VALUE-LADEN RISK ASSESSMENT AND BIOTECHNOLOGY REGULATION IN CANADA

A Thesis Submitted to the College of

Graduate Studies and Research

in Partial Fulfillment of the Requirements

for the Degree of Master of Arts

in the Department of Philosophy

University of Saskatchewan

Saskatoon

By

Rana Ahmad

PERMISSION TO USE

In presenting this thesis in partial fulfilment of the requirements for a Postgraduate degree from the University of Saskatchewan, I agree that the Libraries of this University may make it freely available for inspection. I further agree that permission for copying of this thesis in any manner, in whole or in part, for scholarly purposes may be granted by the professor or professors who supervised my thesis work or, in their absence, by the Head of the Department or the Dean of the College in which my thesis work was done. It is understood that any copying or publication or use of this thesis or parts thereof for financial gain shall not be allowed without my written permission. It is also understood that due recognition shall be given to me and to the University of Saskatchewan in any scholarly use which may be made of any material in my thesis.

Requests for permission to copy or to make other use of material in this thesis in whole or part should be addressed to:

Head of the Department of Philosophy
University of Saskatchewan
Saskatoon, Saskatchewan S7N 5A5

Abstract

Risk assessment is increasingly used by policy makers and scientists to determine the safety of new technologies and how they should be regulated. For technologies such as biotechnology, there is often insufficient information concerning the long-term effects of its applications and so accurate assessments of risk are essential. Canada's regulatory system is science-based and relies on risk assessment to make decisions about which products of biotechnology are safe enough for commercial application. Since regulation involves the loss of certain liberties of individuals in society, it is imperative that any regulatory regime is as objective as possible. Scientific risk assessment seems to be a good way to produce the information, which guides policy makers since it involves quantitative analysis and the production of seemingly objective data. The view adopted by regulators and in current risk assessment practices is that objective means value-free. Therefore, because risk assessment data is scientific it is thought to be objective. This is not the case however.

Risk assessment necessarily involves value assumptions. Assumptions must be made at all stages of the production of risk data. This does not mean, however, that risk assessment is hopelessly subjective. The notion of value-free objectivity can be replaced with the view that genuine objectivity arises through peer review and social discourse. Regulators can then acknowledge the value-ladenness of risk assessment data and the chance for bias can be reduced.

At present, the value assumptions made by industry, government and private scientists during risk assessment go largely unnoticed yet have an effect on the outcome of regulatory decisions. Such assumptions must be recognized in order to ensure that the decisions made about the risks society face are not biased. This is particularly true in the case of biotechnology regulation. The development of the science of biotechnology has occurred

concurrently with the development of the biotech industry. The existence of this biotechnology-industry complex creates the opportunity for industry-biased risk assessments since current regulatory practices require proponents to produce the risk data evaluated by regulators. All members of society will face the risks associated with biotechnology, however, because the release of transgenic organisms involves risks that transcend geographical and temporal boundaries. Regulatory decisions must be based on genuinely objective risk assessment data.

It is possible to make changes to the existing regulatory regime in Canada in order to avoid some of the major problems associated with unrecognized value assumptions in risk assessment. A complete restructuring of the regime is unnecessary, however. Maintaining the current regulatory structure with some minor changes could address these problems. These changes include: creating an independent review board, making explicit that value assumptions are part of risk assessment in government advisory reports, and enhancing the role of regulators. The benefits of biotechnology are unprecedented as are the risks. Canada's regulatory system can better address the risks associated with biotechnology if it acknowledges that risk assessment is value-laden.

Acknowledgments

I would like to especially thank my supervisor Dr. Eric Dayton, without whom this thesis would not exist, for all of his guidance and support. My appreciation goes to my other committee members as well. To Dr. Sarah Hoffman for her comments, suggestions and encouragement. To Professor Will Buschert for his insight, constructive criticism and editorial comments. To Dr. Peter Phillips for his support through invaluable discussions and resources. Thanks to all of you not just for being on my committee but for all of your guidance and assistance.

To my mother for encouraging me to persevere,

and to my father for showing me how.

TABLE OF CONTENTS

List of Abbreviations

ADA – adenosine deaminase

APHIS – Animal and Plant Health Inspection Service

bGH – bovine growth hormone

bST – bovine somatotropin

CBAC – Canadian Biotechnology Advisory Council

CFIA – Canadian Food Inspection Agency

CWB – Canadian Wheat Board

DNA – deoxyribonucleic acid

FDA – Federal Drug Administration

GM – genetically modified

GMO – genetically modified organism

HPB – Health Protection Branch

IGF-I – insulin-like growth factor I

PNT – plant with a novel trait

rbGH – recombinant bovine growth hormone

rbST – recombinant bovine somatotropin

RCBA – risk-cost benefit analysis

rDNA – recombinant deoxyribonucleic acid

RRW – Roundup Ready® Wheat

SSCA – Saskatchewan Soil Conservation Association

USDA – United States Department of Agriculture

WETEC – Wheat Export Trade Education Committee

1. Introduction

A risk is the possibility that some adverse consequence such as a loss or harm will occur. Risks occur frequently, thus making the concept of risk a familiar one. It is often thought that describing a risk is describing a fact about the world, but this is not the case. The concept of risk is evaluative rather than merely descriptive. Risk always involves value assumptions. The degree of severity, character and even identification of a risk can vary from one person to another according to the value assumptions that person has made.

There are myriad sources of risk ranging from improperly tied shoelaces to harmful rays from the sun. Advances in science and technology have led to great improvements in the quality of life but they have also exposed us to new risks. Many new developments in these fields require a certain level of expertise or knowledge in order to understand the risks associated with their effects. Scientific risk assessment is used to characterize the extent of risk associated with a particular technology.

Risk assessment is the process of determining the likelihood and extent of harm caused by a technology, process or product. It involves quantitative analysis of data in order to assign a probability to the occurrence of an unwanted or harmful effect. Regulation of a new technology depends on risk assessment data to determine whether its products are safe enough for use. Nothing is completely risk-free so standards of "acceptable" risk are set. Scientific risk assessment is thought to be a good way to produce objective data, where "objective" is taken to mean "value-free". Since regulation involves the loss of certain freedoms by members in a society, it is important that the data used is as objective as possible. Risk, however, is evaluative and cannot be applied in an objective way if it is understood in this sense. Therefore, it seems that the whole business of risk assessment is

hopelessly subjective. This is only the case, however, if we accept the idea that objective means value-free, which is the view assumed in current risk assessment practices and by regulators. As a result, value assumptions inherent to the assessment of risk go largely unrecognized.

This limited characterization of objectivity should be rejected because it requires complete observer-independence. The notion of value-free objectivity can be replaced with a more realistic account. Longino suggests that genuine objectivity is the outcome of a social process that must have certain features such as shared standards, peer review and a diversity of viewpoints (Longino 181). If risk assessment is to be genuinely objective, it must answer to this enriched and more accurate notion of objectivity.

Failing to recognize that risk assessment is not inherently objective (as in value-free), is problematic for a regulatory system that uses the assessment of risk to make critical decisions about safety. It allows the incorporation of values throughout the production of risk data to go unnoticed. Since regulation affects all members of society, it is necessary to at least attempt to make sure these values are representative of as many as possible, if not all, citizens.[1] Thus, it is important to make sure decisions, which restrict our ability to govern ourselves individually, are made on genuinely objective data. Thompson asserts,

> One fact of postmodern society is that decisions by a few individuals to develop and disseminate new technologies can have enormous impact upon society as a whole. Although there are many instances where these impacts are predominantly beneficial, there are few, (if any) occasions on which they are universally so (Thompson 1998 143).

Genuinely objective risk assessment is necessary for new technologies, such as biotechnology, because it is the primary source of safety data used in regulation.

Biotechnology is a relatively new science with the potential to benefit all of society. The products of biotechnology have innumerable applications and significant market potential.

[1] For further discussion see Sass 135-138.

Transgenic science produces genetically modified organisms (GMOs), which include plants, animals and microorganisms. The risks associated with the release of these organisms, however, could involve hazards of an unprecedented scale. Once released into the environment, GMOs cannot be recalled. Their behaviour outside the laboratory is largely undetermined and unpredictable, making some of the risks associated with biotechnology unknown. The technology to transfer genes from one organism to another has only been available since the early 1970s, so there is a very limited base of knowledge and experience to draw upon concerning the effects these organisms will have on the environment. When it comes to assessing the risks of biotechnology, the newness of transgenic science means that there is often no real world data to calculate potential risk. Risk must therefore be assessed using subjective probabilities assigned by experts. Despite this necessary subjectivity, regulators in Canada, for instance, maintain the view that risk assessment is value-free.

In Canada biotechnology regulation is based on scientific risk assessment. The company or scientist who develops a genetically modified product produces risk data, which is then submitted for review by regulators. There is little or no acknowledgement that the production of risk data involves value assumptions. Therefore the values influencing the risk characterization of a product are typically those of the product proponent. This is of particular concern in the case of biotechnology. From the emergence of transgenic science just over thirty years ago, it was widely recognized that the products of biotechnology could be very profitable. The development of the science occurred concurrently with the development of the business of biotechnology which has created a biotechnology-industry complex. Advances in transgenic science and product development are in large part driven by biotech corporations. These corporations cannot, of course, release their products without going through the regulatory process and the Canadian system of regulation requires that corporations conduct risk assessments of each product submitted for review. Risk

assessments involve value assumptions however, and the values incorporated in these assessments are those of the corporations. It is unlikely that these values are representative of all Canadians, yet all Canadians will be subject to the risks associated with the approved products.

The untenable notion of objectivity as value-free should be discarded and replaced with an enriched understanding of genuine objectivity, which arises out of social discourse. Value-laden risk assessment is less problematic when objectivity is thus understood because genuine objectivity requires peer review and discussion from a variety of people with differing backgrounds. In the regulation of biotechnology, genuine objectivity is less likely to result in industry-biased risk data.

In Chapter Two I discuss the philosophical nature of risk to show that value assumptions are endemic to assessments of risk. I also explain why it is necessary to discard the unrealistic ideal of objectivity in science and risk assessment and offer a different, more useful account of objectivity. Objectivity understood as the product of peer review and social discourse allows for the value-ladenness of risk assessments while mitigating unacceptable bias. Incorporating a number of different assessments from within the scientific community into risk assessments provides a way of producing the objectivity we want guiding policy decisions.

In Chapter Three I discuss biotechnology and the unique set of risks associated with it. My emphasis will be on agricultural biotechnology specifically. Although most of the comments I make do pertain to biotechnology in general, I have chosen to focus primarily on agricultural products and applications because these products directly affect all members of society and currently there is significant debate about their use. Risk assessment is particularly crucial to the development and regulation of biotechnology because our knowledge in this field is so limited and our understanding of how transgenic organisms

interact in the environment is often based on risk data. The co-evolution of biotechnology with the biotech industry has greatly influenced the direction of development in transgenic science. The biotechnology-industry complex and the unprecedented commercial potential of transgenic products result in industry-biased risk assessments. Canada's current regulatory system fails to acknowledge that risk assessments are value-laden and so this bias is not addressed during the process of regulatory approval. Changes to the system over the last five years have further exacerbated this problem since the government relies almost solely on the product's developer, or corporations to produce risk data.

In Chapter Four I discuss three case studies, which demonstrate the effects value-ladenness can have on both the process of risk assessment and on the regulatory process. All three of these cases involve the regulation of agricultural products in Canada through the Canadian Food Inspection Agency (CFIA). The approach of the CFIA typifies that taken by the other regulatory agencies in Canada, however. The first case, which involves the controversy surrounding the use of a chemical herbicide called Alachlor, provides an example of how different value assumptions made in the laboratories of assessors affect the outcome of risk assessments. In the second case, which concerns the regulation of recombinant growth hormone in the US and Canada, value assumptions influenced by the political and economic climate also affected the risk data that regulators relied on to determine this product's safety. The last case I discuss describes the current application by Monsanto for the approval of GM wheat. Current developments and controversy in this case demonstrate that Canada's system of regulation does not account for value assumptions in risk assessment despite the lessons we might have learned from the first two cases.

In the final chapter I offer three recommendations for improving regulation of biotechnology and biotechnology products in Canada. These recommendations require the adoption of a more useful idea of objectivity in science and risk assessment. Subsequently,

the value assumptions in assessments of risk become less problematic in regulation and less likely to produce industry bias. Although value assumptions are endemic to risk assessment, this does not necessarily compromise the objectivity of such assessments if we adopt a more tenable understanding of objectivity. Peer review and collaboration within the scientific community allow for the introduction of many different value systems during the assessment process which alleviates the chance of creating biased data and produces the objectivity we want. While my focus is on the Canadian regulatory regime, biotechnology produces risks that transcend geographical and temporal boundaries. The science is new and we are unable to anticipate many of its effects once transgenic organisms are released into the environment. There must also be consideration given to the risks associated with forgoing the benefits of biotechnology. Objective risk assessments are therefore not only crucial when making regulatory decisions that limit our liberties, they are crucial to addressing the unique and irrevocable risks associated with the tremendous potential of biotechnology.

2. Risk and Risk Assessment

2.1 Introduction

There have been unprecedented advances in science and technology in the last few decades. As our understanding of science progresses, our ability to apply this new knowledge has also rapidly increased, bringing new technology out of the laboratories and into the social sphere. The introduction of new products and processes has enhanced our lives and improved health care, agriculture, education and industry. An increased exposure to risks resulting from the implementation of new technology has occurred along with these improvements, however. Consequently we have witnessed the emergence of risk assessment, a field of research that attempts to analyze, assess and manage the possible risks we face to our health, safety and to the environment. Risk assessment utilizes a cross-disciplinary approach in characterizing and assessing risk. Risk estimation information is then used to inform public policy and ultimately aid in the decisions we must make about which risks are worth taking.

Since much of the preliminary work in risk assessment involves quantification and data analysis, it looks very much like ordinary scientific research. Accordingly, since it is commonly assumed that ordinary science is objective, risk assessment is assumed to be as well. In this chapter I argue that risk assessment is value-laden. I first give a brief overview of the philosophical nature of risk and make the claim that risk itself is not objective as it necessarily involves normative evaluation. The nature of risk shapes the way risk is assessed from its characterization to its quantification. Since the concept of risk itself is evaluative,

risk assessment is evaluative as well. I then discuss objectivity in science and argue that the positivist view of science, as in principle value-free, is untenable. The notion of objectivity as a social process arising out of peer-review and collaboration is more useful to understanding how we might achieve observer-independence in risk assessment. In the third section of this chapter I discuss the nature of risk assessment and argue that value assumptions are inherent in both its quantitative and evaluative stages.

2.2 The Philosophical Nature of Risk

A risk "is the chancing of a negativity—of some loss or harm" (Rescher 5). It is easy to think of risks as mere facts about the world. We use quantifications to make sense of risky procedures in health care, citing one's chances of recovery, death or complications. Very rarely, however, do we think about the philosophical nature of risk or how the factual information used to guide decision-making is generated. Understanding that risks incorporate normative evaluation both in the production of data and, even in identifying what is risky, is crucial to our ability to make use of risk assessment.

The concept of risk is a familiar one: we face risks when we cross the street, try something new, or choose to go left instead of right. Risks are ubiquitous in virtually every aspect of living and are an integral part of nearly every choice we make. In each case we understand risk to be the chance that something unwanted, or possibly harmful, will arise from any given situation. Risks, according to Rescher "face us with the possibility that something untoward may occur, while leaving us unable to foretell any specific outcome with categorical assurance" (5).[2] We cannot choose to avoid all risks since that would be impossible and in many cases, risks are not foreseeable.

[2] Also helpful in this discussion is Baier 263-287.

Rescher claims that “risk is an ontological not an epistemological category” (6-7). He uses this categorization to make the distinction between running a risk and taking a risk and to argue that one can run a risk without explicitly taking a risk (6-7). Rescher distinguishes the risks we take from the risks we face. Risks we face are those that occur through no direct action of our own such as hurricanes or floods, or when we are not aware of the risks associated with our actions. Risks we take are those that result from an action we take, and which we are aware of when we make the choice to take that action. Rescher describes three elements of risk-taking, which must be considered when attempting to characterize risk: choice of action, negativity of outcome, and chance of realization (6). The first element is one’s choice of action, which is choosing to act in a deliberate way to either produce or avoid certain results. The second element refers to the fact that taking a risk involves the possible occurrence of a negativity of the outcome of the choice one makes. The third element is the chance that a given negativity or unwanted outcome is realized. Rescher contends that the second and third elements are most crucial to risk in that one can incur a risk without having taken an action.

Since risk is the potential for the realization of unwanted or adverse consequences, “it is correlative with the prospect that things may go wrong—the chance of a mishap” (5). Thus a situation is considered to be risky if one of its possible outcomes involves a possible loss or harm. Risks involve an account of possible outcomes in light of their probabilities. For example if a person is standing in the middle of a shopping mall, their risk for getting attacked by a shark is quite low because the probability of shopping mall shark attacks is low. If a person is the victim of a capsized boat in shark-infested waters, however, their risk of a shark attack is quite high because the probability of such an attack is high. This situation would be considered quite risky. In neither case can we guarantee the outcome—they are indeterminate and therefore the people in both situations are at risk to some extent. Even if

an event is highly unlikely there is still *some* chance it may occur. Sharks are kept in the West Edmonton Mall aquarium, for example, and measures taken to keep them away from visitors might fail. Moreover, even if one is in a mall without an aquarium, the most that one is entitled to conclude from this is that the risk of shark attack is 'effectively zero', not the assertion that the risk of shark attack is in fact zero (Rescher 36). Similarly, just because an event is very likely, does not guarantee that it will occur; people have survived for many hours waiting for rescue in shark-infested waters. We must therefore rely on an account of the probability of an event's occurrence to determine how much of a risk it might be.

Despite our ability to determine the likelihood of a risk in some situations, judgements must still be made about many of the factors that characterize a risk. Rescher describes three aspects to the nature of risk, which best demonstrate that risk always involves normative evaluation. These are: 1) the characterization of negativities, 2) the incommensurability of negativities and 3) the lack of a common unit of currency with which to measure and compare negativities. In each case, value judgements must be made in order to identify a situation as a risk.

As Rescher notes the chance of a risk being realized is only one of two components of risk. The other component is the negativity of risk. Determining the magnitude of a negativity is a much more complicated task than determining the chance of its occurrence (18). Since risk involves both negativity and its chance or realization, risk must involve normative evaluation. A high-risk situation for one person might not be considered very risky for another depending on the many factors taken into account when evaluating a risk. This causes difficulty in determining the magnitude of a risk. Rescher divides these factors into three categories: character, extent and timing (19). Determining the character of a risk involves identifying what type of negativity might result such as injury, death or the loss of time, money, or social status. The extent of a negativity includes an account of how severe it

is and which or how many people might be affected by its occurrence. It is also necessary to consider the timing and duration of hazards. The effects of an injury such as a broken leg can last for six weeks while a genetic risk can affect many generations. Therefore, if a possible risk involves injury, for instance, there are many dimensions of that injury that must be considered such as its severity, duration, and impact on future functioning, and possible damage to other parts of the body.

Normative evaluation is also required when considering risk because of the practical impossibility of determining all the possible negativities an action might produce. Risks are commonplace in our daily lives but we are not fully aware of them all. We are aware that there is a risk of injury when we cross a busy street but we might not stop to think that we also put an unsuspecting motorist at risk. Hitting someone with a car can cause injury, distress at the idea of hurting a pedestrian or lost wages due to an inability to cope with emotional turmoil.[3] Of course it is not possible to evaluate every possible risk associated with our actions, but the fact that there are so many risks we fail to identify should serve to demonstrate the complexity of risks. In any given case, the anticipated negative outcome may or may not occur. Engaging in an activity where risk may occur exposes a person to the chance that it will but does not guarantee that it will. This is contrary to a common misunderstanding according to which risks can indeed be computed for a given set of circumstances if one utilizes the correct formula.

Determining the negativity of a risk also involves making normative judgements because there is a lack of a common unit of measure with which to express the relative comparative values of all the different types of risks we take.[4] Avoiding risk altogether is impossible, so to determine which risks are worse than others we attempt to quantify them, in order to create a hierarchy of risks. Thus informed, we can choose to act so as to minimize risk while

[3] I assume that a motorist might find it distressing to cause injury to a person.

[4] In this case, I use 'value' to mean a measurement in the assessment or evaluation of one risk against another.

maximizing benefits. If we consider the payoff of a particular action to be of sufficient worth or value, we may be willing to face a higher level of risk than if the payoff was minimal. A rational person might be more willing to face the risk of injury associated with running out into the middle of the street in midday traffic in order to pick up a one hundred dollar bill than they would for a one-dollar coin.

We must be able to measure risks in order to compare and assess them but there is a difficulty in attempting to quantify different negativities outside the laboratory. Using the example above, the risk of injury for a one-hundred dollar bill might be considered low for an office worker who will lose no time at work with a cast on his leg, whereas for someone who makes their living as a dancer, the risks associated with an injury are much more significant. Certainly there are many types of risks and Rescher asks, "At what rate of exchange for example, is one to trade discomfort, boredom, pain, and monetary loss off against one another? For example, is prolonged near-term boredom something inherently greater than brief physical pain in the more distant future?" (20). We must therefore rely on normative evaluation to determine which risks are worse than others and which risks are worth taking or facing.

Understanding the nature of risk is essential to making potentially life-altering decisions. Whether or not a person engages in a high-risk activity depends on their evaluation of the possible harm or benefit they might experience. This sort of value judgement is easy to identify. On the other hand, the normative evaluation that risk involves is not so readily acknowledged. When a situation is considered to be a risk, it is easy to mistake this as a simple characterization of harm. Risks are often expressed as probabilities, which makes it difficult to recognize that normative assumptions are as much a part of risk as are statistics.

2.3 Objectivity in Science

Rather than assuming risks are factual matters in the world, I argue that understanding the philosophical nature of risk, and recognizing that risk always involves normative evaluation, enhance our ability to make use of risk assessment as a tool to guide our use of new technology. It is necessary to consider the notion of objectivity in science in order to understand the role it plays in our reliance on risk data to make decisions. Value assumptions are inherent to risk, and so I argue that objectivity in risk assessment cannot arise from the positivist view of observer-independent science. Instead, if we understand objectivity as a social construct, we can accommodate the normative nature of risk while preserving genuine objectivity. As I shall argue, however, this enriched understanding of the real nature of scientific objectivity dictates a variety of changes in the Canadian regulatory regime regarding the implementation of biotechnology.

Given the incommensurability of qualitative risk comparisons, the attempt to assess risk must involve evaluative appraisals of what will be considered harmful and what will not. The mere quantification of risk is inadequate to establish the claim that risk can be objectively determined since the collection and production of risk data involves making decisions that are guided by values. Since characterizations of risks can vary so broadly, any comparison of them involves evaluation, which necessarily introduces the value-perspective of the assessor. The occurrence of an event, such as a hurricane, is not inherently negative. A hurricane in the middle of the ocean poses no direct hazard to people (though it might pose a hazard to things that people value such as wildlife), and therefore does not constitute a risk, unless there is a non-zero probability that the hurricane may approach a populated region. If there is a non-zero probability, the hurricane does pose a risk even if it never reaches that region. Rescher argues that we

> *ascribe* values to negativities—it is (in large measure) a matter of human decision to assess negativities *vis-à-vis* one another. The sizes or magnitudes of negativities are not pre-existing quantities—they are the derivative result of an evaluative judgment or decision…And so here, man can supply what nature itself leaves untouched. He can introduce a measurement-comparison by taking an evaluative stance, by deciding upon certain essentially normative commitments (27).

Thus, it is difficult to defend the claim that risk assessment is objective when what we consider a risk is not only context-dependent—as in the case of the hurricane—but is dependent on the values we attribute to certain events and their outcomes. We cannot say that a certain outcome is inherently risky without placing it into an evaluative framework in which to understand its riskiness. The factual and normative components are therefore inextricable: they cannot be considered separately and still be useful in the assessment of risk.

Determining the probability of an outcome provides the facts that inform the appraisal and comparison of negativities. Rescher contends that even the often-cited objectivity of measuring is questionable since it involves the comparison of risks, which is an evaluative action. Factual and evaluative information are both vital for understanding and characterizing any type of risk. Decisions made using the data collected by risk analysis introduce elements of the subjective. Rescher suggests, "Questions of causality are of course indisputably factual and scientific issues. But this does not make them unproblematic and uncontroversial" (31). I argue, however, that even the production of seemingly objective data within scientific risk analysis is subject to value assumptions.

In science 'objectivity' typically means that any individual following the same procedure should reach the same conclusion (Fischoff, Watson and Hope 31). Therefore, if objectivity is to be achieved, any expectations, preconceived notions or personal desires of those performing an experiment or conducting research should have no influence on the outcome of such endeavours. This observer-independence is crucial to the notion of objective science since the advancement of scientific knowledge relies on the repeatability of results. If an experiment conducted by many individuals produces disparate results, no definite

conclusions can be drawn before the error is identified. The goal of science is to understand how the world works and to discover the laws governing the behaviour of the world. Therefore, in the quest for scientific truth, we either attempt to understand the law behind an event repeated over and over or we attempt to manipulate something in the world to produce a result that repeats itself and try to understand what causes this to happen. In this pursuit, it is necessary that an observers' own desires or wishes do not interfere with the results of their investigations. Given the nature of the process of science, however, this is difficult to achieve.

Whether or not, and the extent to which, the pursuit of scientific knowledge is objective is not a question I will attempt to address in this thesis. The analysis of how objectivity is achieved in science, however, does have relevance to the discussion of risk assessment, since risk assessment is in part a scientific process. This brief discussion of objectivity in science demonstrates that there has been much debate over the prevalence of value assumptions in science. Where and when these assumptions occur is not of primary importance for this discussion. What is relevant is the acknowledgement that the traditional perception of science as intrinsically objective is not a tenable notion. Rather than using the positivist idea of *objectivity* to mean completely observer-independent, what is needed is an enriched notion of objectivity which reflects the fact that value assumptions are made when conducting scientific research but do not necessarily undermine the genuine objectivity reached by the scientific community. [5]

In the first half of the twentieth century, positivists articulated the notion of objectivity as the pursuit of truth through science. Stemming from this, the positivist notion of science holds that science is in principle wholly value-free and that there is a definite distinction between facts and values in any scientific undertaking. For a positivist, there can be no value

[5] I will use '*objectivity*' to refer to the positivist ideal of observer-independence and value-free throughout this paper.

assumptions in good science because *objective* investigation is the only kind of investigation that can produce the facts we use to inform us about how the world works. There is now, however, a general consensus that values must in fact play a role in science. Putnam contends that even the physical sciences, sometimes considered to be the most *objective* of the disciplines in terms of observer-independence, are nonetheless value-laden because human interests influence both what the questions in science are, and how to go about investigating them (Putnam 1998). Current discussion no longer centres on establishing this fact but, rather, focuses on how science progresses despite its value-ladenness, that is, how a value-laden enterprise can be *objective*. It is widely understood that values do play a role in the understanding of observational or experimental data. This is of great significance to any regime of regulation that appeals to objectivity as the arbiter of legitimacy in quantitative analysis, which is what currently occurs with biotechnology.

Objectivity, and the use of factual information rather than subjective or evaluative information, has largely been viewed as the primary reason for our reliance on science to enhance our understanding of the world. Logical positivists contended that science should be value-free and that there is a marked distinction between fact and value. Facts are characterized as being quantitative, objective information about the world around us obtained through experimentation or observation. What makes something a fact is that it exists whether or not we believe it, or whether we are able to articulate it or not. Facts are things like the speed of light, mass of an electron or the boiling point of water at sea level that, ostensibly, can be observed by anyone using the proper methodology. In the case of risk assessment, factual information is that information produced through scientific method in answer to questions of causality and to determine probabilities.

If what I have claimed about the philosophical nature of risk is true, then the evaluative side of risk assessment, however, also involves answering normative questions regarding the

seriousness or significance of a particular risk. The evaluation of any endeavour relies on ascribing values to the outcome. Values, then, function to guide us in our evaluation of the world around us, and in the questions we ask. Even if there were any such thing as bare facts by themselves they would be useless unless situated in some evaluative context. The positivist distinction between fact and value is accompanied by much debate, which I will not go into further. Even if, for the sake of argument, we can make a distinction between facts and values in science, we cannot ignore the role values play in risk assessment. It is not possible to do science without purposes and those purposes are a part of our evaluation. Neglecting to acknowledge the close relationship between facts and values in risk assessment is to assume that the questions we use it to answer are arrived at through some purely *objective* method. These motivations are value-driven and subjective, and therefore, are intertwined with the objective, factual information of science.

Kuhn for instance, suggests that subjective elements are in fact an ineliminable part of the nature of scientific knowledge. Explanations of what the data obtained through experimentation actually mean require evaluation, which introduces subjective categorizations into how scientists understand the world. Choosing which data are worth collecting and how they are to be interpreted is largely influenced by the expectations and past training a scientist has. Kuhn further asserts that in the decision-making process, the criterion of choice a scientist uses functions as a value. This again tells us that values function to guide us. For Kuhn, values "specify a great deal: what each scientist must consider in reaching a conclusion, what he may or may not consider relevant, and what he can legitimately be required to repeat as the basis for the choice he has made" (362).

While Kuhn's account of the role of values in science is often criticized for potentially giving rise to relativism, Longino has offered a related account that does not lead to relativism. Longino provides an account of objectivity that has particular importance for the

case of risk assessment in biotechnology. Where Rescher argues that questions of causality are indisputably factual, it seems that this is only the case in the most basic data produced (31). For example, though counting the number of people injured by a plane crash is surely an objective task, its outcome depends on how we choose to define injury. Do we include people who lost a limb along with those who stubbed a toe, merely bruised an elbow, were traumatized, lost a contract, or were made late for their wedding? Assuming that the data we use to analyze a risk is objective also assumes that the methodology with which the data was acquired is objective as well, and this is not always the case.

The positivist idea that science is an *objective* pursuit because it relies on quantitative data and reveals the truth in nature is difficult to defend given the evaluative considerations behind the very questions asked in science. This does not mean that objectivity is completely elusive or impossible. Longino contends that "criticism from alternative points of view is required for objectivity and that the subjection of hypotheses and evidential reasoning to critical scrutiny is what limits the intrusion of individual subjective preference into scientific knowledge" (181). She also argues that science occurs within a community and scientific knowledge is produced through a concerted effort within the community. New theories are premised on established ones and the process of peer review subjects advances to scrutiny and criticism from a variety of sources. This process creates a sort of self-regulating atmosphere for the progress of scientific knowledge and thereby transcends individual contributions. Scientific knowledge is ultimately a product of the community, arising through a series of verifications and reviews, even if the original idea is from one individual.[6] Therefore, Longino asserts, scientific knowledge is a kind of social knowledge and the objectivity that results from scientific practice is dependent on the degree to which it withstands criticism from the scientific community as a whole. The greater the number of perspectives used in critically

[6] Of course, not every perspective is going to count such as the opinions of the intellectually immature.

analyzing scientific knowledge, the more likely that knowledge will be objective (in the non-positivist sense) and closer to a description of what occurs in nature rather than a reflection of the background assumptions inherent in its generation (Longino 185). Thus the incorporation of either an individual scientist's or the community's values into a theory or paradigm does not necessarily indicate an absence of objectivity. Instead, "such analysis should be taken as showing the way in which such contextual features have facilitated the use of given data or observations as evidence for some hypothesis by an individual or a community" (Longino 187).

The positivist view of *objectivity* in science can thus be replaced by a concept of objectivity as a social construct. Science does not advance without discussion and the sharing of information; it is a social activity. Longino's claim that scientific knowledge is social knowledge has significant implications in the assessment of risk since much of the current policy is predicated on the assumption that risk data is produced *objectively* in the positivist sense of the term.

After considering the difficulty in establishing objectivity in science, and given the complexity of the nature of risk, it is difficult to argue that any stage of risk assessment can occur in the absence of value judgements. Recognizing the role of evaluation in understanding risk serves to provide a more useful and workable method in assessing risks. I have argued that the assessments of values are incommensurable and that risks always involve values. This does not mean that we are completely unable to compare risks against one another. Rescher contends that risks "do indeed become comparable, extrinsically comparable, once we bring upon the scene an evaluator with an axiological value-perspective of his own…the value scheme of an evaluator can commeasure the otherwise incommensurable" (26). Longino's account of objectivity can be seen as expanding on Rescher's point. Since the production of objective scientific knowledge is fundamentally a

social process, an objective account of risk requires that the role of evaluator be distributed among many participants. This highlights the critical role that value assumptions come to play in understanding how to assess negativities. Combined with an enriched understanding of how we can arrive at an objective assessment through social collaboration, it is apparent that the evaluative framework in which risk assessment is conducted can become an asset. It is important, therefore, to acknowledge that our values do indeed play a role throughout the production of scientific data. Once this is recognized, we can make sure that the values informing our decisions about which risks we will quantify and ultimately take are the ones we want to play such a vital role.

2.4 Defining risk assessment

Having argued that objectivity is produced through peer-review and collaboration, and that risk involves making value assumptions, I define and discuss risk assessment and the processes it involves when used as a method of evaluation. I argue that all the components of risk assessment are value-laden despite its reliance on statistical information and probability calculations.

The evaluative nature of risk demands evaluation throughout the process of risk assessment as well. If judgements must be made to understand or identify a risk, then judgements must also be made to assess a risk. Scientists express risk as a probability. For example, when testing the effect of a reagent, risk to cellular functioning is calculated by simply counting the number of cells at the beginning of the experiment, and comparing this number with how many are left after exposure to the chemical and averaging these observations over several trials. The general case is much more complex than this scenario suggests, however. There is no account of the other types of risks that the cells may be

exposed to other than cell death. For example, the reagent might also have harmed the cell, its ability to function or had a mutagenic effect that may not manifest for many generations. Moreover, a scientific case like this is much simpler than any case of risk outside the lab. The risks people face in their daily lives are much more difficult to measure. How does one quantify the risk of losing their job or breaking a leg? And how would we go about placing a numerical value on the risk of losing out on a potentially beneficial opportunity when we choose one course of action over another?

Since negativities are incommensurable, Rescher suggests that any assessment of risk results in comparisons that are non-standard and perhaps even unacceptable at times. Mere quantification of risk, that is, a statistical assessment of the probability of the occurrence of negativities, is insufficient for making decisions in risky situations. Many other factors must be included to provide a context for understanding risk. The introduction of non-qualitative factors and the necessity of providing a context in which to make a comparison of risk, introduce subjective elements into seemingly objective circumstances.

The risks that we can anticipate allow us to choose whether or not they are worth taking and it is this that gives us some control over what sort of life we lead. In the decision-making process, we are forced to compare one risk against another, which is a difficult task since a risk could be one of many different types of things such as injury, loss of time, or illness. The science of quantitative risk assessment attempts to characterize the probability of a negative outcome through statistical analysis but given the incommensurability of negativities or adverse outcomes, it is difficult to determine to what extent such information should be relied upon when making decisions or creating public policy. [7]

It is necessary to make a distinction between individual risks and societal risks as suggested by Shrader-Frechette (19). Individual risks are those that we freely choose to take,

[7] For my purposes, quantitative risk analysis refers to the statistical characterization of negative outcomes on a case-by-case basis. Therefore, the data produced by risk analysis can quantify a number of different types of risks ranging from injury or morbidity, to costs incurred and labour hours lost.

basing our decisions on our respective circumstances and systems of values (19). Societal risks, on the other hand, are those risks that are involuntarily imposed on us and which are seldom affected by our individual values (19-20). The government or policy makers assess societal risks and decide which risks we will face as a collective since not everyone can feasibly have a say or express their opinions about this. Therefore, not only is it essential that societal risks be assessed accurately, but also since these decisions are much more complex than those an individual makes, there must be some standard procedure through which decisions can be made (Shrader-Frechette 34).[8] This standard procedure is risk assessment.

Risk assessment is the evaluation or analysis of the inherent riskiness of a process, product, technology or action and is used to inform the management of risks. Shrader-Frechette identifies three main components to risk assessment: risk identification, risk estimation and risk evaluation.[9] She explains that to identify a risk, a variety of scientific methods are employed such as epidemiological or toxicological studies. Identification relies on statistical analysis. Risk estimation is the determination of the magnitude of a risk and involves both an examination of, for example, the dose-response relationship and the characterization of the population at risk and an estimation of the dose of a particular substance it receives. Risk evaluation is conducted after the first two steps have been followed and determines the acceptability of a certain risk (Shrader-Frechette 15-29).

The first two components of risk assessment that Shrader-Frechette outlines are often used in a common mathematical definition of risk as described by Rasmussen (196):

Risk (consequence/time) = Frequency (event/time) x Magnitude (consequence/event)

Rasmussen (196) demonstrates that this equation can be used to calculate a variety of risks such as the risk of death in automobile accidents in the United States:

$(15x10^6$ accidents/year)(1 death/ 300 accidents) = 50,000 deaths/year

[8] See also Cutter 37-39.

[9] Although the methodology or risk assessment varies from country to country, the general view given here is that most often employed.

Quantitative characterization of risk, like the example above, is carried out in a number of different ways using a variety of methodologies. Such an approach, however, is limited when attempting to apply it to new technologies, such as biotechnology, since frequency data are often unavailable. Additionally, the inclusion of a temporal component in a calculation like this one makes a comparison between risk assessment data possible. It does not, however, provide a full account of the temporal occurrence of negativities. As Rescher explains, a major disaster

> that kills 1,000 people at a blow is one thing, a chronic hazard that kills the same number over the course of a whole generation is something else, and a dangerous bequest to future generations (unsafely stored nuclear waste, for example, or synthetic genes) is still different in its timing (19).

The calculation of risk using an equation is useful when trying to characterize determinate risks such as car accidents. Such a method cannot adequately address risks involving uncertainty like those associated with biotechnology.

Biotechnology, perhaps even more than some other risky technologies, is characterized by pervasive uncertainty. There is an element of chance in all situations involving risk and, therefore, risks are typically expressed as probabilities. In cases involving uncertainty, however, it is much more difficult to predict the probabilities of various hazards. "Uncertainty is the indetermination, through ignorance or otherwise, of some of the characterizing elements of a risk situation" (Rescher 94). There are no decisively good reasons for risk assessors to believe that they have identified the right potential hazards of rDNA technologies. Neither scientists nor regulators are certain that the risks most often associated with biotechnology are in fact the risks that should be watched for. This is in contrast to the hazards associated with driving a car. Highway engineers can forecast fatalities with considerable accuracy every year even though they do not know how many fatalities will occur. Biotechnological risks are assessed under uncertainty, which requires experts to offer subjective probabilities (i.e., educated guesses) about these hazards.

There are many methods that can be used in evaluating a risk. According to Shrader-Frechette, the most prominent methods of risk evaluation are risk-cost benefit analysis (RCBA) and evaluating acceptable risk.[10] RCBA is the procedure that allows risk assessment to address the complexity of societal decision-making by taking into account different viewpoints, allowing for discussion and providing a well-established basis for argument or agreement (Shrader-Frechette 34). Through a series of steps, RCBA defines the risk problem, describes the relationships among the various courses of actions and their consequences, assigns a common unit to the risk decisions (typically the common unit is money) and then calculates a single numerical value to each of the alternatives which is representative of the difference between the benefits and the risks and costs (Shrader-Frechette 30).

This particular configuration of risk assessment is a prominent one despite some of the limitations and problems it has, which I do not intend to discuss further. Once the risk for a given technology or product has been assessed in the way described, the results are used to make decisions on how to manage such risks in society and the environment which ultimately have far-reaching and widespread effects. Risk assessment, then, plays a crucial role in determining which risks society must face. Value judgements are endemic not only to the evaluation component of risk assessment but also to the identification and estimation of risk since the very question of what we consider to be a risk is based on subjective decision-making.

A final consideration is the perception we have of risk and the usefulness of risk assessment.[11] Since risk assessments are science-based, they are not easily or widely accessible to the general public. Risk assessment is not normally conducted in the public

[10] Although both of these methods are common, I will focus only on RCBA since this is the more prominent of the two approaches and is used in the Canadian regulatory system for biotechnology.

[11] Perceived risk is an area of greater depth than I wish to go into here. I include only a brief mention of it because I feel it does play a role in the development of the policy for biotechnology regulation, however, it is not one of the areas I plan to focus on in this paper.

realm so questions about which risks are worth measuring are not routinely open to public discussion. Additionally, involvement in decisions about risks usually occurs only after a controversy has begun. As a result, when policy makers or scientists appeal to risk assessments when informing the public about the risks involved in some new development or product, it creates the impression that there were no other risks worth measuring or reporting. Risk assessors are looked upon as authorities and this is problematic since it is often unclear who is deciding which risks are significant enough to study, and what the underlying motivation for disregarding the other risks might be. Even when regulatory bodies make these decisions, risk assessors are required to make a number of decisions involving normative issues. The inability to accurately assign a standard currency for risks, as Rescher suggests, makes determining their probability challenging. It would be remiss to undertake the assessment of any type of risk without first understanding the nature of risk itself. The calculus of risk does not merely involve the probability of some unwanted occurrence.

2.5 Problems with value-laden risk assessment

In this discussion I have argued that risk involves evaluation and therefore incorporates value assumptions. Additionally I have shown that normative claims are endemic to risk assessment. Despite the tendency to emphasize *objectivity* in science, value-ladenness does not compromise the usefulness of attempting to characterize and quantify risk. If we recognize that science is not intrinsically *objective* but objective results can be produced through social discourse and examination, then we can apply this notion to the process of risk assessment. Thus, we can rely on risk assessment to help inform our decision-making.

I have claimed that the assessment of risk includes both a factual and a normative side. It is necessary to consider both sides together in any characterization of risk. Rescher suggests

that the factual side is an indisputably scientific issue, although certainly not unproblematic, I further argue that even the data upon which normative issues rely are in fact not *objective*. As Longino maintains, the social account of scientific knowledge and *objectivity* call into question the positivist view. Additionally, it is important to realize that value assumptions play a role in risk assessment whether they are identified or not. Shrader-Frechette argues that risk assessors:

> often forget the methodological assumptions, which limit the validity of their risk-evaluation conclusions. In other words, the real difficulty is not that each of the three stages of risk assessment…involves methodological assumptions but that, in practice, these assumptions are often ignored. As a consequence, risk assessment results are often viewed as far more objective than they really are. This, in turn, means that policy conclusions based on the assessment results are frequently more controversial and value-laden than is thought (48).

There are then two key points concerning objectivity in risk assessment. The first is that, as Shrader-Frechette points out, the value assumptions that are made throughout the process of risk assessment are usually not recognized. This is a detriment to the usefulness of risk assessment in that decisions are made based on incomplete information. It is important to understand why certain risks are considered worth measuring or comparing and why some are dismissed. The second concerns the need for an enriched view of objectivity. The notion of science as an intrinsically *objective* endeavour is hard to maintain, if *objective* means value-free, since it does not recognize the value assumptions that scientists must make. If on the other hand objectivity in science can be achieved by social discourse, then this insight should be brought to bear on the process of risk assessment. The failure to recognize that both risk assessment and science in general are value-laden hinders our ability to utilize the information they provide us because it is impossible to tell how the information they produce was arrived at.

In the Canadian regulatory regime, risk data for genetically modified organisms are produced by the company, which manufactures them, and are not held up within the scientific

community for widespread debate or examination.[12] In fact regulatory risk assessment of all sorts of technologies in many countries such as the United States, Australia and the United Kingdom, have this same general framework. This is due to the persistence of the view that quantitative analysis is *objective* and the data it produces are free from value assumptions. The assessors themselves are often responsible for the perpetuation of this untenable view of risk assessment and thus there is insufficient acknowledgement of any normative component within the analysis of risk.

Ideally, any assignment of the probability of an unwanted outcome should face critical evaluation on a number of perspectives in order to ensure its objectivity and the underlying values of risk assessors ought to be made evident. Our reliance on and perception of factual information as inherently objective presently precludes such an approach. Therefore, the assumptions made by scientists based on contextual and individual values incorporated into risk data go unchecked and subsequently, indirectly inform the normative evaluation of risk.

The salient feature of this discussion of objectivity is complexity. Actual risks by their very nature involve a great many variables, only some of which can be easily identified. Moreover, establishing the role of objectivity in science is much more complex than traditional views of science may imply. Furthermore, not only must the subjective nature of risk be taken into account, but also the difficulty in anticipating the risks of a new technology, such as biotechnology, with which there has been little experience. The tendency to rely on science when faced with advances in technology and its associated risks is not cause for concern because science is a good way to keep informed. What is problematic, however, is assuming that the information used to make decisions about implementing the products of new technology is value-free. Value-laden information is certainly not useless and it need not be discarded. It is the only source of information available, but it is important to

[12] I will discuss the Canadian regulatory process in more depth in the next chapter.

acknowledge that it can be influenced by the desires or attitudes of those who produce or manufacture it.

Knowing the source of information is a part of understanding what that information reveals and how it is to be interpreted. Risk assessment then, ought to begin when deciding which questions are worth answering, or in need of answering, and continue right up to the interpretation of the analysis produced. The government or regulatory body ought to make explicit the value assumptions that guide regulation which would not only enhance the usefulness of risk data, but would also make the regulatory process much more transparent than it is currently. A transparent system of regulation makes information about the risks associated with transgenic science accessible to a much broader range of people who must ultimately face the risks of biotechnology, and since it would be generated from a given set of value assumptions, it would be more accessible to those who do not have the scientific background to make sense of risk analyses. Transparency is essential because not everyone has the ability to interpret sets of morbidity data or contamination levels. It is much easier for someone without scientific training to understand risks when they are described as damages to native insect or bird populations. Since a transparent system makes value assumptions much easier to identify, scientists, citizens and proponents can ensure that the 'right' assumptions are influencing risk assessments. The 'right' assumptions are those that are justifiable in some context of societal discourse. They demand a certain level of expertise to avoid the bias of irrational beliefs an ordinary citizen may have, such as the danger of microwaves, but are subject to revision by interested parties.

The discussion of risk assessment and objectivity so far can be of particular use in the field of biotechnology. The use of rDNA technology to manipulate organisms at the genetic level has the ability to produce myriad new products and processes, which will be incorporated both into our daily lives but also into our surrounding environment. The risks

associated with the development of biotechnology are societal rather than merely individual risks. Biotechnology and its applications affect a much greater percentage of the population than other advances in the last few decades. Nuclear reactors are often contained or isolated from surrounding populations, although they can certainly affect a great many people when something goes wrong. In the case of genomic science, manipulation of the genetic code in a living organism can be passed down from generation to generation. With gene flow, these changes can become widespread and can cause hybridization with other species. Any alteration in the genetic code produces proliferating change once such organisms are released into the environment, and containment is tremendously difficult outside the laboratory. The far-reaching effects of biotechnology demand an account of the values driving not only the science and the industry, but also the regulatory bodies that decide which risks will be faced by all members of society.

3. Biotechnology

3.1 Introduction

In Canada, and most other countries, attempting to address the widespread use of biotechnology, great emphasis is placed on the valuable information risk assessment provides concerning transgenic organisms. As rDNA technology has had such a short history, little is known about the effects its products have both on humans and the environment. Regulatory bodies and scientists rely on risk assessments to address the potential safety concerns such effects may produce. Since risk assessment is value-laden the failure to recognize this aspect of risk assessment is problematic.

I will give a brief overview and background of biotechnology and the concurrent genesis of the biotech industry, which has played a significant role in the pace of developments in rDNA technology as well as the rapid development and incorporation of its applications. This co-evolution necessitates accurate and objective risk assessment since many of the ethical and policy concerns arising from biotechnology have been addressed based on risk data that is presumed to be value-free. The influence of values endemic to risk assessment on the production of this data has gone unrecognized. Since industry serves as a driving force in the field of genomics, public policy has lagged behind the science. Therefore, policy makers rely heavily on the risk data produced by the industry with little acknowledgement that the inherent value assumptions made in the production of this data may not coincide with the existing ethical framework created to help guide the development of this technology.

In this chapter an outline is given of some major risks associated with biotechnology in order to identify why transgenic science provides a unique set of challenges to regulation. I

also discuss the regulation of transgenic organisms in Canada and explain the role risk assessment has in the creation of public policy concerning these organisms. The Canadian government has created a collaborative body (the Canadian Biotechnology Advisory Council or CBAC), which has attempted to provide an ethical framework for biotechnology. The current system is set up in such a way, however, that the value assumptions inherent to risk assessment go unrecognized which results in both an incomplete account of the risks in biotechnology, and the incorporation of these values into the ethical framework upon which regulation is based. This is of particular concern since regulation involves placing constraints on the freedoms of individuals and corporations. Therefore, it is important that the basis for deciding which limitations will be placed on society be made as unbiased as possible by incorporating the values of more than a few select groups.

3.2 Background

In order to understand the role of risk assessment in biotechnology, it is useful to first briefly examine the basis of genomic science.[13] The rapidity of development in our understanding of genes and their interactions within the cell belies the complexity of the science behind their discovery. The unprecedented pace of the advancement of genomic science has resulted in an incomplete understanding of its inherent risks.

Every plant and animal cell contains a nucleus with deoxyribonucleic acid (DNA) that carries the entire genetic code for the organism it belongs to. DNA is made up of alternating sequences of four amino acids: guanine, cytosine, adenine and tyrosine. These nucleic acids bond very specifically to each other forming what are called base pairs. Adenine bonds only with tyrosine and guanine bonds only with cytosine. Long chains of these base pairs make up

[13] For a more in depth description see Klug and Cummings 219-231.

the two strands of DNA (one strand in single celled organisms) and due to their unique bonding pattern, create a double helix, which is the very identifiable structure of DNA.

DNA carries what is often referred to as the 'blueprint' for the structure and function of an organism since, during the development of plants and animals, it is the DNA that dictates the expression of all the traits that it possesses. Sequences of DNA coding for a single polypeptide (a molecule made up of amino acids) are called genes, and can occur alone or in groups. Genes can act either alone or in concert with other genes to code for such things as eye colour, height, disease resistance and body shape. The action of one gene can be isolated and expressed phenotypically, or it can have an effect on the functioning of other genes.[14] Once scientists understood this, it was thought that genes could be removed from one organism with a desirable trait, such as antibiotic resistance, and be placed into another organism without this trait. The discovery of restriction enzymes, which cut the DNA strand at sequence-specific sites, was the key to realizing this advancement. Restriction enzymes allow a scientist to target a desirable gene from one organism, remove it from its host, and attach it to the DNA strand of another organism thus conferring whatever trait the transferred gene codes for. Genetic manipulation of this sort is the basis of what we know today as biotechnology.

3.3 Biotechnology and the emergence of the Biotech Industry

Once scientists had a basic understanding of how DNA and restriction enzymes functioned, the potential of its applications were quickly recognized and the field of biotechnology emerged. The development of this new area of science over the last thirty years has been intertwined with the evolution of the biotech industry. The close relationship

[14] Phenotypic expression is the physical manifestation of the trait a gene or group of genes code for. Thus, having brown eyes or straight hair is the phenotypic expression of the respective gene coding for brown eyes or straight hair.

between technology and industry also produced an increased reliance on risk assessment to guide development and understand safety concerns. There has been very little time to learn about how transgenic organisms interact within the laboratory let alone in the environment. Thus, risk assessment has become the arbiter of development in biotechnology. The co-evolution of biotechnology and industry has contributed to the crucial role risk assessment plays in regulation.

Biotechnology is a rapidly developing science with widespread and far-reaching implications for many areas of society such as agriculture, medicine, pharmacy and industry.[15] It is defined as any manipulation of a biological system through technology (Yount 3). In modern biotechnology, this manipulation occurs through the techniques of recombinant deoxyribonucleic acid (rDNA) technology—that is, the insertion and incorporation of a segment of DNA from one organism (plant, animal or micro organism) into the DNA of another organism. This is possible because most cells in a living organism contain DNA, which codes for its particular development.[16] The structure and function of genes are the same regardless of the type of organism in which they are found.[17] Due to the relatively simple composition of DNA, it is possible, for example, to take segments of bacterial DNA and insert them into the DNA of a plant or animal since the four nucleic acids bond to each other in a specific manner that is not dependent on the type of organism from which it originates. The altered cell becomes capable of producing whichever protein the transferred gene codes for regardless of whether it ever produced it before.

The result of this genetic manipulation is a new or rare product or organism. For example bacteria or any type of animal can be made to produce human hormones with the insertion of the corresponding human gene into their cells. Antibiotic resistance in one strain of bacteria can be conferred to a non-resistant strain using the same methodology. Other applications of

[15] For further discussion about the uses and effects of biotechnology, see Anderson 9-42.
[16] Not all cells contain DNA such as non-nucleated cells (red blood cells).
[17] A gene is a section of base pairs that confers a particular trait or characteristic to the organism.

rDNA technology include the production of industrial chemicals, pharmaceuticals, livestock and new or improved foods. Additionally it can produce advances in forensic science, virus-resistant crops, diagnostic tests for genetic diseases and in fact, new studies suggest there is a promising future in gene therapy for diseases such as ADA (adenosine deaminase) deficiency (Barnum 1). Biotechnology provides the ability to move genes or groups of genes at will, and to decipher and demystify the genetic codes that dictate the structure and development of organisms. It also allows the development of organisms for specific uses and to make or modify products, plants or animals. Transgenic science and its applications were recognized to have enormous potential to improve the quality of life as well as unprecedented commercial rewards for those who could exploit this potential. Thus the evolution of scientific knowledge in biotechnology has occurred hand in hand with the development of the industry it created.

Biotechnology has a long history in domestication and agriculture through selective breeding, winemaking and other familiar processes. Modern rDNA biotechnology, however, had its start just over thirty years ago and has progressed rapidly since then. The first major breakthrough, which contributed to the genesis of rDNA technology, occurred when Watson and Crick discovered the structure of DNA in 1953. [18] This information combined with concurrent developments in the understanding of cellular structure and functioning provided the basis upon which rDNA technology was discovered. By the early 1970s, scientists had discovered how to exchange genes between organisms instead of merely deciphering them. It was at this point that progress in transgenic science began to accelerate and the subsequent development of commercial applications and the industry of biotechnology followed closely behind.

[18] The discovery of DNA is most often attributed to Watson and Crick but they shared the Nobel Prize in chemistry with Wilkes and Franklin, whose work was critical to the discovery.

Despite the relative newness of this science, the immense potential of its products and applications did not go unnoticed. By 1976 the commercial potential of gene manipulation was recognized and inspired the beginning of biotechnology as an industry. Robert Swanson and Herb Boyer founded Genentech in the hope of capitalizing on this new technology in what has become the first of numerous biotech companies (Old and Primrose 4). By 1978 the scientists at Genentech had cloned human insulin, and, in 1982, this became the first rDNA pharmaceutical product to be marketed (Old and Primrose 4). Eight years later, Genentech merged with the pharmaceutical company Roche in exchange for an estimated $2.1 billion. The tremendous financial potential of biotechnology for corporations has had a major impact on the pace of progress in genomic science.

The development of the science of genetic manipulation has been progressing at an unprecedented pace over the last three decades. At the same time, an enormous and even faster-paced industry has emerged based on this science thus creating a biotechnology-industry complex. Since the creation of Genentech, hundreds of biotech companies have been formed, although many have been short-lived. Today large companies such as Monsanto, Novartis and AgrEvo dominate the industry and are responsible for the production of many marketable transgenic products. Consequently, much of the new research is concentrated in commercial applications as these companies compete with each other. With the increased pressure from industry attempting to capitalize on the transgenic organisms they produce, policy makers are under pressure to make safety assessments as quickly and as accurately as possible to keep up with corporate-funded science.

Risk assessment has become an instrumental component of biotechnology regulation since scientists do not have the benefit of years of experience handling and observing these organisms in the laboratory. Bauer and Gaskell argue that biotechnology is “the third strategic technology of the period since the Second World War, following nuclear power and

information technology" (379). In the case of nuclear technology, however, commercial applications were few and regulation was understandably strict enough to quell the emergence of independent companies using nuclear power. The profit potential of applying nuclear technology commercially was minimal and the risks were tremendous. Information technology on the other hand, had enormous potential and the last few decades have witnessed the burgeoning of computer applications in virtually every area life. As compared to nuclear power, say, the risks associated with information technology are minimal, while its benefits are, and have been, considerable. Biotechnology differs from nuclear and information technology in that it combines characteristics of both. On one hand, the ability of transgenic science to alter, improve or change our lives is as great, if not greater than that of the applications of information technology. On the other hand, the risks this science potentially subjects people to are as widespread and far-reaching as those caused by nuclear technology. Many of the risks genetic manipulation might expose society to are unknown and have not been widely tested for since there is great uncertainty as to how to conduct such tests.

The enormous potential of biotechnology to produce financial, environmental and health benefits has resulted in the confluent evolution of biotechnology as a science and as an industry. Bauer and Gaskell suggest that international businesses and companies control progress in transgenic science since "the development and exploitation of genetic engineering techniques is the focus for a growing 'biotechnology movement' at the core of which is a scientific-industrial complex" (380).[19] The benefits or challenges of this scientific-industrial complex are not an issue I will discuss further, nor will I include an account of the ethical issues such a construct raises. The fact that this integrated relationship exists emphasizes the crucial role of risk assessment in informing public policy and the reliance on the information

[19] See also Arundel 98, Colman 33 and Rifkin 15-24.

it can provide. As companies invest more money into rDNA technology, putting these products onto the market in order to profit from their investments becomes a priority. In order to get their genetically modified (GM) innovations approved by regulatory bodies, companies typically must provide risk assessments. According to Dhanda these assessments are based on the premise that "a product should not be released until any and all of the negative effects are found to be absent, and in the case of uncertainty, a company should err strongly on the side of precaution and not release the product" (64). In practice, however, this is often not the case.

Regulators and policy makers rely on the risk information provided by the biotechnology companies to assess the safety of their products. Until a product has met a defined safety measure, it will not move beyond a controlled setting. Since corporate interests play such a crucial role in GM innovation, scientists working outside the biotech industry have had little exposure to new products by the time they are considered for release. As a result, risk assessment serves as the primary source of information and replaces external and independent peer review and experimental replication as a means of evaluation. Canadian regulation and policy has evolved to include the nexus of industry, risk and biotechnology. Doern and Reed report that, based on information from the Centre for Medicines Research International,

> if Canada wishes to be an innovative leader in emerging sectors like biotechnology, it will have to evolve more efficient and effective science-based regulatory capacity capable of fostering industrial competitiveness in global markets while protecting its citizens from avoidable risks (14).

In the case of agricultural biotechnology for instance, the introductions of genetically modified crops in North America "were preceded by a comprehensive safety analysis and decision making process carried out in science-based ways by companies, government agencies, and scientific expert panels" (Horsch 29).

Risk assessment is value-laden and the emphasis that is placed on risk assessment to guide our approach to regulating the release of transgenic organisms into the environment

must take this into account. While in Canada acceptable risk thresholds are primarily dictated by federal legislation, the value assumptions at work in risk assessment remain unacknowledged and largely unarticulated.[20]

3.4 The Risks of Biotechnology

I have claimed that risk assessment is crucial to the regulation of biotechnology. Understanding major risks inherent in rDNA technology highlights the necessity of relying on probabilistic quantitative measure of riskiness. With such a relatively new science, many of the anticipated risks might result from it have never been faced before. The potential for widespread and multi-generational effects has given rise to the call for caution in the implementation of biotechnology applications.

Concern about the safety or rDNA technology was first addressed when animal cells and viruses were incorporated into research. In 1971, Paul Berg intended to insert the genes of a cancer-causing virus (a lambda virus containing SV40 genes) into very common bacteria (Escherichia coli) that could readily infect the human intestine. Robert Pollack, a geneticist also researching rDNA techniques, thought that should this bacteria containing the cancer-causing gene escape from the laboratory it might infect people, with potentially serious consequences (Yount 9). This incident lead the scientists involved to recommend that experiments using recombinant technology should be halted until the potential hazards were evaluated. The subsequent conference to address the possible safety concerns of rDNA technology, held at Asilomar and involving 140 molecular biologists and geneticists, lead to the creation of a set of guidelines which were to govern transgenic science. Four categories of riskiness were identified and helped divide recombinant research. "Category P1

[20] This is particularly evident in the regulation of plants with novel traits by the Plant Biosafety Office division of Agriculture Canada.

experiments presented minimal risk to humans and required no precautions beyond those in normal laboratory practice, whereas those in category P4 potentially were highly dangerous" (Yount 9). This shows that the reliance on the analysis of risk has been an integral component of genomic science almost from its inception. The understanding of GM products and organisms is often generated and expressed by characterizations of their riskiness. Biotechnology produces both organisms that will be confined to the laboratory for research or clinical use and some that will be released into the environment or consumed by people. It is often driven by the market potential of new developments. In the case of agricultural biotechnology for instance, a potentially risky product would be unsuccessful when offered to consumers. Distinguishing between transgenic organisms that are safe enough for release from those that are not depends on accurate risk assessments. The identification of the potential riskiness inherent in rDNA technology was a key component to the development of the genetics.

Current knowledge about DNA and the functioning of genes is incomplete, although advances are made much more rapidly than is the norm in fields like physics or chemistry. It is not unusual, however, to attempt to apply techniques based on incomplete knowledge and, in fact, these applications can often enhance our scientific understanding. In the case of rDNA technology this has been particularly true since it is not known how much of an effect one gene might have on other distally located genes when transferred from one organism to another. There has been so little experience with genetic manipulation that many of the effects it produces are surprising yet this has not slowed the development of technological applications (Yount 11).[21] Rather than setting the pace for development, surprising or poorly understood results occur alongside applications and this produces risks that are also poorly understood. Moreover, there are many applications of biotechnology and thus there are many

[21] See also Bereano 27-28.

different types of risk associated with these applications. As described in Chapter Two, this means that the risks posed by biotechnology must be assessed under uncertainty.

The risks associated with GM innovations can be broadly categorized into three groups: risks to human health, to ecological integrity and, to society. Concerns about health usually arise from the consumption of GM foods or the use of pharmaceuticals produced through rDNA technology. Ecological risks include gene flow, or the uncontrolled spread of transgenic plants into surrounding wild populations. Other ecological concerns include the loss of genetic diversity, increased reliance on pesticides, and harm to nontarget organisms. Societal and economic risks can occur when a long-standing system of farming or manufacture is replaced by the introduction of GM crops. The usurpation of traditional farming methods and local economy by large, profit-driven corporate interests can lead to social and economic upheavals in developing countries.[22]

There are also risks associated with not allowing the development of biotechnology to occur. Advances in transgenic science can be used to alleviate a number of problems affecting throughout the world ranging from starvation in drought-stricken regions to a variety of diseases. Over-regulating biotechnology or severely limiting its applications could result in missed opportunities to benefit many people. Any knowledge that might be gained from the use of biotechnology could be lost if transgenic science is severely restricted. This knowledge also benefits other scientific fields and enhances the general understanding of how biological systems evolve and interact. Only a small number of the potential benefits of biotechnology have been identified and fewer still have been realized. It is vital that these benefits be considered along with their potential risks, and it should also be recognized that there are risks associated with the failure to explore biotechnology both as a science and as a solution to some widespread problems.

[22] A more detailed discussion of these risks can be found in Yarrow 41-43.

In general, risks in biotechnology centre on the fact that little is known about how new or novel organisms interact with their new environments when they are released. Often potential problems are not, and cannot, be detected immediately, which makes determining how risky they might be very challenging. Barnum summarizes some of the more common risks that the public and scientists express concern over which include:

> that genetically modifying plants and animals will turn benign organisms into economically destructive pests or will enhance existing pests through hybridization (sexual out-crossing common in plants); that new biotechnology products (plant pesticides, for example) may cause harm to nontarget species such as insects; that a recombinant virus used in the production of recombinant organisms might detrimentally infect other organisms; that recombinant organisms may eliminate indigenous species through competition, depletion of valuable resources and nutrients, and by incomplete degradation of toxic wastes to even more toxic by-products during bioremediation (195).

Many of these risks are unique to the different areas of biotechnological applications but this is in no way an exhaustive list. In agricultural biotechnology for instance, risks also include increased weediness or gene flow from the novel crop to wild species or non-transgenic crops as well as loss of diversity in plants, which increases their susceptibility to pathogens. There are also allergenicity and toxicity risks associated with transgenic food and genetic risks in the case of gene therapy.

I have identified three broad categories of biotechnological risk. The first two, risks to human health and ecological stability, are the primary focus of risk assessment in the Canadian regulatory regime. Social and economic risks can be just as damaging, however. Increased costs associated with improved crops or food can have a devastating effect on poor farmers. A shift in the autonomy of farmers in developing countries who may become dependent on large biotechnology companies for the improved seeds can change the structure of a society. Not all of these socio-economic risks are quantifiable or easy to measure and thus they are usually excluded from risk assessment although they may be given consideration after analyzable risks are assessed.

Another problem is the lack of knowledge of how to contain or deal with its risks once they occur. In the case of microorganisms, genetic modifications that go awry can be dealt with by eradicating the novel strain but with organisms such as plants or animals, eradication is often not a viable option.

3.5 Biotechnology Regulation in Canada

The role of risk assessment in regulation is not only a key component to the progress of biotechnology, but the information it produces also provides the basis for regulatory decision-making about agricultural biotechnology in Canada. The approach taken by the Canadian system of regulation is different from that of other countries, however, because the trigger for regulation is not merely genetic modification. Regulation occurs when a product contains any novel trait regardless of the process used to confer that trait to the organism. Although this difference provides a useful way of enforcing and addressing regulatory issues, it is problematic for any system to rely on risk assessment without providing a means of addressing its value-ladenness. In this discussion I focus on the regulation of GM plants and foods since there is an emphasis in agricultural biotechnology on transparency and open access to data, but the processes outlined typify the Canadian approach to biotechnology regulation in general.

In Canada, biotechnology regulation and policy development is "science-based". Science-based policy and regulation can be defined as policy and regulatory decision making where scientific knowledge and personnel constitute significant or effective inputs into, or are distinctive features of the relevant decision-making process" (Doern and Reed 5). Thus, decisions concerning the application and use of GMOs are primarily based on scientific

assessments about their safety.[23] Doern and Reed contend that despite cuts to both funding and the number of scientists involved in regulatory and policy functions, there is an increasing dependence of government upon science (8). Since risk assessment of new technologies is integral to the science upon which the policy and regulatory regime depend, it is a central component to regulation.

Biotechnology also results in the emergence of new types of risks, creating changes in the traditional risk-benefit calculus. As the risk paradigm evolves to include scientific and technological advances, "more and more, regulators have to deal analytically, organizationally, and politically with risk assessment, risk management proper, and risk communication" (Doern and Reed 11). Thus, Canada's system of regulation relies on risk assessment to aid government officials to make decisions concerning the release of transgenic organisms. The value assumptions that I have argued are endemic to risk assessment, however, go unnoticed and unchecked. Risk, risk assessment, and the practice of science are not intrinsically *objective* or observer-independent and therefore Canadian regulation and policy incorporate value-laden assessments of biotechnological risks. The reliance on scientific data to inform policy is grounded in the assumption that the data are *objective* and therefore can be relied upon to guide decisions concerning the use of this controversial technology. Ethical considerations occur separately from risk assessment and consequently little thought is given to whether or not the assessment of risk should be included in the broader ethical framework. In her study of the circumstances surrounding the rejection of Monsanto's application to the Canadian government for registration of recombinant bovine growth hormone, Mills argues, "the problems in the relationship between science and policy arise at the point at which judgements are made about the implications of the data" (158). These data are thought to be value-free when in fact they are not. Policy judgements are

[23] Further discussion about science-based regulation of technology occurs in Carlsson 26 and Senker 53-68.

made using value-laden data and these values are those of the company, scientist or institution that produces them.

Regulation in Canada differs from that of other countries because the trigger to regulatory oversight is not genetic modification per se but the existence of novel traits based on substantial equivalence (Canadian Biotechnology Advisory Committee 5).[24] Therefore, if a plant or animal possesses a trait that has not been identified before or approved for release, (i.e. it is not substantially equivalent to something that has already been approved) it is considered to be a novel trait and therefore is subject to regulation. Today, a number of government bodies are involved in Canadian regulation, such as the Canadian Food Inspection Agency (CFIA). The CFIA was created in 1997 and "is the lead governmental bureau in Canada devoted to the regulation of animal, food and plant health as well as consumer safety in regards to the labelling and packaging of food products" (Prince 208). Rather than creating new policy or procedure, agencies like the CFIA utilize existing frameworks of regulation and modify them accordingly to address the unique issues associated with GMOs. In the case of plants with novel traits (PNTs) for instance, which include GM plants, the developer is required to submit the results of a series of field trials before a PNT is approved for unconfined release. At this point,

> "CFIA science evaluators also conduct a critical review of a scientific information package submitted by the proponent. Each application for approval is evaluated on a case-by-case basis that incorporates an examination of the biological processes involved as well as the environmental impact, primarily on agricultural and natural ecosystems…An authorization for an unconfined release is granted only when CFIA has determined that any environmental risks associated with the release of any novel plant are acceptable and/or manageable" (Canadian Biotechnology Advisory Committee 8).

Where the trigger for regulation in general is the existence of a novel trait, the trigger for the approval of a PNT or a GMO, is an assessment of its associated risks.

[24] Substantial equivalence is the concept that "if a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety" (CBAC 25). This definition refers specifically to genetically modified foods but can be adapted to include other genetically modified organisms.

The CFIA was created to consolidate the regulatory functions previously located in four departments—Agriculture and Agri-Food Canada, Health Canada, the Department of Fisheries and Oceans and, Industry Canada. Through the use of a safety-based approach, the CFIA regulates agricultural products, which "includes determining whether a risk assessment is required, performing a risk assessment, implementing risk management, and administering the pertinent regulatory measures" (Prince 220). Although the task of risk assessment ostensibly belongs to the CFIA, the consolidation of a number of regulatory bodies combined with a recent shift in the functions of inspectors, places this role in the hands of proponents.[25] The changes in the Canadian regulatory regime in the last few years have made it more difficult to identify the value assumptions that inform the data decision-makers rely on. The problems with value assumptions in risk assessment are in fact exacerbated under the new system of regulation as I demonstrate through a discussion of case studies in the following chapter.

One of the recent changes in regulation has centred on redefining the role of regulators. In an effort to offset some of the costs associated with regulation and inspection, there has been a shift from the role of regulatory inspectors to that of auditors.

> The CFIA is moving away from a traditional approach to regulation, hands-on inspection by different levels and agencies of government, product by product, towards an inspection system across commodities that relies more on intergovernmental partnerships and on industry responsibilities for quality controls, with government inspectors auditing those controls based on scientific assessments of acceptable risk (Prince 209).

This shift is particularly significant since it places more control in the hands of proponents. Risk assessments are conducted and paid for by proponents according to a set of risk parameters set by the government, and regulators audit this information to see whether or not the product complies with standard safety requirements. Although the CFIA is conducting

[25] This is something I will explain in depth in the next chapter using the CFIA's regulatory procedures as a case study demonstrating biotechnology regulation in Canada.

part of the risk assessment, the proponent produces the data they use. Thus, there is a split in the process of risk assessment, part of which is conducted by the proponent and part by the regulators. Contrary to the position maintained by the CFIA, risk assessment under this new regime of regulation concludes in the offices of CFIA, but it begins in the laboratories of the proponents. Additionally, having regulators acting as auditors exacerbates the problems with making critical decisions about which risks society will face based on value-laden information. Auditing risk data limits the role of regulators and removes them from the data collection and production processes.

Mills asserts that basic research is precluded from the mandate of regulatory scientists and moreover, due to their commitments to uphold confidentiality and proprietary agreements, they have limited communication with those outside the regulatory body. The CFIA states that it uses both internal and external expertise and "the regulatory process as a whole has been subject to extensive consultations with stakeholders over a number of years designed to keep the evaluation process at the CFIA current" (Canadian Food Inspection Agency "Questions and Answers"). If external experts are consulted about a specific product, however, regulatory scientists bounded by proprietary agreements are not free to solicit advice about details or evidence specific to the case they are reviewing. In addition, regulatory scientists must operate under time constraints and be conscious not only of corporate costs and undue regulatory burdens but also of the necessity of protecting public health.

Mills further claims that distinctions between what is reasonable and what is unreasonable are used to define safety within the regulatory system. She notes that if the risk can already be explained on the basis of existing knowledge, then scientists involved in regulatory decisions are unlikely to ask for further data. Therefore objectivity arising from the exchange of information within the scientific community is unlikely in the current regulatory regime.

The move from inspecting to auditing, the proprietary agreements regulatory scientists are bound by, and the pressures these scientists face, all suggest that the Canadian system of regulating biotechnology and its applications is moving in the wrong direction if it is to address the problems of value-laden risk assessment.

The changes in biotechnology regulation have also been accompanied by the creation of an advisory committee which attempts to address the ethical concerns associated with the release of GM products, and which has an indirect impact on regulation. In order to address the growing ethical concerns associated with biotechnology, the Canadian government has created the Canadian Biotechnology Advisory Committee (CBAC), with the goal of providing a framework for formulating public policy recommendations. This framework is meant to serve as a means through which to view public policy regulating GMOs in Canada. The primary function of CBAC has thus far been to produce a set of comprehensive recommendations for improving the regulation of GMOs (in particular, GM food). Significantly, in the 2002 report on the regulation of GM foods, CBAC recommended that "regulatory authorities maintain and strengthen Canada's risk-based approach to the regulation of novel foods and plants with novel traits" and that pre-market risk assessment should be employed using a precautionary approach "to ensure the application of a conservative safety standard in assessing health and environmental risks related to GM and other novel foods, recognizing that this does no imply 'zero risk'"(xv).

CBAC also recommends the employment of precaution when risks associated with a GM product or processes are recognized. Although there is no specific mention of risk assessment, many of the suggestions centre on issues of transparency and the need to make risk data available to the public. In fact, one of the recommendations made by CBAC suggests, "the views of external experts be incorporated in the product evaluation process where the risk assessment is not straightforward or where a precedent might be set by

approval of the product" (xv). This is significant for two reasons. First, I have argued that the idea of *objectivity* as it has been standardly understood in science and risk assessment is difficult to uphold but an enriched understanding of objectivity suggests that unbiased data can be produced through peer review and scrutiny within the scientific community. Secondly, I have claimed that value-assumptions are endemic to risk assessment. The fact that CBAC supports a risk-based regulatory regime, yet recommends that external peer review might only be necessary in certain situations, suggests that there is a mistaken underlying assumption that risk assessment as it is currently structured is *objective* in the sense of being value-free. Therefore, both the regulators and the advisory committee, which indirectly influence the risks we will face from the use of GM products, do not recognize that the risk assessments, upon which we rely to protect us from harm, are value-laden.

3.6 Conclusion

In this chapter I have outlined some of the reasons why risk assessment is crucial to the evolution and advancement of scientific knowledge in biotechnology. The risks associated with transgenic science are unique in that they are far-reaching, often irrevocable and widespread across space and time, necessitate a system of regulation that can accommodate these risks. The fact that there is a biotechnology-industry complex means there is a reliance on the assessments of risks to proceed in making policies that determine how much harm society will be subjected to since much of the research is no longer conducted in the public sphere but is protected by intellectual property agreements. Additionally, the biotechnology-industry complex has the potential to create a regulatory system that is industry-driven and so unbiased information is needed to help determine policy. This ensures that the risks faced are

not influenced solely by the values of those directly involved in the production of GM products.

The Canadian system of regulation is risk-based and therefore the role of risk assessment is crucial to policy development. The regulatory system has undergone some significant changes in the last five years in an attempt to improve efficiency, reduce costs and consolidate a number of disparate departments to a central few. As a result, in the case of the CFIA, what has developed is a proponent-driven, industry-based system, which has limited the role of inspectors to that of auditors. This change makes the consideration of deeper conceptual questions about risk assessment much more difficult to address since the dependence on risk data removes the ability of regulators to ask questions about how this data is collected and what assumptions have been made.

The creation of CBAC has not been sufficient to counter this shift in the wrong direction by regulators. Nor has it adequately acknowledged the value assumptions present in risk assessment. CBAC has no regulatory authority or legislative power so it is unable to alleviate the problems of value-laden risk assessment and the shifting role of regulators. It does, however, provide a forum in which issues of value-ladenness might be addressed. I will discuss the role of CBAC in my recommendations to address the problem in the final chapter.

The use of risk assessment to guide regulation and policy decisions is a very useful way to make sense of a technology that has both technical applications and practical applications to daily life. The characterization of the impact of such a new technology on the environment and society is best expressed as risk. In the quest for a transparent regulatory system, risk assessment is very powerful tool as it makes difficult, complex scientific knowledge accessible to the public. Since the risks of biotechnology will be faced by all of society, it is vital that the risk assessments of transgenic products are objective. Value-laden risk assessments do not include the values of everyone that will be affected by the release of a

GMO. Therefore, what is needed is a regulatory system to address the problems associated with value assumptions in risk assessment. It is also necessary to discard the idealistic view of objectivity as an inherent characteristic of science and replace it with the view that objectivity is a social construct. In doing so, it is possible to incorporate the values that reflect the view of the majority into assessments of risk.

4. Case Studies

4.1 Introduction

In this chapter I will discuss three case studies to demonstrate several ways in which risk assessment is value-laden. These cases show that the Canadian regulatory system does not adequately address the problems inherent in relying on the idealized view of the *objectivity* of risk assessment to make policy decisions about the release of transgenic organisms. Risk assessment is value-laden in a number of ways and each case discussed will highlight the features which I consider to be most important in regulation. Value assumptions occur at two major levels: the internal and the external levels.

By the internal level I mean the assumptions that scientists must make in the laboratory while conducting assessments of risk. Value assumptions are a necessary part of the production of risk data and therefore, scientists must make decisions involving normative issues in order to do risk assessment. The influences, which inform the values at this level, are predominantly internal—either from within the laboratory, the government agency or individual scientist. Thus the values that scientists must adopt, whether consciously or unconsciously, in making assumptions will necessarily influence the assumptions they make. Similarly, if that scientist is working for a corporation or government agency with a certain mandate (protection of health and safety for example), then, once again, the scientist conducting the risk assessment will be influenced by this goal when making assumptions.

The external level on the other hand, includes influences from the world outside the lab. Economics, politics or personal motivations are all external influences affecting the assumptions made during risk assessment. Scientists are not segregated from their surrounding communities and therefore controversies and debates over for example, the use

of a new technology, or the desire to be the first country to release a potentially beneficial product, cannot be dismissed. Assessors are aware that the results of their work will have a direct impact on whether or not a product is approved for regulation and this will have an effect on the assumptions they make. Value assumptions made at both the internal and external levels of risk assessment affect the outcome of regulatory decision-making.

The first case I discuss will briefly give an account of the controversy surrounding the herbicide Alachlor, produced by Monsanto, as reported by Brunk, Haworth and Lee in 1991. New information regarding the safety of Alachlor caused a re-evaluation of its use in Canada. This case involves value assumptions made at the internal level of risk assessment—those that occurred from direct influences within the laboratory during the actual production of risk data. The controversy surrounding the regulation of Alachlor was precipitated by three different consequences of the use of value-laden risk assessment. At the time, regulation in Canada was different than it is today. The consolidation of various departments into the CFIA (for agricultural biotechnology), which was discussed in Chapter Three, had not occurred and regulators had a more direct role in the assessment process. The circumstances of this case demonstrate that even when regulators had a hands-on approach to inspection, the value assumptions endemic to risk reports were unacknowledged. As I argued in the previous chapter, this problem has only been amplified by regulatory changes since 1997.

The second case concerns the regulation of recombinant bovine growth hormone (rbGH) in both Canada and the United States. In this case value assumptions are made at the external level and I will describe the effects they had on regulatory decisions. Mills provides a thorough account of the circumstances surrounding the application by Monsanto to register rbGH. She also outlines some of the reasons why regulators in Canada decided to reject the application while their American counterparts approved it. Mills argues that the decisions, based on identical sets of data, were ultimately based on the value judgements made during

the assessment process and the political and economic context under which scientists and regulators worked in both countries. The background influences and social pressures surrounding the entire regulatory process during the assessment of this hormone resulted in assumptions that were contextually and geographically dependent. The assumptions regulators in the United States made during their assessments were significantly different from those of their Canadian counterparts and, thus, the conclusions they drew were also different.

Despite the significant effect value assumptions had in the first two cases, there is a marked lack of recognition of their importance by the government, industry and the public. I include the public since the risks imposed by biotechnology are broad in scope, as discussed in the previous chapter. The regulation of biotechnology must involve the concerns of scientists, proponents and the public—those who will ultimately be faced with the risks. The very recent application for the use of genetically modified wheat in Canada will be the third case I discuss. The GM wheat case involves assumptions made at both the external and internal levels. The most current debate in the regulation of GM crops is partly based on the widely held view that risk assessment is value-free. It is clear from the first two case studies that a failure to recognize that value assumptions are made, at both the internal and external levels, causes a shift in the controversy. Rather than focusing on whose values should be considered in a debate over GM products, and how to rank them in importance, disagreements occur over the 'purity' of scientific risk assessment.

Since the GM wheat application was made in December 2002, the regulatory process is still under way and therefore few specific details are available. The controversy over the use of GM wheat makes this an interesting case since it is so recent and some of the same circumstances surrounding the Alachlor and the rbGH cases have begun to develop. An additional factor occurs in this case that is not present in the others, however. The application

for regulatory approval of GM wheat has created debates about which risks are relevant to regulation. Canadian wheat growers are very concerned about the economic risks the introduction of this crop will impose on an already economically strained farming sector. American producers on the other hand, insist that economic considerations have no bearing on the regulation of new products since they might sully the 'purely scientific' process of risk assessment. Part of the ongoing debate over GM wheat centres, then, on the widely held view that risk assessment is *objective* and contains acknowledgement of either the internal or external value assumptions. Since 1998, there has been a bilateral agreement between Canada and the United States to collaborate and harmonize some of the features of biotechnology regulation. Combined with the recent changes and shifts in the Canadian regulatory system and the lack of acknowledgement of the role value assumptions play in risk assessment, this agreement puts added pressure on regulators while they decide the fate of GM wheat.

These case studies are used to show how the two levels of value assumptions I have identified affect the outcomes of risk assessment and thus have a direct impact on regulatory decisions based on these assessments. Although regulation centers on risk data and reports, regulators make no attempt to counter the value assumptions they incorporate and, in practice, rely upon. The value assumptions made by risk assessors bias the data regulators use when deciding which products will be made available to the public. This data is not objective, in the sense of value-free, if it is influenced by these assumptions. As I have argued, in questions of which risks society will face, objectivity is a desirable quality in the information used to make such critical decisions about safety. Risk assessment is the one of the only methods available to assess the safety of new technologies and products. If what I have claimed is true, that risk assessment is value-laden in various ways that I have broadly categorized into internal and external levels of value-ladenness, then the untenable notion that

risk assessment is *objective* should be rejected. At all stages of risk assessment *objectivity* fails. Objectivity arising from social discourse as Longino suggests, however, is a good way to address the use of value-laden risk data. Current changes to regulatory procedures in Canada, and the move from a system of inspection to auditing in the last five years, have exacerbated the problems of value-ladenness. The process of risk assessment requires that certain value assumptions be made in order to interpret the results of a particular situation. The social context within which biotechnological risks must be considered dictates that the values determining assumptions in risk assessment are not necessarily those of the majority. This is also a concern when one considers the unique nature of the risks associated with biotechnology. The widespread and long-term effects of biotechnology expose everyone to its associated risks and, therefore, decisions about regulation and policy should not be based on the assumption that risk assessments are value-free.

4.2 The Alachlor Controversy

This case does not involve rDNA technology although it does demonstrate two points of central importance to the discussion of risk assessment in biotechnology. First, it provides an overview of Canada's approach to the regulation of technology and its products.[26] Specifically, it shows how regulation occurred before the consolidation of many small departments into six large ones, and the shift in the role of regulators occurred in the late 1990's. Second, and more importantly, it shows that Monsanto and the Health Protection Branch (HPB) of Health and Welfare Canada made very different value assumptions about risk, which were affected by very different background influences. The assumptions made in this case were at the internal level since they were driven primarily by the mandates of

[26] Although this case occurred in the 1980s and the Canadian regulatory system has changed since then, I think it still provides a general overview of how regulation still occurs. The specific methodology of regulation may have changed but the approach Canadian regulators take remains the same.

Monsanto and the HPB. Since each institution had different goals, their results were markedly different. These differences produced drastically different assessments of the risks of Alachlor. This highlights the problems that arise from internal value assumptions made during the process of risk assessment, particularly when these assumptions go unrecognized or unchecked.

The Alachlor case, in effect, provides a template for discussing the differences both in value assumptions brought to bear on risk assessment itself and the background values, which help to determine which values will be in play during assessment. Therefore, it provides a general picture of similar problems, which could arise when internal value assumptions go unrecognized in the regulation of biotechnology and its products. I will use this case to argue that values influence the outcome of risk assessment at the level of data collection and production. The Alachlor case shows that data produced through scientific analysis nonetheless requires that a number of normative assumptions are made.

Brunk, Haworth and Lee examine the cancellation of the registration by the Canadian Government of an herbicide called Alachlor produced by Monsanto.[27] The decision to cancel its registration was based on risk assessments conducted by both Monsanto and the Health Protection Branch (HPB) of Health and Welfare Canada. The assessment by Monsanto suggested there was very little risk to human health posed by the use of Alachlor while the HPB found that there was significant risk. Both assessments were based on the same data but very different assumptions were made during the review of the herbicide. For example, Monsanto assumed that every reasonable precaution would be taken by applicators to reduce exposure while the HPB assumed that most applicators would take very minimal precautions. Brunk, Haworth and Lee state,

> the conclusions generated by risk assessment are necessarily based upon important normative assumptions, discuss the differences in these assumptions, and the very

[27] A complete account of this case is given in Brunk, Haworth and Lee (1991).

> different conclusions drawn from them. These are necessary, not only in order to bridge the gaps created by the nature of regulatory science, but also, surprisingly, in the very conduct of risk assessment itself (237).

They found that many of these normative assumptions were unavoidable and that divergence in the assumptions made was very influential in determining whether or not Alachlor posed a significant health risk to humans.

Alachlor is a chemical herbicide produced and manufactured by Monsanto Corporation to control the growth of weeds in corn and soybean fields. It had been in use in Canada since 1969 but in 1985 sales of Alachlor were stopped after Agriculture Canada cancelled its registration. The removal of Alachlor from the market was based on information from a risk assessment conducted by the HPB, which showed that it produced a serious risk of cancer to farm workers who applied the chemical. A Scientific Review Board, assembled to address Monsanto's appeal to this decision, later found that the government had overestimated the risk of Alachlor and recommended that its registration be reinstated. Upon comparison of the different reports of Alachlor's risks, however, it was found by the HPB that the use of this product was not safe due to its association with the induction of cancerous tumours in rats. Studies on rats are used to estimate effects on humans and therefore evidence of carcinogenicity in laboratory rats is considered a good indicator that a chemical will cause cancer in humans.

The risk of cancer that an applicator faced from the use of Alachlor was the focus of the risk assessments conducted by HPB and Monsanto in response to the new information regarding its carcinogenicity.

> [The risk of carcinogenicity] was based upon two basic estimates: the first of the quantity of Alachlor sufficient to induce cancer in humans, the second of the levels of exposure likely to be experienced by those who come into contact with Alachlor. The evidence suggested that 2.5 mg/kg/day was sufficient to induce tumours in rats. Since there was little or no direct evidence concerning the effects of the chemical in humans, 2.5 mg/kg/day was simply accepted as the best estimate of a potentially carcinogenic dose, and attention thus focused on the question of likely human exposures (Brunk, Haworth and Lee 237).

Both HPB and Monsanto dealt with questions of exposure by developing reasonable worst-case scenarios. Brunk, Haworth and Lee report that HPB suggested applicators would possibly face an exposure of 2.7 mg/kg/day, which is above the acceptable level. On the other hand, Monsanto suggested exposure levels of 0.0000009 mg/kg/day, which were almost seven orders of magnitude less that HPB's estimate. The Review Board's exposure rate falls in between 0.001 and 0.0001 mg/kg/day. This broad range of exposure estimated was shown by Brunk, Haworth and Lee to be a result of differing value assumptions and not from differing facts.

The influences of the value assumptions made during the assessment of risk are pronounced and Brunk, Haworth and Lee suggest three levels of generality in the assumptions made. The first, and most general level, involved the way assessors prioritized different values. Economic benefits and market freedom were of primary concern for Monsanto and of some concern to the Review Board. HPB on the other hand, was more sensitive to human health and less concerned with economic factors. Brunk, Haworth and Lee claim the Review Board's focus on such factors was based on normative assumptions such as a pro-technology stance, a liberal view of the political order and an instrumental view of rationality (239). As a result, the Board's assessment of the risks associated with Alachlor was conducted within the value framework such assumptions formed. The HPB operated under a safety-based value framework.

The second level of generality according to Brunk, Haworth and Lee involved both conditionally and inherently normative issues.[28] They claim that the differences in exposure rates do not represent different measurements of actual exposure since they were based on the

[28] Brunk, Haworth and Lee describe decisions as conditionally normative when they are made based on values because there is insufficient scientific data available. Thus, Monsanto's desire to protect their economic interests led assessors to make decisions about amortization based on conditionally normative issues. They explain that inherently normative issues are those that are based on 'normalizing' assumptions such as whether or not protective clothing would be worn and if so, whether or not it would be of good quality. These issues are normative regardless of the amount or type of available empirical data.

same data, which were subjected to different assumptions (239). They argue that, in the face of uncertainties, decisions must be made by employing the values one wants to protect, therefore in situations like this, decisions are conditionally normative since values "come into play only in the conditions where there is not enough information available to decide the issue on the basis of the scientific data alone" (241). The assessors in this case were required to make decisions with many uncertainties in factual details, such as the amount of protective clothing worn. The definite conclusions the assessors were required to make were guided by the values they wanted to protect.

The differences in estimates were due primarily to assumptions made about the amount of protective clothing worn by the applicators, how often they would apply Alachlor each year and over how many years they would apply it. The HPB assumed that no protective clothing would be worn while Monsanto assumed full protective clothing would be worn as indicated on the product warning label.[29] Another assumption concerned whether or not exposure to the herbicide should be amortized.[30] "Amortization minimizes exposure estimates; not amortizing maximizes them. Monsanto and the Review Board, sensitive to the projected economic benefits of Alachlor, amortized; HPB, conceiving itself as the guardian of health, did not" (242). These assumptions were used to create an overall scenario of exposure by the assessors and thus greatly affected the estimates of exposure levels applicators were expected to face. The HPB's scenario led assessors to make estimates of exposure much greater than those made by Monsanto's assessors.

In addition to conditionally normative issues, Brunk, Haworth and Lee also discuss the effect of inherently normative issues. Assumptions about these issues included decisions about the quality of protective clothing worn or the integrity of surrounding wells and their

[29] Brunk, Haworth and Lee discuss a number of assumptions made but since they are quite technical I will not mention them here.

[30] Brunk, Haworth and Lee explain that to amortize in this case is to convert a person's total lifetime exposure estimate to Alachlor into a lifetime average daily dose.

ability to prevent seepage. Brunk, Haworth and Lee maintain that identifying these issues as inherently normative rather than empirical is due the fact that there is no standard practice regarding protective clothing among Canadian farmers. Some will wear protective clothing, some will not and others will wear clothing of varying degrees of quality.

> So the question is *not* that of determining the level of exposure under a certain condition, but rather that of determining *which* exposure condition we should take as representing the risk of Alachlor to applicators. It is a matter of first *defining* the 'research worst, medium and best case,' and then deciding among them, all of which requires normative choices (Brunk, Haworth and Lee 244).

Any data or practice concerning the use of protective clothing could be questioned on normative grounds because the quality of such gear requires an assumption of what is considered 'normal'. Therefore the extent and quality of the protective gear used by applicators is considered inherently, rather than conditionally normative by Brunk, Haworth and Lee.

The third level of generality in the value assumptions made was the way the adoption of certain argumentative strategies by the assessors influenced their values. Different strategies were employed to answer questions about who had the burden of proof, the amount of required scientific rigour, and choosing a risk-taking or risk-aversive approach to decision making. Brunk, Haworth and Lee report the HPB adopted a risk-aversive approach, applied a rigorous standard for scientific evidence, and assumed that the burden of proof fell on Monsanto. In contrast, the Review Board and Monsanto held that the government needed to prove Alachlor was unsafe through rigorous scientific standards and that it had been overly cautious in its attempt avoid risk.

The different argumentative strategies used in this case demonstrate the common situation of assessors in their attempt to develop a set of data upon which critical decisions about the use of a product must be made. Scientists working to develop a set of data will make a variety of value assumptions and these values will be determined by various sets of

conditions, which may have an influence on their work. These assumptions must be made in the process of risk assessment and cannot be based solely on factual or quantitative evidence. Brunk, Haworth and Lee argue that they must be based on the values held by the assessor and so they are value-laden. "The assumptions are value-laden because invoking them exposes values held by the assessor, or at least it requires the assessor to take a position in a normative debate" (Brunk, Haworth and Lee 245). I have defined these assumptions as internal because the influences at work occur primarily within the lab or work setting. The values of the individual scientist or those of the institution for which they work affect assumptions about protective clothing or even amortization during the production of the risk assessment data.

The use of Alachlor was determined to pose too great a health risk to farm workers and so its registration was cancelled by the HPB. The reasons for initially approving Alachlor for widespread use in Canada are not relevant to my thesis and so I will not discuss them although Brunk, Haworth and Lee offer a full account of the case in their work. The reason for removing Alachlor from the market resulted from the comparison of different risk assessments conducted with identical evidence. The important feature here is that identical data could produce such disparate conclusions results from the internal value assumptions each set of scientists made during the risk assessment. Although risk assessments produce scientific data, often in the confines of a laboratory or office, it is wrong to assume this information is value-free.

This case shows that two competing sets of values, human health and economic benefits, produced significant disparity in risk assessments that were conducted using the same factual information. Brunk, Haworth and Lee conclude that debates about risk involve identifying different value-frameworks, conceptions of society, attitudes towards technology and towards risk-taking. Therefore "it raises serious questions about how these debates ought to be resolved, and whether their resolution should be put more or less exclusively in the hands of

risk assessment experts and other scientists" (Brunk, Haworth and Lee 245). These are all internal value assumptions because people, who conduct the risk assessments, are influenced by the mandate of the institution or organization for which they work. Internal value assumptions have an effect on the actual risk data produced. Therefore, it is incorrect to assume that scientists and risk assessment experts are conducting value-free assessments.

The Alachlor case shows risk assessments involve many crucial decisions. These decisions require scientists to invoke value assumptions that greatly influence the outcome of their work. Brunk, Haworth and Lee claim that risk assessment is value-laden and therefore it cannot be perceived to be politically neutral simply because it involves the production of factual information. The view that risk assessment is *objective* simply because it involves what appears to be factual information is untenable, which is demonstrated in this case since decisions made by the different groups of scientists were determined by the differences in the background assumptions they made and not in the conclusions that were drawn from the evidence.

Another important feature of this case is the fact that it occurred in the early to mid 1980s. At this point, the current shift in the Canadian regulatory system from inspection to auditing, discussed in the previous chapter, had not yet occurred. Thus, the regulators functioned in the capacity of inspectors which meant they conducted hands-on evaluation and had a much more active role throughout the assessment of risk. Regulators have since become auditors and the cost of risk assessments has become the responsibility of the proponent. As a result, the value assumptions made during assessments are almost exclusively those of the proponent. Unless an independent risk assessment is performed, these values go unnoticed and regulators use this biased information to determine whether or not a product will be released. Maintaining the idea that risk data is *objective* because it is scientific does not address the reality that risk assessment is value-laden. Internal value assumptions like those

made in the Alachlor case obviously have a significant influence on the quantitative characterization of risk.

The Alachlor case highlights a number of ways in which internal value assumptions have real effects in the regulation of technology and its products. The results of risk assessment are critical to decision-making and so it is important that these assumptions are identified or at least acknowledged. Scientists must make certain assumptions about many of the parameters and conditions involved in any risk assessment. We rely on purportedly objective information to make important decisions about the safety of new technologies, yet the necessity of value assumptions in the assessment of risk makes it clear that risk data is not value-free. Had the HBP not conducted their own assessment of Alachlor, there would be no reason to question the data produced by Monsanto since risk data is thought to be *objective* and therefore the discrepancies would between the reports would have gone unnoticed. It is necessary to discard this idealized version of objectivity. Adopting the view that objectivity arises through peer review and collaboration makes value-laden risk assessments less problematic because it requires consensus from a number of scientists, each with a different set of internal value assumptions.

4.3 Recombinant Bovine Growth Hormone Regulation in the US and Canada

Like the Alachlor case, the case of recombinant bovine growth hormone (rbGH) regulation demonstrates the real-world consequences that value assumptions have in the interpretation of risk data.[31] This case is particularly interesting, however, both because it specifically involves a product of biotechnology because it shows the real-life implications these assumptions have had in the regulatory systems of Canada and the United States. In the

[31] Other names for this drug are recombinant bovine somatotropin (rbST) and bovine somatotropin (bST).

case of rbGH, it was the external value assumptions that resulted in the differences in decisions made by the two regulatory agents. Mills provides a thorough account of the events leading up to the 1999 decision by Health Canada to reject Monsanto's application to license rbGH in Canada despite its approval by the US Federal Drug Administration (FDA) six years earlier. Mills contends that the two different regulatory decisions, again based on the same data, show that although there are different approaches to regulation in the two countries, the primary reason for disparity over the approval of rbGH is a result of differing interpretations of scientific evidence. She argues that even though there was agreement about what the evidence demonstrated, the context in which it was reviewed, and the assumptions made by safety assessors, played a pivotal role in arriving at the two different conclusions to the regulation of rbGH.

The hormone rbGH is produced through rDNA technology. Its purpose is to increase milk production in dairy cows, typically by ten to fifteen percent (Mills 7). A number of risks to both human and animal health are associated with the use of rbGH. Although there are always unknown risks with the products of rDNA technology, the debate about the safety of rbGH has centred around two primary concerns to human health. The first concern is whether human health problems, in particular allergic reactions, were increased through the consumption of rbGH treated milk as opposed to the natural bGH already present in milk. The second concern is whether rbGH contributes to an increased cancer risk for those who consume milk from treated cows. There is an elevated level of insulin-like growth factor-I (IGF-I) in the milk of treated cows and studies have shown that this hormone-like substance plays a role in the development of malignant tumours in humans (Mills 104).[32] In addition to

[32] IGF-I mediates the action of growth hormone.

the issues of risks in human beings, the use of rbGH in cows is associated with an increase in common animal health problems such as mastitis, reproductive problems and lameness.[33]

Assessments were conducted by Monsanto, the manufacturer, and submitted for review by government and university scientists in both Canada and the United States. As with other technologies and their products submitted for regulatory review, assessors were required to use the data collected from animal and human health studies to determine whether statistically significant increases had any biological significance. Mills argues that the debate over rbGH regulation was about the meaning of the data and not the data itself. According to Mills, there was little to argue about over the numbers produced by the risk assessments, in fact there was a surprising amount of consensus over the data. How to interpret those data however, was subject to much debate. She claims that scientists had to make assumptions based on both existing dairy practices and on scientific knowledge in existing literature to answer questions about adequate levels of testing, interpretations of statistically significant results, acceptable levels of risk and ultimately, whether the data were sufficient to warrant approval (Mills 104).

In the case of human health concerns, Mills reports that FDA and Health Canada regulators agreed that the use of the drug did not pose a risk to human health based on conventional science.[34] Human studies from the 1950s showed that the use of natural bGH to treat conditions such as dwarfism produced no ill effects. Also, since rbGH is a protein hormone, protein digestion and absorption information in the scientific literature was used to assess the risk of consuming rbGH treated milk and to determine that long-term human health testing was unnecessary (Mills 143). Mills notes that the decision not to proceed with long-term human health testing was questioned by scientists at the Health Protection Branch

[33] Mastitis is an inflammation of a cow's udder caused by a bacterial infection, which must be treated with antibiotics.

[34] Mills defines conventional science as science that has been accepted by an established scientific community.

(HPB) of Health Canada since there had not been any empirical demonstration that rbGH would be unlikely to cause human health problems. HPB scientists argued that more experimentation was required since rbGH is consumed over a lifetime and is a nontherapeutic drug with no benefits to consumers. "However, external panels argued regulatory resources should not be used on low risk cases because absolute safety could never be achieved" (Mills 7). Despite the criticism by some regulatory scientists in Canada, and a few external critics in the United States, rbGH was found to pose no risk to human health and therefore, this conclusion was reported by both countries. The decision to approve rbGH in the US and to reject its use in Canada therefore resulted from the differences in how each regulatory system addressed animal health concerns.

In the case of animal health, reviewers in both Canada and the US decided the problems in animal health data were statistically and biologically significant, however, the extent of this problem was assessed differently by scientists in the two countries (Mills 8). Mills reports that the FDA considered the animal health effects manageable while Canadian regulators considered them to be severe and recommended rbGH be rejected for use by dairy producers. Mills attributes this disparity to both the political and economic situation that resulted in different assumptions scientists in each country made during the regulatory approval process.

Mills argues that the decision in the US was based on two major influencing factors. First, she notes that the FDA considered the farmer to be ultimately responsible for managing animal health problems. Moreover, the monitoring of drug residues in the milk supply was considered to be the responsibility of the monitoring institutions. The reasoning behind this allocation of responsibility was, she claims, based on the fact that a successful farmer had to use various technologies (antibiotics and reproductive techniques) to manage existing animal health problems. Therefore, the farmers should manage any new or increased health problems arising from the use of rbGH. Second, Mill reports that during the time rbGH was

introduced, there was a push in the US to minimize government support for farmers which occurred concurrently with the trend to increase the global competitiveness of US agricultural products through the use of biotechnology. "Under these conditions, rbGH represented a logical means to increase the productive efficiency of American agriculture and its capacity to compete in world markets" (Mills 10).

In Canada, by contrast, the responsibility for animal health problems fell to the regulators, and not the farmers. In fact, the regulators were responsible not only for animal health but also for the viability of Canadian farms. Therefore, the potential risks of rbGH to animal health were considered much more problematic in Canada than they were in the US. Mills notes that increased disease rates in animals, which are treated with antibiotics, were of more concern in Canada because "if a milk tanker is found to contain an unacceptable level of antibiotic residues, the entire tanker of milk is disposed of and the farmer is responsible for the cost of the milk – up to $18,000" (9). If the tanker is disposed of to avoid this cost, then the farmer may not be able to meet their production quota (9). The potential need to increase the use of antibiotics to treat the health problems associated with rbGH was therefore considered a risk to the animal, the farmer and the government.

Mills argues that the two different approaches to regulation in Canada and the US led researchers to conduct their reviews of rbGH with two different sets of assumptions. She contends regulatory scientists depended on existing knowledge in this case and that they had difficulty questioning such knowledge within their respective regulatory structures (142). "The approval of the drug in the United States can best be explained as the result of a regulatory system in which the studies requested and the interpretation of the data was derived from a conventional scientific framework" (Mills 143). The reviewers' expectations, decisions about which studies were required, and their interpretations of the data were all constructed by conventional science. Past studies on the use of natural bGH and protein and

hormone digestion comprised the knowledge base from which reviewers made these decisions. Despite the consensus about the scientific issues involved, the context and assumptions made affected how scientists interpreted the data. Mills claims the rbGH case demonstrates that the assumptions scientists make within their particular political environment can distort complex scientific information. This instance in particular shows that the perceptions of the scientists

> are shaped by context in two different senses. First, the goals and mandate of the institution in which the scientist operates exert a particular kind of pressure on him or her, thereby promoting or constraining particular types of choices. Second, the broader political-economic context also affects scientists' interpretations. The two factors that were most significant here were the nature of the dairy system, and the significance of the biotechnology industry (Mills 5).

The decision to approve or reject rbGH for use on farms was one that affected not just farmers or Monsanto. It affected a large part of society since the drug is used to increase production of such a commonly consumed product. Regulators, using identical sets of data, determined the risk of rbGH was either acceptable or unacceptable depending on the assumptions they made during their assessments. This case illustrates not only the significance of value assumptions in risk assessments, but also shows that they can play a pivotal role in determining the risks society will be exposed to. Like the Alachlor case, Mills demonstrates that risk assessments are value-laden but she goes further to define what sort of circumstances or influences can determine the values scientists employ when attempting to determine the safety of a product. She claims that "A conclusion about safety can only be informed by data, not determined by it, and it was this conclusion that was the source of dispute" (159). This claim is particularly significant when considered in the context of the current Canadian regulatory system.

As discussed in Chapter Two, there has been a shift in the function of regulators from inspectors to auditors. Regulators receive the proponent-produced risk assessments and assess the safety of a particular product based on this information. This shift in function

suggests that the external value assumptions made during the assessment process are not taken into account by regulators. Policy-makers do not consider the assumptions the regulators themselves make and thus there is a compounded value-ladenness to the information used to make decisions about biotechnology. The rbGH case shows that there are many influences involved in the determination of risk. It is not enough simply to assume that risk assessment is *objective* when making decisions about safety. If there had been collaboration among scientists both externally and internally who operated under different sets of influences or within varying contexts, it is likely that the value assumptions would have had less of an influence on the decisions made by the regulators in both countries. Discussion within the broader scientific community might have produced a consensus among the regulators and would have contributed to the production of genuinely objective risk assessment.

4.4 Genetically Modified Wheat

The different conclusions the American and Canadian regulators arrived at in the rbGH case become more significant when considered in conjunction with a more recent product from agricultural biotechnology submitted for approval to the CFIA. Monsanto has developed a form of genetically modified wheat and has applied to the CFIA to assess its safety for its release onto the market. The Alachlor case demonstrated that internal value assumptions occur and in fact are necessary in the risk assessment process. Brunk, Haworth and Lee describe the influence these assumptions had in the outcome of the risk assessments concerning the safety of Alachlor. The rbGH case shows the role external value assumptions play in the regulatory process specifically and how different background influences and pressures in Canada and the US led to different conclusions about the use of rbGH.

Since the rbGH decision in 1999, Canada has entered into a bilateral agreement with the United States concerning agricultural biotechnology. In 1998, the CFIA, Health Canada and the United States Department of Agriculture, Animal and Plant Health Inspection Service (APHIS) agreed to attempt to harmonize those areas of the regulatory review process pertaining to the molecular genetic characterization of transgenic plants. Additionally there was an agreement to "discuss and prioritize future areas of cooperation and information exchange that will facilitate the safe incorporation of transgenic plants into agricultural production and commerce" (Canadian Food Inspection Agency: "Canada and United States Bilateral on Agricultural Biotechnology").

This agreement, along with the two previous case studies, is relevant to the events surrounding the introduction of GM wheat. Although no decision has yet been made about whether or not it will be approved for use in Canada (since the case is still pending) the internal and external value assumptions made in producing risk data and during the regulatory review process will undoubtedly play an influential role in the decision. The current regulatory regime does not adequately account for the value assumptions in risk assessment at either the level of data production by the proponent (internal level), or at the regulatory review level (external level) by those charged with ensuring the safety of the products of biotechnology.

In December 2002, Monsanto Canada Inc. submitted an application to the CFIA for the approval of its Roundup Ready® Wheat (RRW).[35] This is wheat that has been genetically modified to be tolerant to glyphosate, which is the active ingredient in Monsanto's herbicide marketed under the name Roundup®. The impetus for introducing this modified wheat according to Monsanto is to "increase the competitiveness of wheat growers in the Northern Plains and provide a much-needed additional tool in weed control options and improved

[35] For an interesting account of the use of Roundup Ready® foods see Lappé and Bailey 50-62.

profitability for growers" (Monsanto). Among some of the benefits, Monsanto claims that wheat growers of their new product would enjoy broad-spectrum weed control, increased crop safety, increased yield, cleaner grain, simplified weed management and a reduced environmental risk profile (Monsanto).

Among the controversies that have quickly arisen in response to Monsanto's application to the CFIA, are concerns about the potential market acceptance due to fear of GM crops, particularly to export markets such as Europe. Additionally, there has been much discussion over environmental concerns such as the potential for weeds to develop resistance to Roundup® through increased application, and the out of control spreading of volunteer wheat.[36] Another potential risk identified by Van Acker and Entz, is the ability for GM wheat to turn into a nuisance if it cross-pollinates with goat grasses (Van Acker and Entz 174).[37] It was thought that little or no cross-pollination occurs with wheat but this recent study has reported that there is a possibility that cross-pollination does in fact occur specifically with this type of grass.

The Canadian Wheat Board (CWB), which represents the interests of the wheat growers in Canada, reports that upon consultation with a number of research scientists and extension agronomists throughout western Canada it was found that "the majority of the feedback is cautiously neutral to negative towards the introduction of RRW. Many do not feel that the benefit of introducing RRW outweighs the agronomic costs and increased management risk" (Canadian Wheat Board: A Discussion Paper). There was consensus among these experts that the "control of volunteer RRW is likely the single biggest issue of concern, and is believed by many to outweigh any potential benefits in agronomic performance and weed control" (Canadian Wheat Board: A Discussion Paper).

[36] A volunteer is a plant that occurs as a result of seeds or propagative parts of plants growing uncontrolled from previous seeding or from plants escaped from cultivation that have been scattered by natural means. These plants do not occur as a result of current seeding.

[37] See Bartsch and Schmitz for a recent account of how GM plants are monitored once released.

In Canada, the introduction of RRW faces opposition from a number of groups, most significantly, the Canadian Wheat Board but also the Saskatchewan Soil Conservation Association (SSCA), which has expressed concerns about the potential of RRW to cause environmental harm (Saskatchewan Soil Conservation Association). Despite environmental risks, however, the CWB has focused much of its criticism on the economic risks widespread use of Monsanto's new product might result in. Farmers are concerned that they will lose money if the public refuses to buy products made with GM wheat. There is also concern that the export market will avoid Canadian wheat because it is difficult to separate GM crops from non-GM crops. On May 27, 2003, the CWB made a request to Monsanto to withdraw its application for the approval of its modified wheat from the CFIA. In a letter addressed to Mr. Peter Turner, the president of Monsanto Canada Inc., the CWB stated that it

> is extremely concerned that the unconfined release of RRW in Canada will result in significant and predictable economic harm to western Canadian farmers. This harm will occur to those who adopt the technology and those who do not, as well as to others in the Canadian wheat value chain (Canadian Wheat Board).

This letter resulted in a swift response in the United States by its CWB counterparts. The National Association of Wheat Growers and the Wheat Export Trade Education Committee (WETEC) jointly issued a statement on May 28, 2003 suggesting that the action of the CWB was contrary to science-based safety and health regulation principles.

> Market acceptance issues are extremely important, and must be addressed prior to commercialization of a biotech trait in wheat. However, they do not belong in the context of a scientific safety review. A favourable affirmation of safety through a purely scientific process is one piece of the market acceptance puzzle, and should serve to increase consumer confidence" (National Association of Wheat Growers).

This incident illustrates a number of the problems I have identified with the presence of value assumptions in risk assessment and the lack of acknowledgement by those involved in the regulation of biotechnology. The statement by the United States wheat producers emphasizing the need for science-based regulation and the determination of safety through a 'purely scientific' process highlights the fact that there is an enduring view of *objective* risk

assessment and regulatory review. Additionally, the controversy surrounding Monsanto's application to the CFIA based on safety and economic risks, will serve as the background influence for regulators in both Canada and the United States. As the circumstances in the rbGH case showed, the surrounding political climate had an effect on the assumptions assessors made during the regulatory review process.

The GM wheat case also involves the presence of value assumptions at the internal and external levels. It reinforces the need to identify the internal value assumptions made by Monsanto scientists during their preparation of the requisite data. As the developments in the Alachlor case showed, these assumptions can greatly influence the production of risk data and the interpretation of the conditions scientists must make judgements about in their risk reports. Given the current approach to regulation in Canada, it is questionable whether regulators acting as auditors will be able to identify the effect these assumptions might have on the risk data.

Second, this case will be affected by the surrounding controversy as occurred in the rbGH case. The political, economic and corporate pressures under which regulatory scientists must work will influence the assumptions they must make to assess the safety of GM wheat. The fact that there is disagreement between the Canadian and American wheat growers mimics the situation surrounding the regulation of rbGH. In the case of RRW, however, regulatory decisions occur under the added influence of the bilateral agreement between the two countries, which was not a factor in the rbGH case. On the one hand, the effect of this agreement might be very positive since the agreement provides the possibility for an expanded regulatory scientific community in which evidence can be reviewed. Following Longino this is something I have argued previously that is necessary to produce objectivity in scientific endeavours. On the other hand, however, it could result in additional pressure or influence on Canadian regulators by their American counterparts. Therefore, the assumptions

Canadian regulators must make during the review process could be swayed by the larger, more powerful US industry. The letter by the United States wheat growers in response to that of the CWB demonstrates that there already exist conflicting values in the discussion occurring externally from the regulation procedure. This could have an impact on the regulators in Canada who must now keep in mind that market concerns should not play a role in their assessments, despite the contentions of the CWB, if they are to avoid criticism by the US for engaging non-scientific considerations in their assessments. The bilateral agreement between Canada and the US contributes yet another external influence on regulatory risk assessment.

Thus the situation stands as follows. The US regulators will produce their assessment of GM wheat with the US wheat growers expressing positive attitudes towards this product and anticipating the benefits it will have on their livelihood. Canadian regulators, however, will produce their assessment with Canadian wheat growers expressing great concern and trepidation over the introduction of this product onto the market as well as environmental concerns as expressed by external scientists. The presence of the bilateral agreement makes this case more complicated than cases like the regulation of rbGH because the effect of this attempt to globalize biotechnology safety was not a factor in the rbGH case.

A product like RRW requires a very careful assessment of risk since not only is wheat a very commonly grown crop in North America but it also comprises part of the diet of the vast majority of people. Any potential health or environmental risks must be considered carefully before RRW is released onto the market. Since it is such a common crop, and scientists have shown that wheat can cross-pollinate with wild grass, the results of the regulatory review will have widespread effects. The Alachlor case and the rbGH case show that value assumptions are unavoidable and even necessary in both the production of risk data and its review. The current climate surrounding regulation suggests that regulators, like those involved in the

rbGH case, will have a number of external and internal influences affecting the assumptions they make. The GM wheat case, although still pending, is useful in demonstrating the need to acknowledge and understand the role of value assumptions in risk assessment. With this understanding, it is clear that genuine objectivity should be a goal of the assessment process.

Internal and external value assumptions shape much of the data produced by the scientists most closely involved with the development of GM wheat. If these scientists were required to submit their results for peer review, or had their results compared with those conducted by independent risk assessors, risk data would be more genuinely objective than it is at present. The value assumptions that must be made in the production of data would not be limited to those directly involved in the research and thus would be more representative of the values that should be used to guide regulatory decisions that affect all members of society.

4.5 Conclusion

In this chapter I have used three different case studies to describe ways in which risk assessment is value-laden. The assumptions made by scientists and regulators are unavoidable and in fact, necessary. They play an influential role in the decisions the Canadian government makes in the regulation of new technology, including biotechnology. Brunk, Haworth and Lee argue that the Alachlor case demonstrates not only that value assumptions occur in risk assessment, but that they are necessary in order to produce the data needed to understand how safe a certain product is and what sort of risks it might be associated with. From their results it can be seen that values concerning market fairness and viability influenced the risk assessment conducted by Monsanto and the Review Board, which eventually indicated that Alachlor was safe. In contrast, when values concerning

human safety were prevalent, as they were in the HPB, the risks of cancer associated with Alachlor use were considered too dangerous.

Assumptions about seemingly minor details such as the amount and quality of protective clothing worn by applicators, as well as whether their exposure should be amortized or not, were in fact not so minor to the assessment of risk. The presence of value assumptions has a much more significant impact on risk data than is commonly thought, as this case shows. The effects of value-laden risk assessment are not, however, confined to the production of data or even to conclusions about safety. The case of rbGH demonstrates that even the regulatory process itself is affected by the assumptions made both in the laboratory and during the review process.

Mills reports that the decision to reject rbGH in Canada while it was approved in the United States was directly influenced by the judgements made by regulatory scientists during the review process. The political and economic environment within which each group of regulators functioned had an influence on which assumptions they made while reviewing rbGH. She argues that the differences in the background conditions and, therefore, in the judgements made, resulted in the two differing decisions. She claims that even though there was consensus among scientists about the evidence, it was the interpretation of this evidence that played a crucial role in this incidence. Although Canadian and American reviewers decided there were significant problems with the animal health data, they differed in their assessment of the extent of the problem.

Since risk assessment involves both the production of evidence and its interpretation, the results of the Alachlor and the rbGH cases demonstrate two different aspects of value-ladenness. The case of GM wheat, although no regulatory decisions have been made yet, also provides a useful means of highlighting the problem with a regulatory system that does not adequately account for value assumptions. Given the changes the Canadian system has

undergone in the last few years it is evident that although regulation relies on science-based risk assessment, it is still widely held that such assessment is *objective* (i.e., value-free) and, therefore, a good arbiter of technology and safety. Risk assessment is a necessary part of determining the safety of biotechnology, however, it is problematic to assume that it is free from the influence of the values of those involved in its process. This is evident in the Alachlor and rbGH cases. Given the circumstances surrounding the regulation of GM wheat, it is clear that many of the same factors involved in the other two cases are occurring in this one, but with the added pressure of the new bilateral agreement.

Value-laden risk assessment is not *objective,* but we can move towards genuine objectivity in the enriched sense I discussed earlier through collaboration among the scientific community and increased peer review. The emphasis placed on risk assessment to help guide the current approach to the regulation of biotechnology, in combination with the unique and far-reaching effects endemic to this technology, require a re-evaluation of Canada's regulatory system. As demonstrated in the discussion of these case studies, the values that influence assessments of risk are not adequately addressed. This is the topic of my next and final chapter.

5. Recommendations and Conclusions

5.1 Introduction

In this final chapter, I discuss a number of implications of value assumptions in risk assessment. I conclude that these assumptions do not need to compromise our attempts to produce genuine objectivity in assessments of biotechnological risks. It is, however, necessary to discard the simplistic notion of *objectivity* in science and risk assessment, which I have criticized earlier, in favour of the view that objectivity is the result of social discourse and peer review. These assumptions have an impact on the decisions made concerning the implementation of biotechnological products in society. I suggest three possible solutions that the Canadian regulatory regime could adopt in order to accommodate value-laden risk assessment while maintaining objectivity.

These suggestions will include the utilization of regulatory structures that are already in place but could be modified to address this problem, as well as the introduction of a new feature that could be incorporated into the regulatory system. I conclude my thesis by explaining how the nature of risk, combined with the unique features of biotechnology and its regulation in Canada, all contribute to making it necessary not only to recognize value assumptions in risk assessment, but to demand an appropriate solution since their impact upon the risks taken and the risks faced by all members of society is much more significant than is currently thought.

5.2 Recommendations

5.2.1 Independent Review Board

The presence of value assumptions in the process of assessing risks has a considerable influence on the data used to determine regulatory policy concerning the use of biotechnology. In the discussion of the three case studies in the previous chapter I have shown that determinations of safety are dependent on assumptions made about both experimental details and about the objectivity of science as a whole. These assumptions occur at the two levels described at the beginning of Chapter Four. Internal value assumptions are those that are made by scientists, which reflect the influences of their working conditions within the lab such as company goals or individual career motivations. External value assumptions reflect the influences on scientists from the surrounding community, political climate or public debates. Despite ongoing controversy there is still a tendency to ignore or deny the presence of value assumptions by accepting an inadequate view of objectivity, which obscures the fact that assessments are influenced by value judgements. As I have shown, this is problematic and results in an incomplete understanding of risk assessment. In order to determine the safety of a technology, assessors must decide which parameters need to be included in the risk calculus and, therefore, value-ladenness is unavoidable.

The need for accurate risk assessments is not diminished since such assessments are often the only method available to determine how safe a new product or technology is. The problem is not that assumptions must be made in the production of risk data, but that these assumptions, and their effect on decision-making, are often overlooked or ignored. As Shrader-Frechette has argued, “risk assessment results are often viewed as far more objective

than they really are. This, in turn, means that policy conclusions based on the assessment results are frequently more controversial and value-laden than is thought" (48).

Relying on objectivity in the attempt to navigate the biotechnological minefield of risks need not be problematic if the idea of objectivity is understood as a process. *Objectivity*, as an ideal of inquiry, is unrealistic and holding on to this idea so tenaciously does a disservice to those attempting to address the risks associated with biotechnology. Longino's conception of objectivity as arising out of the process of peer review and discussion within the scientific community is particularly fruitful in its application to issues in biotechnology. Subjecting risk assessments to the sort of debate and deliberation often surrounding other scientific endeavours allows for a re-examination of putative conceptions of biotechnological risks. Thus objectivity as an epistemic virtue is possible. This enriched notion of objectivity allows for value-ladenness within the assessment of risk, but ensures that these values are not merely representative of a single group, individual or directive. Failure to acknowledge that value assumptions are unavoidable makes risk assessments undesirably biased because only the values of a select few influence the outcome of these assessments. Since biotechnology is an industry-driven undertaking and the industry produces risk assessments of their products for regulatory approval, the assumptions made in these assessments are typically those that reflect the interests of the industry. These are not the values that should be the sole influence on the decisions the government makes about the risks society will face from biotechnology.

The idea of objectivity as a social construct also lends itself well to biotechnological risks since the assessment of such risks requires an interdisciplinary approach. Nelkin and Pollak argue that the embodiment of highly controversial political and social values in risk assessments results in "requiring institutions and procedures that will allow an open and balanced dialogue and enhance the constructive sense of collective responsibility necessary for legitimate and acceptable decisions" (234). Collective responsibility could begin at the

level of risk assessment, thereby ensuring genuinely objective risk data on which to base regulatory decisions. Debate about risk must occur if the problems endemic to assuming assessments are value-free are to be avoided. Shrader-Frechette maintains that a good way to do this is to "pursue an adversary method of assessment, a method premised on the fact that desirable risk analyses are likely to be a product of rational interaction and compromise among those who disagree about how to evaluate a given risk" (205). Recognizing that there may be adversarial relationships between various stakeholders in the knowledge game is crucial to the social responsibility of science as institution, which has an impact on the rest of society. Objectivity must therefore be the outcome of a process of social discourse among players who cannot all be assumed to be in agreement about social aims and consequences. Longino's account of objectivity as the product of social discourse, and Schrader-Frechette's recognition of the necessity of an adversarial approach to risk assessment, together offer us the resources to address the issues specifically concerning biotechnology regulation in Canada.

My first recommendation for improving Canada's regulation of biotechnology is to create an independent body to conduct risk assessment reviews, addressing value assumptions that occur at the internal level. This review board would exist separately from agencies such as the CFIA or Health Canada, and would be responsible for reviewing the same risk data reports proponents currently submitted to these agencies for approval. It would be comprised of a group of independent, non-industry funded scientists from a variety of scientific disciplines. Having scientists from different disciplines is an important feature in this solution since assessment methodology and parameters vary greatly. For example, it is less likely that the values invoked during the assessment process by a molecular biologist would be similar to those of a chemist. The point at which these values come into play during the assessment process would also vary from one discipline to another, making their influence on

risk data much more evident. The purpose of such a body would be to identify discrepancies, which would, if found, trigger closer examination and perhaps further consultation with the external scientific community. Proprietary rights and confidentiality agreements would be adhered to unless there was a significant discrepancy in the findings of the independent review board and the respective government agency. Then the proponent could choose either to withdraw its application for further study or re-evaluation, or release itself from it claims of privacy to become available for external examination.[38]

A second part of this particular recommendation addresses the issue of transparency. Many of the risks of biotechnology cannot be confined to one geographic area, population, or species—they affect all members of society. Accordingly, current decisions about Canadian regulation emphasize the need for transparency. This transparency occurs after regulatory decisions have been made. Thus, at present, transparency as a tool for public involvement and participation is rendered ineffective because without significant public uproar, approved products are put onto the market with little resistance. Considering a recent article in *Maclean's* which reports that "Canadian biotechs have 17,000 new products in the pipeline", it is difficult to imagine that anyone, let alone a largely uninformed public, would be able to keep track of which products have been approved or not (Leahy 42).

Therefore, in order to make the public and interested parties aware of the product there should be a public statement that a product has been approved for regulation. Such statements are already required in the Canadian system, however, these requirements do not go far enough. Once a product has been approved by both the independent review board and

[38] I am aware that a company would rarely release its claims to privacy. I argue, however, that in issues of safety, public interests usurp the privacy claims of an unregulated technology or product. In some cases, it is possible that external examiners could be held to privacy agreements themselves and thus enter into the regulatory system while maintaining the necessary autonomy required by external consultants. This approach might also force the hands of corporations to produce a higher standard of risk assessment in order to avoid being subject to external examinations. Claims of privacy should not be used to circumvent the stringent regulatory standards that are essential when attempting to introduce any product of biotechnology since we have such limited experience with their long-term effects. This issue involves details of law, which I am not attempting to address here; I merely want to show that there are other ways to approach regulation.

the regulatory government agency, there should be a compulsory lag time in which risk data is made publicly available and all reports are subject to challenge by interested parties. This would address value assumptions made at the external level of risk assessment. Just as possessions to be auctioned off by the government must be announced publicly in the newspapers, biotech innovations tentatively approved for marketability should be announced and include a more thorough account of the risk data. Transparency is only effective if it allows one to see the relevant inner workings of the regulatory system. Currently members of society are asked to believe that risk reports of limited detail made public on government websites after the approval process has occurred is evidence of the transparency of regulation. This is clearly not the case. True transparency is essential to biotechnological regulation, otherwise we are left to imagine that the existing regulatory opacity is in fact, the transparency we demand in issues of safety.

Proponents might argue that publishing risk data would potentially compromise their intellectual property rights. In the case of biotechnology, however, I think the rights of citizens should outweigh those of the corporations. Unlike other technologies or products like computer software or cars, GM products are living organisms that can propagate and interact with the environment. Knowledge of their behaviour is limited at present. Their effects put all members of society at risk and cannot be recalled or cleaned up if something goes wrong however unlikely that may be. Therefore, regulators should require that relevant risk information is widely available to interested parties. It may be argued that corporations may not agree to publish risk data because of the concern that technical information cannot be protected while maintaining transparency. In a few instances, depending on the type of processes involved, this may be a concern. In such cases, my recommendation would be to wait until the corporation has obtained patent or copyright protection before making risk data available to the public. It is not effective to enforce strict regulations on products after a

disaster or unwanted incident occurs. Corporations and scientists should not be able to determine, or largely influence, the risks that will be faced by everyone. Similarly, members of the general public should not be able to halt the progress of transgenic science based on ill-informed fears. The role of regulators must be able to accommodate both corporate and public interests.

The creation of an independent review board, as well as more timely, and effective transparency, would help to address the problems of value-ladenness in risk assessment. Additionally, this recommendation would alleviate some of the problems in separating ethical issues from issues of risk. The use of risk assessment to protect society necessarily incorporates normative considerations. These considerations must be recognized as unassailable components of safety assessments, and they must be accessible to the society they are meant to keep safe.

5.2.2 Acknowledgment in CBAC reports

Public access to risk assessments is a necessity in the case of biotechnology. Levidow and Carr note, "Although scientific fact-finding has always been value-laden, 'risk' controversy has made the constituent values more accessible to public scrutiny" (Levidow and Carr 30). My second recommendation makes use of this feature of risk assessment and the process of regulation in Canada. There needs to be an explicit acknowledgement by the government that risk assessment is value-laden.

At present CBAC attempts to incorporate public opinion gathered through surveys into an ethical framework in which to set issues surrounding the use of biotechnology in Canada.[39]

[39] CBAC's mandate is outlined in Chapter 2.

The recommendations made in CBAC's reports are ostensibly used to inform decisions made by the government. It is not clear, however, to what extent CBAC's publications actually affect these decisions. The efficacy of this advisory committee is widely debated but I do not intend to elaborate on this discussion. The impetus behind including CBAC in my recommendations is based on an attempt to find practical solutions to the problem of value-laden risk assessment and the lack of its recognition by utilizing existing programs, procedures or strategies already present in the Canadian regulatory system. Recommendations to completely reform or restructure Canadian regulations are of limited value since they are unlikely to be employed and easily dismissed as cost-ineffective and unmanageable. Therefore, my second recommendation, although certainly not without its limitations, provides a way for current regulatory structures to be re-evaluated or altered in such a way as to accommodate the problem I have outlined. Additionally, it addresses the problems of value assumptions at both the internal and external levels of risk assessment. CBAC provides an overall ethical framework for the use of biotechnology in Canada but this can and should be extended to include risk assessment. Also, it provides the opportunity for the incorporation of public concerns and values.

The existence of CBAC reflects one of the most visible attempts by the government to address ethical issues in biotechnology and the widespread application of its products. CBAC perpetuates the separation of ethics from risk in practice, however. Levidow and Carr argue that when the state separates risks from ethics, not only are both reduced to specialist tasks, but this "risk/ethics boundary encourages deference to the expert assessment of both safety regulators and professional ethicists" (40). When considering the results of expert assessment in the Alachlor and rBGH cases, combined with the knowledge that risk assessment necessarily involves the incorporation of the assessors' normative considerations, the continued separation of ethics and risk is problematic. As I have argued, biotechnological

risks are widespread and far-reaching. They affect all members of society and thus need to be conducted, or at least reviewed, in the public realm. The task of regulators to provide objective, publicly accessible risk assessments is even more pronounced when one considers the following:

> A study of public perceptions of biotechnology in the US showed that 19 per cent of the people would definitely believe university statements about the risk of genetically altered organisms; only 4.0 per cent would believe the company making the product. Such perceptions do not take into account the fact that university scientists are becoming increasingly linked into industry and their views on risks tend to converge with those of industry. This is also true of some federal agencies, which are closely associated with the promotion of corporate interests (Juma 129).

Value-ladenness in risk assessment is not merely an issue for scientists and regulators. Formal peer review, as I suggested earlier, is one way of addressing this problem but public review should also be included. Public discussion of biotechnological risks can provide an informal review process. Not all public opinions can be used of course, but dispelling the idealized view of *objective* risk assessment is a very useful way of compelling regulators to answer questions the public are asking. The controversy over biotechnological risk "is not merely over scientific methodology, but also over social values…analytic assessors must help both educate the public and to amend, reformulate, and clarify risk assessment methods" (Shrader-Frechette 203).

Since CBAC attempts not only to inform government policy but also to inform the public, I think its role needs to be expanded to include a more developed and explicit mention of guidelines governing risk assessment. By additionally providing a forum of risk assessment procedures in biotechnology amongst experts, it would be able to address questions of risk assessment both in a theoretical and a practical sense. Distally it would allow for the evaluation of theoretical implications of value assumptions in risk and practically, it would provide a means of solving the problems associated with them. From a conceptual point of view, the inclusion of risk assessment in CBAC's ethical framework would provide much

needed public recognition that risk assessment is not value-free and that risk cannot be separated from ethics. This recognition would also reinforce the need for peer reviewed risk data and a more accountable system of regulatory control. For example, CBAC provides a list of the elements it includes in its ethical framework, which encompasses the use of biotechnology. I think one or two statements in this list acknowledging that risk data is value-laden are necessary. CBAC could also include a requirement that companies must submit their data for peer review during the regulatory process. Since CBAC has no legislative authority, however, changes to the way regulation is conducted must occur at the federal level. CBAC reports recommend strategies to the government so it is difficult to predict whether major changes to its mandate would have any real effect on regulation. Including an acknowledgement of value assumptions in risk assessment, however, would at least bring the issue to the attention of those with the power to change regulatory policies. It would also bring the issue to the attention of the public since CBAC reports provide the most accessible means of information about biotechnology regulation to those without scientific training. Although this recommendation seems insignificant since it only involves the inclusion of value-laden risk assessment in CBAC reports, I think it is an important step to dispelling the idea of *objectivit*y in the assessment of risk and our reliance on this untenable notion.

5.2.3 Changes to Canadian regulation strategies

In concluding my discussion of recommendations, I wish to briefly broach the subject of Canada's present approach to regulation in general. As I have indicated earlier, there has been a shift towards regulators taking on the more passive role of auditors rather than the traditional, more hands-on role of inspectors, according to Prince. This development is

unfortunate. It serves to exacerbate the problems brought about by a failure to recognize that risk assessment is inherently value-laden. Although adopting the role of auditors is appealing in its cost-effectiveness, the consequences of failing to recognize the complexity of safety assessments outweigh the economic benefit. In fact, this shift suggests that either the Canadian regulatory system does not recognize that value assumptions are an integral part of risk assessment, or that those who set regulatory policy do not give them the appropriate consideration. The policy of having proponents fill out a risk assessment data report carefully compiled through consultation with international agencies is inadequate to address important problems inherent in conducting these assessments. In preparing reports proponents must still make assumptions, which will influence the character of the data they produce, as we have seen in the Alachlor case.

Having regulators act in the capacity of auditors of risk data is a poor policy from an epistemic point of view because it does not allow for the incorporation of value perspectives from other interested parties. It also makes it much more difficult for regulators to address their concerns over how the data are produced since this would require making additional demands on proponents. As Mills pointed out in her work on the rbGH case, regulators are under many pressures, including time constraints and the reluctance of the regulatory system to overburden proponents.

Although shifting the role of regulators increased the efficiency of regulation by making it quicker and more cost-effective, auditing should just be a preliminary step in the process. A more effective process would be to subject assessment data to a random scientific re-evaluation by regulatory scientists. Randomly choosing one feature or category of data to undergo thorough methodological analysis by regulators keeps costs down and requires proponents to ensure good scientific practice since it would be unknown which aspect of their data would be subject to this more stringent review. Specific questions concerning the

assumptions made by proponents governing their risk assessments should be required. This way, proponents would be required to keep account of any assumptions they make during assessment and justify those assumptions. Regulators would be able to put risk data in the context of the assumptions made by corporate scientists. Corporations might then be compelled to include risk assessments from independent scientists in order to provide regulators with more objective information about the safety of their products. Subjecting these reports to the review board I mentioned in my first recommendation would mitigate the effect industry-biased value assumptions might have had were they left unchecked.

Finally, I wish to address Canada's approach to regulation. At present, this country focuses on a product-based rather than process-based system of regulation. Thus, the trigger for regulation in Canada is not the use of rDNA technology or techniques per se, but rather, the presence of a novel trait that or is not substantially equivalent to a product already approved for regulation.

Given the unique risks inherent to the products and processes of biotechnology this approach is not adequate. Recombinant DNA technology is sufficiently risky and relatively new and, therefore, warrants special consideration in regulation. Canada's product-based system, combined with the regulators acting in the capacity of auditors, suggests the regulatory system places much value on being industry-friendly. Regulation occurs in the context of industry promotion. Cranor suggests that since experts embed moral choices in epidemiological surveys, criteria for risk assessment should be adjusted relative to particular contexts (Cranor 126). Canada's product-based approach was suggested by industry proponents in the European Community but as Levidow notes, this "proposal implied that any hazards could be objectively identified by knowing the genetic composition of a GMO, likewise, the proposal could more readily portray risk assessment as 'objective' by restricting the relevant uncertainties to available scientific knowledge" (Levidow 187).

Obviously the issue of a product-based system is accompanied by a much broader debate than I have included here. Having an industry-friendly regulatory system, or even one that is product-based for whatever reason, does not necessarily need to be problematic. In fact, a product-based system can produce good risk assessments if it is strengthened in certain ways such as the accompaniment of a system that acknowledges value-ladenness in risk assessment, and the view of objectivity as a result of peer review and communication. The criticisms of both product- and process-based systems can be addressed if these measures are taken. As I have argued, many of the problems associated with risk assessment and regulation stem from the untenable notion of *objectivity* in scientific endeavours and thus in risk assessment. I have discussed how many of these problems can be ameliorated by the recognition that risk assessment is not value-free but can be made less problematic through social discourse and the resultant enriched understanding of objectivity. In the context of the Canadian system of regulation, current changes to the system necessitate the employment of these strategies to avoid the unwanted consequences of an industry-friendly regime of regulation. These changes might allow the release of biotechnological innovations based on value-laden risk data. It is clear that, at present, the values informing risk assessment are those of the industry and the regulators. The values influencing risk assessments should be those that reflect the values of society and not only proponents of the technology. Objective risk assessment must be used in a science-based system of regulation. The risks associated with rDNA technology demand an increased level of regulatory control since they cannot be recalled or cleaned up when something goes wrong.

5.3 Conclusion

I have argued in this thesis that value assumptions are endemic to risk assessment. Risk always involves normative assumptions and therefore assessments of risk include such assumptions as well. Science is not objective in the sense that it is not value-free and since risk assessment is a scientific endeavour, it is not objective in this sense either. Therefore, not only is risk subject to the influences of background assumptions and values, but our quantitative assessments of their severity are subject to such assumptions as well.

Rescher argues that negativities are incommensurable and thus there are three major difficulties in relying on risk assessment information to understand the severity of risk. The problem of determining the magnitude of a risk, of the possible negativities an action might produce, and the lack of a common unit of currency with which to compare different types of risks all contribute to the difficulty in relying on risk assessments to inform our understanding of risky behaviour, actions or situations. Despite these difficulties, risk assessment continues to be widely perceived as a scientifically objective practice and thus a good arbiter of risk debate over the use of a number of technologies, products and processes in society.

The fact that risk assessment involves scientific techniques and results in the production of 'pure' data serves to reinforce the view that it is *objective*. As I have argued, however, the notion of *objective* science, or value-free science is untenable. Science is dependent on the assumptions that must be made in the production of any information. The positivist caricature of *objectivity* must be rejected in favour of the acknowledgement of the important role value assumptions play in science from the questions that we want to be answered, to the very production of the data we used to answer them. It is appealing to hold onto the view that science is objective and value-free because if it is,

> it can arbitrate between competing views about social policy options by demonstrating which ones imposed the greatest costs or risks upon the society and which ones generate the greatest compensating benefits; and it can do so by appealing to empirically demonstrable data and scientific principles universally accepted across a pluralistic society (Brunk, Haworth and Lee 235).

Since risk assessment is scientific, it too is considered *objective* and therefore free from normative considerations. As Putnam, Kuhn, Longino and many others have argued, however, science is observer-dependent and value-laden through and through. Thus, when risk assessors, government agencies and society rely on the *objectivity* of science, and therefore risk assessment, "what is essentially a value-laden political decision becomes disguised as politically and morally neutral" (Brunk, Haworth and Lee 245). The information relied on to guide decisions about which risks to face should be neutral information because it is used to restrict the liberties of individuals and corporations. The government in turn is expected to provide protection from new technologies for the general populace and the environment while also protecting the interests of corporations, institutions and individuals. *Objective* scientific risk assessment is supposed to provide this neutrality but, as I have argued, it cannot.

If it is understood that science is not *objective* in the positivist sense, identifying it as the product of social knowledge can enrich the understanding of objectivity. Objective science is dependent on the degree to which it withstands criticism from the scientific community, as Longino argues. It is then possible to have genuinely objective risk assessment to inform regulatory decisions. Risk assessment can also be subject to peer review and extensive debate within the scientific community. The value assumptions that are part of risk and risk assessment would not compromise their effectiveness or usefulness when making decisions about new technology such as biotechnology. If it is understood that such assumptions are a necessary part of the assessment process, then they can be identified and incorporated into the reports produced by assessors. These reports would then be scrutinized or subject to

extensive peer review within the scientific community thereby reducing the influence of particular value assumptions which may not be shared by everyone in regulatory decision-making.

In Chapter Three I gave a brief overview of biotechnology and the special type of risks associated with it. Due to the nature of risks associated with biotechnology, their temporal and geographical extent, and the fact that since transgenic science is so new there is very little existing knowledge with which to anticipate the effects of biotechnological products, regulators rely even more heavily on risk assessments for transgenic products than with any other technology. The need for objective risk assessment, therefore, is even more pressing in biotechnology fields particularly since experience with these organisms is limited and the long-term consequence of their release into the environment cannot be accurately anticipated. Combined with these problems is the very influential role industry has played so far in the progress of biotechnology and the existence of the biotechnology-industry complex. The development of transgenic science has been concurrent with the development of the biotech industry, which has become the major driving force of biotechnology both as a business and as a scientific discipline. The existence of this complex compounds the problems associated with relying on *objective* risk assessment to inform regulatory decisions because it adds the very influential interests of industry proponents to both the assessment of risk and to the process of regulation. Industry interests shape the progress of the science, the risks that get measured, and regulations, yet all of this occurs under the notion that science, risk assessment and therefore regulation, is *objective*.

The Canadian system of regulation is science-based and relies on risk assessments of new technologies like transgenic science to inform policy about its use and products. Despite the importance risk assessment has in regulation, the Canadian system is operated under the assumption that risk data is *objective*. There is no acknowledgement of the value

assumptions that are made in the production of risk data. Since 1997, the regulatory functions of a number of departments were consolidated into six primary departments while at the same time there was shift in the role of regulators from inspectors to auditors as noted by Prince. The CFIA maintains that assessments of risk occur within the confines of its offices however I find this notion problematic given a proper understanding of risk assessment.

As Schrader-Frechette explains, risk assessment occurs in three parts, risk identification, risk estimation and risk evaluation. The government determines the risks that corporations must measure, and then it evaluates the data those corporations submit with their application for regulatory approval. The corporate scientists and not the government scientists however, conduct risk estimation. Therefore, risk assessment is currently a collaborative effort by both the government and the corporation. Value assumptions are made at all three stages and thus corporate interests influence the data produced by risk estimation yet they go unrecognized by the government. Having regulators act as auditors of risk estimation data exacerbates the problems with value-ladenness because they have no way of identifying which assumptions are being made, and at what point during the risk estimation process they become incorporated. Regulatory decisions, then, are based on industry-biased information despite the fact that the forms the corporate scientists must fill out in their applications are produced and audited by the regulatory scientists. The regulatory scientists also make value assumptions in their assessment of the data submitted by the proponents in their determinations of a product's or technology's safety. These two levels of value assumptions, both the internal and external, are integral to the process of risk assessment and to the regulatory system based on it.

In Chapter Four I identified two different levels of value assumptions that occur in risk assessments. The assumptions an individual scientist must make in the laboratory while

conducting the risk estimation portion of risk assessment occurs at the internal level. Internal assumptions were made throughout the Alachlor case as reported by Brunk, Haworth and Lee and resulted in significant disparity in the results of the assessments conducted by the HPB and Monsanto. Regulatory scientists working for the HPB made assumptions that produced a worst-case scenario that was biased in favour of human health concerns while the assumptions Monsanto scientists made were biased in favour of the economic concerns of the corporation.

External assumptions were made throughout the rbGH case as reported by Mills. We saw that political, economic, and job pressures led to the disparity in the conclusions of the Canadian and American regulators despite the consensus about the actual data they based their conclusions on. American scientists placed the majority of the responsibility for animal health and monitoring of drug residues in the milk supply on the farmers. Additionally, government support for farmers in the US was being minimized while their global competitiveness was being increased through the use of agricultural biotechnology. In Canada on the other hand, the responsibility for animal health and drug residues in the milk supply fell to the regulators and there was no push to improve the competitiveness of Canadian farmers through the use of biotechnology.

Assumptions made at either the internal or external levels are not seen to compromise the *objectivity* of the risk assessments used in regulatory decisions. Therefore, industry-biased value-laden data produced during risk estimation is used by regulators who themselves make politically, economically or individually biased value-laden decisions concerning the regulatory approval of the products of biotechnology. The opportunity for socially constructed objectivity is absent since there is no acknowledgment of the assumptions being made at either the internal or external levels or risk assessment. The current developments in the regulatory process of GM wheat are evidence of this fact. This case also shows that even

in the most recent of cases, value assumptions are being made at both the levels I have described yet they are not addressed specifically. It is plausible to assume Monsanto scientists, in the production of the risk data submitted to the CFIA, have not made internal value assumptions since the corporation publicly espouses the benefits of GM wheat to wheat-growers and consumers. Similarly, external assumptions have been made by company scientists and will be made by regulatory scientists who are aware of the controversy surrounding the introduction of GM wheat. Not only can they not escape the public concerns regarding economic, environmental and health risks, but they are also under the added pressure of maintaining the bilateral agreement between Canada and the United States, as well as the possible uproar of the Canadian and American wheat growers.

Much of the debate surrounding GM wheat could be alleviated if we adopted regulatory policies, which reflect the enriched notion of objectivity I have described. Economic risks are significant because they affect the livelihoods of individual farmers, consumers and society. If Canadian farmers are uncompetitive with American or European farmers for instance, then the whole of Canadian society suffers. Rather than depending on the 'purely scientific' process of regulation the American wheat growers use to argue against Canadian concerns of economic risks associated with this new product, such concerns could be incorporated into the regulatory process. Objectivity arrived at through social discourse within the scientific community would not be compromised by incorporating the concerns of economic and financial risks in risk assessments. Since I have argued risk assessment is value-laden, it makes sense to include such concerns rather than to limit the values involved to the corporation scientists and regulators.

Whose values should be informing risk assessment and regulatory decisions? As I have described, the risks of biotechnology cannot be confined to the laboratory or a certain area or population. Transgenic organisms transcend geographical, political and physical boundaries

because they have the capacity to reproduce, crossbreed and disperse themselves in the environment. Since risk assessments must be relied upon to determine the safety of these organisms, and risk assessment is value-laden, then ideally the values of all those who will be affected must be involved in both risk assessment and regulation. This is impossible in practice, however, since not every person can be asked for his or her opinion, we cannot trust that every person's opinion is informed, all of these opinions cannot be incorporated into a coherent course of action since they would vary widely from individual to individual. Objective risk assessment and regulation must be relied upon to inform decisions of the use of transgenic organisms.

Genuine objectivity is a result of broad debate and peer review and policies reflecting this conception of objectivity could allow the ongoing use of risk assessment in the regulation of biotechnology while addressing the value assumptions that are endemic to it. At the internal level, peer review could be confined to those most qualified to conduct scientific assessments. Therefore, the production and assessment of risk data would still occur within the confines of the scientific community, but it would not be limited to the proponents and regulatory scientists. This information would be subject to peer review by scientists in a number of disciplines from a number of settings and would not be submitted to regulators until a consensus had been reached. Value assumptions made at the external level of risk assessment could be addressed by having regulatory decisions open to public debate, thus subject to an informal peer review.

In the previous section of this chapter, I outlined three recommendations that could be implemented to address the problems with value-laden risk assessment. When risk is understood to necessarily involve judgements, it follows that risk assessment is also value-laden. The unique nature of the risks associated with biotechnology and its products, the co-evolution of transgenic science with industry, the enormous economic benefits of

biotechnology and the shift in the role of regulators from inspectors to auditors in the Canadian regulatory system, all compound the problems with assuming that scientific risk assessment is *objective*. Regulatory decisions, which involve the loss of liberties by members of society, must be based on neutral information and so it is not wrong to rely on risk assessment to aid in the determination of which risks we will face as a collective. It is necessary, however, to understand objectivity as the product of extensive discussion and peer review. Therefore, the values that are involved in the risk assessment of biotechnology are not confined to those of a scientific nature nor are they confined to a particular group or agency. Opening the process of risk assessment to both the scientific community to address internal value assumptions, and to the public to address external value assumptions, enhances the ability to produce risk data that is objective. Objective risk assessment is a good arbiter of risk debate. In the case of biotechnology regulation, objectivity is perhaps even more strategic to determinations of safety since the risks we face from transgenic products are mostly unknown or unpredictable. This is a new science and there has been limited experience with not only its long-term effects, but also with the interaction transgenic organisms have in the environment. Once released, these organisms typically cannot be recalled or cleaned up.

Biotechnology includes environmental, health, economic, cultural, societal, and political risks. It also provides an unprecedented tool to solve some of the most persistent and devastating problems that must be faced such as famine, genetic disease, lack of resources, poverty, health problems, environmental degradation and pollution. Reaction to possible risks should not be based on unconvincing evidence or unfounded fears. The interests of corporations should not be allowed to determine which risks will be measured or what is an acceptable level of risk. Care must be taken to avoid relying on *objective* scientific risk assessment, which I have argued, is not genuine. Decisions concerning the safety of

biotechnology should be open to broad debate and include risks of many types not only to make risk assessment genuinely objective and thus a useful tool, but also to address the concerns of as many of the people who will ultimately be left to face these risks.

References

Anderson, Luke. *Genetic Engineering, Food and our Environment*. Vermont: Chelsea Green, 1999.

Arundel, Anthony. "Measuring the Economic Impacts of Biotechnology: From R&D to Applications." *The Economic and Social Dynamics of Biotechnolgy*. eds. de la Mothe, John and Jorge Niosi. Boston: Kluwer, 2000. 83-100.

Baier, Annette. *Postures of the Mind: Essays on Mind and Morals*. Minneapolis: University of Minnesota Press, 1985.

Barnum, Susan. *Biotechnology: An Introduction*. Scarborough Ont.: Wadsworth, 1998.

Bauer, Martin and George Gaskell. "Towards a Social Theory of New Technology." *Biotechnology: The Making of a Global Controversy*. eds. Bauer, Martin and George Gaskell. New York: Cambridge UP, 2002. 379-404.

Bereano, Philip. "Some Environmental and Ethical Considerations of Genetically Engineered Plants and Foods." *Changing Nature's Course: The Ethical Challenge of Biotechnology*. ed. Becker, Gerhold. Hong Kong: Hong Kong UP, 1996. 27-35.

Brunk, Conrad, Lawrence Haworth and Brenda Lee. "Is Scientific Assessment of Risk Possible? Value Assumptions in the Canadian Alachlor Controversy." *Dialogu*e, XXX (1991), 235-247.

---. *Value Assumptions in Risk Assessment: A Case Study of the Alachlor Controversy*. Waterloo, Ont.: Wilfred Laurier UP, 1991.

Canada. Canadian Biotechnology Advisory Committee. *Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee*. Aug. 2002.

Canada. Canadian Food Inspection Agency Plant Biosafety Office. *Canada and United States Bilateral on Agricultural Biotechnology*. 9 April 2003, <www.inspection.gc.ca/english/plaveg/pbo/usda/usda01e.shtml >.

Canada. Canadian Food Inspection Agency Plant Biosafety Office. *Submission to CFIA for approvals of Roundup Ready Wheat questions and answers.* 2 March 2003, < www.inspection.gc.ca/english/plaveg/pbo/monsane.shtml>.

Canadian Wheat Board. *A Discussion Paper on Agronomic Assessment of Roundup Ready Wheat*. 15 April 2003, < www.cwb.ca/en/publications/farmers/pdf/rrw.pdf>.

Carlsson, Bo. "A Systems Framework for the Study of Economic and Social Dynamics of Biotechnology." *The Economic and Social Dynamics of Biotechnolgy*. eds. de la Mothe, John and Jorge Niosi. Boston: Kluwer, 2000. 9-27.

Colman, David. "Biotechnology and Agriculture." *Ethics and Biotechnology*. eds. Dyson, Anthony and John Harris. New York: Routledge, 1994.

Cranor, Carl. "Some Moral Issues in Risk Assessment." *Ethics*, 101(1990), 123-143.

Cutter, Susan. *Living with Risk: The Geography of Technological Hazards*. New York: Edward Arnold, 1993.

Dhanda, R. *Guiding Icarus: Merging Bioethics with Corporate Interests*. New York: John Wiley and Sons, 2002.

Doern, Bruce and Ted Reed. Eds. *Risky Business: Canada's changing science-based policy and regulatory regime*. Toronto: University of Toronto Press, 2000.

Fischoff, Baruch, Stephen Watson and Chris Hope. "Defining Risk." *Readings in Risk*. eds. Glickman, Theodore and Michael Gough. Washington D.C.: Resources for the Future, 1991. 30-49.

Horsch, Robert. "Biotechnology and Sustainable Development." *Biotechnology and Biosafety: Proceedings of the Fifth Annual World Bank Conference on Environmentally and Socially Sustainable Development*. eds. Serageldin, Ismail and Wanda Collins. Washington D.C.: The World Bank, 1999. 25-30.

Juma, Calestous. *The Gene Hunters*. Princeton N.J.: Princeton UP, 1989.

Klug, William and Michael Cummings. *Concepts of Genetics*. Toronto: Collier Macmillan. 1991.

Kuhn, T. "Objectivity, Value Judgment and Theory Choice" *Readings in the Philosophy of Social Science*. eds. Brody, Baruch and Richard Grandy. New Jersey: Prentice-Hall, 1989. 356-368.

Lappé, Marc and Britt Bailey. *Against the Grain: The Genetic Transformation of Global Agriculture*. London: Earthscan Publications, 1999.

Leahy, Stephen. "Biotech Hope and Hype." *Maclean's* Sept. 30, 2002: 40-42.

Levidow, Les. "Antagonistic Ethics Discourses for Biotechnology Regulation." *Contested Technology: Ethics, Risk and Public Debate*. ed. Rene von Schomberg. The International Centre for Human and Public Affairs, 1995. 179-189.

Levidow, Les and Susan Carr. "How Biotechnology Sets a Risk/Ethics Boundary." *Agriculture and Human Values*. 14 (1997): 29-43.

Longino, Helen. "Values and Objectivity." *Science as Social Knowledge: Values and Objectivity in Scientific Inquiry*. Princeton, N.J.: Princeton UP, 1990.

Mills, Lisa. *Science and Social Context: The Regulation of Recombinant Bovine Growth Hormone in North America*. Montreal and Kingston: McGill-Queen's UP, 2002.

Monsanto. *Bringing New Technologies to Wheat: Information on the Development of Roundup Ready™ Wheat.* 28 April 2003, <www.monsanto.com/monsanto/content/media/wheat.pdf.>.

National Association of Wheat Growers. *Wheat Organizations Restate Need for Science Based Regulation of Biotech*. 28 May 2003, <www.wheatworld.org/html/news.cfm?ID=318>.

Nelkin, Dorothy and Michael Pollak. "Problems and Procedures in the Regulation of Technological Risk." *Societal Risk Assessment: How Safe is Safe Enough?* eds. Schwing, Richard and Walter Albers Jr. New York: Plenum, 1980. 233-253.

Old, R.W. and S.B. Primrose. *Principles of Gene Manipulation: An Introduction to Genetic Engineering*. Mississauga Ont.: Copp Clark. 1994.

Prince, Michael. "The Canadian Food Inspection Agency: Modernizing Science-Based Regulation." *Risky Business: Canada's changing science-based policy and regulatory regime*. eds. Doern, Bruce and Ted Reed, Toronto: University of Toronto Press, 2000. 209-233.

Putnam, H. "Perceiving Facts and Values" *Philosophy* 73.283 (1998), 5-19.

Rasmussen, Norman. "The Application of Probabilistic Risk Assessment Techniques." *Readings in Risk*. eds. Glickman, Theodore and Michael Gough. Washington D.C.: Resources for the Future, 1991. 195-205.

Rescher, Nicholas. *Risk: A Philosophical Introduction to the Theory of Risk Evaluation and Management*. Washington, D.C.: University Press of America. 1983.

Rifkin, Jeremy. *The Biotech Century*. New York: Penguin Putnam, 1998.

Saskatchewan Soil Conservation Association. *Roundup-Ready Wheat Position Paper*. 30 April 2003, <http://ssca.usask.ca/Positions/RRposition.htm>.

Sass, Hans-Martin. “Moral Risk Assessment in Biotechnology.” *Changing Nature’s Course: The Ethical Challenge of Biotechnology*. ed. Becker, Gerhold. Hong Kong: Hong Kong UP, 1996. 127-144.

Senker, Jacqueline. “Biotechnology: Scientific Progress and Social Progress.” *The Economic and Social Dynamics of Biotechnolgy*. eds. de la Mothe, John and Jorge Niosi. Boston: Kluwer, 2000. 53-68.

Shrader-Frechette, Kristin. *Risk Analysis and Scientific Method*. Boston: Reidel, 1985.

Thompson, Paul. *Agricultural Ethics: Research, Teaching and Public Policy*. Ames: Iowa State UP, 1998.

Van Acker, R. and M. Entz. “Agronomic Benefits and Risks of Using Roundup Ready Wheat in Western Canada.” *Proceedings Manitoba Agronomist Conference,University of Manitoba, Winnipeg*. 2001. 173-180, <www.umanitoba.ca/afs/agronomists_conf/proceedings.html>.

Yarrow, Stephen. “Biosafety Issues of Genetically Engineered Herbicide-Tolerant Plant: Agriculture and Agri-Food Canada’s Perspective.” *Biotechnology, Biosafety and Biodiversity*. eds. Shantharam, Sivramiah, and Jane Montgomery. New Hampshire: Science Publishers, 1999. 41-50.

Yount, Lisa. *Biotechnology and Genetic Engineering*. New York: Facts on File. 2000.