to deal with those risks

(Commonwealth of Australia 2000a, section 68 (e)).

Additionally, the Regulator is granted the power to vary the licence by adding, removing or changing imposed licence conditions (Commonwealth of Australia 2000a, section 71). While these provisions allow the Regulator to make changes to a licence in light of new information, neither of the provisions encourage the Regulator to be proactive in terms of calling for or generating this new information. If there was a requirement for regular licence reviews and renewals, (such as that provided in the Protection of the Environment Operations Act (NSW Government 1997)), a clear opportunity would exist for new information to be incorporated into risk assessments. Without a specific requirement for licence reviews and renewals, the question of whether new information regarding risks will be comprehensively assessed and applied to licences already granted is left to the discretion of the Regulator.

The lack of a requirement for ongoing assessment and review of licence decisions effectively inhibits responsive risk management. Without a legislative requirement for reviewing decisions and risk assessments in light of new evidence or experience in the field, the current regulatory framework fails to establish the type of ongoing monitoring requirements that were highlighted in chapter three as an essential feature of what constitutes precaution/uncertainty based decision-making.

The provisions for monitoring that do exist in the Act really only relate to the specific licence conditions applied by the Regulator. For example, section 64 of the Act states that:

(2) It is a condition of a licence that if:

(a) a person is authorised by the licence to deal with a GMO; and

(b) a particular condition of the licence applies to the dealing by the person;

the person must allow the Regulator, or a person authorised by the Regulator, to enter premises where the dealing is being undertaken, for the purposes of auditing and monitoring the dealing.

(Commonwealth of Australia 2000a, section 64).

This gives the Regulator the power to audit and monitor licensed dealings, but this only applies to the specific conditions applied to the licence – the Regulator is given the power to monitor dealings to make sure that the licence holder is adhering to any conditions imposed on the licence.

While it has been suggested that funding biosafety research is a vital part of operating an efficient regulatory system (Shapiro 1990), the responsibility for monitoring for unintended ecological impacts may be viewed as one rightfully belonging to the licence holder rather than the Regulator[74]. Section 65 of the Act does state that it is a uniform licence condition that the licence holder inform the Regulator if he or she:

(a) becomes aware of additional information as to any risks to the health and safety of people, or to the environment, associated with the dealings authorised by the licence; or…

[74] This argument may be made in the Australian case because of the limited government funding allocated to the OGTR and the expectation that the regulatory system will progress towards a model that is able to recover its own costs through application fees.

(c) becomes aware of any unintended effects of the dealings authorised by the licence.

(Commonwealth of Australia 2000a, section 65).

This provision suggests that licence-holders must report any unintended impacts they observe. Interestingly, though, this is not the same thing as requiring ongoing monitoring for potential adverse impacts. Without any monitoring requirements, relying on the party that stands to benefit from continued commercial production to observe and report negative impacts seems particularly problematic.

It is also worth noting that while the Act clearly states that the Regulator can issue licence conditions for data collection, including studies to be conducted (Commonwealth of Australia 2000a, section 62 (h)), in the case of INGARD® cotton this did not occur[75]. For example, in the response I received from the OGTR on my written submission it was stated that "there are currently few, if any, published data that would enable a rigorous evaluation of potential risks to the structure and function of multi-trophic 'food-webs' via secondary, tertiary or higher order effects of Bt toxins" (Benyei 2003). Despite this clearly acknowledged knowledge deficit, the gathering of data to enable a rigorous assessment of this risk was curiously not made a condition of the licence.

[75] Interestingly, one of the licence conditions placed on Bollgard II® cotton was the collection of information on "the effects of the GMO on key pests and beneficial insects (including Diptera) and soil microorganisms" (OGTR 2002b, pt. 2.11). Why a similar condition was not placed on the INGARD® licence (which was granted after Bollgard II® had been approved) is unclear. As the information on the issue used in both assessments was almost identical, the difference may stem from different evaluators performing the assessments or from the idea that INGARD® would eventually be phased out of production and therefore further data collection was not required. It is also interesting to note that one of the scientists working on the Bollgard II® data collection program (who wished to remain anonymous) indicated that there has been minimal funding and assistance from the applicant for this project.

Without requirements for ongoing research and monitoring efforts, particularly in areas where the Regulator has deemed the available information insufficient, the ability of the current regulatory system to engage in risk assessment and management practices capable of rapidly responding to newly emerging risks is severely curtailed. Requiring the party that stands to benefit from continued commercial release of a GM product to report any adverse effects observed, rather than requiring them to monitor and report on those issues where information for rigorous risk assessment has been deemed lacking, seems a particularly weak monitoring requirement. Finally, while the Regulator may have the legal power to monitor whether or not licence holders are adhering to their licence conditions, an equally important monitoring task should be whether the imposed licence conditions are adequate. Without requiring ongoing monitoring and without clear provisions for regular licence reviews and renewals capable of incorporating new information and experience, the current framework of regulation arguably fails to provide the ongoing monitoring representative of a precaution/uncertainty based approach to decision-making.

3.5 Range of Policy Options

While the legislation does not formally establish a baseline of comparison or outline the way in which decisions about risk acceptability should be arrived at, in practice, the Regulator uses current industrial practices as the comparative baseline for deciding risk acceptability. This means that for GM crops, a potential risk to the environment is deemed to be acceptable by the OGTR if that level of risk is seen as no greater than that posed by conventional, chemically intensive agriculture. For example, in the final RARMP for INGARD® cotton, section three dealing with the decision on the application states that:

> *It is concluded that there are no risks to public health and safety or to the Australian environment arising from the proposed release of GM insecticidal INGARD® cotton that are additional to those posed by the commercial production of conventional cotton... Therefore the Regulator has issued licence number DIR 022/2002*
>
> (OGTR 2003b, p.9)

The executive summary provided for this RARMP cited the same baseline of comparison for risk acceptability but used slightly different phrasing that reveals a clearer picture of the position taken by the agency on the risks associated with the conventional commercial production of cotton. The executive summary stated that:

> *The Regulator considers that no risks to human health and safety, or to the Australian environment, will result from the continued commercial release of INGARD® cotton, above the very low risks posed by commercial production of non-GM cotton.*
>
> (OGTR 2003b, p.III)

This baseline of comparison for risk acceptability was reiterated in the response I received (from the head of the OGTR's evaluation branch) to my written submission on the draft RARMP for INGARD® cotton. In this response it was stated that "adverse impacts on non-target and beneficial insects will be less than the impacts associated with the use of conventional insecticides" (Benyei 2003). These statements on the decision made in this case demonstrate that conventional agriculture serves as the baseline for acceptable risk comparisons. The rationale behind using conventional agricultural practices as the baseline for acceptable risk comparisons is that the risks posed to the environment by conventional agriculture have already been accepted by society and therefore,

as long as the levels of risk posed by GM crops are no greater, then they too should be considered acceptable.

This approach to determining risk acceptability clearly ignores the psychometric literature on risk perception that suggests that people use a range of factors to decide what an acceptable level of risk is, factors such as familiarity, controllability and reversibility[76]. If these factors were included in considerations of acceptable levels of risk for GM crops, we may very well find that the Australian public are not prepared to accept a lower level of physical risk to the environment from GM crops in comparison to the risks from conventional agriculture because the risks from GM crops are seen as unfamiliar, uncontrollable and irreversible. One could also argue that setting chemically intensive conventional agricultural practices as the comparative baseline for risk acceptability is setting a particularly low standard by which to judge the environmental impact of GM crops, especially given the unfamiliar, uncontrollable and irreversible nature of these impacts.

While critics of the psychometric paradigm may argue that the incorporation of these factors is why the public's approach to risk acceptability is an irrational one, an even more fundamental critique of using conventional chemically intensive agriculture as the baseline of acceptable risk comparisons can be made. Using conventional agriculture as the baseline assumes that the public does indeed consider the levels of risk to the environment from conventional agriculture to be acceptable. One could, however, argue that if the Australian public was fully informed about the practices occurring in conventional agriculture or if the public were given a choice between intensive chemical use

[76] Psychometric research on risk perception is described in detail in chapter three section 2.1.

and a more benign alternative, then the level of risk to the environment from conventional agriculture could in fact be rejected as unacceptable[77].

There is, in fact, already extensive debate in Australia about the environmental risks associated with conventional approaches to cotton production; with many viewing the chemical and water intensive nature of conventional cotton growing practices as unacceptable. Slovic (1992) suggests that psychometric studies consistently demonstrate that people actually view current risk levels as unacceptably high for most activities, referring to this as a distinction between accepted and acceptable risks. Setting chemically intensive agriculture as the sole baseline for acceptable risk comparisons is assuming that the public is fully informed about current agricultural practices and the risks these practices pose to the environment and that even if given a choice, these practices and the levels of risk they pose to the environment would be deemed acceptable by the broader public both now and into the future. I would argue that this is a highly questionable set of assumptions.

Using conventional agriculture as a baseline for determining risk acceptability works to inhibit the consideration and implementation of a range of policy options. By solely comparing the risks posed to the environment from GM crops to those associated with conventional agricultural practices, the full range of options available for achieving particular objectives is not considered. For example, when a GM crop has been designed to minimise insect damage, the risks to the environment posed by this crop are not being compared to alternative means of achieving this objective, such as integrated pest

[77] Indeed, this position was arguably demonstrated by the public submissions discussed in section 3.3, which indicated discomfort towards the environmental risks associated with conventional cotton cropping practices.

management (IPM). The lay panel report from the consensus conference on gene technology recommended assessing GMOs against the viability and impacts of choosing non-GMO options (Lay Panel 1999) and while conventional chemical based approaches may be seen to represent one of these options, according to the panel's interpretation, other less conventional approaches, such as IPM, would represent another option worthy of analysis and comparison in the assessment process. Criticisms of using conventional agricultural practices as the only benchmark for comparison and not comparing GM crops with practices such as organic farming have also featured strongly in debates in the United Kingdom (Oreszczyn 2005).

One of the key questions chosen by the lay panel for discussion at Australia's consensus conference on gene technology related to what constitutes acceptable risk; who decides this and how (Lay Panel 1999). Through the subquestions posed on this issue, there was a clear recognition within the lay panel that what constitutes acceptable risk would vary significantly within the community and that essentially, all answers on this issue would be subjective. While adopting this position implies the need for broad-based deliberations on how determining risk acceptability can be approached, the current framing of regulation has left this matter completely unaddressed. In their analyses of the Act, both Tranter (2003a) and Lawson (2002) have highlighted the inherent subjectivity of risk acceptability and criticised the Act for not acknowledging the value judgements involved in these decisions. By simply using conventional agriculture as the sole baseline for comparison, the problems and limitations of this approach are sidelined and risk acceptability is presented as objectively quantifiable. Using only conventional agriculture to determine risk acceptability works to maintain the status quo of industrial agricultural practices and limits the ability of the regulatory system to implement a range of

policy options that could assist with handling the problems associated with ignorance and indeterminacy.

3.6 INDEPENDENCE OF THE REGULATOR

The process of performing risk assessments and developing risk management plans is in practice performed by evaluators within the OGTR. The RARMPs developed by these evaluators must then receive the approval of the Regulator before a final decision is made. While I focus on discussing Australia's current Regulator in this section, it is important to note that information on the evaluators working within the OGTR is not freely available to the public. While RARMPs must be made publicly available, these documents contain no reference to the authors or evaluators that worked on them. There is also no outline of the structure of the office available on the OGTR website or in their published materials and there is certainly no public list of agency employees. While it may be argued that this is to protect the identity and privacy of office employees, the fact that other regulatory agencies, such as the APVMA, are able to provide organisational charts and employee names, positions, and contact details on their website (APVMA 2005b) raises questions about why there is so little transparency in relation to the OGTR's structure and employees. The very limited information publicly available on OGTR evaluators essentially means that the process of risk assessment and management is performed by a body of unnamed and unseen people.

In this chapter, I have already highlighted some of the areas in which evaluators will be forced to use their individual discretion (e.g. defining environmental endpoints). This means that although the interests and values of individual evaluators become important for how the process of risk assessment and risk management planning is performed, and particularly how issues of

incertitude are handled, there is currently a lack of transparency on this matter. The lack of information available on those who actually develop and write RARMPs, limits the ability to critically examine how these documents and the decisions contained therein may have been shaped and influenced by the history, knowledge and values of individual evaluators[78]. While this lack of information limits the ability to question the independence of these evaluators, since sole responsibility for final decision-making does rest with the Regulator, questioning the independence of the person appointed to this position is an equally relevant pursuit for understanding the framework for regulatory decision-making.

A number of concerns were raised during the Senate inquiry on the ability of the legislation to ensure the independence of the statutory officer. While the Bill did state that all potential conflicting interests of the Regulator had to be disclosed in writing, the committee concluded that the importance of having an independent Regulator required this provision to be strengthened (Senate Committee 2000, pt. 4.11). Concerns were also raised about the regulatory system being administered by a single statutory officer rather than a statutory authority with a multi-person board. The IOGTR advised the inquiry that this issue had also been debated during the Bill's development and although some jurisdictions had expressed a preference for a statutory authority, the IOGTR believed that the Bill contained sufficient provisions to ensure that the Regulator was authoritative and independent (Senate Committee 2000, pt. 4.18). Despite the position of the IOGTR, the Senate committee chose to emphasise the importance of having an impartial Regulator and concluded that the pressure

[78] When I requested more information on the evaluators who worked on my case study crop of INGARD® cotton, I was simply informed that they were all "scientists". This served to imply that the process of risk assessment and management was a technical one performed by 'objective' scientists and therefore the characteristics and interests of those conducting the work was irrelevant.

and level of responsibility involved with the position was too great to confer on one person (Senate Committee 2000, pt. 4.20).

Despite the Senate committee recommendation that there should be a three person board forming a statutory autority, the Act maintained the use of a single statutory officer to administer the legislation. The Act did, however, change in an attempt to accommodate concerns relating to conflicts of interest. Section 118 of the Act now reads:

> *(5) The Governor-General must not appoint a person as the Regulator if, at any time during the period of 2 years immediately before the proposed period of appointment, the person was employed by a body corporate whose primary commercial activity relates directly to the development and implementation of gene technologies.*
>
> *(6) The Governor-General must not appoint a person as the regulator if the person has a pecuniary interest in a body corporate whose primary commercial activity relates directly to the development and implementation of gene technologies.*
>
> (Commonwealth of Australia 2000a, section 118).

While these requirements were inspired by recommendations made by the Senate committee, it is important to highlight that the statements made in the Act do not exactly match what was recommended. The committee recommended that an individual who had worked for a "regulated entity" within the two years prior to appointment be precluded from holding the office of the Regulator, while the legislation was adapted to preclude a person who had been employed by "a body corporate" dealing with gene technologies. Employees of public research institutions and universities can conduct research into and seek to commercialise gene technologies and these institutions will

then be subject to the regulatory system. While these institutions may not be bodies corporate, they are potentially regulated entities with employees possessing an interest in gene technologies. The wording in the Act therefore differs significantly from what was recommended by the Senate committee because rather than precluding anyone who had recently been employed by an organisation dealing with gene technologies from holding the position of Regulator, the Act only precludes those who have recently been employed by a body corporate. Additionally, the Senate committee recommended that a person with a financial or other interest in a regulated entity be precluded from appointment, while the Act states that it is only a financial interest in a body corporate that would preclude somebody from the position of Regulator. Again, this represents a weaker version of what was actually recommended by the Senate committee because financial and other interests have been reduced to pecuniary concerns only.

The recommendations made by the Senate committee in relation to the appointment of the Regulator were specifically directed at trying to ensure independence and impartiality. In considering the first person appointed to this role, the rephrasing of the recommendations in the Act becomes particularly interesting. In December 2001, Dr. Sue Meek took up the position of Australia's first gene technology Regulator under the new system established by the Act. During the two years prior to her appointment as the Regulator, Dr Meek was employed by the Department of Commerce and Trade in Western Australia as the executive director of the Science and Technology Division. While this employment clearly does not exclude her from appointment to the position of Regulator according to the Act's requirements, her impartiality and lack of interest in the commercialisation of gene technologies is in fact highly questionable.

According to the *curriculum vitae* (CV) that was attached to the media release relating to her appointment (Wooldridge 2001), Dr Meek has had a long history of involvement with fostering the commercialisation of gene technologies. For example, from 1991-1994, Dr Meek was the manager of the Emerging Industries branch of the Western Australian Department of State Development. Her CV clearly states that in this role, Dr Meek was responsible for "improving the State's capacity to identify, develop and adopt opportunities from strategic R&D intensive industries such as…biotechnology". Before taking on this position, Dr Meek managed the Biotechnology Branch of the Technology and Industry Development Authority where it is stated she was responsible for "promoting the establishment and development of biotechnology-based industry" and "encouraging the application of biotechnology to existing industry". Prior to this employment, Dr Meek was the technical director of her own company "Sue Meek and Associates" which is described as a consultancy business "specialising in the commercialisation of biologically-based ventures". During this time (1984-1988) Dr Meek also served as the executive officer to the South Australian Biotechnology Promotion Committee.

While Dr Meek may not have worked for a regulated entity in the two years prior to her appointment, her 10 year involvement in the promotion of biotechnology commercialisation must raise questions about her impartiality for the role of Australia's gene technology regulator. Had the Act framed a regulatory system involving a statutory authority with a three person board as recommended by the Senate committee, Dr Meek's prior history in promoting biotechnology commercialisation may not be as significant because her authority would have been limited. However, Dr Meek is currently the single statutory officer responsible for administering Australia's gene technology

legislation and holds ultimate authority over whether or not GMOs are approved for environmental release. With a history of employment as a biotechnology proponent and advocate, one must question whether Dr Meek is really the best candidate for making impartial regulatory decisions about GMOs.

In addition to her 10 years of employment working to promote and encourage the commercialisation of biotechnologies, Dr. Meek's CV also lists her as a member of AusBiotech. AusBiotech is Australia's biotechnology industry organisation and according to its website, it is "dedicated to the development, growth and prosperity of the Australian biotechnology industry" working to "facilitate the commercialisation of Australian bioscience in the national and international marketplaces"(AusBiotech 2005). The website goes on to say that:

> *In assessing the current needs and issues faced by Australia's core biotechnology companies, AusBiotech's Strategic Business Plan addresses the requirements to build an appropriate environment to enable companies to grow, help them globalise and position Australia as a significant biotechnology industry for increasing international investment and interest*
>
> (Ausbiotech 2005).

This means that even if we accept that her past employment history is irrelevant, her membership with AusBiotech (still current at the time of writing) must raise questions about conflicting interests. While her appointment may be legally compliant because the legislation only refers to the preclusion of those holding pecuniary interests in a body corporate dealing with gene technologies, the other types of interests demonstrated by her membership of this

organisation would certainly seem to warrant consideration. If the Regulator is a member of an organisation that aims to develop a prosperous biotechnology industry and build an environment that enables biotechnology companies to grow, how can she be capable of impartial decision-making in relation to regulating gene technologies? As a member of AusBiotech, Dr Meek must have an interest in promoting the biotechnology industry in Australia (an interest also evidenced by her previous employments) and surely this interest conflicts with her ability to administer a regulatory system for gene technologies in an unbiased way.

Australia's regulatory system for the environmental release of GMOs as framed by the Act, grants a single person unparalleled authority over the decision-making process. Currently, only those people with recent employment or financial interests in a body corporate dealing primarily with gene technologies are precluded from appointment to this position of authority. As evidenced by the current appointee, this element of the regulatory framework fails to ensure that an impartial and disinterested party will always occupy the important role of Australia's gene technology Regulator.

4. CHAPTER CONCLUSION

In this chapter I discussed the framework for Australia's current regulatory system for gene technologies as established by the Gene Technology Act 2000. I highlighted how a technical discourse of risk focussing on scientifically quantifiable dangers has been adopted for decision-making. I demonstrated that supporting this technical discourse of risk is a realist concept of the environment that further works to marginalise the consideration of social, ethical and political concerns. I argued that complementing this technical discourse of risk and realist concept of environment is a positivist

understanding of science that views this form of knowledge as objective and uninfluenced by social values and norms. Despite the existence of non-scientific committees, I argued that regulatory framing has limited the influence of non-scientific concerns over decision-making processes for individual applications and granted scientific knowledge primary authority. I also highlighted how through the appointment of committee members to the GTTAC, reductionist sciences have been preferenced to the detriment of more systems based approaches. Additionally, I discussed how even though measures for public participation exist in the current system, the technical approach to risk and the environment that has been adopted, the narrow framing of the mechanisms for participation and the types of concerns deemed within the scope of the assessment all severely limit the degree to which members of the public can have their concerns influence decision-making processes. I also discussed how the lack of free and complete access to all scientific studies cited in risk assessment documents inhibits the ability of members of the public to critically reflect on this knowledge. Finally, I discussed the limited arrangements for monitoring in the regulatory framework and the lack of mechanisms capable of ensuring the independence of the appointed gene technology Regulator.

All of these discussed factors of the regulatory framework lead me to argue that while the current system for GMO regulation in Australia does contain non-scientific advisory committees, a statement of a precautionary principle and provisions for public participation, the influence of these factors is marginalised within a largely technocratic discourse of regulatory decision-making. While the current regulatory system attempts to purvey a sense of balancing deliberation and analysis, the research presented in this chapter suggests that in actual fact, the framework privileges the process of scientific analysis and minimalises the influence of deliberation and non-technical concerns. This

means that in relation to the discussion in the theory chapter, I classify the current regulatory system as more representative of a science/risk than precaution/uncertainty based approach to environmental decision-making.

A CASE STUDY OF SCIENTIFIC RISK ASSESSMENT: BT COTTON AND NON-TARGET ORGANISMS

Analysis should be independently reviewed as to it assumptions, calculations, logic, results and interpretations. This point is particularly important and often neglected. A review of what conclusions can be drawn is critical, since it is the conclusions that form the basis of a risk decision.

- Stern & Fineberg (1996)

[A]s the leading contradictions of our civilisation have passed from simple class struggle and nuclear warfare to the destruction of the natural environment by our industrial system, the sciences of ecology and risk assessment have become central. Since these fields are both essentially affected by high uncertainties and high decision stakes, the political manipulation of uncertainty is now the focus of any relevant epistemology

- Funtowicz & Ravetz (1992a)

The purpose of risk assessment under the Act is to identify risks to human health and the environment and to make an estimate of the level of risk based on scientific evidence. Risks to all living organisms and relevant ecosystems will be considered.

- OGTR (2004)

CHAPTER OUTLINE

In the context chapter of this thesis, I described the existence of contested environmental values and widespread scientific uncertainty as a key problem facing the regulation of rDNA technologies. In the theory chapter I discussed some of the limitations of adopting a science/risk based approach to regulatory decision-making and outlined a precaution/uncertainty based framework that would encourage an engagement with the problems of contested values and the presence of different forms of incertitude. In the chapter dealing with Australia's regulatory framework for GM crops I argued that the current regulatory system is more representative of a science/risk than precaution/uncertainty based approach to decision-making.

To explore how science is used in the practice of regulatory decision-making in Australia, this chapter presents a detailed deconstruction of the OGTR's assessment of the risk Bt cotton poses to non-target organisms. My investigation into the use of science and the handling of incertitude in this case study is structured around the assessment's three key sections on vertebrates, invertebrates and microorganisms. For each of these groups of organisms, I ask the following three broad questions: How reliable are the cited scientific studies? How has the scientific information been used? and How adequate and appropriate are the conclusions drawn? In reviewing the risk assessment in this way, I aim to understand not only how science has been used in the practice of Australia's regulatory decision-making for GM crops, but also explore how the process of scientific risk assessment has handled uncertainty, ambiguity, indeterminacy and ignorance.

In conducting a detailed case study investigation into a risk assessment and how it has handled science and incertitude, I am engaging in what I see as a

form of extended peer review. Without being a "scientific expert", I review the process of risk assessment in a broad and more general sense, believing that this has the potential to positively contribute to the process of decision-making by revealing and making explicit any inconsistencies, hidden assumptions, value judgements and/or alternative ways of interpreting and representing the scientific information. Following this review, in the concluding section of this chapter I develop a framework that others wishing to operationalise and apply the notion of extended peer review can use as a tool to inform and structure future investigations into scientific risk assessments.

THE OGTR'S RISK ASSESSMENT OF BT COTTON AND NON-TARGET ORGANISMS

In the final RARMP for INGARD® cotton[79], appendix three details the OGTR's assessment of the risk this crop poses to non-target organisms. In the opening section of this appendix it is stated that:

> *If INGARD® cotton is toxic for other non-target organisms, the potential hazards could include adverse impacts on:*
>
> - *Safety of feed for livestock (for example, livestock fed cottonseed meal or hulls)*
> - *Wildlife, including mammals, fish and birds*
> - *Invertebrates, including beneficial insects (pollinators, parasitoids or predators of insect pests); and*
> - *Microbial organisms, particularly soil microorganisms, with direct impact on growth of crops on farms*
>
> (OGTR 2003b, pt. 176)

In my review of the risk assessment I focus on the final three categories of non-target organisms. My exclusion of impacts on livestock has been motivated by a primary interest in environmental impacts associated with growing GM crops, rather than the impacts associated with using their end products. This is not to say that a similar review of the assessment relating to livestock impacts would not be worthwhile, just that it is outside the scope of this particular project.

My review of the OGTR's assessment of Bt cotton and its non-target impacts is therefore organised around the three key organism groups of vertebrate

[79] Hereafter simply refereed to as Bt cotton, except when comparisons between INGARD® and other forms of Bt cotton are being made.

wildlife, invertebrates and microorganisms. For each of these categories, my review will discuss the reliability of the scientific studies cited in the risk assessment, the way in which scientific information has been used and finally, the adequacy and appropriateness of the conclusions drawn. While I briefly reiterate the criteria and issues used to structure my analysis in the boxes below, for a more detailed and elaborate discussion of these please refer back to section 3.2 of the methods chapter.

Criteria used to gauge the reliability of scientific information

1. **Who performed the study?**
2. **Where was the study conducted?**
3. **What was the test material?**
4. **What was the exposure pathway?**
5. **What was the length of the study?**
6. **What was the size of the study?**
7. **How many repetitions were made?**

Questions guiding the analysis of how science has been used

1. **What is the depth of critique?**
2. **How has the study been interpreted and represented?**
3. **What assumptions are present?**
4. **What values are evident?**
5. **How comprehensive is the assessment?**

1. VERTEBRATE WILDLIFE

1.1 BIRDS

1.1.1 THE RELIABILITY OF CITED SCIENTIFIC STUDIES

In dealing specifically with the potential impacts of Bt cotton on birds, the RARMP cites three supporting references. The first of these is Campbell (1985). This reference is cited as a dietary study conducted with Bt cottonseed and birds that demonstrated no negative impacts. This reference comes from researchers independent of the applicant and has been peer-reviewed, initially indicating a reliable source. Upon closer examination, however, Campbell

(1985) is revealed as a study on pollination and gene dispersal that makes no mention of Bt cotton or its impact on birds. This means that, despite the appearance of reliability (based on peer review and independence indicators), the substance of the study has no connection whatsoever to Bt plants and/or their non-target impacts, and therefore has no relevance for this particular risk assessment.

The second study cited in relation to the assessment of Bt cotton's impact on birds is that of Gallagher et al. (2000). This study is cited together with Campbell (1985) as a dietary toxicity study with Bt cottonseed. Unlike Campbell (1985), however, Gallagher et al. (2000) is indeed an avian dietary study using Bt cottonseed and is therefore relevant to the assessment. It is, however, an unreviewed study that was sponsored by the applicant organisation (Monsanto). It is a laboratory study conducted with a single bird species that is not found in Australia (the Northern Bobwhite Quail). The experiment used the particularly small sample size of five birds (with four replicates per treatment[80]) and they were fed the treatment for only five days. Finally, the experiment tested cotton modified to express the Cry2Ab2 protein, while INGARD® cotton has been modified to express the Cry1Ac protein. These factors combine to suggest that this particular scientific study holds a low reliability rating in this context.

The third source cited specifically in reference to the impacts on birds is Betz et al. (2000) - a peer-reviewed paper with two of the three authors being Monsanto employees. This reference is cited to support the statement that "in the United

[80] A replicate is essentially a copy of the experiment. In saying that there were four replicates per treatment, it means that the experiment included four copies of each set of treatment conditions. Replication represents a way to quantify the variability of observed results within a particular treatment as a basis for assessing the significance of variation *between* treatments.

States, there have been anecdotal reports of increases in the populations of hummingbirds in the fields of the INGARD® cotton" (OGTR 2003b, pt.200). As this reference is simply reporting anecdotal evidence from the United States for birds that do not live in Australia, it appears to be less reliable for the assessment process than the study cited above. Betz et al. (2000) is also cited earlier in the RARMP in support of the more general statement that "the naturally occurring Btk proteins have been shown to have no deleterious effects to fish, avian species, mammals and other non-target organisms" (OGTR 2003b, pt.195). Betz et al. (2000) is a paper that reviews the scientific literature rather than a scientific study itself. In terms of reporting on impacts on avian species, the only study with birds featured in the review is that of Gallagher et al. (2000) as already discussed above.

A second reference used to support the general statement of safety for a range of non-target organisms including birds (as cited above) is EPA (2001a). Again, this reference represents a review document rather than a scientific study, but as part of a regulatory assessment from another country, it could be viewed as a highly relevant source. In EPA (2001a), reference is made to an unreviewed, applicant sponsored study on Northern Bobwhite Quail and Bt cottonseed by Campbell and Beavers (1993). This laboratory study was performed over five days with three replicates of ten birds, and in contrast to Gallagher et al. (2000), used cottonseed expressing the Cry1Ac protein. While the short time frame, limited number of species tested and unreviewed status mean the reliability of this study might still be considered rather low, the fact that it used cottonseed expressing the Cry1Ac protein makes it a more relevant study for the OGTR's assessment than that of Gallagher et al. (2000). This raises questions as to why this study was not directly referred to, and I can only assume that this is the study that the RARMP meant to cite instead of the irrelevant Campbell (1985).

1.1.2 THE USE OF SCIENTIFIC INFORMATION

One of the most curious aspects of how science was used in the assessment of Bt cotton's impacts on birds is the citation of the irrelevant reference Campbell (1985). While it seems likely that the RARMP intended to refer to Campbell & Beavers (1993), the fact that a completely different and irrelevant study was cited raises serious questions about the assessment's attention to detail. Interestingly, even the title of the paper is enough to indicate that it is not a dietary study with Bt cottonseed. The title of Campbell (1985) is "Pollen and Gene Dispersal: The Influences of Competition for Pollination." The citation of an irrelevant reference suggests that during the process of decision-making there has been inadequate evaluation of the reliability and relevance of the scientific studies cited as informing and supporting the risk assessment.

Without citing the Campbell & Beavers (1993) study directly, the risk assessment relies on the less directly relevant Gallagher et al. (2000), even though the citation of EPA (2001a) means that an awareness of a more relevant study should have existed. While the EPA accepted Campbell & Beavers (1993), in a factsheet for Cry2Ab2 in cotton (EPA 2005) they critiqued the method used in Gallagher et al. (2000). The EPA criticised the study for the short time frame used and because only 10% cottonseed meal in the diet was tested. The EPA requested that prior to full commercial approval, a longer (6 week) study be conducted with appropriate proportions of cottonseed meal in the diet so that hazards associated with continuous exposure could be adequately assessed (EPA 2005).

This means that not only did the risk assessment not refer directly to the more relevant study of Campbell & Beavers (1993), it also failed to critique the

unpublished study that formed the basis of the assessment for birds (Gallagher et al. 2000). This was despite its obvious limitations in terms of assessing the potential for long term chronic effects and despite the EPA suggesting that studies framed in this way are inadequate for a rigorous assessment of risks. Through failing to critique the study at all, the RARMP appears to assume that potential chronic effects are either impossible or irrelevant and that the impacts on all bird species can be deduced from a study of one, even if this is a species that is not found in Australia[81]. Additionally, it assumes that 10% of the diet is an appropriate proportion for testing and that the impacts of the Cry2Ab2 protein will be the same as that of Cry1Ac. All of these assumptions represent judgements that could be debated.

In stating that Gallagher et al. (2000) was conducted using raw INGARD® cottonseed, the RARMP misrepresents the study's method[82]. As stated in section 1.1.1, this study actually tested cotton modified to express the Cry2Ab2 protein, while INGARD® expresses the Cry1Ac protein. While Gallagher et al. (2000) used Bollgard® cotton as a control in the experiment (and the cotton marketed in the USA as Bollgard® does express the Cry1Ac protein), all of the conclusions drawn in the study relate to the test line expressing Cry2Ab2. It is also worth noting that although Bollgard® and INGARD® both express the Cry1Ac toxin, they have been created using different transformation events and different cotton varieties and therefore an argument could be made for them requiring separate testing for a 'sound' scientific assessment of risk[83]. Without a request for separate testing, there appears to be an underlying assumption in

[81] It is worth noting at this point that Power & McCarty (1997) suggest that the idea that ecological risk assessment practices can reliably extrapolate conclusions of safety to all species from studies with a single species is a fallacy.
[82] I would also like to note that in the RARMP bibliography, the report number of Gallagher et al. (2000) is inaccurately cited as MSL 1678 rather than MSL 16178.
[83]One reason for why this might be argued is because toxin expression levels vary between different crops and different transformation events (Clark et al. 2005).

the RARMP that not only can different Bt toxins be considered largely equivalent in their impacts, but also that there have been no changes brought about in the plant through the process of inserting foreign genetic material (i.e. through insertional mutagenesis or pleiotropic effects) that may have a negative impact on non-target organisms.

The RARMP states that "In the field, seed cotton is present as large lint-covered seeds that are unattractive to avian species, so birds are not likely to be exposed to the insecticidal proteins expressed in the seeds" (OGTR 2003b, pt. 193). This statement is interesting when compared to one that appears in the cited EPA (2001a) document. According to the US EPA assessment, one of the non-target organisms most likely to be exposed to the toxin in Bt cotton fields is birds feeding on cottonseed. This clearly demonstrates a divergence in opinion between the two regulatory authorities on the potential exposure of birds to the toxin. When viewed in combination with the way in which the RARMP did not refer to the EPA's critique of method (as discussed above), it appears as though the RARMP has selectively cited information from this source, ignoring rather than engaging with statements that may challenge assumptions underpinning the assessment.

It is also important to note that in relying on a study conducted with Bt cottonseed only, the RARMP has failed to consider, and assess scientifically, the risks that might be posed to birds through other exposure pathways. For example, birds may be exposed to the toxin not only through consuming cottonseed, but through consuming insects that have fed on the cotton plants (Clark et al. 2005). With no multi-trophic testing for birds cited or requested, the RARMP has completely failed to consider other pathways through which birds may be exposed to the toxin and the risks associated with these.

1.2 FISH

1.2.1 THE RELIABILITY OF CITED SCIENTIFIC STUDIES

The RARMP cites one specific source in its assessment of the impact Bt cotton may have on fish (OGTR 2003b, pt.198). Li & Robinson (2000) is an unreviewed study performed by independent researchers but sponsored by Monsanto. This study involved feeding commercial catfish a diet with 20% processed Bollgard II® cottonseed. The study was conducted in a laboratory over eight weeks with five replicates of 20 fish per treatment. While the unreviewed status of this study and the fact that it was conducted with Bollgard II® rather than INGARD® cotton are key factors leading me to suggest that this study is of only moderate reliability for this particular risk assessment, another key concern is that the Cry2Ab2 protein in the processed meal is stated as being below quantifiable levels in the experiment (Li & Robinson 2000). Using highly processed meal with no quantifiable level of Bt toxin may represent an appropriate exposure pathway for understanding the risk to commercial fisheries, but it has no relevance for the risk Bt cotton may pose to wild fish.

1.2.2 THE USE OF SCIENTIFIC INFORMATION

Despite the fact that the only study cited as informing the assessment of the risk to fish tested a form of Bt cotton expressing a different toxin to that being assessed and that the toxin was not present in a quantifiable level in the feed, no critique of the study's method or relevance to the assessment was made in the RARMP. Interestingly, the RARMP made no mention whatsoever of the fact that the level of Bt toxin tested in the study was below quantifiable levels.

Through the use of a highly processed diet, the study by Li & Robinson (2000) really only examines the potential risk to fish farmed for commercial purposes that are fed highly processed cotton meal. As such, it can not be relied on to

allow a comprehensive scientific assessment of the risk INGARD® may pose to fish living freely in waterways. The use of Li & Robinson (2000) as the only scientific study informing the assessment indicates not simply an assumption that all fish species will respond to all Bt toxins in the same way, but that fish existing in wild waterways will not be exposed to the toxin at all. In the RARMP it is clearly stated that "Cottonseed or pollen is not expected to enter aquatic habitats in any significant quantity, and therefore aquatic species will not be exposed" (OGTR 2003b, pt. 194). What this statement reveals is that rather than relying on detailed scientific information, the assessment of the risk Bt cotton poses to fish is based on the assumption that aquatic species will not be exposed. Interestingly, this assumption itself does not appear to have been tested for reasonableness; it is simply an unsupported expectation.

Relying on this untested expectation that cottonseed will not enter aquatic habitats in any significant quantity fails to consider other potential ways in which fish may be exposed to the toxin. For example, in a recent Australian study on the potential impacts of Bt cotton on soil communities, it is stated that more information is needed on the potential for Bt toxins bound to soil particles to move into aquatic ecosystems (Gupta & Watson 2004). While the RARMP states that water runoff (from both irrigation and storms) is generally retained on cotton farms and that this practice will minimise the amount of soil residues entering natural waterways (OGTR 2003b, pt. 194), this fails to account for the indeterminacy associated with whether this management practice will always be in place and effective on all farms.

1.3 MAMMALS

1.3.1 THE RELIABILITY OF CITED SCIENTIFIC STUDIES

In discussing the risk Bt cotton may pose to mammals, the RARMP refers to the assessment detailed in appendix two on human health and safety, stating that

the acute oral toxicity studies detailed in this appendix demonstrated that the Cry1Ac and NPTII proteins showed no adverse effects on mice, rats or rabbits. The first of these acute toxicity studies is Naylor (1996). Naylor (1996) is an unreviewed study conducted by Monsanto that tested the toxicity to mice of the purified CryIIA toxin when administered through injection. The test was performed for eight-nine days. As this study was performed by the applicant, remains unreviewed, used a purified form of a different Bt toxin and only ran for up to nine days, it can be viewed as a scientific study with a low reliability rating for this risk assessment.

The second study cited in relation to the NPTII protein is another unpublished study by Monsanto, Berberich et al. (1993). Unfortunately at the time of writing, the OGTR had still not been able to locate a copy of this study to send to me for this review. They were also unable to locate three of the other unpublished studies cited as evidence for the claim that Bt microbial products have shown no observable effects in acute oral toxicity testing with rats and rabbits: David (1989), Carter & Ligget (1994) and Barbera (1995)[84]. The one published study that the RARMP cited in its assessment of mammalian toxicity was that of McClintock et al. (1995).

McClintock et al. (1995) is a paper from the US EPA that reviews mammalian toxicity studies performed using Bt microbial pesticide formulations. In relation to rats, it cites not only acute toxicity studies, but also a study performed over 90 days and another over two years. Even though it is not a scientific study as such, as a regulatory authority's peer-reviewed summary of a number of

[84] Over several months I made three separate requests for a copy of these studies and was informed during the writing of this chapter that the OGTR had been unable to locate them. The reference details for these reports provided in my bibliography were therefore taken from the RARMP.

scientific studies, one of which has been conducted over two years, it can be viewed as a resource of some reliability. It is, however, a review of studies conducted with insecticide formulations of Bt and is therefore arguably, on its own, not enough to inform a detailed scientific assessment of the risk Bt cotton poses to mammalian organisms.

The other two scientific studies that are cited in the RARMP as informing the risk assessment for non-human mammals (excluding livestock animals) are both unreviewed laboratory studies performed by the applicant. The first of these is Naylor (1993), which is a study examining the effect of injecting mice with two doses of the purified Cry1Ac protein. Both doses were administered on the first day of the study but the mice were observed for up to eight days. The second study is that of Naylor & Folk (1994), which fed rats Bt cottonseed as 10% of their diet for four weeks. As this particular study was performed over four weeks and actually used Bt cotton as the test material, I would suggest it represents the most relevant of all the studies cited on mammalian toxicity.

1.3.2 The Use of Scientific Information

The cited study which I deem to hold the highest relevance for an assessment of the risk Bt cotton poses to mammals, Naylor & Folk (1994) found a statistically significant decrease in mean body weight and/or weight gain and in food consumption in rats administered 10% Bt cottonseed in their diets. The authors of this study suggested that this may have been due to decreased palatability of the Bt seed. There was also a statistically significant increase in the weight (relative to body) of the liver and testes in the male rats. The authors did not attribute this to the treatment because no significant effects in absolute organ weights were seen. While the significant differences observed in this study were not deemed important by the authors, others may interpret these results as

worthy of investigation by independent researchers willing to submit their work to peer review.

Interestingly, in referring to this study in appendix two, the RARMP notes the effects of decreased consumption and weight gain (claiming reduced palatability as the most likely cause) but then states that "There was no other evidence for toxicity or other adverse signs during the study or in post mortem analysis of the organs" (OGTR 2003b, pt. 166). This statement fails to mention the observed changes in the relative weight of the liver and testes of male rats, and fails to engage in a discussion about why this may have occurred. The RARMP's statement may therefore be viewed as misleading because the only post mortem analysis performed on the organs involved weighing the rats' kidneys, liver and testes and this did, in fact, show a statistically significant difference. The study also states that an extensive list of tissues were retained but were not examined microscopically. One wonders whether a more detailed post mortem analysis might have revealed other statistically significant differences.

The RARMP was also inconsistent in the way it reported the findings of this study. While reference to Naylor & Folk (1994) in appendix 2 noted the difference in consumption and weight gain, in appendix 3 it is stated that all of the studies cited in appendix 2 on mammalian toxicity showed no adverse effects. It is also interesting to note that in the two year study performed on rats reviewed by McClintock et al. (1995), a decrease in weight gain was also observed[85]. While the RARMP states that this decrease was not considered to be related to Cry protein toxicity, as Naylor & Folk (1994) also observed a decrease

[85] It should also be noted that if Bt cottonseed has a decreased palatability for mammals and this leads to decreased weight gain, this would be a highly significant issue for the use of this GM seed in livestock feed.

in weight gain this arguably creates reasonable grounds to call for further investigation, especially since no post-mortem analysis of organs appears to have been conducted in the two year feeding study.

Although McClintock et al. (1995) is cited in the RARMP as indicating the safety of Bt toxins to rats and rabbits, curiously no mention is made of the studies performed on mice as reported in this review paper. McClintock et al. (1995) reports that when mice were injected with the strain of Bt used to create INGARD® cotton, various frequencies of mortality were observed. It is reported that for three of the six registered isolates of *Bacillus thuringiensis* subsp. *kurstaki,* significant mortality of 70-100% was observed, with most deaths occurring within 72 hours. Additionally, it is stated that clinical observations included "hunched posture, increased activity, rough fur, edema, abdominal sensitivity and eyes crusted closed. Upon necropsy, treated mice showed small abdominal abscesses, enlarged spleens, pale kidneys and hemorrhagic lungs" (McClintock et al. 1995).

While it may be argued that these results are not relevant to the assessment – because Bt cotton was not the test material or because injection does not represent a realistic exposure pathway - some of the other cited studies could also be criticised on these same grounds and yet they have been included without question. With the RARMP citing only those studies reviewed by McClintock et al. (1995) that could be used to support the assumption of specificity and ignoring those representing a challenge to this assumption, the assessment does not appear to be based on a process of objective scientific assessment. While I would argue that as all of the studies reviewed by McClintock et al. (1995) were performed with insecticide formulations and not Bt plants, their reliability for this particular assessment should be subject to

critique, there is no evidence whatsoever that the RARMP has critically considered the appropriateness and relevance of any of these studies, preferring instead to selectively refer to those studies showing no negative impacts and ignoring those that do.

It is also interesting to note that the RARMP has misrepresented the methodologies of some of the scientific studies. The RARMP cites Naylor (1996) as an acute oral toxicity study performed on mice using purified Cry1Ac protein in doses up to 4300mg/kg administered twice, three hours apart (OGTR 2003b, pt. 142). In actual fact, Naylor (1996) is a study using purified CryIIA protein administered in doses of up to 4000mg/kg, 4 hours apart. The scientific study that the RARMP should have quoted to support its description was actually Naylor (1993). Perhaps not surprisingly, the RARMP's citation of Naylor (1993) is also incorrect. The RARMP cites Naylor (1993) and Naylor & Folk (1994) as both representing four week rat feeding studies using Bt cottonseed. Contrary to this description, however, Naylor (1993) is an acute oral toxicity study (lasting only up to 8 days) that tested purified Cry1Ac on mice.

In claiming that both Naylor (1993) and Naylor & Folk (1994) are 4 week rat feeding studies using Bt cottonseed, the RARMP is implying that there is more evidence for safety than really exists; it is suggesting that the cited results have been confirmed by more than one study. This inaccurate presentation is not only of concern because of how it misleads the reader, it is also concerning because it again raises questions about the assessment's attention to detail. It certainly appears as though during the decision-making process, the interpretation of scientific references presented in the RARMP has not been critically reviewed and checked against the actual method and findings

reported by the authors. This allows the RARMP to misrepresent the content and findings of studies in a way that is arguably far from scientific.

Finally, while it is suggested in the RARMP that Naylor & Folk (1994) represents a study performed with INGARD® cottonseed, there is no way to deduce from the actual study if this in fact correct. The study itself only refers to MON46001 and MON46002. While the OGTR may well have been informed that these codes referred to INGARD® cotton and its parental line, without direct reference to this in the actual study and in light of the other misrepresentations already highlighted, I am not convinced that this is necessarily the case. As it was a study performed in Monsanto's US laboratories, I would specifically question whether they used INGARD® cotton in this particular study and not the US version of Bollgard®. Interestingly, the quality assurance audit statement attached to this study refers to it as a one month feeding study with MON4600 (rather than MON 46001) and Mon 46002. While this may simply be a typographical error, it only complicates an understanding of what the actual test material used in this study was.

1.4 Adequacy and Appropriateness of Conclusions

The key conclusion drawn in the RARMP for toxicity to wildlife vertebrates is stated as follows:

> *toxicity studies with Cry1Ac protein and/or INGARD® cotton tissue indicate that INGARD® cotton will not be more toxic to mammals, birds or fish than non-GM cotton*
>
> (OGTR 2003b, pt. 231).

The first point I would like to make about this conclusion is that for both birds and fish, none of the cited studies were actually testing either the Cry1Ac protein or INGARD® cotton tissue as all were focused on Bollgard® cotton and the Cry2Ab2 protein. In relation to mammals, it is worth noting that only one of the cited studies that I was given access to used Cry1Ac protein and that only one used INGARD® cotton material (with the question of whether INGARD® material was actually used in this study remaining unclear). This particular conclusion also makes no clear reference to the assessment's use of the studies reviewed by McClintock et al. (1995), which used Bt insecticide formulations. This is despite the fact that this particular paper was cited more times than any other in the assessment of Bt's mammalian toxicity. Finally, this conclusion is also making the questionable assumption that results from studies performed with a single species can be used to generalise toxicity for all birds and fish.

Following a similar format, alternative ways to view the data and draw conclusions from it might be as follows: Limited studies with Cry2Ab2 and/or Bollgard® cotton tissue indicate no toxicity to Northern Bobwhite Quail or channel catfish. Single studies performed using purified CryIIA and Cry1Ac protein indicate no acute toxicity to rats or mice, while studies performed on these mammals with Bt insecticide formulations and Bt cotton tissue have demonstrated some negative impacts. How these negative impacts relate to the test material and the toxicity of Bt proteins requires further investigation.

The first statement in the RARMP dealing with toxicity to wildlife is that "The toxic effects of Cry1Ac are highly specific for lepidopteran insects" (OGTR 2003b, pt. 195). Through the way in which the RARMP selectively cited and misrepresented scientific studies, as well as ignored certain exposure pathways and failed to critique study methodologies, it becomes apparent that this belief

in specificity was a key assumption underpinning the assessment. If it was not a key assumption, then we would expect there to be a comprehensive assessment process that critically evaluated the strength of the evidence at hand. Instead of a comprehensive and critical assessment, however, the RARMP has adopted an assumption of toxin specificity that has allowed a generalised conclusion of safety to be made from very limited information.

For example, for birds, the conclusion of safety is based on a single, unpublished and unreviewed study that was sponsored by the applicant. A study that tested a form of Bt cotton expressing an entirely different protein on a single non-Australian bird species through one exposure pathway for a very short period of time. For fish, the OGTR also drew a conclusion of safety based on a single unreviewed study that was sponsored by the applicant and that used a form of Bt cotton expressing an entirely different protein. This study did not even have a quantifiable level of Bt protein in the test material and involved a method that was criticised by the US EPA on the basis of its quantities and time frame. For mammals, the conclusion of safety was primarily based on short term studies conducted with purified proteins or insecticide formulations. When Bt cottonseed was used as a test material, negative impacts were observed but this failed to impact on the conclusion of safety. When reviewing the quality of the cited evidence in this way, it can be seen that rather than a detailed, critical and comprehensive scientific assessment of the risk Bt cotton poses to vertebrate organisms, the RARMP's conclusion has been heavily influenced by an assumption of toxin specificity.

The assumption that the Bt toxin expressed by INGARD® cotton is highly specific is most likely based on past experience with Bt sprays or purified forms of the toxin. Many scientists (all of whom have been quoted in the RARMP at

some stage) have, however, suggested that the safety of Bt plants can not be simply deduced from studies with Bt sprays or purified toxins (McClintock et al. 1995; Jepson et al. 1994; Goldburg & Tjaden 1990; Ponsard et al. 2002; Hilbeck et al. 1998b; Hilbeck et al. 1999). This is because the form of Bt toxin and how it is delivered by Bt plants differs significantly from both Bt insecticide formulations and purified proteins.

One of the key differences between Bt sprays and Bt plants is the fact that Bt plants generally express an active form of the toxin. In Bt sprays, the toxin exists in an inactive protoxin form. To become toxic, this protoxin must be broken into pieces and one of the key reasons why Bt toxins are said to be specific is because the conditions required to cleave the protoxin (high pH, for example) are thought to only occur in insect guts[86]. With Bt plants expressing the active core fragment of the toxin, however, this important barrier to its activity has been removed and this clearly has the potential to affect its specificity[87].

Another key difference between Bt sprays and Bt plants is that while Bt sprays are rapidly degraded by sunlight, Bt cotton plants express the active toxin through both their roots and leaves for the length of the growing season. This means that GE plants significantly extend the temporal and spatial availability of Bt toxins in the environment. Additionally, GE plants create novel pathways through which organisms might be exposed to Bt toxins. For example, constant expression of the toxin in the plant means that insects feeding on the leaves may be exposed to a much higher level of the toxin than when rapidly degrading sprays are used and that predators (such as birds and small mammals like bats) that feed on the herbivorous insects may also then be exposed. In simply

[86] For more detail on this issue, refer back to the methods chapter, section 3.4.2
[87] For further discussion on the issue of whether Bt cotton expresses the protoxin or an active core fragment, please see section 2.2.2 of this chapter.

claiming that Bt toxins are highly specific and therefore assuming that risks to non-target organisms are low, the RARMP is failing to consider the important differences between Bt plants and Bt sprays and any consequences these differences may have for the assumption of specificity.

When considering the reliability of the scientific inputs and the way in which science was used in the assessment process, the conclusion drawn on Bt cotton's risk to vertebrate wildlife appears to only have support through the way in which information from scientific studies was selectively and uncritically reported and in some cases blatantly misrepresented. The conclusion drawn makes sweeping generalisations that are not really based on detailed scientific assessment, but rather, which have been heavily influenced by an assumption of toxin specificity and an assumption that the impacts Bt plants will have on non-target vertebrates will be identical to those from Bt insecticide formulations and/or purified forms of Bt toxins.

2. INVERTEBRATES

In the final RARMP, the assessment of impacts on invertebrates is discussed in three sections: studies conducted under controlled conditions, studies conducted in the field and multi-trophic studies. While my analysis will also follow this format, I have added an additional subheading and section in my discussion, "Studies under controlled conditions - prey mediated effects". This is to assist in handling the large number of studies cited in this section and to help highlight an area where my participation as an engaged researcher had an impact on the document being analysed.

2.1 STUDIES CONDUCTED UNDER CONTROLLED CONDITIONS

2.1.1 THE RELIABILITY OF CITED SCIENTIFIC STUDIES

As all of the studies cited in this section of the assessment have been conducted under controlled laboratory conditions, I will describe the studies in terms of my other reliability criteria, particularly who conducted the study, whether it has been peer-reviewed, the test material used and the timeframe within which the study was conducted.

The first study cited in the assessment of invertebrate impacts is Macintosh et al. (1990). This is a published study that was performed by Monsanto, testing three different purified Bt proteins, one of which was Cry1Ac. The purified Cry1Ac protein was cleaved to its trypsin resistant fragment or active core. The study states that it examined 17 agronomically important insects (from five different orders) as well as one species of mite. The insect species examined in this experiment were all agricultural pests rather than insects considered beneficial in agricultural settings. These species were chosen as the experiment was designed to test the range and efficacy of Bt toxins against important insect pests, rather than any potential negative impacts the toxins may have on beneficial insects. The sample size used was five - ten insect larvae (with no mention of replication) and the experiment ran for up to seven days recording mortality and/or leaf damage. The only insects reported as susceptible to the toxin in this experiment were lepidopteran species. Despite this being a published study examining the Cry1Ac protein, the use of a purified form of the toxin in combination with the short timeframe, small sample size, lack of repetition and restriction to insect pests means that although perhaps relevant to the assessment, its reliability in this context is limited.

The RARMP then cites Sims (1994b) and Sims (1995) as studies that have compared the activity of the core Cry1Ac toxin with that of the full length protein. Sims (1994b) is an unpublished study from Monsanto testing the

activity of the two forms of the toxin on ten species of pest insects from five different orders. These experiments were run for no longer than seven days with sample sizes and replicates varying with the species tested. The range was between ten and twenty four for sample size and between two and sixteen for replicates. As an unpublished laboratory study from the applicant testing purified proteins rather than Bt plants and using relatively small sample sizes of insect pests only, the results of this study could arguably require further corroboration. Despite the presentation in the RARMP suggesting that Sims (1995) provides this corroboration, Sims (1995) is actually a paper that has simply published the findings from Sims (1994b) as well as the findings from other Monsanto sponsored investigations into beneficial insects (Maggi 1993a & 1993b; Palmer & Beavers 1993a, 1993b & 1993c). As these individual studies are also cited in the RARMP, their details are discussed below.

For beneficial insects, the RARMP lists "more extensive studies" as demonstrating safety (OGTR 2003b, pt. 208). For larval and adult honey bees, the RARMP cites Maggi (1993a & 1993b). Both of these are unpublished studies that were sponsored by Monsanto but conducted in independent laboratories. These studies tested both the core toxin and the full length protein. Maggi (1993a) tested the substances on 40 adult bees, with three replicates, for up to seven days. Maggi (1993b) tested the substances on 50 bee larvae, using four replicates and with the time frame dependent on the time it took for the bees to emerge (study lasted 48 hours after the emergence of the last bee in the control treatment). As both of these studies report unpublished results from experiments using purified toxins rather than Bt plants, the results may be considered relevant but of a low reliability rating for the assessment.

For parasitic Hymenoptera, the RARMP cites Palmer & Beavers (1993c) and Sims (1994b). Palmer & Beavers (1993c) tested the full length Cry1Ac protein on 25 wasps in two replicate groups for up to 23 days. For ladybird beetles, the RARMP cites Palmer & Beavers (1993b) and Sims (1994b). Palmer & Beavers (1993b) tested the full length protein on 25 beetles in 2 replicate groups for up to 30 days. Finally the RARMP cites Palmer & Beavers (1993a) and Sims (1994b) as studies conducted on green lacewing larvae. Palmer & Beavers (1993a) tested the full length toxin on single larvae of the green lacewing in 30 replicate test chambers for 11 days. All of the three studies by Palmer & Beavers were sponsored by Monsanto but conducted in independent laboratories and all three remain unpublished and unreviewed. As Sims (1994b) did not examine beneficial insects, all references to this study made in this section of the assessment are inaccurate and arguably irrelevant. While the RARMP claims that these studies demonstrate no adverse effects on beneficial insects, the unpublished and unreviewed nature of the studies and the fact that they all used purified proteins rather than Bt plants as the test material raises questions about their reliability for this particular assessment.

In discussing impacts on collembolans, the RARMP quotes Sims & Martin (1996) as a study demonstrating no adverse effects. In this study, various purified Cry proteins (one of which was Cry1Ac) were added to aqueous suspensions of Bakers yeast and fed to ten insects in five replicate groups for 21 days. This study was conducted by Monsanto and remains unreviewed and unpublished, which when combined with the small sample size and use of purified toxin as the test material, makes it a study with limited reliability for the assessment process.

As all of the studies cited so far on invertebrate impacts used purified forms of the toxin rather than Bt plants, it was encouraging to see the RARMP cite Yu et al. (1997) as a study on two soil arthropods (a collembolan and an orbatid mite) using transgenic cotton leaves containing Cry1Ac. As an independent and peer-reviewed study, at first glance this appeared to represent the first scientific study in the assessment of invertebrate impacts that could be given a high reliability rating. Unfortunately, this study was actually conducted using the Bt vegetative insecticidal protein Vip3A, which the authors state bears "no similarity to delta-endotoxins" (Yu et al. 1997). Additionally, this study did not use the soil arthropods cited in the RARMP, but rather, tested the Vip3A protein against the black cutworm, the fall army worm and the European corn borer. As this study was conducted with a protein said to bear no resemblance to those being expressed in Bt cotton, I view it as a study of only marginal relevance to the assessment process.

2.1.2 The Use of Scientific Information

The first notable aspect of how studies conducted under controlled conditions were used in the assessment of invertebrate impacts is that none of the cited studies were subjected to critique. There is no mention of the limitations of findings from studies conducted under controlled conditions or the limitations associated with testing purified proteins rather than GM plants. Additionally, there is no critique applied to the studies in terms of whether they use an active core fragment of the toxin or the full length protein in their testing. While this lack of critique again demonstrates that studies are not distinguished in terms of relevance and reliability for the assessment process, it also serves to suggest that laboratory studies with either form of the purified toxin are considered acceptable evidence for the assessment process. This point becomes particularly relevant for the discussion in section 2.2.2 below.

In reading widely among the scientific studies examining this issue, I uncovered some methodological critiques, none of which were mentioned in the RARMP. For example, Clark et al. (2005) critique the method of Sims & Martin (1996), suggesting that the route of exposure used is ecologically unrealistic and that it is unclear whether the protein would have been consumed under the experimental design used. Clark et al. (2005) also highlight, as I have done, that studies with purified proteins have low ecological relevancy. Additionally, MacIntosh et al. (1990) suggest that studies using insecticide formulations are flawed as it is impossible to determine the activity of individual proteins. While I acknowledge that my review has some limitations in terms of considering the appropriateness of different methodologies (and certainly suggest that further research could be conducted along these lines), considering and critiquing the methodologies used in cited studies should arguably have been a key component of the risk assessment process.

The degree of misquoting occurring in this section on invertebrate assessment is a particularly concerning element of how the science has been used. As I mentioned above, according to the way it is presented in the RARMP, Yu et al. (1997) is the scientific study that appears to be the most reliable for the assessment. This is primarily because it is the only study cited in this section that has been independently conducted, peer-reviewed and most importantly, which is said to use Bt cotton as the test material. The fact that this study does not use transgenic cotton containing Cry1Ac as claimed by the RARMP and actually tests a protein said to bear no similarity to that expressed in INGARD® cotton is particularly worrying. It is also concerning that the RARMP makes an incorrect statement about what organisms were tested in this study. These

factors combine to indicate that the study has been seriously misrepresented in the RARMP.

This example of false referencing leaves me questioning how this could occur when once again, even the title of the paper ("The *Bacillus thuringiensis* vegetative insecticidal protein Vip3A lyses midgut epithelium cells of susceptible insects") should have been sufficient to indicate that the RARMP's representation was incorrect. I also wonder how an incorrect reporting of the two key parameters of an investigation could pass unnoticed by all the scientific evaluators and reviewers involved in the assessment. Once again, it appears as that long as a scientific study is cited as evidence for a statement, neither the statement nor the study itself come under review.

In addition to this false referencing, there are also a number of more subtle examples of the RARMP misrepresenting scientific information. The first of these relates to the way in which Sims (1994b) and Sims (1995) are presented side by side as "other studies" comparing the activity of the toxic core fragment and the full length protein (OGTR 2003b, pt.207). As I noted in section 2.1.1 of this chapter, Sims (1995) is a paper that has published the results of Sims (1994b). In this sense, they both represent the same study and it is therefore misleading to refer to them as "other studies" in the plural sense. It could be argued that as Sims (1995) also includes results from studies by Maggi and Palmer & Beavers, the RARMP's use of the term "other studies" is accurate. The problem with this is that the statement that follows then becomes a misrepresentation.

Following the citation of Sims (1994b) and Sims (1995) as "other studies", pt. 208 of the RARMP claims that "More extensive studies have also been carried

out on beneficial insects" and cites individually all of the studies that were incorporated into the review by Sims (1995). What these terms like "other studies" and "more extensive studies" imply is that there have been a number of people performing these experiments and all have arrived at the same findings. This gives the reader the impression that the experiments have been replicated with the same result and therefore that the weight of the evidence for the claim of safety is strong. What the RARMP is doing, however, is presenting the same information as if it were coming from a number of different sources and I view this as misrepresenting the weight of the evidence.

This misrepresentation is particularly worrying in the presentation of the studies with parasitic Hymenoptera, ladybird beetles and green lacewing larvae. In pt. 208 of the RARMP, it is stated that studies with these organisms have been conducted by Palmers & Beavers (1993a, 1993b & 1993c) and Sims (1994b). Of primary concern here is that Sims (1994b) did not test impacts on any of these organisms. It could be argued that the RARMP meant to refer to Sims (1995) in all three of these instances. However, while Sims (1995) did refer to these three organisms, the paper was presenting the findings of the research conducted by Palmer & Beavers in 1993. This means that even if this was a simple typographical error and the RARMP meant to cite Sims (1995) on these three occasions, it would have arguably still been a case of misrepresentation because two references would have been given for what was effectively the same set of experiments.

2.2 Studies Under Controlled Conditions – Prey Mediated Effects

Within the section titled "Studies under controlled conditions", the RARMP discusses a number of studies that it describes as analysing prey-mediated

effects of Bt toxins. Before I go on to review these studies and how they have been handled in the RARMP, it is important to note that in the consultation version of the RARMP, none of these studies were referred to and the potential for prey-mediated effects was not discussed at all. In a submission I made to the OGTR on the consultation RARMP, I raised concerns about the assessment of non-target impacts and criticised the Regulator for failing to consider the multi-trophic studies performed by Ponsard et al. (2002), Hilbeck et al. (1998a, 1998b & 1999) and Meier & Hilbeck (2001). In a reply letter that I received from the OGTR it stated "You…indicated the importance of gathering data in ecologically-realistic, multi-trophic contexts. Thank you for highlighting this matter, which, in response to your submission, we have now addressed" (Benyei 2003)[88].

What this means is that all of the studies I discuss in this section on prey-mediated effects were not incorporated in the OGTR's initial risk assessment. While it is understandable that these studies may not have been mentioned by Monsanto in their licence application, I find it curious that a regulatory body performing a literature search on Bt crops and their non-target impacts would fail to unearth these studies. The work performed by Hilbeck and her colleagues in particular, is widely cited in the published literature in this field. Despite this deficiency, I was initially excited that my participation appeared to have had an impact on the assessment process by prompting the Regulator to engage with these studies. A more detailed analysis of the way in which these studies were handled (as discussed in section 2.2.2), however, raises questions about the degree of this impact.

[88] While the final RARMP contains a new section entitled "Multi-trophic studies of Cry toxins", which I address later in this chapter, reference to the studies I highlighted is actually made in the section titled "Studies conducted under controlled conditions".

2.2.1 The Reliability of Cited Scientific Studies

In presenting information on prey-mediated effects, the first study cited in the RARMP is Hilbeck et al. (1998a). This is an independent and peer-reviewed paper that tested the effects (on both mortality and development time) of feeding the beneficial insect predator *Chrysoperla carnea* (*C. carnea)* prey that had consumed corn expressing Cry1Ab. In this study, 50 *C. carnea* larvae were used per treatment and each experiment was repeated four times. The experiment was conducted until the insects had completed their three larval stages. This study found that the mortality of *C. carnea* larvae was increased by consuming prey that had fed on Bt corn. This applied for prey that were both susceptible and non-susceptible to the Bt toxin, and the authors suggest that this indicated that the effects were not simply a result of *C. carnea* consuming sick prey, but rather, could be directly linked to Bt related factors. The study also noted that all the larval stages of *C. carnea* demonstrated a prolonged development time in contrast to the control when feeding on Bt susceptible prey that had consumed Bt corn. This impact on development time was suggested as linked to the suboptimal value of the susceptible prey as a food source.

The second study cited in the discussion of prey-mediated effects is Hilbeck et al. (1998b). In this independent and peer-reviewed study, Hilbeck and colleagues incorporated the purified Cry1Ab protein into a liquid diet fed directly to *C. carnea.* 30 larvae were tested per treatment and each treatment was repeated five times. The experiment again ran until the insects reached maturity (approximately 37 days). In this study, the mortality of *C. carnea* fed the Cry1Ab protein was consistently higher but no or only small differences in development time were observed. In comparing the results from this study with those from the study discussed above, the authors suggest that the processing of the toxin

in the herbivore's gut may lead to the toxicity being retained or increased for *C. carnea.* In support of this idea, they reference the work of Haider et al. (1986) as showing that the specificity of Bt toxins can be altered by different digestive fluids reducing the protein to different sizes.

The third study on prey-mediated effects referred to in the RARMP is that of Hilbeck et al. (1999). In this independent and peer-reviewed study, the active Cry1Ab toxin and the protoxins of Cry1Ab and Cry2A were incorporated into the diet of the same two prey organisms used in Hilbeck et al. (1998a). These prey organisms were then fed to *C. carnea* larvae with 30 larvae used per treatment. The experiment was repeated four times and again ran until the insects reached maturity (over 30 days). Once again, this study found that the average mortality of larvae raised on Bt-fed prey was always significantly higher than the non-Bt control. Interestingly, this study found that, while decreasing the concentration of the Cry1Ab toxin in the prey diet simultaneously decreased the observed mortality of *C. carnea,* this mortality was not affected by decreasing the concentration of protoxin incorporated into the diet. It was also found that there was 34% higher predator mortality than prey mortality. The authors suggest that this may indicate that the prey organism is processing the toxin to a product that lethally affects *C. carnea* but not itself.

In comparing the results of this study with those of Hilbeck et al. (1998a&b), the authors note that the prey-mediated experiments required a four times lower concentration of Bt toxin to create the same rate of mortality seen in the direct feeding study. They also highlight that in the experiments using Bt plants, mortality was approximately 10% higher than those observed in the experiments using the purified toxin. These comparisons lead them to suggest

that not only are there Bt protein x herbivorous prey interactions that magnify toxicity, there are also herbivorous prey x plant interactions contributing to toxicity. The authors present their findings as challenging the assumption that the specificity of Bt toxins as expressed by plants can simply be inferred from experience with Bt insecticides and suggest that their studies demonstrate that multi-trophic level testing is essential for understanding the potential impacts Bt plants may have on beneficial insects.

As independent and peer-reviewed studies that repeat the experiments, use relatively large sample sizes and examine impacts through the ecologically realistic pathway of multi-trophic consumption, these studies can be viewed as having significant reliability for the assessment process. The diversity of approaches applied and compared across the different studies can also be seen to enhance this reliability. The focus on Cry1Ab and Bt corn rather than Cry1Ac and Bt cotton is, however, a factor limiting their reliability for this particular assessment. The authors suggest that further experimentation on this issue under field conditions is important, and while I would certainly agree, I would also suggest that the results of these studies indicate that multi-trophic testing of the impacts of Bt cotton on beneficial predators is desirable for a sound scientific assessment of risk.

The RARMP does then goes on to cite a multi-trophic study conducted using Bt cotton expressing the Cry1Ac protein – Ponsard et al. (2002).This study was independently conducted and peer-reviewed and examined effects of both Bt cotton and lepidopteran prey that had ingested it on the adult longevity of four important Heteropteran predators of cotton pests. Four replicate trials were used for two of the Heteropteran predators, while three replicates were used for the other two. In using predators that were collected from the field, the number

of organisms tested in each replicate trial varied (from 10-36) depending on the number that could be collected on a given day of testing. The experiment ran until the predators had completed their lifecycle. The authors report that for two of the predator species (*Orius tristicolor* and *Geocoris punctipes*), longevity was significantly decreased in comparison with the control whereas no effect was observed for the other two (*Nabis* sp. and *Zelus renardii*). The authors suggest that this indicates a divergence in susceptibility between different Heteropteran predators. In line with Hilbeck and colleagues, Ponsard et al. (2002) also suggests that the toxin may become modified in the prey insect's gut in a way that makes it toxic to beneficial predators. To support this suggestion, the authors also refer to the work of Haider et al. (1986) demonstrating that processing by different larval gut proteases can alter the toxicity of Bt proteins.

The reliability of this study for the assessment process can be deemed high as it is independent, peer-reviewed, used Bt cotton expressing the Cry1Ac protein and tested impacts through ecologically realistic multi-trophic pathways. The variations in sample size and replicates for the different species may be viewed as factors limiting the reliability rating. As the study and its method passed peer review, however, I am not sure that these variations should be seen to have too large an impact on the study's overall reliability for the assessment process. While even the authors of this study emphasise the importance of testing under field conditions, as potentially the most relevant laboratory study cited in the RARMP so far, the results would seem significant and worthy of further investigation and consideration in a sound scientific assessment of risk.

The final study cited in the section on prey-mediated effects is Meier & Hilbeck (2001). This is another independent and peer-reviewed study considering multi-trophic impacts of Bt corn on *C. carnea,* except the focus of this particular study

is on the behaviour of the predator and their prey preferences. In this study, the third instars of *C. carnea* were observed to significantly prefer feeding on *Spodoptera littoralis* that had not consumed Bt corn rather than those that had. When given the choice between aphids (*Rhopalosiphum padi*) that had fed on Bt and non-Bt corn, however, no preference was observed. This is potentially related to the fact that aphids feed on the phloem of the plants where there is said to be no Bt protein expressed. All three larval stages also showed a preference for *R. padi* over *S. littoralis* regardless of whether they had fed on Bt corn or not. The authors link their results to other studies showing that defensive chemicals expressed by plants can be passed on to predators via prey organisms and that having prey consuming these chemicals in their diet can therefore deter predators. In making this suggestion, the authors emphasise the importance of conducting more studies on the learning and behaviour of beneficial insects. This study is of a similar reliability rating for the assessment process as those of Hilbeck et al. (1998a&b) and (1999) discussed above. As an independent, peer-reviewed study that examines impacts through multi-trophic pathways, it is a study of value for the assessment process but the relevance of its results are qualified by its use of Bt corn rather than Bt cotton.

2.2.2 The Use of Scientific Information

The discussion of these studies on prey-mediated effects represents the first instance where the RARMP can be found engaging in a critique of the cited scientific studies. After citing the findings from Hilbeck et al. (1998a&b) and (1999), the RARMP states that:

> *It is difficult to extrapolate the results of these studies with Cry1Ab expressed in corn to potential impacts of Cry1Ac expressed in cotton, because corn expresses the core Cry1Ab toxin whereas INGARD®*

> *cotton expresses the full-length protein that requires activation in the insect gut before becoming toxic.*
>
> (OGTR 2003b, pt. 213)

The key concern in this statement appears to be that the study was conducted with a core toxin and this makes it less relevant for the assessment process. If this is the case, it must be asked why the same criticism was not directed at other studies cited in the invertebrate assessment that also used a core toxin in their experiments (MacIntosh et al. 1990; Maggi 1993a; Maggi 1993b; Sims 1994b; Sims 1995). If the key concern is that the study used Bt corn that expressed Cry1Ab and not Cry1Ac, again the question would have to be asked why this same criticism was not directed at other studies cited in the assessment that used a Bt plant expressing a different protein (Gallagher et al. 2000; Li & Robinson 2000). Furthermore, MacIntosh et al. (1990) found that the Cry1Ac protein was approximately four times more active than Cry1Ab and therefore, it could be argued that there is the potential for any adverse effects observed with Cry1Ab to be worse for Cry1Ac.

The application of this selective critique of the test material used in the scientific studies gives the distinct impression that the RARMP has uncritically accepted the results of those studies with findings that conform to the assumption of toxin specificity, but critiqued the method of those studies presenting negative findings that challenge this key assumption. This selective application of critique is particularly interesting considering that the studies subjected to critique were only incorporated into the assessment after they were highlighted in my written submission. While the final version of the RARMP has incorporated a discussion of these studies, their impact on the assessment process has been limited. Methodological critique has allowed them to be

sidelined as irrelevant while other cited studies containing similar methodological limitations remain unchallenged.

While it is certainly interesting that these scientific studies reporting negative findings were only addressed in the assessment after being highlighted by a member of the public and were then the only scientific studies to have their test material critiqued in the RARMP, the critique itself can be challenged on a number of grounds. The first of these is that, in critiquing the studies because they used Bt corn expressing the core Cry1Ab toxin, the RARMP is failing to acknowledge that Hilbeck et al. (1998b) actually tested both the full length and core Cry1Ab protein. In presenting the results of the studies by Hilbeck and colleagues, the RARMP states that they tested purified protein or lepidopteran larvae fed on either purified protein or corn expressing the protein (OGTR 2003b, pt. 212). This fails to acknowledge that the studies also used non-lepidopteran prey in the experiments and that Hilbeck et al. (1998b) tested both the full length and core protein and found comparative mortality rates for both. By going on to critique the studies by Hilbeck and colleagues for using Bt corn expressing the core Cry1Ab toxin, the RARMP is ignoring the various test materials employed in the different studies, despite having described some of these in the preceding paragraph.

Another pertinent point about the critique being applied to marginalise the relevance of these studies is that it does not seem to conform with other statements made in the RARMP. In an earlier discussion on the exposure of invertebrates to the toxin it is stated that:

> *species feeding on lepidopteran larvae may be exposed to both the full length Cry1Ac protein and the activated core toxin, since their*

> *lepidopteran prey may have ingested INGARD® cotton tissues and metabolised the full-length protein, leaving the core toxic element 'free' in the insect's gut*
>
> (OGTR 2003b, pt. 204)

While the above quote seems to indicate awareness that predators may be exposed to the active toxin through their consumption of prey, this makes the later critique of the relevance of the Hilbeck et al. (1998a&b) and (1999) findings somewhat incoherent. The RARMP has acknowledged that invertebrates may be exposed to the core toxin through the consumption of prey and the studies by Hilbeck and colleagues have demonstrated potential negative impacts through this route of exposure. To dismiss the relevance of these findings on the basis that the plant involved expressed the core toxin rather than the full length toxin seems to be at odds with the notion that exposure to the core toxin can occur through the consumption of the prey anyway.

A potentially more important problem relating to the accuracy of the critique is whether INGARD® does actually express the full length Cry1Ac protein as claimed. This RARMP was structured around the belief that INGARD® cotton expresses a full length Bt protein rather than an activated toxic core as expressed by most other Bt plants. This is, however, a questionable assumption. In an email correspondence from CSIRO scientist Ray Akhurst, I was informed that:

> *It is not entirely clear what form of the toxin is expressed in transgenic cotton. The protoxin gene is used and so the protoxin (ca 130kDa) is produced. However, our investigation showed that the Cry1Ac in INGARD cotton was about 65kDa, which is around the*

> *size of the activated toxin. Although the 65kDa suggests that the protein is in the toxin form, we have not confirmed that the protoxin has been completely reduced to the toxic core (i.e. it may be slightly larger and reduced to the core within the insect)*
>
> (Akhurst 2005).

This means that, although there is uncertainty about the form of Cry1Ac expressed in INGARD® cotton, the size of the protein suggests that it is in the active form. If this is true, it not only raises questions about the accuracy of the critique applied to the studies by Hilbeck and colleagues, but it also raises serious questions about how the expression of an active core toxin may impact on risk assessment. Even if the protoxin has not been entirely reduced to its toxic core, important questions still remain. Both Hilbeck et al. (1998b) and Ponsard et al. (2002) cite the work of Haider et al. (1986) as demonstrating that the specificity of Bt toxins can change with the size of the protein and the way it is processed in an insect gut. If the protein being expressed by INGARD® cotton is of a size that represents neither the full length protein nor the completely reduced toxic core, then this raises questions about the appropriateness of the assumption of specificity that underpins much of the risk assessment.

Activation of the toxin in the insect gut is commonly viewed as an important element contributing to the specificity of Bt toxins. The risk assessment for Bt cotton has been based on the belief that the full length protein is expressed and the assumption that as such, its bioactivity is highly specific. It now appears, however, that there is uncertainty about the form of Cry1Ac expressed in INGARD® cotton. I would argue that this issue really requires further clarification before an accurate and sound scientific risk assessment is possible

as the impacts of a full length protein and an activated core toxin on invertebrates within multi-trophic food webs could arguably differ substantially.

As Ponsard et al. (2002) actually used Bt cotton as their test material for examining prey-mediated effects, one might expect that this study would be considered relevant to the assessment process. Once again, however, we find the RARMP critiquing this study that reports negative findings. After documenting the results of this study, the RARMP states that "the inconsistent experimental approach among other technical considerations reported in this paper highlight the need to interpret the study's results with caution" (RARMP 2003b, pt.213). The variations in the experimental approach used by Ponsard et al. (2002) are justified by the authors as the result of attempting to achieve "greater realism" in their experiment. The variation appears not to have been considered significant enough by expert peers to disqualify the paper from publication and yet it appears to have been significant enough for the RARMP to effectively ignore the findings. The RARMP states that the results must be interpreted with caution but as there were no requests for further research or monitoring or a conclusion that invertebrates may be exposed to prey-mediated effects, the results appear to have been interpreted as irrelevant.

The final issue relating to the critique of methodologies that I would like to discuss in this section relates to critiques occurring within cited scientific studies. Hilbeck et al. (1998b) critique the experimental method used to attain the results reported in Sims (1995)[89]. Hilbeck et al. (1998b) question the high control mortality rates of this study (up to 30% after only nine days) and says

[89] Sims (1995) describes the results attained in the unreviewed study by Palmer & Beavers (1993a) examining the impact of Bt toxins on *Chrysoperla carnea.*

that "a population suffering 30% mortality may be stressed". They also question whether the method reported in Sims (1995) would actually have allowed the larvae to ingest Bt proteins because the experiments coated eggs with Bt proteins while chrysopid larvae actually feed by sucking the contents of the egg out. Finally, Hilbeck et al. (1998b) question the timeframe used in the study. The experiments reported in Sims (1995) only exposed larvae to Bt proteins for a small portion of their development time (up to nine days), a timeframe within which Hilbeck and colleagues suggest much, if not all, of the increased mortality they observed would have been missed depending on the larval development stage chosen.

What is particularly interesting here is that one of the scientific studies cited in the assessment is clearly critiquing the method used in another but this critique has not been mentioned in the RARMP. Even if the evaluators performing the assessment are not qualified to pick up methodological flaws, when questions are raised in peer-reviewed studies cited elsewhere in the assessment, the RARMP could be expected to at least engage in the discussion. By failing to report and consider the methodological problems of Sims (1995) as outlined by Hilbeck et al. (1998b), the RARMP again appears to be uncritically accepting studies that report findings supporting the assumption of specificity.

In dismissing the findings of studies on prey-mediated effects, the risk assessment is clearly concerned with minimising false positives, (e.g. saying that there is the potential for harm when really there isn't), or what are referred to as Type I errors (Fairbrother & Bennett 1999; Barrett & Abergel 2002). Minimising false positives is an important part of scientific practice; however, minimising false negatives (or Types II errors) must be an important part of regulatory practice (Fairbrother & Bennett 1999). In risk assessment and

regulatory settings, a false negative (concluding there is no impact when in fact there is) is arguably far more serious than a false positive. For example, if you assume that there will be no impact and you are wrong, this is a serious error with the potential for disastrous consequences; whereas, if you assume there will be an impact and further testing reveals this not to be the case, then the consequences of the error are likely to be far less significant. In dismissing the findings of studies on prey-mediated effects, the RARMP is in danger of making a Type II error and committing the serious regulatory mistake of drawing a false negative conclusion[90].

What this section has indicated is that although the risk assessment did incorporate a discussion of the scientific studies on prey-mediated effects after I raised the issue in a written submission, in handling this information, the RARMP marginalised the impact of the studies' results on the assessment of risk by engaging in its first instance of methodological critique. In my submission, I requested additional data collection on non-target impacts in light of these studies and/or ongoing monitoring as a licence condition. Although the RARMP described the significance of the results as "unclear", it did not request either increased data collection on prey-mediated effects or ongoing monitoring efforts as a means of clarification. While laboratory studies demonstrating safety were accepted without question, the discussion of negative findings from the prey-mediated studies concluded with the statement that "Studies of Bt toxin-expressing plants conducted in field situations are significantly more informative" (OGTR 2003b, pt.214).

[90] Interestingly, while the regulatory authority of the Netherlands originally concluded that Bt crops would pose no risk to non-target organisms based on an assumption of specificity, this judgement was reconsidered when its expert advisory committee highlighted multi-trophic effects and impacts on soil ecosystems as issues involving a high degree of uncertainty. This lead to a regulatory reconsideration and requests for increased evidence of no effects before commercial licences for Bt crops could be granted (Schenkelaars 2005).

2.3 STUDIES CONDUCTED IN THE FIELD

2.3.1 THE RELIABILITY OF CITED SCIENTIFIC STUDIES

The first field studies cited in the RARMP are those of Addison (2001a & 2001b). It is stated that these are studies on the effects of INGARD® cotton on non-target arthropod populations and were conducted in Queensland over two seasons. Both of these studies are unpublished reports from Monsanto and unfortunately, despite lodging a request for a copy of these studies on three separate occasions, the OGTR has been unable to provide me with these reports and I can therefore make no further comment on their reliability[91].

The second reference cited for field studies is Fitt & Wilson (2002). The RARMP states that this represented a series of large scale field experiments over three growing seasons. The study was carried out on one unreplicated field site in 1994/1995, continued on three sites in 1995/1996 and when commercial production began in 1996/1997, the study examined five different commercial cropping sites. It is stated that the research plots used were mostly several hectares in size. The RARMP states that the only significant difference observed in these studies was a reduction in specialist *Helicoverpa* parasitoids during one season. This is described as expected because INGARD® cotton was designed to reduce populations of *Helicoverpa*, the host insects for these parasitoids. This study was conducted by independent researchers and published as part of conference proceedings. As an independent and published Australian field study performed using INGARD® cotton, it is a study with a high reliability rating for the assessment process.

[91] As for the other studies I was unable to view, the reference details listed in the bibliography have been taken from the RARMP.

The next cited reference is an independent and peer-reviewed study by Mensah (2002). The RARMP states that this reference reports on studies conducted in New South Wales over both the 1996/1997 and 1997/1998 cotton growing seasons and compared "the abundance of predatory beetles, bugs, lacewings and spiders in INGARD® and conventional cotton fields" (OGTR 2003b, pt. 217). After highlighting how both conventional and INGARD® crops were sprayed with insecticides as required during commercial production, the RARMP claims that the INGARD® crops received between 25-60% fewer sprays and generally had higher levels of all predators examined. The study involved trials conducted at three different sites (170ha, 132ha and 50ha in size) with four replicate treatments at each study site. As an independent and peer-reviewed study conducted in Australian INGARD® cotton fields, this can also be viewed as a study with a high reliability rating.

The fourth field study cited in the assessment is an American study by Naranjo & Ellsworth (2002). This study was independently conducted and published as part of conference proceedings. The study reported on two investigations, the first comparing natural enemy abundance and arthropod diversity in conventional cotton fields and cotton expressing the Cry1Ac protein in 1999 and 2000. The second study examined comparative rates of predation and parasitism in Bt and non-Bt plots in 2001. The field research plots ranged in size from 0.03-0.15ha and each treatment was replicated four times. The RARMP cites this study as indicating that the diversity and abundance of predators is unaffected by the Cry1Ac toxin and that the level of parasitism and predation was also unaffected. While this study can be seen to hold some relevance for the assessment process, the fact that it was conducted in America and used very small plot sizes limits its reliability rating.

The final study cited in the section on field trials is that of Xia et al. (1999)[92]. This is cited as a study conducted in China that showed an average increase in insect predators of 24% in INGARD® over conventional cotton due to a reduction in insecticide use (OGTR 2003b, pt. 219). While this study has been independently conducted and published, no detailed description of experimental method was provided so I cannot report on the time frame of the study, how large the plots sizes were, how insects were collected or any other details relating to how the results were arrived at. The paper also provides no references and is very confusing in its expression at times. As a study conducted in China with no detail of experimental method, I would class this as a study with a low reliability rating for the assessment process.

2.3.2 The Use of Scientific Information

Considering the titles provided in the reference list, the RARMP seems to have misrepresented Addison (2001a & 2001b). In the body of the RARMP, these are referred to as studies on INGARD® cotton, while the titles given in the reference list suggest that they have actually examined Bollgard II® ("Bollgard II – Non-target arthropod East 1999/2000" and "Bollgard II – Non-target arthropod East 2000/2001"). Unfortunately, I cannot be sure of this or any other potential misrepresentations as copies of the studies were not released to me. There is, however, misleading presentation in the way the RARMP refers to the study by Fitt & Wilson (2002). The beginning of pt. 216 of the RARMP cites Fitt & Wilson (2002) as "a series of large scale field experiments over three growing seasons in Australia" showing no negative impacts. Further down the same paragraph, the RARMP states that "Studies of invertebrate abundance were also conducted in commercial cotton crops in the 1996/1997 season" (OGTR 2003b, pt. 216). The term "also" here suggests an additional study to those

[92] The RARMP bibliography inaccurately cites the journal title for this article as Acta Gossyppi Sim rather than Acta Gossypii sinica.

mentioned in the opening sentence of the paragraph. In actual fact, the 1996/1997 season is one of the three seasons studied by Fitt & Wilson as referred to earlier. This means that the use of the word "also" is another subtle example of how the RARMP has misleadingly presented studies in a way that gives the impression that there is more supporting evidence than actually exists.

In citing the Fitt & Wilson (2002) study results, it is interesting that the RARMP fails to mention the finding that outbreaks of aphids were found to occur earlier in the unsprayed conventional and Bt cotton crops and that in some cases, aphids were significantly more abundant in the Bt cotton crops than in the unsprayed conventional cotton. While this may not represent a negative impact of the Cry1Ac toxin on non-target insects, it could potentially be viewed as important information for assessing environmental risks as it indicates the emergence of secondary pests that may then need to be controlled by broad-spectrum pesticides. As the RARMP often refers to a reduction in pesticides as representing a positive impact of Bt cotton for non-target organisms, any results indicating potential future challenges to this should arguably be discussed in the assessment rather than ignored.

It is also interesting to note that both Fitt & Wilson (2002) and Naranjo & Ellsworth (2002) refer to the laboratory studies conducted by Hilbeck and colleagues, with Fitt & Wilson (2002) specifically highlighting how these studies can be seen to identify a potential hazard to non-target organisms. Both of these field studies were cited in the original consultation version of the RARMP and this really raises the question as to why the prey-mediated studies by Hilbeck and others were not examined in this earlier version of the assessment. In reading the papers cited, the evaluators would have been alerted to the

literature on prey-mediated effects and should arguably have then included them in the original assessment.

One of the most interesting details about how scientific studies conducted in the field were used in the assessment relates to the way in which Mensah (2002) was cited. The RARMP states that this was a study comparing INGARD® and conventional cotton fields. Actually, the focus of this study was on integrated pest management approaches (IPM) and how they compare to both conventional and INGARD® cotton production. What is particularly interesting about this is that the study reported that at all study sites, the highest number of predators were found in plots managed using IPM methods. The study also found that the cotton yields of the IPM managed sites were not significantly different to those of conventional and INGARD® cotton crops and that the average gross margin per hectare was actually highest under the IPM treatment.

While I believe the RARMP is seriously misrepresenting the content of this study by failing to mention its use of IPM methods as the primary comparison and failing to report any of the positive findings associated with this, I can also find no reference in the study to the 60% fewer insecticide sprays used on INGARD® referred to in the RARMP. The study does, however, mention that the IPM managed plots required up to an average of 50% fewer insecticides than the INGARD® plots (Mensah 2002). Most of the insecticides required to commercially produce an INGARD® crop are reportedly for late infestations of *Helicoverpa armigera* and for secondary pests (Mensah 2002). If the risk assessment had made a point of comparing the performance of INGARD® cotton with IPM methods as well as with conventional cotton cropping

practices, the RARMP's presentation of this study's results would arguably have been more accurate.

Interestingly, the study by Mensah (2002) was also not referred to in the consultation version of the assessment. As the final RARMP discussed the studies on prey-mediated effects but largely dismissed the results by suggesting that studies conducted in the field were significantly more informative, there was arguably a need to have a number of field studies informing the assessment. As the only study on INGARD® conducted in the field in Australia cited in the consultation version was that of Fitt & Wilson (2002), the OGTR potentially viewed that of Mensah (2002) as an additionally useful resource. By failing to document and engage with the key findings of this study in relation to the advantages of IPM management methods over INGARD® cotton for impacts on non-target organisms, however, the study's findings have only been selectively reported.

It also seems strange that despite having seven years of commercial INGARD® cotton production before this assessment was conducted (and a number of years of field trials before that), Mensah (2002) and Fitt & Wilson (2002) were the only two published studies on non-target invertebrate impacts in Australia. It is also interesting to note that recent independent peer-reviewed Australian research reports slightly lower numbers of Chloropidae and Drosopillidae (Diptera), damsel bugs (Hemiptera Nabidae) and jassids (Hemiptera Cicadellidae) in INGARD® compared to conventional cotton (Whitehouse et al. 2005). The authors of this paper suggest that the effects of these differences should be monitored over the long term. Of course, without licence reviews and renewals, it is unclear how this recent research will impact on the Bt cotton licences already issued.

The two concerns I have in relation to how the Naranjo & Ellsworth (2002) study was quoted in the assessment again relate to misrepresentation and selective reporting. In the RARMP it states that the collection methods involved in the study included pitfall trapping, sweep nets, beat buckets and plant inspections. The study itself, however, states that only the results from sweep nets and pit fall traps are reported. A finding of the study that the RARMP fails to mention is that seasonal densities of some of the natural enemies were significantly lower in Bt plots. While this difference was not consistent across seasons, it was a negative finding of the study that the RARMP failed to document and discuss.

I find the assessment's citation of Xia et al. (1999) also particularly problematic. My main concern in relation to this study is the complete lack of critique that it receives. While the RARMP critiqued the relevance of the Ponsard et al. (2002) study based on an inconsistent experimental approach, Xia et al. (1999) appears to outline no clear experimental approach at all and yet this critical scientific flaw receives no mention. The study is also almost incomprehensible due to endless errors in expression and presentation. Compounding this problem of no clear critique of a questionable study is the fact that the RARMP also only selectively reports the findings. Xia et al. (1999) reported that Bt cotton had very significantly reduced numbers of parasitoids and that when *Helicoverpa* were no longer the main pests, then spider mites, aphids and thrips took over this role. Again the RARMP appears to be ignoring information on the problem of secondary pest emergence and what a decreased number of parasitoids might mean for IPM approaches.

By assuming that the only relevant comparison for considering the non-target impacts of INGARD® cotton is with conventional cotton, the RARMP appears to be sidelining the flow on problems that could be created by the emergence of secondary pests and a reduction in populations of specialist parasitoids. The assessment also involves a clear assumption that INGARD® reduces insecticide use, that this has a positive impact on non-target organisms and that this situation will continue indefinitely. At one point, the RARMP states that:

> *The commercial release of INGARD® cotton has reduced the use of broad-spectrum insecticides on Australian cotton crops and several studies have found that overall numbers of non-target invertebrates in INGARD® cotton fields are the same or higher than in conventionally sprayed fields of non-GM cotton. Increased numbers of non-target invertebrates are likely to relate directly to reductions in chemical insecticide use*
>
> (OGTR 2003b, pt. 219).

The strangest thing about this statement is that, although suggesting that "several studies" have found no negative effects, no reference details are provided to support this statement, nor are there any references provided to support the statement that INGARD® has reduced the use of broad-spectrum insecticides. While I have already questioned the longevity of this decrease in insecticide use given the reported problems with secondary pest emergence, perhaps a stronger challenge to this comes from the cited study of Mensah (2002). While the RARMP did not mention this, Mensah (2002) observed no consistent reduction in pesticide applications for INGARD® when compared to conventional cotton. Mensah (2002) also states that these findings support those of the Economic Research Survey of the USDA (1999) where it was also found that transgenic plants do not significantly reduce the use of chemical

insecticides. While INGARD® cotton may reduce insecticide use, statements on this in the RARMP really require the support of detailed empirical references; especially since these claims are contradicted by one of the studies referred to in the RARMP. Empirical studies with a clearly detailed method are also required so that it is clear whether or not the plant's own expression of a pesticide has been incorporated into the equation. As the RARMP is required to consider long term risks (OGTR 2002a), it is also important that consideration is given to the question of how long the benefit of reduced insecticide applications is expected to last given the potential problems posed by secondary pest emergence and the development of insect resistance.

2.4 Multi-trophic Studies of Cry Toxins

The final section in the risk assessment dealing specifically with invertebrates is one entitled "Multi-trophic studies of Cry toxins". This section is new to the final version of the assessment as it did not appear in the consultation RARMP. In my submission on the consultation RARMP for INGARD®, I highlighted my concern that the assessment had not considered multi-trophic impacts and the scientific literature on this issue (as discussed in section 2.2 above). While the scientific studies on this issue raised in my submission were discussed in the final RARMP under the heading "Studies conducted under controlled conditions"[93], a new section on multi-trophic impacts was added. In this new section, the focus is on potential indirect impacts on ecological communities rather than on prey-mediated effects.

[93] It is worth noting that placing the multi-trophic studies that reported negative findings under the title "Studies conducted under controlled conditions" rather than under "Multi-trophic studies of Cry toxins" works to marginalise their relevance by emphasising the laboratory element of the studies rather than their use of realistic exposure pathways.

2.4.1 The Reliability of Cited Scientific Studies

The key paper informing the RARMP's discussion of multi-trophic studies is Groot & Dicke (2002). This paper is independently written and peer-reviewed. It reviews the scientific information on "Insect-resistant plants in a multi-trophic context" rather than reporting original research. As a published paper reviewing scientific studies on Bt plants in multi-trophic contexts, it can be seen as highly relevant for the assessment process. The paper is cited in support of the RARMP's statement that indirect impacts on arthropod community structure have been demonstrated in the field but that this probably reflects the dispersal of predator species to non-GM habitats rather than any direct prey-mediated toxic effect (OGTR 2003b, pt.220).

The other studies referred to in this section of the RARMP are those of Addison (2001a & 2001b) and Naranjo & Ellsworth (2002). These studies are cited as demonstrating that the abundance of predators and parasitoids is not negatively affected by Bt cotton. As I mentioned previously, I have been unable to acquire a copy of the Addison studies and so can not comment on their relevance or reliability for the discussion of multi-trophic impacts. I reviewed the study by Naranjo & Ellsworth (2002) in section 2.3.1 above and concluded that it was relevant to the assessment but that its reliability for this assessment was qualified by the use of small plot sizes and an American field context.

2.4.2 The Use of Scientific Information

The RARMP cites Groot & Dicke (2002) as supporting the idea that altered arthropod communities in Bt cotton fields are likely to be the result of predator dispersal due to decreased prey abundance rather than any direct or prey-mediated toxic effect. While Groot & Dicke (2002) do suggest that in contrast to generalists, specialist natural enemies are likely to move to alternative sites if a

GM plant reduces the density of their prey organisms, this is a minor aspect of the paper's findings. The paper by Groot & Dicke (2002) emphasises a range of other issues in relation to multi-trophic impacts that the RARMP has not reported and/or discussed.

In their discussion of dispersal, Groot & Dicke (2002) draw attention to the fact that there is a lack of field studies that have examined impacts on specific predator and parasitoids species rather than overall population density in general. They also highlight the potential problem of herbivores sequestering the Bt toxins and using them in their defence against carnivorous enemies (a process already demonstrated with allelochemicals). They discuss the uncertainty that still surrounds the question of what happens to Bt toxins inside the guts of non-target herbivores and whether these herbivores could act as intermediaries that pass the toxin along the food chain to their predators. The authors also discuss the problem of Bt toxins binding to the soil and retaining their toxicity and the impacts this may have on non-target organisms in multi-trophic contexts. Importantly, they highlight the differences between Bt sprays and Bt plants that prevent a simple inference of safety and also suggest that the effects on non-target organisms reported to date are likely to be an underestimate as the more recent Bt crops have much higher levels of expression. Finally, the authors conclude that "studies on the multi-trophic aspects of transgenic insect-resistant crops are badly needed" (Groot & Dicke 2002).

None of these issues raised by Groot & Dicke (2002) are reported or discussed in the RARMP's discussion of multi-trophic studies. This source has been selectively cited to suggest that dispersal rather than toxicity explains altered invertebrate community structures. By choosing not to engage with all of the

other questions and concerns raised in the paper, the RARMP appears to again be citing evidence that supports an assumption of toxin specificity while not engaging with issues that may challenge this assumption. It is also interesting that despite the conclusion by Groot & Dicke (2002) that studies on multi-trophic impacts are badly needed, no request for data collection on this issue was made in the licence conditions for INGARD® cotton.

Even if we accept that dispersal to different habitats is the only effect Bt cotton will have on invertebrate communities, the decision not to request more information on this is surprising because the RARMP clearly states that the "Potential impacts of such dispersal does not appear to have been investigated" (OGTR 2003b, pt.221). Rather than requesting that these potential impacts be investigated to allow for a sound scientific assessment, the RARMP refers to Addison (2001a & 2001b) and Naranjo & Ellsworth (2002) as demonstrating that the abundance of predator and parasitoids species is not adversely affected by Bt cotton and therefore any dispersal that may have happened is "unlikely to be ecologically significant" (OGTR 2003b, pt.221). If the issue remains uninvestigated and the RARMP makes statements like 'unlikely to be significant', this is clearly an example of the assessment relying on assumptions and judgements rather than empirical evidence.

It is also worth noting that in this particular discussion, the RARMP only refers to the studies by Addison (2001a & 2001b) and Naranjo & Ellsworth (2002), while in the earlier section on field studies, the papers by Fitt & Wilson (2002) and Xia et al. (1999) were also part of the discussion. What is interesting about this is that both Fitt & Wilson (2002) and Xia et al. (1999) observed reductions in specialist parasitoids in Bt cotton fields. By not referring to these two field studies in the discussion on multi-trophic impacts, the RARMP is able to claim

that no adverse effects on predators and parasitoids have been observed and infer that any dispersal would be unlikely to be significant. Rather than engaging with the problem of observed reductions in parasitoids, a lack of information on whether this is due to dispersal and what impacts this dispersal may have on ecosystem structure and function, the RARMP instead selectively cites only those field studies that enable the issue of dispersal to be sidelined as "unlikely to be ecologically significant" (OGTR 2003b, pt. 221).

The issue of indirect ecological impacts is arguably an area of high indeterminacy. It would be near impossible for the OGTR to gather enough empirical evidence to allow a sound scientific assessment of all the potential 'ripple effects' (their phrasing) that Bt cotton may create through the food web. Rather than admitting to the problems associated with this and being transparent about how decisions have been made in the face of this indeterminacy, however, the RARMP section on multi-trophic studies begins with the statement that:

> *The potential for insecticidal Cry toxins expressed by GM plants to impact on ecological communities in the natural environment in unexpected indirect ways, by affecting interactions between organisms elsewhere in the 'food web' has been considered*
>
> (OGTR 2003b, pt. 220).

This statement immediately raises questions such as: What does it mean to consider unexpected impacts? Are they still unexpected if you have been able to consider them? What is the relationship between consideration and sound scientific risk assessment, particularly in cases where it is claimed that the issue has not yet been investigated?

For issues of indeterminacy such as how Bt cotton will alter invertebrate community structures and the impacts this may have on complex interacting food webs, risk assessors will need to make inferences and personal judgements, which will be influenced by beliefs and assumptions. What is important is that there is a recognition of this rather than an attempt to suggest that decision-making is a simple process of scientific risk assessment.

2.5 Adequacy and Appropriateness of Conclusions

Following the assessment of the risks Bt cotton poses to invertebrates as reviewed here, the RARMP concludes that:

> *Studies conducted under controlled conditions and in the field indicate that populations of key non-target invertebrates are unlikely to be affected by the Bt toxin. Indeed it is likely that their populations would be favoured by associated decreases in the use of broad-spectrum insecticides.*
>
> (OGTR 2003b, pt. 231).

This conclusion clearly indicates that a comparison with conventional chemically intensive agricultural practices has been an important element in assessing the risk Bt cotton poses to non-target organisms and arriving at a decision on the acceptability of this risk. While the assessment did not actually cite any scientific studies demonstrating a decrease in the use of broad-spectrum insecticides with Bt cotton, there is a clear assumption that this is the case and will remain so indefinitely. Challenges to this conclusion could therefore be mounted in terms of whether Bt cotton does substantially decrease the use of broad-spectrum pesticides, how long this reduction can be expected

to last and whether the comparison with conventional chemically intensive practices is the only relevant one for deciding on risk acceptability.

It is also worth highlighting here that this conclusion appears to reveal a form of risk/benefit analysis, while the OGTR has only been charged with the task of assessing risk. In the Risk Analysis Framework (2004) used by the OGTR, it is stated that:

> *The exclusion of benefits means that where there may be some beneficial impact on human health or the environment from the GMO this does not form part of the Regulators decision. An example of such a situation could be where the deployment of a GM crop resulted in reductions in the use of a pesticide…The Regulator may acknowledge that there may be such benefits, but does not consider them in the risk assessments that are prepared as part of the decision-making process.*
>
> (OGTR 2004, pt. 47)

As the likelihood of benefits features so prominently in the conclusion relating to invertebrate impacts, it appears as though an understanding of benefits has been drawn into the risk assessment and decision-making process.

The use of the terms "unlikely" and "likely" in the conclusion on invertebrate impacts suggests knowledge about probability that does not exist. It also represents value judgements that could easily be debated, depending on how much emphasis is placed on the different studies (particularly those using multi-trophic testing systems) and what are considered to be 'key non-target invertebrates'. It could contrastingly be concluded that studies on the invertebrate impacts of Bt cotton have produced conflicting results and that

there are some pathways of exposure that require further investigation. Additionally, it could be argued that the conclusion of the assessment should relate to the impacts of Bt cotton as a whole and not just the Bt toxin. One reason for this is that while the toxin itself could be viewed as unlikely to affect key invertebrates, there may be risks associated with changes in the distribution and abundance of insect communities created by Bt cotton. In this case, the emphasis might be on ecosystem structure and function rather than individual organisms or species and the conclusion might be that assessing impacts across so many species interacting through various interconnecting food chains represents an element of indeterminacy for the assessment process and therefore continued monitoring efforts are important.

With so many different species, various suggested pathways of exposure, conflicting results from limited information, and debate about the relevant comparisons, it could be argued that any general conclusions drawn from the scientific studies available on the impacts of Bt cotton on non-target invertebrates remain open to debate and are therefore not particularly robust.

3. MICROORGANISMS, PARTICULARLY SOIL MICROORGANISMS

The first half of the assessment on microorganisms deals with the issue of exposure while the second half of the assessment focuses on toxicity. To assist with handling the large amount of information dealt with in relation to microorganisms, I have also chosen to discuss these two sections separately, although it should be noted that the assessment as a whole clearly requires their integration.

3.1 EXPOSURE OF MICROORGANISMS TO INGARD® COTTON

3.1.1 THE RELIABILITY OF CITED SCIENTIFIC STUDIES

The first two references cited in the RARMP in relation to microorganisms are Saxena et al. (1999) and Stotzky (2000b). Both of these references are cited in support of the statement that in addition to being exposed to Bt toxins when the cotton plants decompose, microorganisms may also be exposed as a result of the plants exuding the toxin through their roots, as observed in Bt corn (OGTR 2003b, pt. 222). Saxena et al. (1999) presents the findings of a laboratory study examining Bt corn (expressing Cry1Ab) for 25 days. This is an independently conducted, peer-reviewed and published paper. As such, it holds a reasonable reliability rating for the assessment process, although this is qualified by the fact that it studied Bt corn expressing Cry1Ab rather than Bt cotton expressing Cry1Ac. Stotzky (2000b) is also an independent, peer-reviewed paper but it represents a review of the published scientific research on the persistence and biological activity of Bt toxins in the soil rather than an empirical study. As an independent and published paper reviewing the scientific information on this issue, however, it is a relevant and reliable reference for the assessment process.

The RARMP goes on to cite Gupta et al. (2002) as demonstrating that the roots of INGARD® cotton also release the Cry1Ac protein into the soil during growth. This was, however, qualified in the RARMP by the statement that this release was not quantified in the soil and the mechanism for release was not clear (OGTR 2003b, pt. 222). Gupta et al. (2002) is an independently conducted laboratory study examining INGARD® cotton plants published in conference proceedings. Analysis of the plants occurred from four - nine weeks after germination. As an independent, published study conducted on INGARD® cotton plants, it has a high reliability rating for the assessment process, limited only by not being conducted under field conditions.

In discussing the issue of the exposure of soil microorganisms to Bt toxins, the RARMP states that the level of exposure is "likely to decrease with time as a result of soil biodegradation" (OGTR 2003b, pt. 223). The RARMP refers to Ream (1994b) and states that this study compared the rate of biodegradation for Cry1Ac in INGARD® cotton plants with that of the purified Cry1Ac protein. The plant derived Cry1Ac degraded with a half life of 41 days while the purified protein took 9.3-20.2 days. Ream (1994b) is an unreviewed and unpublished laboratory study conducted by Monsanto. The purified toxin was incubated in the soil for 54 days while the cotton tissue samples were only incubated for 42 days. These factors mean that despite its use of cotton tissue expressing the Cry1Ac protein, its reliability for the assessment process is low relative to those discussed above.

The next study cited in the RARMP for the exposure of microorganisms is Palm et al. (1996). This paper is cited as another study on Bt toxin degradation rates that found variable results but indicated half lives for Cry1Ac degradation from 2.2-46 days (OGTR 2003b, pt. 223). Palm et al. (1996) is an independent, peer-reviewed study that used different lines of Bt cotton (one expressing Cry1Ab and another two expressing Cry1Ac) as well as a purified form of the Cry1Ac toxin. The study involved 5 different microcosm experiments (with varying toxin concentrations and soil types) that ran from 28-140 days across three replicates. When judged according to my criteria, although this study was not conducted under field conditions, it can be given a relatively high reliability rating.

Head et al. (2002) is a paper cited in the RARMP as investigating the presence of Cry1Ac protein in field soils that had been under INGARD® cotton cultivation for 3-6 consecutive seasons (OGTR 2003b, pt. 224). This study was conducted by

Monsanto but was also peer-reviewed and published. The soil samples analysed were collected 3 months after the last tillage of the cotton plants into the soil and all samples are reported as showing no detectable level of Cry1Ac protein. The study used three samples from six different sites as well as a control soil sample taken from outside Bt cotton fields. As a peer-reviewed and published study that was conducted on field soils that had had years of Bt cotton cultivation, this study is certainly highly relevant to the assessment process. Its reliability is, however, reduced by the fact that analysis was conducted by the applicant organisation and the field conditions and soil types studied were those of the United States rather than Australia.

After the RARMP's discussion of Head et al. (2002), the following statement is made: "The typically rapid breakdown of Bt proteins in the soil, including that of Bt potatoes (Cry3Aa) and Bt corn (Cry1Ab), indicates that these proteins are not likely to accumulate at biologically significant levels" (OGTR 2003b, pt. 224). Three studies are cited in support of this statement – Palm et al. (1994), Sims & Holden (1996) and Head et al. (2002). I have already discussed the quality of the Head et al. (2002) study above. Palm et al. (1994) is an independent and peer-reviewed laboratory study that examined persistence of Bt toxins in the soil using leaf tissue from some cotton plants modified to express Cry1Ab and others expressing Cry1Ac. Three replicate soil samples were tested at 7 day intervals for 4 weeks. As a four week independent and peer-reviewed study using Bt cotton tissue, this is another study with a relatively high reliability rating.

Sims & Holden (1996) is a laboratory study conducted by a unit of the Monsanto company that is peer-reviewed and published. It used Bt corn expressing the Cry1Ab protein as its test material. The corn tissue was

incubated for 43 days, with two replicate samples taken at six different time periods. The samples were then mixed into an artificial insect diet for bioassays on 48 larvae for 7 days. The reliability of this study is limited by the fact that it used Bt corn as a test material, was conducted by the applicant and did not examine impacts under Australian field conditions.

To further support the statement that Bt proteins are not likely to accumulate in the soil, the RARMP claims that cotton in Australia is generally grown in alkaline soil in which the toxins "would desorb from clay soils and be degraded by soil microorganisms" (OGTR 2003b, pt. 224). While no reference is cited to support the notion of desorption occurring in alkaline soils, two references are cited after the statement that cotton in Australia is generally grown in alkaline soils with a pH between 7.5 and 8.5. These references are the Cotton Cooperative Research Centre (CRC) NUTRIpak and Tapp & Stotzky (1998). The NUTRIpak is an information CD created by the Australian research organisation the Cotton CRC. This particular CD is provided as a practical guide on cotton nutrition for farmers. As a guide produced for Australian farmers by an independent cotton research organisation, it can be expected to be a reliable source for citing information on the pH values of cotton growing soils in Australia.

Tapp & Stotzky (1998) is an independent and peer-reviewed laboratory study examining the persistence and toxicity of Bt proteins purified from insecticide formulations. This study examined the persistence and activity of the toxin in three different types of soil by using insect bioassays and ran for 6 months. The study also specifically tested the effect of soil pH on the persistence of Bt toxins. As an independent and peer-reviewed study that was conducted over a 6 month timeframe, this can be classed as a reference with a good reliability

rating. It is, however, limited by not using Bt cotton tissue and being a laboratory study rather than one conducted in the field.

3.1.2 The Use of Scientific Information

The RARMP cites Saxena et al. (1999) as demonstrating the exudation of Bt toxins through the roots of GM plants. There are, however, a number of other statements made in this study that the RARMP does not report on. These include that further investigations are necessary to understand the impacts of Bt toxins on soil organisms and that as receptors have been found in non-target insects, there may be a risk that non-target insects and organisms in higher trophic levels may be affected by the toxin. This study also summarises the work of other soil scientists showing that Bt toxins bind rapidly and tightly to soil particles and in doing so, retain their insecticidal activity, persist in the soil and become resistant to microbial degradation.

Stotzky (2000b) is also cited as demonstrating root exudations but once again, other important statements made in this study were not reported. Similarly to Saxena et al. (1999), Stotzky (2000)[94] reports rapid and tight binding of Bt toxins on clays and humic acids where they retain their insecticidal properties but have a reduced susceptibility to degradation. Other relevant findings reported in this paper but not mentioned in the RARMP are that toxin activity was detected after 234 days (the longest time tested), bound toxins from *Bacillus thuringiensis* subsp. *kurstaki* were found to be more toxic than free toxins and bound toxins were not being utilised as a source of carbon. In this paper reviewing the available scientific information, Stotzky also concludes that Bt toxins could accumulate to concentrations that may pose a hazard to non-target

[94] While the RARMP refers to this study as Stotzky (2000b), upon examination of the assessment's bibliography I found that the reference details for Stotzky (2000a) and (2000b) are identical. In light of this I have chosen to simply refer to this study as Stotzky (2000).

organisms if production exceeds consumption, inactivation and degradation. Additionally, this paper highlights the potential indirect hazard to non-target organisms through tritrophic interactions. Stotzky (2000) suggests that these hazards are exacerbated by having the plants expressing the active toxin because non-target organisms in various trophic levels could be susceptible without requiring the high gut pH and enzymes necessary to activate the protoxin.

After reviewing the available scientific information on the persistence and activity of Bt proteins in the soil, Stotzky (2000) concluded that before the widespread use of Bt plants:

> *the persistence of their products and the potential effects of the products on inhabitants (e.g. microbiota) of soil and other habitats must be thoroughly evaluated. Unfortunately such studies were apparently not conducted, nor requested by the relevant regulatory agencies before the release of Bt- containing and other transgenic plants*
>
> (Stotzky 2000).

This echoes the conclusion reached by Saxena et al. (1999) that there is not enough information to be able to adequately judge the impact Bt plants will have on soil organisms and communities. Despite these conclusions of the cited studies, the RARMP's assessment made no mention of any limitations in information and did not request that further studies be conducted. This means that through selectively reporting information from the cited studies, the RARMP has effectively concealed scientific uncertainty.

The study by Gupta et al. (2002) contains statements that seem to contradict the RARMP. As I discussed previously, whether the Bt cotton plants are expressing the active core fragment or the protoxin will have potentially important implications for how risks are assessed. While the assessment has assumed that INGARD® cotton plants express the protoxin, Gupta et al. (2002) makes a statement suggesting otherwise and this should arguably have inspired some kind of further investigation or discussion. Also, while the RARMP concludes that accumulation of the Bt toxins is unlikely to occur, Gupta et al. (2002) (and Stotzky 2000) contrastingly suggest that there is potential for Bt toxins to build up in the soil. Finally, as in the two studies already discussed in this section, Gupta et al. (2002) also highlight the need for further research (specifically in relation to changes in soil populations and biological functions as well as the potential for persistence of large quantities of Bt toxins in the soil and contamination of the wider environment through erosion and drainage). Once again, however, the RARMP obscures these areas of uncertainty by making no mention of the way in which the cited studies refer to the necessity for further research.

The discussion in this section has so far focussed on findings within the cited papers that have not been mentioned in the RARMP. The handling of the study by Ream (1994b) is particularly interesting in this sense because the RARMP does not mention the author's own critiques of the method used. The RARMP uses the findings of Ream (1994b) to suggest that the exposure of microorganisms will decrease with time as the toxins are degraded. Ream (1994b), however, highlights a number of problems associated with the method used to gain his results. The author states that sieved cotton tissue powder was used but not all of it passed through the sieve so the amount used in the experiments was not necessarily representative of the whole plant. He also

stated that some dissipation of the purified protein's bioactivity was observed when the soil samples were stored at -80degrees and that the samples may therefore have originally contained a higher level of bioactivity than the results reported. It is also worth noting that this study used a line of cotton that was never commercialised and that two of the treatment levels were reportedly too high to provide estimates of the half life for degradation given the time frame of the experiment. By failing to critique the method of this paper, even when the author himself noted a number of methodological issues affecting the results, the RARMP is clearly failing to critically judge the reliability of the scientific inputs used and appears to be unquestionably accepting and reporting positive results.

The RARMP cites Palm et al. (1996) as another study examining degradation rates for the Cry1Ac toxin and states that half lives in the order of 2.2 – 46 days were observed. What the RARMP fails to report in this case is that in only 4 of the 11 experiments did the data fit an exponential curve giving half lives of 2.2-46 days. The study also states that the rate of decay varied greatly between experiments and therefore decay and persistence will depend greatly on the conditions of the experiment or field release. This implies that sweeping generalisations on this topic are inappropriate and detailed experiments in field conditions or soils used to grow Bt cotton are really necessary to conduct a sound scientific assessment of risk. It is also worth noting that the study states that low amounts of toxin may persist for several weeks or months (the RARMP makes a similar statement but without reference support) and that this may be of concern if any non-target organisms are affected at low doses or if repeated use of plants causes accumulation. The RARMP does not discuss the potential risks associated with persistent low dose exposures. This could be seen as linked to the fact that the information required to assess this risk in a

scientifically robust manner is not available. Rather than highlighting the potential risk and requesting more information, however, the RARMP appears to have simply excluded consideration of this potential problem from the assessment.

In terms of method, Palm et al. (1996) states that a proportion of the toxin remains unrecoverable from the soil and that recovery efficiency varies with soil type. It was also stated that in experiments where the extractable concentration of the toxin decreased over time, it was unclear whether the cause of the decrease was biotic degradation of the toxin or its slow adsorption to soil particles. The RARMP only cites Palm et al. (1996) for degradation rates and does not mention the methodological problems associated with distinguishing between degradation and adsorption and with extracting all Bt toxin from the soil for quantification. The difference between degradation of the toxin and its binding to soil particles through adsorption is a particularly important distinction for assessing risk because, as previously mentioned, Bt toxins retain their bioactivity when bound to soil particles. While the RARMP does state that "The Cry1Ac protein adsorbs to various soil components (e.g. humic acids, clay minerals), rendering it resistant to microbial degradation" (OGTR 2003b, pt. 223), no mention is made of how this issue may impact on the rates of degradation cited in the assessment. It is also rather curious that no reference details are provided to support this statement on adsorption despite a number of the studies already cited (including Palm et al. 1996) engaging in a discussion of this issue.

The study by Palm et al. (1994) is also cited to support the statement that the typically rapid breakdown of Bt proteins in the soil means they are not likely to accumulate. In actuality, this study states that extractable toxin was detected at

every time point in all samples, which seems to contradict the claim that rapid degradation will limit accumulation. The study also states that there is a portion of the toxin that binds tightly to the soil, the fate of which cannot be determined by current extraction treatments. The authors clearly state that whether the bioactivity of non-extractable toxin decreases at the same rate as the extractable is unknown and they therefore suggest that further research and methodological improvements for extraction are required. As with the other requests for further research I have discussed, the RARMP fails to report on this field of uncertainty. It also completely fails to discuss the methodological problems associated with extracting the toxin from the soil and distinguishing between adsorption and degradation.

Head et al. (2002) is a study conducted in the field to assess whether Bt toxins were present following Bt cotton cultivation and whether they were accumulating across seasons. Firstly, the RARMP misrepresents the method of this study by suggesting that it was performed with INGARD® cotton when it was actually conducted with Bollgard®. While I have already raised questions about whether these two varieties can be considered equivalent for the risk assessment process, what particularly concerns me here is that in citing Head et al. (2002) as a field study looking at INGARD® cotton, this is falsely giving the impression that the studies were conducted in Australian cotton fields. Given that a number of the studies highlight the importance of soil type and actual field conditions for understanding the persistence and activity of Bt toxins, this misleading presentation seems particularly significant. It is also curious that after over five years of commercial Bt cotton production, there was no information from studies conducted at Australian field sites that could be cited on this important issue of toxin persistence and accumulation.

A further issue with the way the Head et al. (2002) reference has been cited in the assessment relates to methodological critique. I mentioned earlier how Ream (1994b) states that some dissipation of the purified Bt protein's bioactivity was observed when soil samples were stored at -80 degrees. This methodological approach was also used in Head et al. (2002). The RARMP did not report this particular finding from Ream (1994b) and as there was no critique of the method used in either study, the question of the impact this storage process may have on results relating to persistence and accumulation in the soil remains undiscussed and unexamined.

Along with most of the other studies cited in this section, Head et al. (2002) suggest that further research is required. They suggest that further research into Cry1Ac dissipation in crop fields at different times in the season as well as immediately after incorporation of residues into the soil is necessary. The authors suggest that this research is needed to understand the potential impact of Bt residues on soil non-target organisms but once again, the RARMP makes no mention of this uncertainty and the call by the scientists involved for further research.

The RARMP also cites Sims & Holden (1996) as suggesting that a rapid breakdown of Bt toxins will limit accumulation. While this again represents a failure to consider methodological problems with extraction and distinguishing between degradation and adsorption, what I find particularly interesting about the way in which this scientific study is cited relates to the relevance of laboratory vs field studies. The authors of this study specifically state that they are not sure how their results would compare with field situations as degradation rates would vary with soil type, microbial composition, climate and depth of tillage. Despite this statement coming directly from the authors of

the study, the RARMP did not discuss these limitations on how the results could be interpreted. What makes this particularly interesting is that the negative impacts on non-target organisms reported in the studies by Hilbeck and colleagues were marginalised in their importance for the assessment because they were laboratory studies conducted with Bt corn. Sims & Holden (1996) is also a laboratory study conducted with Bt corn and yet there is no suggestion that its findings lack significance for the assessment process, and this is despite the authors themselves claiming that the relevance of their findings for field conditions can not be assumed.

The way in which the pH of soil is discussed in the assessment is also particularly interesting. The final version of the RARMP states that Australian cotton is generally grown in soil with a pH ranging from 7.5-8.5, citing the Cotton CRC NUTRIpak (2003) to support this statement. What the RARMP does not convey is that this NUTRIpak also states that the application of fertilisers can change soil pH. It also fails to report that in the Cotton CRC SOILpak (2003) released for farmers, it is stated that the optimum pH range for cotton lies between 5.5 and 7 and that the soil pH under Australian conditions is often greater than 7 and occasionally less than 5.5. Adding to this complexity is the fact that in the consultation RARMP, the common soil pH for cotton fields in Australia is cited as 6-6.5, based on a personal communication with Australian cotton researcher Gary Fitt (OGTR 2003a, pt.211).

If the optimum pH for cotton growing is between 5.5 and 7, and pH can be changed through the application of fertilisers, it could be suggested that the soil pH of cotton farms will vary with management practices and that acidic to neutral pH values will be preferable. This arguably means that how farms are managed is important for a sound assessment of risk but that these managerial practices represent an element of indeterminacy for the assessment process.

This indeterminacy has not been discussed or clearly considered in the RARMP. It is simply stated that Australian cotton soils are generally alkaline and that Bt toxins will desorb from clay soils under an alkaline pH (OGTR 2003b, pt.224). While the RARMP does not cite any scientific studies for this statement on desorption under alkaline conditions, I assume that this information has come from Tapp & Stotzky (1998), which the RARMP erroneously cites in support of the claim that Australian cotton growing soils are generally alkaline. While Tapp & Stotzky (1998) did test persistence under a range of pH conditions, interestingly, they only tested soils up to a pH of 7.3 and therefore arguably did not test soils with a pH in the range that the RARMP claims is common for cotton growing in Australia.

It is also interesting to note the difference in the language used in the scientific study and the RARMP. Tapp & Stotzky (1998) state that "adsorption of the toxins on clays decreased with an increase in pH, which may have rendered the toxins more susceptible to biodegradation", while the RARMP states that "generally in Australia cotton is grown in alkaline soil, with a pH ranging from 7.5-8.5, in which Bt endotoxins would desorb from clay soils and be degraded by soil microorganisms" (OGTR 2003b, pt. 224). From these statements it can be seen that not only have desorption and decreased adsorption been interpreted as equivalent, but in substituting a word like "would" for that of "may" the RARMP is implying certain knowledge and removing qualifications linked to uncertainty.

The key finding of Tapp & Stotzky (1998) was that persistence of Bt toxins varied with soil type. While this would seem to imply that testing under Australian field conditions is crucial for sound scientific risk assessment, the RARMP made no request that these types of studies be conducted for the

assessment or as part of a detailed monitoring program. An additional conclusion drawn from this study was that accumulation of the toxin was possible, especially if Bt crops were being grown in clay soils with a low pH. As the CRC SOILpak (2003) states that cotton in Australia is grown on heavy clay soils and occasionally under a pH of less than 5.5, it seems that pH will not always be neutral-alkaline as the RARMP indicates and therefore research and monitoring across a range of locations would seem important for sound scientific assessment.

It is also interesting to note that, in the consultation version of the assessment, an independent and peer-reviewed study by Crecchio & Stotzky (1998) was cited to support the claim that at a pH of 6-6.5, Bt toxins are released from clay and degraded by microorganisms (OGTR 2003a, pt. 211) but that in the final version of the RARMP this study is not cited at all. What is particularly interesting about this is that not only was this study falsely cited in the consultation version of the assessment as demonstrating Bt toxins being released from clays and degraded, but that it actually studied the binding of the toxin to humic acids and found that when bound to these acids, the biodegradability of the toxin was reduced. The final conclusion of this particular study was that Bt toxins from GM plants could persist, accumulate and retain their bioactivity and that this persistence could pose a hazard to non-target organisms. While the misquotation of this study in the consultation version of the RARMP is of concern, the fact that the final version failed to mention the study, its findings or conclusions at all is perhaps even more worrying. The assessment's conclusion that Bt toxins are unlikely to accumulate in Australian soils seems to directly contrast with the conclusions reached in a number of the cited scientific studies, which contrastingly suggest that accumulation is a serious possibility requiring further detailed and

contextualised research (Crecchio & Stotzky 1998; Tapp & Stotzky 1998; Stotzky 2000; Gupta et al. 2002). This represents another issue for which the RARMP is in danger of drawing a false negative conclusion.

In summary, I have found that information from the scientific studies cited on the issue of microorganism exposure has been selectively reported in the majority of cases and that fields of uncertainty highlighted by the scientists have been ignored in the documentation of the assessment. Additionally, there has been no critique of methodologies used, even when the authors themselves have highlighted the limitations associated with testing procedures. Indeterminacies associated with management practices have been sidelined as unimportant and sweeping generalisations have been made despite the cited scientists drawing particular attention to the variability of results across different testing conditions. Finally, conclusions appear to have been reached that contrast rather starkly with those reached by scientists whose work has been cited in the assessment.

3.2 Toxicity of INGARD® Cotton for Microorganisms

3.2.1 The Reliability of Cited Scientific Studies

The first study cited in the section dealing with the toxicity of INGARD® for microorganisms is Donegan et al. (1995). This is a study examining the impact of both the purified Cry1Ac toxin and cotton leaves containing Cry1Ac from three different transgenic lines on the numbers and species of protozoans, bacteria and fungi in soil. This is a peer-reviewed laboratory study published in an academic journal. The experiments ran for either 28 or 56 days and were repeated three times. The study was funded and reviewed by the US EPA and was approved for publication as an EPA document. While limited by being conducted under controlled laboratory conditions, as a published peer-

reviewed study that has been approved by the US EPA and which tested cotton tissue expressing the Cry1Ac protein, it can be viewed as a reliable study for the assessment process.

The RARMP then cites Donegan & Seidler (1998) as a "second study" that "again" examined the impact of purified Cry1Ac and cotton expressing Cry1Ac on soil microorganisms (OGTR 2003b, pt. 227). This reference is a chapter in an edited book on biotechnology written by independent scientists. The experiments described in this chapter do not appear to differ from those detailed in Donegan et al. (1995) and from a careful reading of both references, I conclude that the studies discussed in both papers are the same and therefore their relevance and reliability can also be deemed the same.

The third study cited in this section on toxicity is that of Gupta et al. (2002). The RARMP states that this study examined decomposition rates of INGARD® and non-GM cotton plant material and found that INGARD® decomposed more slowly. It also states that while fungal colonisation and microbial activity on INGARD® were found to be greater, the utilisation of carbon by rhizosphere microorganisms was reduced (OGTR 2003b, pt. 228). I reviewed the quality of this study in section 3.1.1 and concluded that as an independent, published study conducted on INGARD® cotton plants this was a study with a high reliability rating for the assessment.

Following the citation of findings from Gupta et al. (2002), the RARMP states that many of the experiments examining the issue of Bt toxin persistence in the soil have been conducted using bulk soils or soil components (OGTR 2003b, pt. 229). It then cites Palm et al. (1996), Koskella & Stotzky (1997) and Stotzky (2000a) as examples of these types of studies. I have already discussed Palm et

al. (1996) and Stotzky (2000) in section 3.1.1 and so will focus on Koskella & Stotzky (1997) here. This is a study that examined the microbial utilisation and insecticidal activity of free and bound Bt toxins. It is an independent and peer-reviewed laboratory study that conducted experiments using purified Bt toxins and repeated all experiments at least twice. The reliability of this study is high according to independence and review criteria but is arguably limited by being a laboratory study using purified toxins.

The RARMP cites Griffiths et al. (1999) to support the statement that "Bulk soil generally does not support populations of microorganisms as high as those in the rhizosphere or as high as in cropping situations where plant residues are incorporated into the soil" (OGTR 2003b, pt. 229). The RARMP then suggests that the situations supporting higher populations of microorganisms are "likely to favour the rapid degradation of Bt toxin" (OGTR 2003b, pt. 229). Griffiths et al. (1999) is an independent and peer-reviewed study but it did not examine Bt toxins or GM plants. It reports on the impacts on community structure of soil microorganisms following the addition of a synthetic root exudate at different loading rates. As an independent and peer-reviewed study is can be deemed a reasonably reliable study but its relevance to the assessment is indirect.

The final reference cited in the assessment is that of Brimecombe et al. (2001). This reference is cited in support of the statement that although "antibiotic production by non-pathogenic bacteria has been implicated in suppression of some plant diseases", the involvement of neomycin or kanamycin has not been reported (OGTR 2003b, pt. 230). This final section of the assessment discusses the effects of the NPTII enzyme on microorganisms and while stating that direct effects have not been tested, the statement provided above is made to support the conclusion that NPTII is not expected to impact on microbial populations or

disease susceptibility. Brimecombe et al. (2001) is a chapter in an edited book written by independent academics. The book is on the Rhizosphere and the chapter deals specifically with the impacts of root exudates on rhizosphere microbial populations. While not focussing on Bt cotton or GM plants, it can be viewed as a reliable resource for general discussions of the rhizosphere.

3.2.2 The Use of Scientific Information

One of the methodological criticisms that could have been raised against Donegan et al. (1995) is that the experiments only used cotton leaves in their study of the impacts of Cry1Ac on soil microorganisms. This approach fails to consider the Bt toxins that are exuded into the soil through the growing plants' roots and therefore does not account for any potential impacts that this increased level of Bt toxin may have on microorganisms. The RARMP's failure to acknowledge this limitation of the study provides another example of a lack of methodological critique of the cited scientific studies.

A potentially more concerning element of how science has been used on this occasion, however, involves the selection of information. One of the key findings of this study that the RARMP did not discuss at all was that different effects on soil microorganisms were observed for the different lines of transgenic cotton tested. The authors state that since no effects were observed when the purified toxin was tested, the differences observed between the GM cotton lines suggested that "genetic manipulation or tissue culturing of the plants may have produced a change in plant characteristics, aside from B.t.k. toxin production, that can influence growth and species composition of soil microorganisms" (Donegan et al. 1995). The authors conclude their paper with the suggestion that it is important to "anticipate and monitor for potential ecological effects that may result from changes in plant characteristics other

than expression of the inserted gene(s)" (Donegan et al. 1995). In failing to report the key finding of differences between the GM lines tested and not mentioning that the scientists suggested this was related to changes in the GM plant's characteristics aside from Bt toxin production, the RARMP is effectively concealing potential sources of risk arguably requiring assessment.

Obviously assessing risks from unintended side effects associated with the process of genetic modification or tissue culturing would be a difficult process. What this clearly would require, however, is emphasis placed on the importance of using the specific line of GM cotton for which a licence is being requested in the experiments informing the risk analysis for that crop. As changes may have occurred in the plant beyond desired toxin production, the assumption that the assessment can be soundly conducted by considering the effects of the toxin in isolation would need to be abandoned and the assessment would ideally be conducted on the GM plant as a whole. This position would question the comprehensiveness of an assessment based on studies using purified toxins or other lines of Bt cotton as there may be impacts and risks that are not being adequately and accurately assessed by this approach. Similarly to other studies, Donegan et al. (1995) also showed that their findings differed according to the soil type tested and this reiterates the importance of testing the whole plant under ecologically realistic conditions for an assessment to be truly based on 'sound science'.

One of my key concerns with how the Donegan & Seidler (1998) reference was cited in the RARMP relates to the way in which it was represented as a separate set of experiments to that reported in Donegan et al. (1995). As I mentioned above, the RARMP refers to it as a "second study" that "again" examined impacts of Bt cotton on soil organisms (OGTR 2003b, pt. 227).The RARMP's

reference to these as two studies is a misleading presentation that makes it appear as though there is more experimental evidence than actually exists. The reference details given in the bibliography for Donegan & Seidler (1998) are also incorrect and misleadingly suggest heightened relevance. The bibliography states that Donegan & Seidler (1998) is a chapter in a book entitled "Biotechnology in Australia" (OGTR 2003b). In fact, the book is called "Biotechnology in Agriculture and Forestry". By suggesting that the book focuses on biotechnology in Australia, the implication is that this study was either conducted under Australian conditions or was particularly relevant to the Australian context. The study was in fact conducted in America with no particular relevance to the Australian situation. While this error may not have been intentional, it is still misleading and should have been picked up if a thorough review of the assessment had been conducted.

Just as for Donegan et al. (1995), Donegan & Seidler (1998) also draws particular attention to the differences observed between the transgenic lines tested and suggests that other changes in the plant's characteristics have taken place as a result of genetic modification or tissue culturing and that these have lead to the observed impacts on soil communities. Once again, however, the RARMP makes no mention of this observed impact or the author's interpretation of its cause. This paper also concludes with the statement that risk assessment of transgenic plants really needs to address and monitor ecological effects resulting from these types of changes and yet this too has not been taken on board in the RARMP. The RARMP does state that this study suggests that "the apparent changes in microbial species composition may have the potential to impact on soil processes and may be of ecological significance" (OGTR 2003b, pt. 227), yet this statement appears to have no impact on the conclusion of the assessment or the conditions placed on the licence. Again, it seems as though

potential risks to ecosystem services and functions have been sidelined in importance during the assessment.

Donegan & Seidler (1998) also state that impacts on non-target organisms have not been fully evaluated and that the results should only be viewed as relevant for the specific methods and test conditions used in their experiments. The authors clearly state that they see additional research as required to determine the scope, extent and significance of their results for other settings and situations. As with all other calls from the cited soil scientists for more research, however, no mention is made of this element of uncertainty surrounding the results of the cited study and no request for this further context-specific research is made in the RARMP.

One of the interesting features of the way in which the study by Gupta et al. (2002) is used in this section of the assessment is how the cited results relate to claims made earlier in the assessment. The RARMP states that Gupta et al. (2002) found slower decomposition rates for Bt cotton despite greater microbial activity being observed. This contrasts directly with how the RARMP interprets Donegan et al. (1995) in a preceding paragraph, where it is stated that:

> *Donegan et al. (1995) noted that the stimulatory effects observed [on bacterial and fungal population levels] were short term and suggested that the transgenic plants may have decomposed faster than the parental plants and thus more rapidly provide nutrients for microbial growth*
>
> (OGTR 2003b, pt. 226).

The fact that the cited study by Gupta et al. (2002) reported a contradictory result, that Bt cotton decomposed slower than the conventional variety, was an element of ambiguity not discussed in the RARMP.

It is also worth noting that while the RARMP mentions the reduced carbon usage observed by Gupta and colleagues, there was no discussion of what this might mean, what its long term effects might be or how it might relate to risk assessment. This appears to be an example of the RARMP reporting scientific findings but not clearly integrating them into the assessment. By failing to discuss the potential flow on effects from reduced carbon usage and not engaging in a discussion of the ambiguity surrounding the relationship between changes in bacterial and fungal populations and decomposition rates, the RARMP is arguably demonstrating a preference for assessing the impacts Bt cotton has on organisms over an assessment of its impacts on communities or ecosystem functions. This emphasis represents a value judgement on what should be protected in the environment and one that could surely be debated.

One of the most striking aspects of the way in which Koskella & Stotzky (1997) was cited is that it was criticised in this section as a study using soil components but the results of the study were not mentioned. Interestingly, the unreported findings of this criticised study include that Bt toxins appear resistant to utilisation as a source of carbon when bound to soil particles and that their availability as a nitrogen source is also reduced. By not reporting these findings, the RARMP again demonstrates a lack of interest in considering any potential risks this may pose to soil communities and/or ecosystem functions. Koskella & Stotzky (1997) also suggest that as active toxins that do not require solubilisation and cleavage, important barriers to Bt toxin specificity have been removed by their expression in GM plants and therefore beneficial insects and

organisms at higher trophic levels could be harmed. By not reporting this statement from the scientists, the RARMP leaves the assumption of toxin specificity unchallenged and manages to keep risks associated with multitropic interactions marginalised in importance.

The method of Koskella & Stotzky (1997) is criticised because bulk soil and soil components do not support high populations of microorganisms like the rhizosphere and soil under cropping situations, which is suggested would favour rapid degradation (OGTR 2003b, pt. 229). While this appears to be another example of methodological criticism only being applied to studies observing negative impacts, it is also worth noting that rapid degradation is an assumption without evidential support and one that fails to engage with the problems posed by toxins resisting degradation through adsorption and the slower decomposition rates of Bt cotton residues observed by Gupta et al. (2002).

Following the statement on assumed rapid degradation, the RARMP states that "CSIRO is currently studying the impact of INGARD® cotton on rhizosphere microflora and microfauna" (OGTR 2003b, pt. 229). Unfortunately, no preliminary results from this study were incorporated into the risk assessment and as there are no provisions for regular licence reviews and renewals, any findings from this study will arguably struggle to have an impact on the decisions reached through this risk assessment. When examining findings from CSIRO research released in 2004, the problematic nature of this situation becomes particularly obvious. Gupta & Watson (2004) report that Bt toxin from dead cotton leaves was not observed to be as rapidly degraded by soil microorganisms as expected. They claim that this is potentially due to the toxins binding to soil particles and becoming unavailable for degradation. If this

recent research is seen to negate the assumption of rapid degradation, then the lack of a flexible regulatory system that can incorporate the results of recent research into a risk assessment becomes a serious problem.

In section 3.2.1, I suggested that Griffiths et al. (1999) was of questionable relevance to the assessment process. Griffiths et al. (1999) was cited in support of the statement that bulk soils do not support populations of microorganisms as high as the rhizosphere or cropping situations (OGTR 2003b, pt. 229). This is a false citation as no statement of this kind is made in the paper. The reference that should have been cited in support of this statement is Brimecombe et al. (2001), which suggests that a large availability of substrate in the rhizosphere means that microbial biomass and activity are generally much higher there than in bulk soil. It is, however, worth noting that even this reference makes no mention of the comparison with cropping situations as stated in the RARMP.

In citing Griffiths et al. (1999) when Brimecombe et al. (2001) should have been cited, the RARMP also ends up citing Brimecombe et al. (2001) incorrectly, with this paper saying nothing about antibiotic production by non-pathogenic bacteria. Interestingly, there are other potentially relevant issues from this source that the RARMP did not present or consider. For example, in Brimecombe et al. (2001) it is stated that populations in the rhizosphere are supported by carbon inputs. This statement would lead me to question the implications of the findings showing Bt cotton decreasing carbon usage by rhizosphere microorganisms (Gupta et al. 2002; Koskella & Stotzky 1997). Brimecombe et al. (2001) also states that a stimulated rhizosphere community can be either beneficial or harmful to the plant and that root exudates can attract pathogenic populations. As Bt toxin has been shown to be exuded by the roots of GM cotton plants, this statement leads me to question the risk there is

of this root exudate attracting pathogenic populations. It is also stated that changes in pH from fertiliser applications can lead to large changes in microflora and that the impacts of fertilisation on root exudation and populations requires further research. In not reporting this information from the cited reference, the RARMP has failed to consider whether fertilisation could lead to higher rates of Bt toxin exudation, whether Bt exudation may attract pathogenic populations and whether the decreased utilisation of carbon by rhizosphere microorganisms may adversely impact population levels, community structure or ecosystem function.

In summary, then, the way science has been used in this section of the assessment demonstrates methodological critique only being applied to studies with negative findings[95] and contradictions between the cited information not being addressed. Ambiguity, such as that stemming from the variation in rates of toxin degradation reported, and the uncertainty this is seen to create for an accurate assessment of risk, have effectively been ignored, as have all calls for further research. There were examples of false referencing and misrepresentation as well as a highly selective use of information. No mechanisms appear to exist for recent research that might contradict assumptions underpinning the assessment to be fed back into the decision-making process and have an impact on the decisions taken. There was also no evidence that a comprehensive and independent review of the analysis within the RARMP had been conducted. Finally, there were types of risks (such as those associated with unintended changes in plant characteristics and those affecting ecosystem functions) that remain largely unaddressed, unconsidered and effectively concealed by the way in which scientific information was used.

[95] The application of methodological critique to studies indicating a potential risk but not those showing no harm is a situation Levidow (2002) suggests is occurring across a number of scientific institutions dealing with the risks of GM crops.

3.3 Adequacy and Appropriateness of Conclusions

Three of the conclusions listed in the RARMP for non-target organisms relate to impacts on microorganisms, particularly soil microorganisms. These are:

> – *Laboratory studies indicate that Cry1Ac protein has no adverse effect on the growth of various bacteria, fungi and protozoans.*
> – *The presence of INGARD® cotton plant material in the soil only produce transient changes in soil microbial communities*
> – *Natural degradation of Cry1Ac in the soil limits bioaccumulation*
>
> (OGTR 2003b, pt. 231)

The wording of the first conclusion listed here is interesting because although it may be reasonable to say that *Cry1Ac* showed no *adverse* effect on the *growth* of various bacteria, fungi and protozoans, an alternative reading of the scientific studies cited in the assessment may conclude that *Bt cotton plants* expressing Cry1Ac have been shown to *increase* bacterial and fungal populations in the soil and whether this represents a positive, negative or neutral change remains *unclear*.

While the second conclusion moves from Cry1Ac to INGARD® plant material and notes that changes were observed for this test material, the emphasis in this conclusion is clearly on the changes in soil communities only being transient. Interestingly, in the consultation version of the RARMP, the wording of this conclusion was that "the presence of INGARD® cotton plant material in the soil may produce transient changes in the soil microbial communities" (OGTR 2003a, pt. 214). Note that the term "may produce" has been replaced by "only

produce" in the final version of the assessment. This change in wording between the two versions of the assessment is significant because the term "may produce" implies that transient changes are a possibility, while "only produce" admits that changes are occurring but marginalises the significance of this impact. It is interesting that these two different emphases in the conclusions stem from an assessment of the same scientific studies.

The conclusion that natural degradation of Cry1Ac in the soil limits bioaccumulation is perhaps the most curious. In drawing this conclusion, the RARMP is failing to engage with the range of problems raised in the cited scientific studies for reaching a conclusion like this. For example, it fails to account for the problem of Bt toxins binding to soil particles, retaining their bioactivity and resisting degradation, particularly their binding to the clays that predominate in Australian cotton growing soils and the methodological problems associated with differentiating between degradation and adsorption. Following the example set by the other two conclusions in this section, it could be contrastingly claimed that laboratory studies indicate that Bt toxins bind rapidly and tightly to soil particles and that upon being bound their bioactivity is retained and their susceptibility to degradation reduced. It could then be concluded that although limited field studies in America have shown no evidence of bioaccumulation, methodological problems and the differences between field conditions in Australia and America mean that further research is required to determine the potential for accumulation in Australian soils.

The alternative conclusions that I would draw from my own reading of the scientific studies cited in the assessment would be that there is a large degree of uncertainty surrounding the impacts Bt cotton will have on soil communities and the ecosystem functions these communities perform. The ambiguity and

conflicting results reported in the literature emphasise the importance of testing under ecologically realistic conditions and monitoring across a range of locations under various management practices. Drawing firm conclusions on the impacts of Bt cotton on microorganisms requires further contextualised research and improved methodologies.

4. UNCITED STUDIES

The focus of this chapter has been on reviewing the scientific information cited in the RARMP on Bt cotton's non-target impacts. Before I draw my final conclusions from this analysis, however, I believe it is useful to discuss some of the available studies that were not cited in the risk assessment. These are studies that I unearthed either through reference being made to them in the cited studies, or through a general literature search on Bt crops and non-target impacts. All of the excluded studies that I discuss in this section were independently conducted, peer-reviewed and published before the risk assessment took place, and as such, were readily available to the evaluators. While these studies may not have been included in the assessment for benign reasons such as they were not known or were deemed irrelevant, the types of themes appearing across these excluded references suggests the sidelining of various forms of incertitude during the risk assessment process.

One of the things that struck me during my review was the paucity of research conducted under Australian field conditions. In justifying my choice of Bt cotton as a case study crop (see chapter four, section 2.5), I suggested that one of my reasons was that, in addition to field trials, this crop had been commercially grown for 6 years previous to the risk assessment being conducted and therefore, I expected Bt cotton to be the crop for which the most field data would be available. There were, however, only two references that I had access to in which the data for non-target impacts had been collected under Australian

field conditions – Fitt & Wilson (2002) and Gupta et al. (2002). There is, however, another Australian field study that could have been cited in the assessment – Fitt et al. (1994).

Fitt et al. (1994) is a study from field trials of Bt cotton conducted in 1992-1993. The Bt cotton used in these field trials expressed Cry1Ab rather than Cry1Ac and this may have been a reason for it not being cited in the assessment, although given that data from other studies using plants expressing Cry1Ab was incorporated into the assessment, this reason alone seems unjustifiable. In this study, the authors highlight the potential for secondary pests (such as sucking insects) to emerge as a major problem for Bt cotton. The potential problem of secondary pest emergence and the need to consider it in assessment processes was also referred to in another excluded study – Dale et al. (2002). In this paper reviewing the literature on the environmental impacts of transgenic crops, the authors state that "Assessment may need to be made of the possibility that the ecological niche vacated by a primary crop pest could be filled by a secondary herbivorous pest" (Dale et al. 2002). The problem of secondary pest emergence as highlighted by both of these excluded studies was not considered in the RARMP.

In discussing secondary pest emergence, Fitt et al. (1994) state that issues like this have highlighted a "lack of ecological understanding of the population dynamics" of minor pests such as mirids, aphids and thrips. This means that two of the studies excluded from the risk assessment raised an issue that is potentially worthy of assessment, but attention was drawn to the fact that assessing the risk of something like secondary pest emergence is made particularly difficult by the uncertainty that surrounds our understanding of insect population dynamics. Rather than discussing this potential risk and the

problems of assessing it due to ecological uncertainty, the RARMP did not consider secondary pest emergence, did not mention the studies and therefore omitted a potential risk and the field of uncertainty surrounding it.

The issue of uncertainty and its impact on risk assessment was also a key theme in an excluded study by Wolfenbarger & Phifer (2000). This reference reviews the published scientific literature on the ecological risks and benefits of transgenic plants and as such, would seem a highly relevant resource for the assessment process. Through its publication in the highly reputable journal *Science* and its high citation rate in the literature, any claim that this paper was excluded from the assessment simply because the evaluators were not aware of its existence seems highly questionable, and if true, an indication of a poor approach to ensuring comprehensive scientific data informs the assessment. Wolfenbarger & Phifer's review of the scientific literature concludes that key experiments on both environmental risks and benefits are lacking and that the complexity of ecological systems creates inevitable uncertainties for assessing the risks of transgenic plants. They suggest that the assessment of long term, higher order impacts is particularly challenged by high levels of uncertainty.

In addition to the problem of uncertainty for conducting risk assessments of GM plants, Wolfenbarger & Phifer (2000) also highlight problems stemming from indeterminacy and ignorance. In talking about how ecological relations include higher order interactions that are "intrinsically difficult to test and evaluate for significance at limited temporal and spatial scales" (Wolfenbarger & Phifer 2000), the authors are clearly describing a problem of indeterminacy. Their reference to how variability in impacts across different environments, species and cultivars complicates the process of risk assessment could also be seen as a description of problems posed by indeterminacy. In concluding their

review of the scientific information available on risks, the authors state that "[e]cosystems are complex, and not every risk associated with the release of new organisms, including transgenics, can be identified, much less considered" (Wolfenbarger & Phifer 2000). This is clearly a case of the scientists being sensitive to the issue of ignorance and how it affects the ability to assess risks associated with GMOs. Unfortunately, by excluding this study from the assessment process, the RARMP fails to likewise reflect on the impact uncertainty, indeterminacy and ignorance have on the ability to produce a sound scientific assessment of risk.

Wolfenbarger & Phifer (2000) also highlight the problem of ambiguity. In describing the scientific literature on the effects of Bt toxins on beneficial insects, the authors refer to the existence of contrasting results. This variance in reported results on beneficial insects is also highlighted by the excluded studies of Schuler et al. (1999), Deml et al. (2002) and Dutton et al. (2002). Through highlighting this problem of ambiguous results, Wolfenbarger & Phifer (2000) state that the variance could stem from different sensitivities across different species and different concentrations of toxins being expressed in different plant lines. This suggests that for a risk assessment, it is important to draw on tests dealing with the specific crop plant under examination and to not generalise results across various species. Deml et al. (2002) echo this by suggesting that the variability of results reported indicates that tests will need to be conducted on a species level. Schuler et al. (1999) state that this ambiguity highlights the importance of developing standardised methodologies for testing and monitoring impacts on beneficial insects. Rather than clearly acknowledging this problem of ambiguity and engaging in a debate about how it should be handled, the RARMP effectively accepts positive results without question while criticising methods used to attain negative findings. By excluding these three

studies specifically drawing attention to the variability in results and offering alternative means of approaching this problem, the RARMP has failed to engage transparently with the problem of ambiguity.

In addition to marginalising the findings relating to impacts on beneficial insects from Hilbeck and colleagues, the RARMP did not include another study showing similar findings in its assessment. Dutton et al. (2002) also examined maize expressing Cry1Ab and its impacts on the predator *Chrysoperla carnea* through multi-trophic pathways. With findings that supported the existence of prey mediated effects, Dutton et al. (2002) suggested that further studies were needed to understand what happens to Bt toxins when ingested by different herbivores. It is also interesting to note that another excluded study (Schuler et al. 1999) suggests that impacts on the third trophic level can be complex and unexpected and that risk assessment really needs to include tests with several tritrophic systems. By not citing these studies and the support they offer for potential prey mediated effects and the importance of tritrophic testing, the RARMP is effectively sidelining this risk from detailed assessment.

Another important issue that is raised by Dutton et al. (2002) is the potential for the process of gene insertion to create changes in the plant aside from toxin production that may have an impact on non-target organisms (e.g. changes in the nutritional quality or secondary metabolism of the plant). In my discussion of how Donegan et al. (1995) was cited in the RARMP, I highlighted how their conclusion that unintended side effects of the modification process were impacting on soil organisms was not reported in the RARMP. Interestingly, this issue was also one raised in the other excluded studies of Schuler et al. (1999) (in relation to impacts on parasitoids) and Malone & Pham-Delègue (2001) (in relation to impacts on bees). As I have previously stated, the task of assessing

risks associated with unintended changes in a GM plant's characteristics would face serious challenges related to uncertainty and ignorance. Rather than acknowledging the issue and the problems associated with assessing the associated risks, the RARMP has not cited three scientific references that explicitly raise the potential for pleiotropic effects and insertional mutagenesis to impact on non-target organisms, and in citing Donegan et al. (1995), the RARMP simply does not mention the fact that this study claims to have observed these types of impacts.

The uncited study of Malone & Pham-Delègue (2001) suggests that the potential for unintended changes in a GM plant's characteristics aside from Bt toxin production means that tests conducted with whole plants become important, a point I mentioned in section 3.2.2. Echoing the point made by Schuler et al. (1999), Malone & Pham-Delègue (2001) also call for the development of standardised testing procedures for the non-target impacts of GM plants and suggest that the toxicity testing methods used for chemical insecticides are not entirely appropriate for GM plants. Unfortunately, the RARMP has no clear guidelines for what constitutes an acceptable testing procedure for regulatory science and does not appear to acknowledge that appropriate approaches for assessing the safety of GM plants may differ from those accepted for chemical insecticides.

This idea of standardising what is measured and how, so as to clarify what counts as 'sound science' for the regulatory assessment process, is interesting when considered in light of the excluded study by Jepson et al. (1994). This paper specifically focuses on the issue of developing appropriate test systems to determine the ecological risks posed by Bt crops. In this paper, the authors suggest that one of the key problems facing 'objective' risk assessment is

determining what to measure and how to interpret the results. Selecting appropriate methods to test for effects is highlighted as a problem, as is the issue of selecting appropriate ecological and toxicological endpoints around which to structure the types of measurements made. How different types of tests (e.g. laboratory, field, single species, multi-trophic etc) can be interpreted is also presented as debatable. What this paper is effectively highlighting is the ambiguity and value judgements involved in what is measured by a scientist and how the results are interpreted during regulatory decision-making. In failing to engage with this highly relevant paper, the RARMP is not only sidelining these challenges to objective risk assessment, but is also failing to take account of the claims made in this paper that growth and fitness need to be examined in addition to toxicity, and that large scale, long term monitoring is required for both changes in insect species abundance and diversity and effects across different soil types at different times of year.

In relation to impacts on soil, the RARMP fails to include two key scientific studies in its assessment process (beyond that of Crecchio & Stotzky (1998) that I discussed in section 3.1.2). These are Tapp & Stotzky (1995) and Tapp et al. (1994). Both of these studies focus on the issue of Bt toxins binding to soil particles. Tapp & Stotzky (1995) show that the toxins are capable of rapid binding and that bound toxins have increased toxicity over free toxins. Tapp et al. (1994) suggests that the adsorption and binding observed in experiments with Bt toxins represent a mechanism by which the toxins could accumulate and persist in the soil. It is also worth noting that the excluded study of Wolfenbarger & Phifer (2000) also reported on the issue of Bt toxins binding to soil particles and how this binding inhibits degradation. In discussing how the cited studies were used in the assessment, I highlighted how the issue of toxin binding was sidelined in importance for conclusions relating to persistence and

degradation and the exclusion of these three studies seems to support this notion.

It is worth noting at this point that a report on Australian studies conducted on the soil impacts of Bt cotton was released in 2004 and its findings offer a number of challenges to the accuracy of the risk assessment. While the OGTR can of course not be expected to account for findings that are made after the date of its assessment, I briefly discuss the results here to highlight the existence of assumptions and value judgements in the assessment and to emphasise the importance of having a flexible regulatory system that is able to respond to new discoveries and incorporate recent research findings into an assessment of risk.

Gupta & Watson (2004) begin their report with a clear acknowledgement of the uncertainty that surrounds the potential for Bt toxins to persist in Australian soils, an uncertainty that was not clearly acknowledged in the RARMP. Gupta & Watson (2004) go on to detail how they found that the levels of Bt toxin expressed through the roots were actually higher than those found in the leaves and how this meant that the amount of Bt toxin in the soil was therefore significantly higher than previously assumed. They called for further research on the fate of this root derived toxin and the potential for it to accumulate through binding, particularly since the majority of Australian cotton soils are highly reactive clays that could adsorb the toxin, protect it from degradation and thus create the potential for accumulation.

Gupta & Watson (2004) also report an increase in fungal colonisation of Bt cotton residues, differences in microbial successional changes on decomposing Bt cotton leaves, a lack of rapid degradation of Bt leaves and differences in carbon and nitrogen ratios between Bt and conventional cotton. They suggest

that all of these issues require further investigation and long term research. They also highlight problems with the methodologies used to test for the presence of Bt toxins in soil and suggest that evaluations under Australian field conditions are vital for understanding the impacts Bt cotton may have on soil communities and fertility. Interestingly, they claim that although the second part of their project was to investigate the impacts of Bt cotton on soil biodiversity and essential ecosystem functions, this work could not be conducted due to a lack of funds. This means that not only do the results of this recent research contradict the assessment's assumption of rapid degradation limiting toxin accumulation and indicate a range of issues that require further investigation, but the study also highlights the problem of available funding influencing what regulatory science is conducted.

By discussing some of the available scientific literature that was not incorporated into the RARMP, the aim of this section has been to provide further evidence for a lack of engagement with the problems posed by various forms of incertitude (i.e. uncertainty, ambiguity, indeterminacy and ignorance), to further demonstrate how assumptions and value judgements can enter what is claimed to be an 'objective' and 'sound scientific' assessment of risk and to emphasise the importance of having a flexible and reflective regulatory system.

5. CHAPTER CONCLUSION

In this thesis I have advanced the argument that when science is used in a policy setting for issues involving high degrees of uncertainty and disputed values, the assurance of quality and reliability requires review by an extended community of peers. Having described the existence of contested values and scientific uncertainty as conditions under which Australia must make regulatory decisions on the environmental release of GM crops, I suggested that

this is a policy problem where the use of science in decision-making can legitimately be subject to extended peer review. In this chapter, I have therefore taken the risk assessment relating to Bt cotton's impact on non-target organisms as a case study and conducted what I view as a form of extended peer review to explore the quality and reliability in how science has been used in the practice of decision-making.

To conduct this extended peer review of a particular risk assessment, I compiled two lists of criteria by which I could gauge the reliability and robustness of the risk assessment's construction. The first set of these criteria was based on collectively held standards in relation to what constitutes quality in scientific information, particularly in relation to who conducted the study and how it was undertaken. The second set of criteria focussed on how scientific information was used in the assessment and particularly related to the widely recognised standards of accuracy in representation, consistency in treatment and comprehensiveness of information.

In conducting critical appraisal of the risk assessment process, it is important to reiterate that my aim was not to criticise the assessment as inaccurate and attempt to present a 'true' assessment of risk. Rather, my primary aim was to challenge the OGTR's claim that risk assessment is an objective process (OGTR 2002a, p. 15) and to highlight the contribution that social science analysis of science-based risk assessment can make to regulatory decision-making. As an attempt to operationalise the notion of extended peer review in application to risk assessment, I also specifically aimed to uncover and make explicit some of those areas where assumptions, judgements and values had influenced the assessment process.

Deciding what constitutes acceptable evidence was one important area where my review revealed judgement being exercised in the risk assessment process. Questions such as: What is an appropriate test material (e.g. purified Bt toxin, Bt plants, Bt cotton plants, INGARD® cotton plants) and how much weight can be given to experiments using different materials? What is an appropriate test system (e.g. controlled laboratory conditions, microcosm experiments, field trials etc) and how much weight can be given to the results stemming from these different test systems? What should be measured (acute toxicity, chronic toxicity, growth and fitness indicators etc) and what range of organisms should be tested (e.g. one indicator species, a range of species, particular families or orders etc)? All of these questions require judgement to be exercised in the process of risk assessment. The subjectivity involved in interpreting the importance of results from different studies and deciding what constitutes acceptable evidence has not been clearly acknowledged by the OGTR.

An area where values were clearly influencing the content and shape of the risk assessment was in relation to how the objective of 'protecting the environment' was interpreted. From my review of the process, the assessment appeared to focus on the risks of toxicity to individual organisms, rather than on risks to more systems based parameters such as population dynamics, community structures, and ecosystem services and functions. This point was perhaps most clearly revealed in the RARMP's organisation around types of organisms rather than levels of organisation or systems. Value was also clearly placed on measuring impacts in terms of mortality, rather than other fitness related factors such as growth and/or reproduction. Additionally, emphasis was placed on acute impacts, rather than more chronic impacts occurring over longer time periods.

It is also revealing to note that in the opening section of appendix three, in which the potential hazards to non-target organisms are described, it is stated that these include adverse impacts on "microbial organisms, particularly soil microorganisms, with direct impact on growth of crops on farms" (OGTR 2003b, pt. 176). This reveals a clear value judgement in the sense that organisms (or at least soil organisms) are not being seen to have any intrinsic or inherent value in the assessment. Rather, adverse impacts are considered a hazard if there is a direct impact on the growth of crops on farms. This indicates that not only is environmental value seen to rest with organisms rather than systems in the risk assessment, negative impacts on organisms or systems such as the soil are only considered important if there is a direct impact on the economics associated with crop growth.

Some of the key assumptions informing the risk assessment revealed by my review include the assumption that the process of genetic modification has changed nothing in the plant aside from the desired toxin production, that the activity of purified Cry1Ac is equivalent to the bioactivity of Bt cotton and that this toxin is highly specific to Lepidoptera. Indeed, the first conclusion listed in the RARMP regarding toxicity of INGARD® cotton to non-target organisms is that "the toxicity of Cry1Ac is specific to Lepidoptera and the conditions required for its toxicity do not occur in any non-target organisms" (OGTR 2003b, pt. 231). I find the listing of this statement as a conclusion of the assessment rather curious. While the impression is given that the information provided in the assessment allows a conclusion of specificity to be drawn, I have suggested in my review that specificity appears more as a guiding assumption for how scientific information has been reported and treated.

In addition to the first general conclusion about specificity, the RARMP also concludes that "the introduced proteins are already widespread in the environment through the presence of bacteria to which they are native" (OGTR 2003b, pt. 231). What I find particularly interesting about both of these general 'conclusions' is that they imply that INGARD® cotton is expressing the protoxin rather than the active core. While there may still be some uncertainty surrounding this issue, I would argue that this issue is highly significant for the accuracy of these 'conclusions' and for the assessment in general and therefore, that any uncertainty still surrounding this issue would need to be resolved for a sound scientific assessment of risk to be possible.

Rather than transparently engaging with the uncertainty surrounding this important issue, however, the RARMP has been structured around what appears to be the questionable assumption that INGARD® cotton plants are expressing the protoxin form of Cry1Ac and that the impacts on non-target organisms will therefore be highly specific. In adopting these key assumptions, the RARMP fails to consider how the expression of an active toxic core may impact on the risks posed to non-target organisms and also how unintended changes brought about in the plant through insertional mutagenesis and/or pleiotropic effects may also pose risks to non-target organisms. The adoption of these guiding assumptions has led to any uncertainty surrounding them being suppressed (e.g. the uncertainty relating to impacts on soil communities) and any ambiguity about them arising through reported results being sidelined and explained away through methodological critique (e.g. the treatment of studies showing the potential for unexpected prey-mediated effects).

In addition to suppressing important fields of uncertainty and marginalising results that create ambiguity, my review also revealed an avoidance of 'messy'

types of risk (Jasanoff 2003) that would be difficult to analyse because of challenges associated with indeterminacy. The types of risks I am referring to here are those relating to flow on effects such as prey-mediated impacts, those linked to changes in population structures (such as the changes observed in soil communities) and those risks that stem from managerial issues, such as the potential for synergistic effects from farmers' use of other chemicals and fertilisers in tandem with Bt cotton crops[96]. The complexity of natural systems, social behaviours and the interconnections between the two create an element of indeterminacy that makes an objective and sound scientific assessment of these kinds of risks close to impossible. Rather than acknowledging this problem and negotiating a way of addressing and handling it, these types of risks are sidelined in the assessment process.

The framing of decision-making as an objective and science based approach to risk assessment has seen a particularly reductionist approach to assessment adopted. In assessing risk, the OGTR has effectively reduced the GM plant to the individual toxin it has been modified to produce and this means that any unintended changes in the plant's characteristics that have occurred and which may also represent a risk to non-target organisms become hidden. The environmental impacts considered are reduced to acute organismal toxicity so that impacts arising through interrelations (both between natural systems and between social and natural systems) as well as impacts on broader ecosystem services and functions become sidelined. This reductionist approach to risk and to environmental value is arguably a way of containing and concealing the problems of incertitude that would face a more holistic or systemic approach to conducting environmental risk assessment.

[96] I would suggest that the difficulties associated with indeterminacy also meant that the potential 'flow on' risks to non-target organisms from horizontal gene transfer events and the use of the cauliflower mosaic virus promoter were left unaddressed in the RARMP.

5.1 Reliability Rating and Reflective Questioning

After structuring and conducting my own critical appraisal of this case study risk assessment, I have developed a framework that could be used to help operationalise the notion of extended peer review by offering a tool for others wishing to engage in this kind of analysis. I call this framework "Reliability Rating and Reflective Questioning".

The 'Reliability Rating' part of the framework represents the first level of analysis where the reliability of scientific studies is rated according to four broad questions: Who? Where? How? and What Now? Essentially, these questions refer to *who* conducted the scientific research (e.g. applicant, applicant-sponsored scientists, independent researchers), *where* the research was conducted (e.g. laboratory, field trials, country), *how* the study was undertaken (e.g. what was the test material, over what time frame, what replication and sample size), and *what* the status of the study is *now* (e.g. peer-reviewed, published etc)? Leaving these questions purposefully broad allows each person adopting the framework to adapt the criteria for each question (the information given here in brackets) to suit the specific assessment and/or policy-decision under review.

The 'Reflective Questioning' part of the framework follows from the second level of my analysis. After conducting this analysis I observed a number of recurring patterns in how science was used. To create this framework I have used these observed recurring patterns to shape a set of questions that those examining risk assessments and/or the use of science in policy can reflect on during the course of review. In presenting these key issues and illustrative questions for reflective questioning, I do not wish to foreclose the potential of other useful questions arising. While these questions have been drawn from

patterns observed in my own analysis, I would encourage others to expand, build upon and/or clarify potentially useful questions for reflecting on the quality of risk assessment processes, especially in terms of how science and incertitude are handled.

The key issues and illustrative questions an extended peer community may wish to reflect on include:

1. **Presentation** (How is the scientific study presented in the assessment? Are the full reference details provided and are they accurate?)
2. **Representation** (Is the way in which the study's results are described accurate? How are the findings and methodologies represented? How well does the representation match that provided by the authors?)
3. **Selection** (Has information from the study been selectively used? What has been incorporated and what has been omitted?)
4. **Interpretation** (How has the study and its importance been interpreted? How does this compare with the authors' interpretation? What has been inferred from the study?)
5. **Critique** (Has the study been critiqued in the assessment? Are critiques reported in the literature applied? Is critique consistently applied?)
6. **Assumptions** (What does the use of science reveal about the assumptions and values underpinning the assessment? How clearly are these communicated?)[97]

[97] If an acronym for these issues of reflective questioning would be useful, I suggest that CRISPA(Critique, Representation, Interpretation, Selection, Presentation, Assumptions) might be the easiest to remember, although I believe the order in which the issues are presented above represents a more logical way to conduct the questioning exercise.

As an example of how the results of Reliability Rating and Reflective Questioning may be presented, I have summarised some of the information from my own review in tables 1, 2 & 3 (presented at the end of this chapter). Again it is important to highlight that others adopting the framework would be free to structure their own specifically relevant criteria for the questions of Who, Where, How and What Now, and could present their findings in an alternative format[98]. I present these tables simply as a summary of some of my own research findings and an example of how results from Reliability Rating and Reflective Questioning exercises may be represented. Some interesting patterns from my review that are revealed through this table format include:

1. For vertebrates, the overall reliability of the evidence was weak and yet there was a complete lack of critique of these studies.
2. For invertebrates, the least reliable studies were misleadingly presented and uncritiqued, while those with a higher reliability rating were subject to critique that was inconsistently applied.
3. For microorganisms, the majority of the cited information was independent and peer-reviewed but the treatment of almost all of these studies involved a selective use of information and a removal of qualifications.

Through Reliability Rating and Reflective Questioning, the process of extended peer review could be used to improve the quality of risk assessment as an environmental decision-making tool. Ideally, risk assessment processes and extended peer review through reliability rating and reflective questioning would need to have an iterative relationship, with negotiation between the scientists and the extended peer community encouraged. In the case of

[98] For example, I have chosen to represent my reliability ratings with colours but others may wish to assign different approaches numerical values and thereby represent the reliability rating exercise in a quantitative manner.

Australia's current regulatory process for GM crops, this could involve performing the review on a consultation version of a risk assessment document and then feeding the review back into the decision-making process. The process could also occur through the established system of committees, although ideally, if this was to occur, committee meetings should be open to interested members of the public. It would also be useful to have face to face meetings between the scientists on the GTTAC, the evaluators, and those engaging in extended peer review processes, whether they be committee members or otherwise. This would be useful not only because the extended peer community could ask questions relating to scientific matters, but also so that negotiation and deliberation around points of dissent could be conducted directly, creating opportunities for transformative mutual learning.

Finally, it is important to highlight that extended peer reviews of risk assessment processes conducted by different people with different backgrounds and different fields of knowledge would of course reveal different things. In particular, different people will differentially construct what counts as the most reliable form of evidence. This means that it would be useful to have more than one individual performing an extended peer review if it is a tool being employed to improve decision-making processes. I would suggest that encouraging the articulation of different values through the process would be important if using the framework as a decision-making tool. If this articulation occurred during the process of extended peer review, areas where divergent values strongly influence risk assessment outcomes could be identified and used as strategic points for broad based negotiations that explicitly attempt to engage lay members of the public. The review process itself could be performed by different stakeholders, advisory committee members, self selected members of the community or by people specifically chosen for the different perspectives

they would bring to the process[99]. An extended peer committee could be established or a less formal and more flexible approach may be selected. The important point to highlight though, is that the aim of employing a process of extended peer review and encouraging the negotiation of science through frameworks such as Reliability Rating and Reflective Questioning would not be to try and produce a 'true' assessment of risk, but to create a robust process for decision-making in the face of contested values and incertitude.

[99] For example, I would have found it beneficial to have additional people review the risk assessment in terms of the relevance and adequacy of the methodologies employed in the various scientific studies as well as in terms of the statistical calculations made.

Please see print copy for Table 1

Please see print copy for Table 2

Please see print copy for Table 3

CONCLUSIONS AND RECOMMENDATIONS

CHAPTER OUTLINE

This chapter begins with a summary of the thesis content. Through this summary I review the subject matter of each chapter and how the material detailed in each connects to and builds upon the research presented in preceding chapters. In summarising the content in this way, I am able to draw the thesis together and highlight the flow of my argument. Following this summary, I present the conclusions I draw from this research. The conclusions I detail specifically relate to the handling of contested values and widespread uncertainty in environmental decision-making. I describe my conclusions on this topic both in relation to my survey and synthesis of theoretical literature and my critical appraisal of Australia's environmental regulation of GM crops.

In the following section of this chapter I detail the recommendations I would make as a result of this thesis research. These are recommendations for both policy and the practice of decision-making and for future research. I begin by outlining what my thesis research implies for the future direction and evolution of Australia's environmental regulation of GM crops. In presenting recommendations for this policy practice, I suggest both incremental adjustments that could be made to the current system for decision-making and some more radical changes that would be more difficult to implement. Presenting these two types of recommendations for decision-making means that my research offers both practical ways to move forward and more forward looking ways in which practice could be directed.

In concluding this chapter with a presentation of recommendations for future research, I highlight some of the areas where my research indicates further

investigation is either warranted or desirable. This serves to highlight areas worthy of further examination by either myself or others interested in this field. In the final concluding section, I specifically highlight what I view as the original contributions of this thesis. While this chapter represents the formal conclusion of the thesis, an appendix is also attached. This appendix has two sections - a 'Preface' (written early in my research) and an 'Epilogue' (written when my research was complete). This appendix represents my reflections on this research project and includes a discussion of both the important events and experiences that helped shape my research question and the way in which my own values and assumptions have influenced the research methods and conclusions.

1. CONTENT SUMMARY

In my introductory chapter, I began by clearly articulating the research problem at the heart of this thesis. I described this problem as critically appraising Australia's environmental regulation of GM crops and suggested that not only did this choice of problem represent a response to initial research, it was also motivated by a desire to contribute to a planned review of Australia's gene technology legislation. The introduction chapter also highlighted the complex nature of this contextualised research problem and suggested that as such, it would benefit from a transdisciplinary approach to research. I then outlined some of characteristic concerns, processes and challenges of transdisciplinary research, as well as ways in which the quality of these endeavours might be judged. Finally, the introduction foreshadowed the thesis content with a summary of each chapter.

In the context chapter that followed the introduction I provided some background, contextual detail relevant to my research project on Australia's environmental regulation of GM crops. I began by outlining the history of rDNA technology and described a shift in the controversy surrounding it from a focus on the potential escape of GMOs from research settings to concerns relating to their deliberate environmental release for commercial production. I then suggested that social debate surrounding this technology has created pressure on governments to regulate the release of GMOs to minimise not only potential adverse effects on human health but also on the environment. In the section on modern environmentalism I emphasised how the environment is now a key social and political concern but argued that the existence of competing environmental values and beliefs complicates the process of environmental decision-making. Finally, the context chapter discussed the dominance of a discourse of risk in technological decision-making and drew

attention to the problem scientific uncertainty creates for adopting this discourse in the environmental regulation of GMOs.

Having suggested that contested environmental values and widespread scientific uncertainty create a problem for adopting a risk based approach to the environmental regulation of GMOs, in the following theory chapter I surveyed literature on risk and uncertainty in environmental decision-making from a number of social science disciplines. This review of the literature aimed to develop an understanding of what an ideal process for decision-making under these conditions might involve. This survey covered psychometric research, cultural theory, constructivist understandings of science and risk and typologies of incertitude. Synthesising the implications from these bodies of research, I outlined what I described as a precaution/uncertainty based approach to environmental decision-making. In contrasting this approach to traditional realist science/risk based approaches, I suggested that the key distinguishing features of a precaution/uncertainty based approach made it more appropriate for decision-making dealing with the difficult conditions of contested values and incertitude.

Having arrived at and described the theoretical framework that a precaution/uncertainty based approach was the most appropriate way to conduct environmental decision-making for rDNA technologies, I then went on to describe the methods I would employ to critically appraise Australia's regulatory system for GM crops in light of this framework. In the chapter on research methods I began with a description of how I would approach my exploration of the regulatory framework established by legislation. I then outlined how I intended to deconstruct a case study scientific risk assessment

before describing and justifying my choice of Bt cotton and its non-target impacts as that case study.

After outlining the methods developed for exploring my two key analytical themes of the regulatory framework and the practice of risk assessment, the thesis went on to detail this empirical work. The first part of this work was a critical appraisal of whether the framework for Australia's regulation for GM crops was more representative of a science/risk or precaution/uncertainty based approach to environmental decision-making. Covering the key distinguishing themes of the discourse of decision-making, the role awarded science, the avenues available for public participation, the conditions for ongoing research and monitoring and the range of policy options considered (as well as the additionally important issue of the independence of the Regulator), I presented an analysis that argued that Australia's regulatory system could be classified as a predominantly science/risk based approach to decision-making.

As the process of so called 'objective' scientific risk assessment was revealed as the cornerstone of Australia's regulatory decision-making on GM crops, I then went on to conduct a detailed investigation into the practice of decision-making by deconstructing a case study risk assessment document. The risk assessment I chose to deconstruct was that conducted by the OGTR on Bt cotton and its impacts on non-target organisms. My review of this risk assessment followed the format of the document itself and was organised around the three key non-target organism groups, vertebrate wildlife, invertebrates and microorganisms. For each of these groups of organisms, I used a range of criteria to explore three broad questions: What is the reliability of the cited scientific studies? How has scientific information been used? and How adequate and appropriate are the conclusions drawn? Finally, I developed a framework of Reliability Rating and

Reflective Questioning to assist with operationalising the notion of extended peer review as a way of negotiating the use of science for policy to improve environmental decision-making processes.

After selecting the research problem of providing Australia with a critical appraisal of its environmental regulation of GM crops, this thesis has therefore:

1. Identified the existence of contested values and widespread scientific uncertainty as a key problem facing Australia's environmental regulation of GM crops,
2. Surveyed theoretical literature on how this problem can be most appropriately handled in decision-making processes,
3. Synthesised a theoretical framework for the critical appraisal of our regulatory system based on contrasting traditional science/risk based approaches with emerging precaution/uncertainty based approaches to decision-making,
4. Analysed Australia's regulatory system using this theoretical framework and argued that despite its limitations, a predominantly science/risk based approach to decision-making has been adopted,
5. Deconstructed an example of science/risk based decision-making to highlight more concretely some of the limitations associated with this approach, and
6. Developed a framework that can be used to improve environmental decision-making processes by encouraging and enabling the negotiation and extended peer review of science for policy.

2. CONCLUSIONS

From my research into the context within which Australia's environmental regulation of GM crops occurs, I conclude that one of the most challenging

problems facing regulatory decision-making is the existence of fiercely contested environmental values in modern society and widespread scientific uncertainty and debate about the potential environmental impacts of GM crops.

From my research into the theoretical literature on how these problems should be approached in regulatory settings, I conclude that adopting a realist discourse of risk for decision-making has a number of severe limitations associated with it. Not only does this approach fail to adequately consider the way in which the public deems factors beyond probabilities and mortality rates relevant for assessing technological risks and their acceptability, it also fails to recognise the way in which divergent perceptual filters (e.g. cultural biases and myths about nature) can be adopted by social actors and how this allows divergent assessments of risks to occur. It also fails to recognise the way in which scientific knowledge is shaped by social and cultural factors and how there can therefore be no truly 'objective' assessment of risk to unproblematically dictate decisions. Additionally, when realist approaches to risk are adopted in decision-making, they fail to adequately account for the full range of types of incertitude that must be handled and this increases the extent to which diverse values and perceptual filters can shape divergent positions on the risks. This problem of different types of incertitude affecting decision-making is particularly evident in the environmental regulation of rDNA technologies.

Collectively, these challenges to the adequacy of employing realist approaches to risk in decision-making demand a shift away from focusing solely on so-called 'objective' risk analysis as a decision-making tool, towards a focus on the need to handle incertitude and competing values through balancing risk analysis with the negotiation of incertitude. In emerging process based

approaches to what it means for decision-making to be precautionary, approaches that balance analysis with negotiation (approaches I have referred to as precaution/uncertainty based), a number of key components can be identified. Firstly, the role for science in policy must be reimagined. The limitations of scientific knowledge must be recognised and when applied in a policy setting, it must be exposed to critical reflection from not only other scientific disciplines but also from social scientists and the community more broadly. In regulating rDNA technologies, the issues of concern are not simply scientific, so members of the public and their diverse views and values must be engaged in decision-making processes. Regulatory concerns should not be limited to science and it should be recognised that social, ethical and political concerns can not in fact be separated from science. To adequately handle incertitude, regulatory decision-making processes for rDNA technologies must also involve the consideration of a range of policy options and detailed measures for ensuring ongoing research and monitoring on environmental impacts.

In spite of the limitations associated with traditional science/risk based approaches to decision-making for the environmental regulation of GM crops, Australia has largely adopted this problematic framework. A discourse of risk clearly dominates the regulatory system and there is pervasive reference to the notion of risk assessment as an objective scientific process. Although Australia has included non-scientific advisory committees within its regulatory system, their influence has been limited by regulatory framing so that science retains primary authority over the decision-making process. Non-scientific concerns are also not only currently marginalised in regulatory considerations, they are also framed as issues best represented by groups of experts. While the regulatory system does contain avenues for public participation, these have

been framed in such a narrow way as to exclude the types of concerns that actually predominate in the community. There is little commitment to the importance of ongoing research and monitoring in the Australian regulatory system and the consideration of a range of policy options is currently inhibited by the use of conventional agricultural practices as the sole baseline of comparison for assessing the acceptability of the environmental risks associated with GM crops. The extensive problems associated with framing Australia's regulatory system as a science/risk based approach are currently compounded by the lack of a truly independent decision maker.

The current framework for Australia's environmental regulation of GM crops implies that decisions are based on a process of objective scientific risk assessment. After conducting a detailed investigation and deconstruction of a case study risk assessment document, I conclude that the process is in fact far from objective. Assumptions, values, and subjective judgements shape the risk assessment process in a number of both subtle and overt ways. This occurs through processes such as the selective use of scientific information, inconsistent application of critique, misleading presentation, misquotation and the removal of qualifications. There is currently almost no acknowledgement or engagement with the important issues of incertitude affecting the decision-making process and consequently, there appears to be a tendency to sideline and thus effectively conceal various forms of uncertainty. There is also currently inadequate evaluation and quality assurance of the reliability of both cited scientific studies and the risk assessment process. This has the potential to create serious problems in the future, particularly in terms of public trust should risk assessments prove to be inaccurate or the current regulatory system is shown to have misused science.

There is an urgent need for Australia's regulatory system for GM crops to begin to shift away from the complete reliance on science and risk assessment to inform decision-making. There is a need to recognise the impact various forms of incertitude have on decision-making and how scientific risk assessment is conducted. Australia's regulatory system must start to evolve towards a more precaution/uncertainty based approach that acknowledges the importance and the influence of incertitude and actively seeks to transparently engage with the challenges associated with this through encouraging critical reflection on the use of science, increasing the avenues available for broad based public participation and deliberation, actively considering a range of policy options and supporting ongoing research and monitoring. To assist the development of a precaution/uncertainty based approach to decision-making, knowledge for policy must be seen as the result of a process of negotiation, not an objective product. My recommendations for how this shift could begin to occur are outlined below.

3. RECOMMENDATIONS FOR POLICY

Australia's environmental regulation of GM crops is currently focussed on scientific risk assessment understood in a realist sense. To overcome the numerous problems associated with this approach, the system must evolve so that it transparently engages rather than attempts to suppress the challenges associated with contested environmental values and various forms of incertitude. Some of the recommendations I would make for how we can begin to do this within the broad institutional framework already in place are outlined below.

Science must begin to be negotiated in decision-making. Recognising the importance of various forms of incertitude in assessing the environmental risks

associated with GMOs and acknowledging that scientific knowledge can be shaped by social and cultural factors means that this form of knowledge can no longer be viewed as simply an objective product informing decision-making. Science for policy must increasingly be seen as a process rather than a product (Irwin & Michael 2003); where scientific knowledge is exposed to critical reflection from across the community, deconstructed according to varying values and beliefs and renegotiated in the decision-making process. If we are to retain risk assessment as a decision-making tool, the assessment itself and the scientific studies cited within it must be exposed to a process of extended peer review. The framework of Reliability Rating and Reflective Questioning developed in this thesis could be used to encourage and guide this process. The Reliability Rating and Reflective Questioning framework could be applied to draft risk assessment documents by either members of the non-scientific advisory committees and/or interested members of the extended peer community. Ideally those conducting this form of extended peer review should have opportunities to directly engage with risk assessors, scientific advisors and regulatory decision makers in an iterative process that encourages transformative mutual learning.

To enable the acceptance of a broader concept of risk, all three advisory committees should be given equal access to and influence over the decision-making process. This would mean changing the legislation so that it is no longer only the GTTAC that must be consulted on licence applications and whose advice must be taken into account. While this need not occur for all types of dealings, all three committees should have equal opportunities to participate in decisions relating to the deliberate environmental release of GMOs for the purposes of commercial production.

Embracing a broader concept of risk also suggests that members of the public should have avenues available for involvement that extend beyond written submissions. There needs to be a process for public participation that encourages and enables social learning. One way this might occur within the current institutional framework would be to make committee meetings open to members of the public. This would allow members of the public to directly participate in decision deliberations but it would also create an opportunity for them to express their social, political and ethical concerns relating to the technology. Open committee meetings could be facilitated through commercial in confidence information being excluded where necessary. Another approach may be to actively involve members of the public in Reliability Rating and Reflective Questioning exercises either individually or during open committee meetings.

If open committee meetings are not appealing, I would recommend holding public deliberations and negotiations on strategically selected issues of importance. These issues of importance may be identified through having an extended peer community conduct exercises such as Reliability Rating and Reflective Questioning to highlight key areas of debate. For example, if we were to retain risk assessment as the key decision-making tool, the types of issues I believe should be the subject of strategic broad based negotiations (based on my own example of extended peer review) would include appropriate environmental endpoints for assessment processes and criteria for judging risk acceptability. There could also be negotiations held around criteria for judging the quality, reliability and strength of different forms of scientific evidence for the decision-making process.

A really important factor for enabling both critical reflection and increased public participation in regulatory decision-making is free and complete access to all scientific studies cited in risk assessment documents. Commercial in confidence information could be excluded where absolutely necessary but I would certainly recommend that open access to regulatory science is essential for robust environmental decision-making processes.

To assist with transparency I would also recommend that OGTR staff and their qualifications and interests be publicly listed and that those evaluators working on individual licence documents be listed as authors. The current situation of having risk assessments performed by nameless 'scientist' employees only perpetuates the myth of objective assessment and discourages assessors from taking responsibility for their judgements. It would also be useful to have the structure of the OGTR (including where different staff members fit into that structure and how they can be contacted) available on the agency's website. This would enable interested members of the public to not only better understand the regulatory system, but also to directly contact people relevant to their concerns and enquiries.

Regular licence reviews and renewals are vital if we are to have a regulatory system that is responsive to new information generated in the nascent research field of the environmental impacts of GM crops. I would recommend that commercial licences should initially be reviewed within a period of no longer than five years. This would enable recent research to regularly feed back into the regulatory system. To avoid overburdening applicant organisations with lengthy administrative requirements, this review need not necessarily require the organisation to submit another detailed licence application. The original

application and licence conditions could simply be reviewed according to the most recent research conducted in the field.

Our regulatory system must enhance its commitment to ongoing research and monitoring. I believe that for any areas where risk assessment encounters contradictory results or serious gaps in the knowledge, any licences granted should be subject to conditions that request further research on these issues. This will be particularly important for issues (such as impacts on soil communities) where there is widespread acceptance within the scientific community that knowledge in the field is deficient. Increasing the requests for further data collection would assist responsive risk management, particularly if combined with a requirement for regular licence reviews and renewals. While the question of who should fund this research is bound to generate diverse responses, I would suggest that each application for deliberate release submitted to the OGTR could incur a monitoring levy, the collective result of which could then be used to fund independent research on the issues identified to be of importance.

To assist with unearthing and articulating the important fields of uncertainty that require further research, I would also suggest that the Australian regulatory system would benefit from conducting a Science Review process similar to that conducted in the United Kingdom (UK). In the UK this involved a panel of various natural and social scientists as well as non-specialists assessing the available evidence on GM crops, with specific attention granted to identifying important areas of uncertainty. The UK panel, for example, recommended further research be conducted on potential changes in soil ecology, farmland biodiversity and the consequences of gene flow (Oreszczyn 2005). As the Australian context may generate additional or alternative issues of

importance, I would recommend that we assemble a review panel of our own rather than simply adopt the findings of the UK group.

All of the above recommendations represent the steps I see as important for moving our current institutional arrangements towards an approach that is more representative of precaution/uncertainty based decision-making. They are recommendations for how we can begin to enlarge our conception of risk, critically reflect on science in decision-making, encourage increased public involvement and enhance our commitment to further research in fields of uncertainty. I would however also like to make some recommendations for policy that would be less easy to implement in the short term, recommendations that are more focussed on what an alternative over-arching framework for decision-making could involve. To move away from the centrality of risk assessment, decision-making approaches could be alternatively structured around the types of concepts outlined below.

The process of considering technical and social concerns through multi-criteria appraisal techniques could be used to structure decision-making processes. In a technique referred to as multi-criteria mapping, a range of policy options are considered by participants in the exercise (Stirling 1997). Participants decide criteria by which to appraise the options (as well as the weight they will give each criterion) and then evaluate the various options according to these criteria. The various options are then ranked in desirability by the weighted sum of the scores. When this task is performed by a range of participants, the various responses can be analysed for their similarities, differences and sensitivity to different factors and fed back to participants for reflection and potentially, revision. A pilot example of multi-criteria mapping showing how it may be used to inform decision-making on GM crops has been conducted by Stirling &

Mayer (1999). The multi-criteria mapping approach to decision-making expands the understanding of what is relevant to decision-making deliberations by engaging with social concerns and allowing value judgements to become an explicit part of the decision-making process. It also effectively allows for the consideration of a plurality of policy options.

A pilot example of a technique called critical systems heuristics (the CSH framework) has also been conducted on the issue of GM crops (Carr & Oreszczyn 2005). The CSH framework is designed to elicit and structure community concerns about a technology so that they can then be systematically used in decision-making processes. It is suggested that this approach can be employed to complement techniques such as scientific risk assessment. The CSH framework is based around the idea that when people disagree on an issue such as GM crops, they are often using different frames of reference. By asking questions and comparing responses relating to what the participant thinks ought to be and what is, the CSH approach seeks to not only make values more explicit, but also to allow and encourage reflexive debate about these values. As a tool for decision-making, the CSH framework offers a way to both directly engage with the challenge posed by diverse values and enable issues beyond technical concerns to enter the decision-making process.

Brian Wynne (1992) has suggested that there should be a move away from assessing the risks of particular technologies to discuss and debate the social trajectories certain developments represent. This would mean that rather than case-by-case assessment of particular applications of rDNA technology, decision makers should actually encourage discussion and debate over agricultural biotechnology as a whole, both over the social conditions of its development and their desirability and over the future direction of societal

development this technology implies. This would permit decision-making deliberations to actively incorporate social concerns such as those relating to ownership of the technology, who will control our agricultural future and whether the technology concentrates power in an undesirable way.

To broaden the notion of what is relevant to political decision-making on rDNA technology and its application to agriculture, I would also suggest that Australia would benefit from a national imagining or envisioning project. As a society living on a continent with ancient soils and a drought/flood cycling climate, the focus of the past 200 years on an attempt to impose European style agriculture has taken its toll. With serious concerns relating to salinity, river health and soil erosion now becoming increasingly prominent, and debates about the role for GMOs becoming increasingly intense, I believe the time is right for Australia to engage in a discussion of what our vision for the future of agriculture in this country involves. Nationally, we have had a similar process occur in relation to ecologically sustainable development and in the state of Tasmania, a communal vision of the future was developed through the Tasmania together project[100]. If we were to hold deliberative envisioning projects around the nation and compile some sense of a collective or shared vision for Australian agriculture, decision-making processes could begin to focus on how we can move towards this ideal. Obviously a collective ideal vision for the future of Australian agriculture would not remain static and therefore to adopt envisioning as a decision aiding tool, the process would need to be continually revisited across time.

[100] For more information on this project see www.tasmaniatogether.tas.gov.au

4. RECOMMENDATIONS FOR FUTURE RESEARCH

Having conducted this research project into Australia's environmental regulation of GM crops, there are a number of areas I view as warranting further investigation. One of the areas where I found information particularly deficient was that relating to the history of gene technology regulation in Australia. There is currently very little academic description or analysis of how the regulation of biotechnology has developed over time in this country, and particularly, how this regulatory development relates and connects to other important social developments in Australia. There is also extensive scope for comparative consideration of our regulatory system. While there is currently an increasing body of literature comparing regulatory approaches to, and risk assessments on, GM crops between the United States and European contexts, there is very little work that positions Australia within this setting and a comparative approach to understanding the strengths and shortcomings of our system has certainly not been the focus of this research project.

I would also suggest that further research developing and evaluating mechanisms for public participation in decision-making would be desirable because although increased public participation is espoused by a range of theorists, there are currently few examples of the empirical evaluation of mechanisms to achieve this. There is a need for this type of research both in a general sense and more specifically in relation to GMO regulation. While I have criticised the avenues available for public participation in Australia's environmental regulation of GM crops in this thesis and have made some recommendations for how they might be improved, there certainly remains extensive scope for the development of evaluative frameworks and their application in relation to participation in GMO decision-making. Approaches

such as that taken by Ross (2004) that directly engage with the experiences and opinions of participants would be particularly informative.

This thesis has presented Reliability Rating and Reflective Questioning as a framework through which the notion of extended peer review may be operationalised but I would certainly recommend that others interested in encouraging and enabling a broader community to critically reflect on scientific information and risk assessment conduct further research in this field. This might involve developing alternative frameworks to assist the task of extended peer review or working to extend or adapt the Reliability Rating and Reflective Questioning approach to assisting robust decision-making. The extension and/or adaptation of the Reliability Rating and Reflective Questioning framework could logically be approached by its application to other risk assessments or contexts.

To add to the Reliability Rating and Reflective Questioning exercise conducted in this thesis, I would particularly recommend that others contribute to and become engaged in the task. For example, one of the limitations of this transdisciplinary project has been its minimal collaboration with stakeholders and bodies of knowledge outside of academia[101]. Having developed the Reliability Rating and Reflective Questioning Framework through this PhD research, however, I would suggest that a useful way to extend it would be to incorporate broader members of the community in the process, particularly through having them define their own criteria for acceptable evidence and sets of reflective questions. I see potential for the definition of these to occur through interviews or focus groups with stakeholders and other interested parties. The

[101] This was partly a result of the nature of a PhD and the need for it to represent independent academic scholarship.

various criteria and questions developed could then be shared amongst participants for further reflection before being applied in a process of review. It would be fascinating to see the similarities and differences between the criteria and questions developed by different groups and to analyse their implications for the process of risk assessment.

In terms of further research I see as desirable on the environmental impacts of Bt cotton specifically, I would recommend that scientists be funded to continue examining the impacts of this GM crop on soil communities and functions. I would also recommend increased multi-trophic testing on the impacts this crop may have on non-target organisms[102]. While I see multi-trophic testing as important for all organisms, the impacts of this crop on vertebrates appears particularly under-researched at present and I would suggest that multi-trophic testing of the birds and bats feeding in Australian cotton fields is particularly desirable. It would also be useful to conduct ongoing comparisons on how this GM crop's environmental impacts relate to those of both conventional chemically intensive farming and farming that uses integrated pest management techniques[103].

Another field of research worth pursuing would be the consideration of national regulatory frameworks in light of globalisation processes. With a world that is inherently interconnected in an ecological sense, but which is also becoming increasingly interconnected in an economic sense through global trade practices, the issue of national regulatory systems for things like GMOs

[102] Multi-trophic effects and the impacts on soil communities have also been identified as knowledge gaps by the expert advisory committee to the Dutch regulatory authority (Schenkelaars 2005) and by the United Kingdom's Science Review panel (Oreszczyn 2005).
[103] Conceivably, the information on ecological systems that may be generated through research funded on the non-target impacts of Bt cotton could then be fed back into the development of improved integrated pest management approaches.

becomes particularly interesting. The impact of free trade agreements on national regulatory systems and the development of global governance structures for GMOs would both be areas worthy of additional research.

Finally, this thesis has said little on why the discourse of risk remains dominant despite its clear limitations and why it might be difficult to implement the types of changes recommended in this thesis. Further research on the power relations involved in the risk discourse would be highly informative but have unfortunately been outside the scope of this thesis. This research on interests and power relations would be particularly useful in the Australian setting if it was connected to an historical analysis of the development of both our current regulatory system and the biotechnology industry more generally.

5. CHAPTER CONCLUSION

In this chapter I have summarised the content of the thesis and highlighted how each chapter builds on the work conducted in the previous one. I outlined the conclusions I draw from this work and detailed my recommendations for both policy practice and future research. As a body of work, this thesis makes a number of original and significant contributions to knowledge. The synthesis of literature on transdisciplinary research makes an important contribution to current efforts to theorise this approach to research by articulating some of its characteristic concerns, processes and challenges and by offering ways in which the quality of transdisciplinary endeavours may be assessed. The survey of literature on risk and uncertainty in environmental decision-making likewise represents a creative synthesis of information because it constructs a theoretical framework that helps articulate a process-based approach to precautionary decision-making.

The analysis of Australia's regulatory framework for GMOs is unique in both its detail and approach. By using the theoretical framework developed through my cross-disciplinary synthesis of literature, the analysis of Australia's regulatory framework crosses a range of themes linked through the notion of precaution/uncertainty based decision-making. The breadth of issues considered using this approach and the detailed texture of the analysis make it a significant contribution to the very limited range of scholarly work conducted on Australia's regulatory system for GMOs. The case study analysis of the risk assessment conducted on Bt cotton and its non-target impacts is also original in style and content. Having crafted a unique way to operationalise the notion of extended peer review that combined social and scientific approaches, I presented a richly detailed deconstruction of scientific risk assessment in practice. Informed by this case study research, I crafted a new framework for the development of robust approaches to environmental decision-making: Reliability Rating and Reflective Questioning.

Finally, I consider that my research is significant in a practical sense because it contributed to the government commissioned review of the operation of the Gene Technology Act 2000. In November 2005, after I had completed the main body of my research, I attended public and stakeholder consultation sessions where I presented my analysis and recommendations to the review committee. I therefore achieved the goal I set for myself when I began this research project because not only did I conduct research that critically appraised Australia's regulatory system by drawing on a range of theoretical literature on environmental decision-making, I also produced practical recommendations for how the regulatory system could be improved and delivered these to the government sponsored review committee. This means that this research has

made a number of original contributions to scholarship and achieved both the analytical and practical goals established at the beginning of the project.

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APPENDIX:
REFLECTIONS

1. PREFACE

This thesis has been coloured and shaped by who I am as a person. I, in turn, have been coloured and shaped by the events and environment of my life. In this preface, I want to talk a little about who I am and how I came to be engaged in this research project. In doing so, my aim is to generate another dimension to my work. I want you as the reader to know who I am so you can consider how this might have influenced my choice of research problem, methods and outcomes, but I also write this preface as a record for my own reflection on these issues. I therefore hope this preface can act as a tool, assisting in both my personal task of reflection on my research and enabling and encouraging others to reflect on the process of knowledge generation. What follows then is a rather informal account of my childhood, education, work experience and passions, particularly as they relate to this research project on Australia's environmental regulation of genetically modified (GM) crops. While I see this preface as a vital introduction to my research, for those not awarding importance to reflective practice or unconcerned about my background, the thesis can in fact be read as a complete document omitting this discursive preface. I would however urge you to take the time to sit back with a cup of tea and allow me to introduce myself.

Growing up with the name 'Fern' meant that I was always being asked if my parents were hippies. From an early age I began to question who and what these 'hippies' were and why people thought my parents must fall into that category. These questions opened a door for my exploration of a community of people and a set of beliefs that were structured around a concern for the

environment. As I grew older and learnt more about the state of the world, I too began to share that concern. While my interest in environmental matters may be seen as some form of nominal determinism, I prefer to see it as an interest that, while perhaps originally sparked by being given a 'hippy' name, as developed over time became driven more by the challenges I saw facing the world than by my name alone.

While my parents would certainly not be considered hippies in any conventional sense, the way they raised me did build a love of the outdoors and a respect for the natural world. My father is a horticulturist and my mother a casual primary school teacher. I was raised on a small sheep farm until the age of 5, then on an agricultural research station focussed on fruit varieties until I was 13. Some of my sweetest childhood memories come from that environment. I remember wiling away hot summer days under the shade of grapevines draped in bird netting; lying on my back reaching up to pluck the dark juicy balls and dropping them one by one into my mouth until I had to shuffle on my back to the next bunch. I remember sitting on the veranda beside a honeysuckle bush with a bowl of blueberries by my side. One blueberry, the tiniest tasty sip of a honeysuckle flower and then another blueberry. Flower, blueberry, flower, blueberry until the sun went down. I remember walnuts and almonds, feijoas and nectarines, peaches and plums, apples and cherries. Growing up on the research station showered my childhood in the fruits of diversity.

Ever since those early days, my family's favourite hobby has been endurance riding. This involves a weekend camping in the bush, where those competing aim to complete an 80km flagged trail on horseback. The horses undergo veterinarian checks before, during and after the race and must demonstrate signs of fitness (sound footing, acceptable heart rate etc) at every stage before

the rider can be awarded the belt buckle signalling a successful completion. While I failed to share my family's all consuming passion for horses and the 80km ride, I did spend many weekends of my childhood camped with my family and the horses in various bush locations. Waking up at 5am and watching hundreds of horses canter off into the darkness still sets my heart racing and the joy of relaxing around a campfire remains one of my very favourite things to do.

When I was 13 we moved from the research station to a property where my parents had land for the horses, day jobs to feed the horse passion and growing children, sheep to help cover the costs of the farm, dogs to help with the sheep, chickens for the eggs we all love to have for weekend breakfasts, a vegetable garden for all the things we should eat for dinner, guinea pigs to help with the grass, views to enjoy with a drink as the sun goes down and a house up the road for my grandparents. Despite longing for all of these things now, as a teenager, a certain part of me always thought I resented it. I wanted to be in the city where the action was. Better still, I wanted to be in America where I had consumed that everything was better. As I grew older and spent more time in the big smoke of Sydney, I found it, well, more than a little smoky for my tastes. Yearning for something more than the box I thought my small town put around me but repulsed by the pace and surface of city life, upon finishing school I decided to continue my studies in the 'big country town' of the nation's capital, Canberra.

At high school I had enjoyed both Biology and English subjects and although I knew I wanted to attend university, I had no clear vision of my destiny in a single profession at the ripe old age of 18. This made the day I had to write down my preferences for a university degree incredibly daunting. I literally

flipped through the guide that listed Australian universities and their different courses trying to find something that I thought I would enjoy. I always seemed to be sacrificing something when I made a decision. I enjoyed learning about plants, animals and the environment, but I also enjoyed reading novels and arguing about politics and philosophy. Then there it was, an Arts/Science degree at the Australian National University (ANU) in Canberra, no need to choose between them, no need to specialise in a particular profession from the first year, it was perfect!

I primarily focused on political science subjects in my Arts degree and wandered across biology and ecology subjects in my science degree. In the latter years of my degree I decided to enrol in a subject called "Biotechnology in Context". While I initially selected the course simply out of interest, as I began studying the development and application of biotechnologies within a social context, I began to see that this was an area where the knowledge from my two degrees could be brought together. While I learnt about a number of different biotechnologies and the social, ethical and environmental questions that they raised in this subject, it was the question of the environmental impact of agricultural biotechnologies that particularly sparked my interest. This was most likely because it was an issue upon which my experiential background and disciplinary knowledge converged.

After studying "Biotechnology in Context" in the third year of my degree, I took a year off from my studies and travelled overseas. This was not my first adventure into foreign lands as I had received a fully paid scholarship to spend three months in Germany when I was sixteen. That early experience really opened my country girl eyes to the existence of different countries and cultures and just how incredibly large and diverse the world really is. When I took the

year off to travel again, I decided to return to Germany to improve my language skills. I worked in Germany for 6 months as an au pair and then backpacked around Europe for 6 months. In that time, I spent one month as the camp leader for a group of international volunteers undertaking restoration work in forests of the former East Germany. Coordinating this project was an unforgettable experience that enabled me to indulge my passion for the outdoors and learn about the challenges of managing the peace between people from very different backgrounds.

The whole experience of working and travelling alone through Europe for a year made me realise that not only is the world full of natural diversity, there is also a huge degree of social and cultural diversity that is worthy of respect. I also began to realise that Australia was indeed a lucky country. When I visited a German forest on a sunny winter weekend and found that this 'wilderness' experience was to be shared with literally thousands of other people, I began to realise that the wide open spaces and ancient diverse landscapes of my home land were truly things to be treasured. My interest in how to restore and maintain the environmental health of Australia became particularly important to me following my travels in foreign lands.

Upon returning to university to finish my degree, I was given the special honour of being asked to tutor the "Biotechnology in Context" subject that had so interested me before I left to go travelling. I was thrilled to be offered this position (especially as I was still an undergraduate) not only because it gave me the opportunity to learn more about biotechnology in a social context and to share this knowledge with others, but because it also gave me an opportunity to work more closely with an academic that I had developed enormous respect for. The commitment of Dr. Jeremy Evans to teaching science in a social context

and bridging the educational divide between the natural and social sciences, in the face of ongoing administrative and disciplinary challenges, has been a real inspiration to me.

After tutoring this subject for a semester I became more and more interested in the debate I saw occurring over whether biotechnology could improve the environmental impact of agriculture or whether it would result in new and more difficult environmental problems. I thoroughly enjoyed hearing both sides of this debate presented by the students in tutorials and particularly enjoyed feeling compelled to think ever deeper about what it meant to be concerned for the environment.

At the conclusion of the semester and my undergraduate degree I decided to spend the 6 months before the subject was to be taught again travelling around Australia participating in a program called "Willing Workers on Organic Farms" (WWOOF). Through this program, travellers receive free accommodation and food for a few hours work on an organic property. I decided that this was the perfect way for me to see more of the countryside, learn about organic farming and ask people involved in this industry how they felt about biotechnology. This working holiday took me to the very ends of the earth, (the southern most tip of Tasmania!) and there I met the man of my dreams. Having fallen in love with Tasmania and a Tasmanian, it became very hard to return to Canberra to teach the following semester but my desire to continue my involvement in the biotechnology course was enough to see me make the return journey. Fortunately for me, my love decided to uproot his life to follow me.

When I returned to Canberra for tutoring this time, Dr Evans had retired and the course had been taken over by an open minded and incredibly talented scientist Dr. Barbera Van Leeuwen. While I still tutored the subject and enjoyed the position, I was disappointed as I had hoped to undertake an Honours project with Dr Evans in the following year. As it turned out, my partner was offered a promising opportunity that saw us both return to Tasmania to live in 2001.

While my partner returned to fishing the Tasmanian waters, I enrolled in the Political Science Honours program at the University of Tasmania. There I was encouraged to follow my interest in biotechnology issues in both my course work assignments and thesis. I wrote papers on patenting living organisms and 'terminator' technologies and my thesis explored the paradigm of thought supporting the development of recombinant DNA technologies. During my honours year I also tutored a subject on global environmental politics and worked as a research assistant for an environmental politics lecturer, Dr. Kate Crowley. Upon being awarded a first class honours degree I decided to try and enter the workforce on a full time basis.

I have worked in a number of different positions to support my education over the years. I have cleaned toilets and temples, graded cherries, looked after children, modelled clothing, waited tables and even worked on a research project for the World Bank. Over this time I have learnt that while you can do just about anything to survive, it is often worth working for less money if you can find a job that you enjoy and which you believe is contributing something positive to social and natural communities. After my Honours degree I took up a position as a canvasser for the Wilderness Society.

In Tasmania, environmental politics has blossomed since the 1970s when campaigns against the damming of wild rivers built to a fever pitch and resulted in the protection of the Franklin. The Wilderness Society was established during this time and continues to have a strong presence in the community through its current fervent campaign to save the oldgrowth forests of Tasmania from clearfelling. Having seen the enormous devastation and waste associated with clearfelling policies first hand, I was keen to be involved in the Wilderness Society efforts to talk to the community about these issues and inspire them into action. I felt that working with this organisation would enable me to gain insights into the day to day operations of environmental non-governmental organisations and provide me with an opportunity to earn some money while working for a cause I believed in.

While this canvassing job was enormously challenging, it was also incredibly rewarding. As I spent each day talking to different people on the streets about how they felt about Tasmania's forest policies, not only was I sharing my knowledge with them, they were sharing their knowledge and experiences with me. I learnt a lot about the Tasmanian people and their environmental beliefs and concerns during this time but I also learnt a lot about myself and was forced on a number of occasions to reflect on my own system of beliefs and how to accommodate the multitude of interests and opinions that exist in society.

After almost 2 years living in Tasmania, my partner became restless and talked to me about his need to leave the state and see the rest of the country. Empathising with the confines that growing up in small communities can create, I decided to apply for PhD scholarships on the mainland. Having performed an internet search looking for universities with an interest in the environmental implications of biotechnologies, I came across the BELSA

(Biotechnology, Ethical, Legal and Social Aspects) group at the University of Wollongong. I went on to contact Dr. A. Wendy Russell from this group and began talking to her about the possibility of working on a PhD project together.

Dr. Russell had a particular interest in the GM cotton grown in Australia, which was modified to express a toxin that killed caterpillar pests. This type of application always seemed to feature in environmental debates about biotechnology because of the claimed benefit of reduced pesticide use. Critics of the technology would, however, contrastingly claim, among other things, that it did not represent a long term solution and addressed symptoms rather than the cause of environmental problems in agriculture. This crop therefore seemed to represent an ideal case study for exploring the debate about the environmental impact of agricultural biotechnologies. As Dr. Russell was situated in a Biological Sciences department, and I envisaged taking more of a social science based approach to my research, we arranged a cross faculty enrolment with co-supervision from the Science, Technology and Society program in Arts.

If I am to be entirely honest in this preface I would have to admit that when I began thinking about my PhD project, I had already adopted a position in this debate. I identified with an environmental community and a body of beliefs that rejected biotechnology as a desirable direction for Australian agriculture. I did, however, find this position substantially challenged by the suggestion that biotechnologies could reduce pesticide use. While I could see how an environmental argument could be made against biotechnologies despite this apparent benefit, I felt that this had to be quite a sophisticated argument that was not currently being well made. I began to think that perhaps that could be the focus of my PhD project - to make a robust argument against agricultural biotechnologies.

As I began to undertake initial research into the topic, however, I began to see that the debate about the environmental impact of GM crops was occurring between people and organisations operating from different premises, different beliefs about the environment and what it meant to protect it. Additionally, I realised that there was no conclusive scientific evidence on the potential environmental impacts of GM crops. The realisation that there were different environmental discourses and widespread scientific uncertainties involved in the debate began to shift my research interest towards how Australia negotiated these challenges in their decision-making process. I became interested in how we were making decisions in the face of conflicting values and uncertainty. As such, I became less concerned with what constituted a 'right' decision (or proving that my particular position was 'right') and more concerned with what would constitute a good process for making decisions about the deliberate environmental release of GM crops and how well Australia was performing in this regard. My decision to focus on this issue was cemented when I sat in on an undergraduate course run by my Arts supervisor Dr. Stewart Russell. The engaging way in which he presented the complex and multifaceted field of risk really lead me to embrace the idea of exploring Australia's regulatory system.

So that is how I came to be here, engaged in this research project on Australia's environmental regulation of GM crops. I had an interest in environmental issues, I grew up in an agricultural setting, I studied both arts and science at university and found the regulation of GM crops an area where these disciplines and my background converged. As an issue where my institutional and experiential knowledge combined with my interests and passions, I decided that it was the perfect topic for a PhD research project. As my initial research led me to realise that different people would have different positions

on the issue depending on their own personal environmental beliefs and values, I began to move away from being concerned with proving that my position was the right one and began to pursue a research interest in how Australia had gone about making regulatory decisions in the face of the challenges posed by competing values and scientific uncertainties. The process and results of this investigation are recorded in the following pages of this thesis. I only hope that reading about them proves as interesting, thought provoking and rewarding as researching and writing about them has been.

1. EPILOGUE

In the introduction to this thesis I presented reflection as an important part of transdisciplinary research practice. In the early stages of my research, I reflected on the events and environments of my life that had an important influence on how I chose to define my particular research problem. These reflections were recorded in the preface to this thesis. As I have now completed this research project, I would like to bring the process of reflection full circle by considering how my values, beliefs and assumptions may have influenced the research methods and results.

As the preface indicated, when I began this research project I had already adopted a position in the GMO debate that rejected GM crops as the most appropriate way forward for Australian agriculture. I identified with a community of people that saw the environment as more than a resource for human consumption and manipulation and I valued systems-based approaches to agriculture that focus on encouraging biological diversity and cycling nutrients. While my sensitivity and respect for cultural diversity saw me shift away from a desire to prove that my position was 'right' and define my research interest as how Australia was making regulatory decisions in the face of contested environmental values and scientific uncertainty, there are at least two key areas ways in which I can see that my values have influenced my approach to researching this topic.

The first of these is in my theoretical framework of science/risk - precaution/uncertainty based approaches to environmental decision-making. In creating this theoretical framework, I adopted the position that precaution/uncertainty based approaches were preferable for the environmental regulation of GM crops. While I see this position as informed by the theoretical

literature, it may well be that the literature I chose to survey was in fact informed by my position. By this I mean that my own beliefs about the inadequacies of scientific knowledge and the inappropriateness of a focus solely on technical concerns, may have led me to survey only the literature that supported this position. While this was certainly not a conscious decision, with the huge amount of material potentially available to a transdisciplinary survey of literature on risk and uncertainty in environmental decision-making, I cannot deny that someone possessing an alternative set of beliefs may have created a very different theoretical framework. For example, I did not survey literature on this topic from the natural sciences. If I had done this, I would arguably have uncovered a range of techniques specifically designed to quantify and handle scientific uncertainty, and therefore, I may have presented a theoretical framework within which an uncertainty based approach to regulatory decision-making may still have relied on scientific expertise[1]. While I would argue that a framework such as this would fail to accommodate the challenges posed by the types of uncertainty described in this thesis as ambiguity, indeterminacy and ignorance - forms of uncertainty that are inevitably confronted when dealing with the complexity and magnitude of environmental interactions - my point is simply that the theoretical framework I developed and the literature on risk and uncertainty I surveyed, were parts of my research where I can see the potential influence of my own value judgements.

The second area where I can identify the potential influence of my own value judgements is in the selection of non-target impacts as the case study risk assessment. While I justified my selection of this case study in chapter four

[1] It is pertinent to note here that the case study RARMP I analysed demonstrated no use of any techniques to communicate and/or manage scientific uncertainty in the decision-making process and therefore, would arguably still have been open to criticism under a theoretical framework advocating a more science-based approach to handling uncertainty .

section 1.6 (and I stand by this justification), I can see how someone operating under a different set of values may have selected a different case study for analysis. In addition to impacts on non-target organisms, the OGTR also assessed Bt cotton for toxicity and allergenicity for humans, weediness, the transfer of introduced genes to other organisms and the development of insect resistance (OGTR 2003b). Someone with an interest in demonstrating the effectiveness of the current regulatory system may have selected an issue such as insect resistance as a case study because there has been far more research on this topic than on non-target impacts and therefore the degree of uncertainty involved could be expected to be less. While I specifically chose non-target impacts so that I could explore how incertitude had been handled in the decision-making process, it could be suggested that the selection of this issue allowed me to more easily highlight problems with the risk assessment process than the selection of another issue (such as weediness or insect resistance) would have allowed. Of course, this claim remains unsubstantiated until a similar process of deconstruction is conducted on these risk assessments, particularly since many of the problems I noted with the risk assessment (such as false referencing, selection of information and a lack of critique) were not necessarily related to problems posed by uncertainty.

Having said this, though, my selection of impacts on non-target organisms as a case study was partly based on a value judgement. As I mentioned earlier, I value agricultural systems that respect and encourage biological diversity. As such, the risks to non-target organisms from GM crops are of particular interest to me. This means that my choice of this case study was partly based on what it is I value.

Having reflected on how values may have influenced my research method, I can also see ways in which they could be seen to have influenced my conclusions and recommendations. For example, if I was supportive of agricultural biotechnologies, I may not have recommended a national imagining or envisioning project because in recommending this approach, the implicit assumption is that current approaches to agriculture are not working or will not be appropriate in the future. If I thought they were working and/or were appropriate, there would be no need to recommend a process envisioning change. As the currently dominant chemically intensive approach to agriculture is accommodating and embracing biotechnologies, someone in favour of these technologies would arguably not see any need for the community to envision radical change. While I stand by this recommendation because there is nothing to exclude those with a biotechnological vision for Australia being included in an agricultural envisioning project, the fact that I made this type of recommendation can be linked to my assumption of the need for change.

In fact, as the current regulatory system seems to support the development and use of biotechnologies in general, it could be argued that a proponent of this technology may not have recommended any of the changes I suggested were important. All of the recommendations I made for policy were essentially focussed around the need to broaden the range of concerns and the actors involved in the policy process. This would make decision-making more complex, slow the process down, and arguably, make the approval of biotechnologies more difficult. Based on rapid and favourable decision-making within a narrow framework of concerns, a biotechnology proponent would arguably support the largely technocratic approach to regulatory decision-making that currently exists in Australia and may, in fact, have made recommendations that further limited the scope of the regulatory system.

Indeed, a proponent of biotechnology would have written an entirely different thesis. They would have had different interests framing their research problem, different assumptions influencing their methods and different values guiding their recommendations. This does not, however, negate the value of this thesis. This thesis has value for the field of environmental decision-making because it involves original and independent critical research that engages with a key problem in a unique way and offers recommendations for both future research and the evolution of policy processes. I believe that by creatively synthesising various bodies of literature, conducting detailed analysis and creating a new framework to assist robust decision-making processes, this research makes a significant contribution to both academic knowledge and practice of regulatory decision-making. Specifically, I believe that the critical appraisal of Australia's regulatory system presented in this thesis highlights some very important problems with the way in which the process of decision making is currently being presented and conducted; problems that have the potential to undermine both the system's ability to safeguard the environment and to maintain public trust. Finally, I believe that by reflecting on and acknowledging some of the subjectivities involved in this research, I have only served to strengthen its value.