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Carleton University

**Deconstructing a “Science-Based” Regulation: Towards Rendering the Risks of
Genetic Engineering Visible**

**A thesis submitted to
the Faculty of Graduate Studies and Research
in partial fulfillment of
the requirements for the degree in
Master of Arts**

Institute of Political Economy

**by
Lucy Sharratt**

Ottawa, Ontario

**January 2001
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DECONSTRUCTING A "SCIENCE-BASED" REGULATION:
TOWARDS RENDERING THE RISKS OF GENETIC ENGINEERING VISIBLE

submitted by Lucy Sharratt, B.A. Hons.,
in partial fulfilment of the requirements for
the degree of Master of Arts

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Abstract

In this thesis I argue that, in Canada, restrictive definitions of risk are produced through the construction of a “science-based” regulation of genetic engineering. Science-based regulation defines the risks of genetic engineering as technical issues where scientific criteria are privileged in risk regulation above non-scientific considerations such as socio-economic and ethical concerns. The science basis thus constructed dismisses the qualitatively new risks of genetic engineering. It marginalizes lay knowledge and restricts lay participation in risk evaluation. I argue that science alone is unable to evaluate the risks of genetic engineering in agriculture and that the construction of science-based regulation enhances the risks of genetic engineering and aggravates lay-expert conflict in risk evaluation. I argue that the narrowing of definitions of risk to scientific or technical issues is shaped by a particular policy community in order to successfully commercialize products of genetic engineering. Science based regulation is used to promote innovation and legitimate genetic engineering. I conclude that in order for abandonment of genetic engineering to become a political possibility, lay knowledge and non-scientific criteria in risk evaluation must be engaged and contestation must move outside regulatory institutions that are now implicated in risk manufacture and legitimation.

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Chapter One

1. Introduction

There are many terms that are used to describe genetic engineering or genetically engineered organisms including transgenics, genetically altered or genetically modified organisms, and biotechnology or "modern biotechnology." Though these terms could be used interchangeably, the defining and naming of genetic engineering is highly contested. Through the Canadian Environmental Protection Act, the Canadian government defines biotechnology broadly as, "the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms, in their natural or modified forms."

(Canada, Workshop 1993: 6) The Saskatchewan biotechnology industry lobby group Ag-West Biotech Inc. offers the following explanation of the use of the term biotechnology:

"Biotechnology involves the use of biological technologies to produce agricultural products and manufacture foods. The term biotechnology is sometimes used to describe traditional food processing methods, such as the use of microbes in the manufacture of cheese, wine and bread. More often, biotechnology is used to describe advanced methods of plant and animal breeding, including genetic engineering." (Ag-West Biotech Inc. Autumn 1998: 2) In this thesis I will argue that genetic engineering is distinct from other techniques that are generally included in the term biotechnology, traditional plant breeding in particular, and maintain the importance of pulling genetic engineering out of this blanket term.¹ I argue that the term genetic engineering

¹ For the sake of convenience I use the term "biotechnology industry" to describe the industry that develops and owns products of genetic engineering for agriculture, the self-named "Life Sciences Industry." Though there are distinct corporate cultures within the biotechnology industry, the community of biotechnology proponents in

offers the most accurate description of this new technology and will argue this position through an analysis of its risks.

The biotechnology industry had hoped to introduce genetic engineering onto the market without naming the technology or its products for the public or even farmers.² There is no labelling or segregation of genetically engineered foods in Canada or the United States, currently the two largest markets for these foods. To date there are over 40 genetically engineered plant varieties approved by the Canadian government (most are varieties of corn, canola, soy and potato), but without labelling no shopper can identify these foods on grocery store shelves. It is only since the summer of 1999 that media attention and the campaigns of non-governmental organizations have made any diversity of information on genetic engineering available to the public. Since 1995 when the first genetically engineered food was approved for sale, Canadians have been eating genetically engineered ingredients without their knowledge - most having never even heard of genetic engineering.

Simon Barber of EuropaBio, Europe's premier biotechnology industry lobby group, attempts to leave genetic engineering unnamed altogether:

Eight years ago, working in the Food Production and Inspection Branch of Agriculture Canada, I decided that there was no such thing as "biotechnology." I considered that there was a quickly growing knowledge base about living things (biology) and, resulting from this there were new methods of harnessing biological systems (technology) for our own benefit...Today I remain convinced that there is no "biotechnology," yet the public is

Canada is a closely knit like-minded group of individuals, corporations, and "not for profit" groups that converge in a push for the successful development and commercialization of genetic engineering.

² Monsanto advertised its new "NatureMark" potatoes in seed catalogues without making clear that the insect-resistant potatoes were produced through genetic engineering (the transfer of a gene from the soil bacteria *Bacillus thuringiensis* or Bt into potato DNA). Likewise, consumers were handed a pamphlet in grocery stores that introduced them to, "NatureMark potatoes - grown in a better way": "these plants have a built-in protein taken from nature which is part of a family of proteins used by home gardeners for more than 30 years." (Monsanto quoted in Kneen 1999:116-117) As Brewster Kneen observed, NatureMark was identified itself as a potato seed company based in Boise, Idaho rather than as a subsidiary of the multinational chemical company Monsanto. (1999:117)

concerned about “it” and governments have developed and continue to develop national and international horizontal legislation to control “it.” (Barber 2000)

The Canadian Food Inspection Agency uses the term “novel foods” in its regulation of genetic engineering, a term that was created to accommodate the regulation of genetically engineered products but was specifically designed to avoid naming the process of genetic engineering and avoid distinguishing it from those already established in agricultural production. Canadian regulation is based on a review of the products of genetic engineering rather than the processes. I will argue that this is only one way in which Canadian regulation refuses to acknowledge the new character of genetic engineering and works to deny and conceal its risks.

I argue that naming genetic engineering is a first step in making the risks of this new technology visible. Throughout this thesis I will analyse the risks of genetic engineering and what I argue are institutional failures to recognize and deal with them. My examination focuses on the structures and discourses of a “science-based” regulation for products of genetic engineering in agriculture in Canada that I argue are designed to deny and conceal these risks.

In research for my undergraduate thesis on the struggle in Canada over the introduction of the genetically engineered drug recombinant Bovine Growth Hormone (rBGH), I spent a great deal of time with industry policy documents and I was immediately struck by the repetition, and vagueness, of a central demand put forward by industry associations for “science based” regulation of genetic engineering. I had thought that the scientific basis was assumed; why was industry pressing this point? I wanted to unpack the industry demand for science based regulation and identify and scrutinize the actors and interests behind its promotion. Through my research I have come to understand that the “science basis” of regulation is a significant concept that I argue is used as a defining tool in shaping the regulation of this new technology. I argue that the regulatory review process for products, often

referred to as the "approval process," can be seen as the clearest expression of government policy towards genetic engineering. The industry has centered many of its demands on the shape of this process and relies heavily on structures of, and trust in, government regulation to ensure the future of this technology.

Science is the center of safety reviews for new food and agriculture technologies but the science based review for genetically engineered products is a particular construction. Through this thesis I argue that the construction of science based regulation serves specific purposes towards the commercialization of genetic engineering and is integral, not just to commercialization strategies, but also to industry communications strategies or strategies to gain public acceptance. In pressing for science based regulation industry has anticipated challenges to their definitions of the risks and benefits of genetic engineering. I argue that the privileging of scientific criteria in regulation narrowly circumscribes the parameters of inquiry into the risks of genetic engineering to technical issues and expert knowledge, thereby excluding social and ethical concerns and constraining public participation. In this thesis I am not able to examine the possibilities for public or lay participation in risk evaluation nor investigate the possible valuable contributions of lay knowledges to risk evaluations of genetic engineering but I will suggest their character and some broad implications of their engagement.

Since beginning my inquiry into the construction of science based regulation, details of Health Canada's review of rBGH have drawn my attention to some complexities of using science in policy making and some of the difficult realities of regulatory practice. Scientific evaluators in Health Canada alleged that they were pressured to approve products of questionable safety, as a direct result of industry pressure for speedy regulatory approval. Their story highlights some manifestations of industry influence over the use of science in the

regulation of genetic engineering and suggests multiple dimensions to the story of science in policy making.

Over the course of my research for this thesis the struggle over genetic engineering has become subject to a new level of public and media scrutiny (such that the media have renamed genetic engineering "Frankenfood"). In response to growing demands from the public for government to describe and justify the regulation of genetic engineering there has been an increasingly rigorous adoption by government and industry of the rhetoric of the science-basis. I have watched the science basis of regulation be used by both government and industry as the core concept in assurances to the public of the safety of genetically engineered foods. I argue that as genetic engineering becomes more controversial and as opposition to its use in agriculture grows, we are seeing an extended enrollment of "science based" regulation in ways that point toward the engagement of government regulation in industry profit maximization strategies. I am interested to see the future success of this strategy as well as its implications for democracy and the future of genetic engineering, particularly if institutions are confronted with lay knowledge and public participation, moving risk evaluation outside regulatory structures and expert dominated risk assessment.

2. Concept of the Risk Society

In this thesis I use the concept of the risk society to shed light on the risks of genetic engineering. I argue that the perspective of the risk society is helpful in making the risks of genetic engineering visible. Ulrich Beck, leading proponent of the risk society thesis, describes the risks that characterize and comprise the risk society as risks of a qualitatively new type. I draw on Beck's description of these risks to examine the character of the risks of genetic engineering. I

examine features of the risks of genetic engineering including the ability of these risks to cross boundaries of time and space. Using the concept of the risk society I can place genetic engineering among other risks that are manufactured in industrial society and, from here, engage in a broader and deeper analysis of the origins of these risks and the implications of their manufacture and management for risk evaluation and democracy.

The concept of the risk society is also useful in examining the role of science in the manufacture of risk and the inability of science and institutions of industrial society to manage these risks. The use of science in government and industry strategies of commercialization and legitimation is problematic in a number of ways. The use of science appeals to a lay trust in science that may no longer exist. As Beck argues, mistrust in science and a lay consciousness of risks challenge scientific risk assessment. Beck's thesis offers an approach to understanding the failures of conventional risk management as, in part, a function of the character of the risks themselves.

In industrial society, technologies such as genetic engineering promise liberation from uncertainties that threaten disease, hunger, and death. Scientific "advancement" promises perpetual progress toward a more secure future³ but I agree with Beck that the outcome of these attempts to overcome uncertainty is the manufacture of risks of a qualitatively new type. Science and scientific progress promise security but are exposed in the risk society as creating new insecurities where the marvels that science can produce, it cannot control.

Science is at once one of the causes, the medium of definition, and the source of solutions to risks. (Beck 1992:155) Science is centrally implicated in the manufacture of risk where the

³ In 1999, Dupont, now a major investor in genetic engineering technologies, changed their company slogan from "Better Things for Better Living" to *The miracles of science*™. When asked whether Dupont is a materials company or a Life Sciences company, Dupont CEO Chad Holliday responds that the corporation is a science company. (Holliday 1999)

victories of science propel perpetual innovation in industrial society and produce new and increasingly complex risks that threaten both life and livelihood. As Beck argues, "it is not their failure but their *success* that has *dethroned* the sciences." (1992: 161) Raymond Murphy argues that, "if science accepts credit for the achievements of applied science, then science must accept blame for the harmful consequences of its development." (1994: 194) In the risk society, consciousness of the role of science in risk manufacture and the inability of science to calculate and manage risks ultimately undermines the epistemic authority of science.

In industrial (risk) society we are asked to accept risks as accidents rather than as intrinsic to high technologies, manufactured. Charles Perrow (1984) names the failures of high technologies "normal accidents," as a description, not of their frequency, but of the inherent volatility of technological systems. Perrow argues that accidents in technological systems are uncommon, even rare, but that this is not at all reassuring if failures result in extreme harm or catastrophe. (1984:5) High technological systems such as nuclear power and genetic engineering are built around complex and tightly coupled interactions such that no matter how effective safety mechanisms are, "accidents" are inevitable. The defining of high technology risks as accidents is part of constructing the fiction that science produces certainty. (The biotechnology industry defends its definition of acceptable risk by arguing that there is no such thing as zero risk.) In industrial society the institutional regulation of risk through reliance on conventional scientific risk assessment constructs, in Beck's term, a "security fiction" that risk calculation and predictability are possible.

According to Beck, security fictions ultimately break down in what he calls "anthropological shocks" where disasters or technological failures make risks suddenly apparent to lay people and create new conditions of fear. While Beck argues that lay mistrust and critique of science are a result of such failures, Brian Wynne argues that these disasters simply propel pre-

existing lay mistrust of high technology and expert knowledge to the fore. (Wynne) In the risk society lay consciousness of risks seeps into the everyday as the tools or means of living themselves become threats to life. Risks that cannot be controlled, managed or even detected by the institutions of industrial society collapse assurances of scientific mastery over nature and break apart the security fictions upon which industrial society is based.

Beck defines experience as sensory understanding of the world and argues that in the risk society experience, once the main authority and judge of truth, becomes the quintessence of the subjective, a relic and a source of illusion because risks in the risk society are invisible. (1995:15) We cannot rely on our senses, Beck argues, because they are unable to detect the new risks. In the risk society, however, science is equally a source of illusion and many risks remain invisible to scientists and scientific method. Thus the new dangers remove the conventional pillars of safety calculation. (Beck 1996:15,13) Risks of the risk society create new challenges for institutions of industrial society engaged in risk management activities.

Security in science is used to sell genetic engineering but, paradoxically, fear is also cultivated by the biotechnology industry in a dire diagnosis of the world's problems - problems for which genetic engineering is promoted as the only solution. Genetic engineering is sold as the solution to world hunger and increasing environmental degradation in an attempt to justify and legitimate genetic engineering as a technological fix for problems that are largely social, political, and economic rather than technical. Ag-West Biotech Inc. describes the need for genetic engineering in the following terms: "a growing world population puts immense pressure on food production capabilities. The environment is under stress from traditional farming techniques,

pollution and shifting weather patterns."⁴ (Ag-West Biotech Inc. 1993) Monsanto Company, one of the world's largest chemical multinationals and a world leader in the development of genetically engineered products for agriculture, uses both fear and promise to sell the benefits of genetic engineering. Monsanto characterizes world hunger in neo-Malthusian terms as the result of overpopulation. Monsanto defines food insecurity as a technical problem that can be reduced to a simple equation, demanding a scientific solution:

By the year 2050 there will be 10 billion people on earth - nearly twice the number of today; they will require more than twice the amount of food we produce, for the increased population plus needed improvements in diet and nutrition. (Monsanto *Common Ground*: 2) The principle problem that faces agriculture worldwide - over the next 40 years and beyond is that current techniques will be insufficient to provide food output and diet improvements that will be needed...Only by continuing to innovate through improved systems, imaginative chemistry and biotechnology can we hope to achieve global sustainable agriculture. (Monsanto, *Common Ground*: 16)⁵

The flip-side of risk is benefit and promises of advantages of genetic engineering are a powerful component of the industry's risk definition (risk-benefit analysis). Faced with the global threat of hunger and environmental degradation Monsanto promises "Food, Health, Hope," achievable through the limitless possibilities of science and high technology innovation:

Imagine farm animals that produce leaner meat and more milk at less cost. Biotechnology offers new ways to improve the health and efficiency of farm animals...New ways to improve the competitiveness and profitability of farmers...And, new ways to make food healthier for consumers. Monsanto scientists are working with nature to develop innovative products for people of today and in the future. (Monsanto Company advertisement, Fall 1988)

⁴ Rather than identifying techniques of industrial agriculture as a source of environmental degradation the biotechnology industry places blame on traditional agriculture practices, criticizing organic agriculture for soil erosion and extensive land use. (Monsanto *Common Ground*)

⁵ International aid agencies have criticized Monsanto and others for using hunger in the developing world to justify genetic engineering. (*The Independent* July 25 1998)

Monsanto's slogan "Food, Health, Hope" describes its attempts to shape lay fears and hopes. While dismissing "unfounded fears" Monsanto works to cultivate others. I argue that this attempted manipulation of popular fears forms part of a coercive corporate communications strategy that is appropriate to selling food security based on structures of dependency. As Vandana Shiva argues, the "Life Sciences Industry," rather than creating and trading in life, peddles in death. (1998)

Dependency on corporately developed and owned technologies for food production is an insecure future for farmers. It is the precarious dependence on high technologies and the emerging consciousness of their risks that forms the risk society. Monsanto declares that, "farming today is more science than art," where their technologies offer more control, precision and predictability than traditional farming practices, including traditional plant breeding. (Monsanto *Common Ground*: 5) The possibilities offered by scientific successes allow corporations like Monsanto to define agricultural productivity and food security in terms of technological invention and intervention. Processes of industrialization are replacing farming with agri-food production systems that substitute biological processes with products of science such as chemical pesticides, transforming natural uncertainties in food production into manufactured risk. I argue that the scientific "solutions" introduced into agriculture through processes of industrialization have created dependency on high-technologies and enhanced insecurity. I will discuss this dependency as a feature of industrialization in agriculture through an examination of the origins of genetic engineering in the technologies and social relations of the Green Revolution. I link the concept of the risk society to an analysis of the role of capitalist innovation in risk manufacture in order to examine what I argue are the capitalist underpinnings of the risk society. Schumpeter's theorizing of innovation is helpful in exploring the dynamics of innovation for profit that push new technologies forward. I engage work in the

political economy of agriculture to locate genetic engineering in a specific time and place in the history of capitalist innovation in agriculture and inquire into the place of genetic engineering in processes of risk manufacture.

I argue that the state is using risk regulation to fulfil its roles in promoting innovation and legitimating the introduction of new technologies. I argue that the elevation of scientific criteria through the science-based regulation of genetic engineering is part of an overall strategy to successfully and definitively launch the "Life Sciences" industry. Actors in the biotechnology industry explicitly demand the privileging of scientific criteria in product review above other considerations such as socio-economic and ethical concerns. This privileging of science is supported by historical processes that have elevated the status of quantifiable or codifiable knowledge and excluded and delegitimized other knowledges. I want to acknowledge the contributions of feminist critiques of western science that inform my examination of the processes and the implications of this elevated status.

I will explore the possibility that the attempted manipulation of lay fears and hopes may be rejected in lay risk evaluations and lay critiques of science. I offer my critique of the use of science in the regulation of genetic engineering as a challenge to the definitional authority of science and industry and to those definitions of our lives and living, our relationships to food, nature, and to one another, that are produced through genetic engineering. I argue that public struggle over genetic engineering must conclude in a validation of lay knowledges and knowledge systems.

3. Analytical Tools

I use the work of Paul Pross (1986) to identify actors engaged in regulation and policy formation, members who constitute what Pross calls a "policy community." I examine the relations of members of the policy community to one another and to policy outcomes. In examining processes of regulation formation I wish to account for the dynamic relations between actors where the configuration of the policy community can alter as the political struggle over the regulation of genetic engineering and the definitions of risk change. While focussing on actor influence over processes of regulation formation I wish to argue, as Liora Salter does, that regulatory changes are far more complex than the term "deregulation" suggests. Salter argues that political economy critiques of regulation tend to focus on industry "capture" of regulatory agencies in an analysis that directs attention away from important dynamics internal to regulatory agencies. I examine the testimony of Health Canada scientists, at union grievance and Senate hearings, in order to investigate relationships inside the department.

The policy community constructs what Jane Jenson calls the universe of political discourse, a concept which I use to further develop my examination of processes of regulation formation. Jenson's concept enables an investigation into the processes of meaning construction in the struggle over the regulation of genetic engineering in agriculture. I explore how the elevation of scientific criteria is achieved through the universe of political discourse as described by Jenson: "Within the universe, the parameters of political action are established by the process of *limiting the set of actors* accorded the status of legitimate participants; *the range of issues* considered within the realm of political debate; *the policy alternatives* considered feasible for implementation; and, finally, *the alliance strategies* available for achieving

change." (1986:26)(emphasis added) The policy community constructs the universe of political discourse where the universe serves to further limit the set of actors accorded status as legitimate participants in policy formation.

Steve Tombs and Dave Whyte's study (1998) of the strategies used by corporate actors to promote their interests in the regulation of the British offshore oil industry reflects many of the relations that I investigate in the universe of political discourse as influencing, and being replicated in, the regulation of genetic engineering. Tombs and Whyte argue that the rhetoric of the need to survive international competition can become unchallengeable and thus a powerful propaganda tool for industry in pressing their demands on government regarding the shape of regulation. I examine how, in the regulation of genetic engineering, the rhetoric of efficiency and competition is used to press for the speedy and largely unquestioned commercialization of products. In the case of British policy toward the offshore oil industry, there is a symbiotic relationship between the deregulation discourse of government and the demands of industry. Tombs and Whyte elucidate how corporate demands are supported by key themes, including globalization discourses. Drawing from this analysis, I identify five main themes that dominate the universe of political discourse around the formation of regulation of genetic engineering. These themes emerge in the industry discourse that promotes genetic engineering and are key in shaping regulation as well as in influencing daily decision-making inside government departments. I identify regulatory agencies as actors enrolled in constructing the universe of political discourse and I investigate the role of bureaucracies in supporting and reproducing industry themes.

4. Chapter Outline

In chapter two I introduce genetic engineering as a scientific and industrial project of control. I define genetic engineering through an examination of its risks, both physical and social, and describe how these risks fit into the profile of risks of the risk society. I introduce institutional failure in the risk society in terms of the role of science and institutions in the manufacture of risk as well as in risk assessment. I suggest the incorporation of a political economy approach to risk society study in order to take account of the capitalist underpinnings of risk manufacture. I introduce a political economy approach through an examination of the origins of genetic engineering in the technologies and social relations of the Green Revolution. Genetic engineering is thus placed in a context of historical processes of industrialization in agriculture and the rise of agribusiness and capitalist risk manufacture. I end the chapter with an examination of lay mistrust in science and lay-expert conflict over risk.

In chapter three I examine the appeal to science by the state in risk regulation. Science is used by the state in response to the challenges posed by the risks of genetic engineering. Institutional crisis is discussed in this chapter in terms of the failure of scientific risk calculation and expert risk assessment. The institutions of industrial society fail to come to terms with uncertainty and continue instead to rely on the language of certainty through the enrolment of science in policy processes. The privileging of science in the regulation of genetic engineering enhances unrealistic expectations of science and further marginalizes lay knowledge, constraining democratic participation. In the case of genetic engineering this approach reflects an industry strategy to use science-based regulation for commercialization and legitimation. The state has an important role to play in promoting innovation and legitimating the introduction of new technologies and I examine the appeal of science in terms

of the state's interest in meeting these goals. I end this chapter with an examination of the construction of science based regulation in international regulation.

In chapter four I outline the actors and strategies, through an examination of the policy community and the construction of the universe of political discourse, that are key in forming the discourse and structures of science based regulation. I describe the mutually reinforcing relationship between the policy community and the universe of political discourse. I argue that industry actors dominate a policy community whose primary goal is the commercialization of genetic engineering. The universe of political discourse that is created by the policy community further restricts the circle of actors who participate and the range of issues considered. I argue that the push for "science-based" regulation is an expression of industry dominance in the policy community and over the themes of the universe of political discourse. I outline five themes that I argue dominate the universe of political discourse and I examine the incorporation of these themes into the regulatory framework and regulatory practice. I examine industry demands for science-based regulation of genetic engineering.

In chapter four I also briefly look at consultations and expert committees that I argue are constructed to legitimate the regulation of genetic engineering and restrict public debate. These constructions serve to segregate non-scientific concerns and further marginalize lay knowledge. The unequal balance of power in the policy community is reflected in stakeholder consultations that are bound by the restrictions of a regulatory framework that accepts the benefits of genetic engineering while denying and concealing risk.

In chapter five I argue that the abandonment of genetic engineering needs to become a policy option and that to achieve this public debate has to move outside the site of the regulatory system and the policy community to new spaces of resistance where lay risk evaluation can be legitimated. I argue that public struggle over genetic engineering must

conclude in a validation of lay knowledge and knowledge systems and that this would mean, at the least, the incorporation of social and ethical considerations in risk evaluation. I briefly look at public protest to government approval of rBGH as suggestive of possibilities for lay evaluation in making risk visible.

The definitions of risk that are constructed through the science-based regulation of genetic engineering enhance risk. These definitions are the product of a policy community and universe of political discourse that is dominated by industry. The regulatory narrative denies the new character of genetic engineering and describes the risks of genetic engineering as physical or technical only, excluding consideration of possible threats to social identity. The risks of genetic engineering need to be made visible.

Chapter Two

Towards Rendering the Risks of Genetic Engineering Visible

Introduction

In this chapter I introduce genetic engineering in agriculture as a scientific, commercial, and social project of control that manufactures qualitatively new risks. It is these risks that I argue largely define genetic engineering. Drawing from critiques of genetic engineering offered by scientists and social critics, most prominently scientists Vandana Shiva and Mae-Wan Ho, I argue that genetic engineering is an unstable science that is inherently dangerous. Shiva and Ho argue that genetic engineering is based on faulty assumptions about the natural world and the ability of science to know and control it. I argue that the consequent risks challenge conventional risk calculation and risk management models, models that form the basis of Canadian government regulation of genetic engineering.

In this chapter I locate genetic engineering and its risks in the "risk society." The concept of the risk society highlights the features of qualitatively new risks that are manufactured in industrial society as well as the challenges that these risks pose to institutions of industrial society. The notion of the risk society offers a sociological approach to understanding the effects of lay risk consciousness on critiques of science and industrial society at this point in time. The risk society thesis and related risk literature challenge institutional reliance on science and expert knowledge in risk assessment.

I suggest the incorporation of political economy analysis to the sociology of the risk society in order to render the risks of the risk society increasingly visible. Through a political

economy approach that identifies actors and examines their relations to one another I inquire into processes of risk manufacture in industrial society and examine the capitalist underpinnings of the risk society. I trace the role of power and capital in risk manufacture through the dynamic of innovation for profit as seen in processes of industrialization in agriculture - in a history from the rise of transnational agribusiness through the Green Revolution to the current commercial project of genetic engineering. This examination points to the origins of risk in capital accumulation strategies and offers an historical and political context from which to scrutinize institutional attempts to regulate risk.

In the last section of this chapter I outline how both the social and physical risks of genetic engineering are subject to lay risk evaluations that conflict in significant ways with expert risk assessments. In this conflict, lay mistrust of science and centralized expert knowledge becomes a central challenge to the regulation of risk. I will introduce lay mistrust as a challenge to the use of science in government risk assessment.

1. New Sciences and Qualitatively New Risks

1.a: Genetic Engineering Distinguished From Traditional Plant Breeding

The biotechnology industry, as part of an aggressive public relations campaign that aims to alleviate popular fears about genetic engineering, defines genetic engineering in agriculture as an extension of traditional plant breeding techniques. (See Ag-West Biotech Inc. Autumn 1998, Ag-West Biotech Inc. *From Field to Plate* undated, Canadian Produce Marketing Association December 1995) Dr. Wilf Keller of the Plant Biotechnology Institute at

the National Research Council, for example, argues that, "biotechnology is used for the fine tuning of living organisms. We are altering - not creating."⁶ (Canada, Workshop 1993:18)

This definition invites familiarity with genetic engineering through an association with the established and trusted (culturally accepted) techniques of traditional plant breeding, techniques that lay peoples judge as having no catastrophic potential and generally acknowledge as the foundation of our food supply and the source of food security. Yet genetic engineering is dramatically different from traditional breeding practices in both its method and outcome as well as in the social relations embedded within. Rather than an extension or speeding up of traditional plant breeding, genetic engineering is an entirely new and high-risk technology. Genetic engineering is described by the biotechnology industry and by the Canadian government as "improving" existing knowledges and methods (creating "enhanced food") rather than creating entirely new processes and products.

Traditional plant breeding techniques are farmer developed and controlled methods of selective breeding that rely on the sexual reproductive processes and capacities of organisms. Here farmers select plants or animals that exhibit desired traits and breed these together to develop organisms with the strongest and most reliable expression of these characteristics. In plant and animal breeding the reproductive systems of organisms form the parameters of experimentation. In contrast, genetic engineering is not restricted by reproductive processes but can move outside them to allow for trait selection at the molecular level. Using new and highly technology-dependent methods, including "gene guns" and viral vectors,⁷ molecular biologists can insert or transfer specific genetic material directly into the DNA of foreign organisms. This

⁶ Wilf Keller is an outspoken supporter of genetic engineering and was Vice Chair of the government-industry Food Biotechnology Communications Network.

⁷ Tiny metal particles coated with genes are fired from a gene gun directly into plant cells or viruses are used to transport DNA.

ability to move individual genes without having to breed whole organisms together is more than a speeding up of traditional plant breeding. It is an entirely new process of trait selection.

The science of genetic engineering enables the transfer of genes between species that do not interbreed in nature, crossing over the previously impenetrable "species barrier."⁸ In crossing the species barrier a molecular biologist can introduce "exotic" or foreign genes into a host organism. Genes are also spliced across the "kingdom barrier" where, for example, fish genes have been inserted into the DNA of tomatoes and a gene from the soil bacteria *bacillus thuringiensis* (Bt) has been introduced into potato DNA.⁹ These transfers would never have occurred in nature and are only possible through the science of genetic engineering.

The development of traditional breeding techniques is a history of lay or indigenous knowledge systems applied to food production.¹⁰ These techniques were developed through experimentation on the land and were grounded in daily labour for community and familial survival. In contrast, genetic engineering emerges from the laboratory as the product of a particular scientific paradigm and expert knowledge that relies on conventions and methods negotiated through the history of western biological sciences. The technology is removed from the land and people who work the land and is generally not understood by, or accessible to,

⁸ Though some species that are closely related may breed in nature, their offspring are usually infertile. This is a natural safety device to prevent the mixing of possibly incompatible genes and secure the survival of the species. (Steinbrecher and Kennet 1998:3) Gene jumping between unrelated species may occur but is rare and would happen only within a context where species are exposed to one another, a phenomenon that would not be possible, for example, with the exchange of genes from a fish to a tomato.

⁹ The tomato with the fish gene was engineered to be frost resistant (this product is currently not on the market). The transfer of the Bt toxin gene into potato confers resistance to the Colorado Potato Beetle. The gene is also used to confer insect resistance in corn varieties.

¹⁰ Lakshman Yapa uses the term "traditional" to mean a community where the conduct of activity and transfer of knowledge is based on experiences that are transmitted from one generation to another in processes of knowledge exchange that are informal and oral. (Yapa 1993: 265)

farmers.¹¹ Because genetic engineering is an expert knowledge it is more easily centralized and privately controlled. Private ownership is a defining feature of genetic engineering that contrasts dramatically with the shared knowledge of traditional food production systems, knowledge that is passed from generation to generation. Later in this chapter I will return to an analysis of private ownership as central to risk manufacture in my examination of processes of industrialization in agriculture. In contrast to plant breeding techniques that are traditionally held as common heritage for communal survival, contemporary patent regimes allow for the private ownership of life forms as “inventions.” The science of genetic engineering is privately owned for private profit and, as I will discuss later in this chapter, the products that have been developed and are currently on the market reflect the prospective role of the technology in corporate strategies for capital accumulation.

1.b: Reductionist Science and Risk Manufacture

Proponents of genetic engineering argue that, “genetic engineering has revealed the universality, beauty and order of the rules of biology.” (Nossal and Coppel 1990: 151) In their research that became the foundation of genetic engineering, Francis Crick and James Watson described the structure DNA as a linear one-way flow of information. (Rose *et al.* 1990: 58) The Saskatoon Research Centre of Agriculture and Agri-Food Canada advertises their capability to characterize, isolate, and manipulate enzymes and genes. (Saskatoon Research Centre May 1998)

¹¹ Some scientists refer to genetic engineering as a “kitchen sink technology” and view the barriers to entry as slight. The science itself is however highly technology-dependent. There are possibilities for farmers to be involved in the research and development of genetically engineered organisms but there is an overwhelming neglect to engage farmers in aspects of agricultural research generally.

The genetic makeup of organisms is portrayed as understandable and controllable but much of nature cannot be broken up into independent parts, decontextualized, and studied in isolation. R.C. Lewontin argues that it is pure ideology to suppose that this separation is possible. (1991: 15) The science, and what I argue is ideology, of genetic engineering aims to identify and name individual genes and their characteristics in order to recombine genetic material. The DNA of each organism is viewed as a "genetic code" or "blueprint" and it is this code that the science of genetic engineering seeks to understand, categorize, and manipulate.¹² With genetic engineering each organism is defined by the characteristics and functions of its genes as they are identified, understood and catalogued by scientists. The broad scientific and commercial goals of genetic engineering are summed up in Monsanto Company's description of their research; under the heading "Life Sciences: An Expanding World of Opportunity for Monsanto" the corporation explains that scientists at their "Life Sciences Research Center," "study the chemical and biological factors that control the growth, development and health of plants and animals. These scientists are exploring ways to improve the genetic makeup of plants and bacteria, a field of science often referred to as DNA technology or genetic engineering. This research promises many beneficial products." (Monsanto 1991)

Genetic engineering assumes that organisms can be broken down into separate and identifiable parts and that an organism is a sum of these (genetic) parts; but Mae-Wan Ho argues that it is mistaken to believe that biological nature in the form of genes is fixed and unchanging, and can be sorted from environmental influence. (Ho 1998: 46) The gene is not the only factor governing the emergence of traits in living organisms and the splitting up of nature

¹² Ruth Hubbard and Elijah Wald argue that the language of genes is a convenient tool for science communications but that, "in a sense, the "gene" no longer has a physical reality for molecular biologists. The material reality is DNA." (Hubbard and Wald 1997:43) There are a number of ways

into its supposed independent parts oversimplifies or ignores complex relationships, distorting the picture of the whole. It is on these grounds that Vandana Shiva and Mae-Wan Ho critique genetic engineering as a reductionist science that is inherently unstable and dangerous. (Ho 1998, Shiva 1995)

The reduction of organisms to their genetic code offers simple explanations of cause and effect that enable the physical exchange and engineering of individual genes but, as Rose *et al* (1990) argue, science does not have to be correct in order to offer explanations of the world and enable manipulation. Science can instead be seen as a partial or incomplete knowledge where enough of the "laws" of nature are understood to allow for manipulation but not to understand natural processes in full or indeed the possible consequences of interfering with them. (Murphy 1994) Processes of scientific research are classically characterized as "discovery" where each successive revelation has the potential to overthrow existing understandings. This view suggests that science is a partial knowledge (Murphy 1994, Suzuki 1999) and that through science we produce ignorance. (Ravetz) The science of genetic engineering can be used to alter organisms and yet molecular biologists still call 95 per cent of genetic material "junk DNA" simply because they have no idea what its functions are.

Genetic engineering assumes that genes can be controlled but evidence of unexpected gene expression and emergent properties or "pleiotropic effects" counters this assumption. The results of gene splicing are unpredictable.¹³ Ricarda Stienbrecher and Faye Kennet argue that, "we know very little about what a gene (or for that matter any of its DNA sequence) might trigger or interrupt depending on where it got inserted into the new host (plant or animal)."

in which genetic relationships can be explained; many scientists for example stress the importance of the activities of proteins in determining traits.

(1998:4) Petunia flowers, for example, that were spliced with a gene to engineer the colour red expressed this trait but were also less fertile and the growth of their roots and leaves was altered. (Stienbrecher and Kennet 1998:4) Similarly salmon that was genetically engineered with a growth hormone gene not only grew big and fast but also turned green. These unexpected consequences suggest unpredictable interactions. These interactions may include possibilities for the creation of new toxins or allergens in genetically engineered foods as well as the potential for deep ecological disturbances.

The theory of chaos and complexity offers one perspective on genetic engineering as partial knowledge. As an alternative view of nature, chaos and complexity allows that instability exists at every point in the natural world and that perpetual uncertainty will continually defeat determinism and predictability. (Gleick 1987) Here uncertainty is not identified as a problem to overcome, an impossible task and a dangerous project, but as a reality to come to terms with. A view of chaos and complexity may offer insight into the failures of genetic engineering to provide promised precision and predictability.

Lewontin (1991) argues that organisms construct their environments rather than adapt to them. He argues that organisms are not the passive consequences of external and internal activities beyond their control but that they define their own environments.¹⁴ This "constructionist" view allows for recognition of a dynamism inherent to organisms and

¹³ The techniques of gene splicing are also imprecise. The transfer of genes using viral vectors or "gene guns" is random, hence the use of antibiotic resistant marker genes to trace the inserted genetic material.

¹⁴ Lewontin argues that using the language of external and internal environments to describe the life of organisms creates an artificial dichotomy. Steven Rose *et al* warn against falling into "interactionism" where the split between organisms and their environments is assumed and priority is given to the individual over the collective, providing space for a reduction to cause and effect relationships. (Rose *et al* 1990)

ecosystems and the possibility that the designs of scientists can be defeated by the dynamism of organisms.

Attempts to impose production paradigms on organisms through genetic engineering can be defeated in a complex web of relationships. Dairy cows' systems, for example, are unable to successfully conform to the production paradigm imposed by the veterinary drug recombinant Bovine Growth Hormone (rBGH). rBGH is a genetically engineered drug designed to increase milk production in cows by 10-15 per cent. The drug forces a cow to greater milk production but places enormous stress on the animal's system. rBGH was denied approval in Canada partly based on evidence that the drug has adverse animal health effects including lameness, a shortened lifespan and increased incidents of udder infections (mastitis). These pervasive health problems may be understood as manifestations of resistance in the animal's system to the reduction of its functions to factory-like production¹⁵ (I will examine this case in chapter five).

Feminist critiques of science have made significant contributions to analyses of scientific thought as value-laden rather than value-free or neutral. Scientific conclusions are seen as reflecting the social values and power relations of a specific time and place. Vandana Shiva incorporates feminist analysis of reductionist science into her critique of genetic engineering as expressing a social commitment to control that reflects existing economic and social relations. I will argue through this thesis that the various expressions of the commitment to control in genetic engineering are a source of risk. The splitting of organisms into genetic

¹⁵ The reduction of the animal to factory is explicit in pharmaceutical research into the use of animals as "bioreactors" to produce drugs in their meat or milk. Pharmaceutical corporations are reconstructing production relations on the farm, naming the prospective industry 'Pharming': "Animals are playing a major role in many of the discoveries our scientists are making by acting as 'factories' where health-giving substances can be produced." (Ag West Biotech Inc. September

"building blocks" serves the manipulation of those parts. It facilitates the ultimate commodification of life and the manipulation or control of its forms for human (industrial) purposes, but in the next section of this chapter I examine how this manipulation manufactures risks of a qualitatively new type that move across boundaries of time and space.

1.c: Risks Across Time and Space

The manipulation of genes is based on assumptions about the possibility and desirability of control. While physical manipulation of genomes continues to be possible it creates risks of a qualitatively new kind, risks that cross boundaries of time and space. These features of risk are described by Ulrich Beck and Barbara Adam as characteristic of risks of the risk society. The risks created through genetic engineering are global because of their ability to cross spatial boundaries and they are risks that threaten future generations because they cross boundaries in time.

Risks Moving Across Time

In 1990 Nossal and Coppel argued of genetic engineering that, "the technology, as such, is entirely safe," and that, "with the *benefit of hindsight*, it is now possible to state that none of the conjectural hazards materialized."¹⁶ (Nossal and Coppel 1990) (emphasis added) Nossal and Coppel argue that fears about the safety of genetic engineering are illusionary and can now

1994) "Herds of transgenic animals could be farmed for proteins, blood and organs." (Roslin Institute quoted in Ho 1998: 170)

¹⁶ This "hindsight" of 1990 offers no experience whatsoever as the first genetically engineered food was only approved for commercialization in Canada in 1995.

be put to one side. I argue however that the risks of genetic engineering may not be manifest for generations and may never be understood, if identified at all. The risks that form the risk society cannot be limited in terms of time but are characterized by invisibility and long latency periods. (Beck 1992, Adam 1998) Consequently it is unlikely that we can even trace many risks back to their original sources. The environmental and human health risks of genetic engineering extend in time to affect peoples and environments of the future in unknown ways.

These features of the complex and potentially far-reaching physical risks of genetic engineering clearly pose challenges to risk calculation and regulation. Barbara Adam argues that industrially produced risks are often recognizable only once they have been identified through the mediating loop of science and technology. (Adam 1998:10) Science holds a contradictory place in assessing risk in the risk society as science is centrally implicated in risk manufacture. Science is one of the few tools available to identify risks but science is not capable of calculating risks that defy time and space. The limitations of science are revealed in failed attempts to calculate the new risks born of science.

There are few ways that science can establish cause and effect relationships such that effects into the future can be assessed. Monsanto Company for example, refuses to conduct long-term human health studies into the relationship of its product recombinant bovine Growth Hormone (rBGH) to Insulin Like Growth Factor-1 (IGF-1) which is proven to promote growth in cells and is widely linked to cancer. It is unlikely however that even with these tests, efforts to conclusively eliminate or establish a link between rBGH and cancer would succeed. Many established scientific methods may be unable to determine even the immediate risks posed by the use of genetic engineering in agriculture. Conventional toxicology for example faces new challenges in the assessment of the safety of genetically engineered foods for human consumption. The usual method for testing a new food additive is to feed lab animals until a

toxic effect is observed and can be measured. The problem is in feeding the animals enough food for the test without profoundly changing their diet. (*New Scientist* 17 April 1999) Using conventional toxicology, scientist Arpad Pusztai of the Rowett Institute in Scotland found that rats fed genetically engineered potatoes suffered damaged organs and depressed immune systems.¹⁷ ("Ousted scientist and the damning research into food safety," *The Guardian*, 12 February 1999)

There are many possibilities for health risks posed by the consumption of genetically engineered foods including the creation of new toxins and allergens. The insertion of foreign genes may create new proteins that alter gene expression and result in potential harm to humans. No long-term testing has been conducted to determine the safety of consuming genetically engineered foods but neither has there been research to determine what long-term studies would look like and what they might achieve. Without labelling of genetically engineered ingredients the problem of tracing adverse health effects back to their source is compounded.

Barbara Adam (1998) discusses risk in terms of a timescape perspective. The risks of genetic engineering express a deep conflict between industrial and natural time. Industrial design for precision and predictability conflicts with uncertainty or chaos and complexity in nature. In the case of genetic engineering the imposition of constructs of industrial time upon relations in natural time creates a brittle relationship that can break apart with potentially catastrophic consequences. Uncertainty remains despite efforts to overcome it. In aspiring to certainty, the science of genetic engineering creates a new kind of risk.

¹⁷ Dr. Pusztai discussed his findings on British television and argued that it is, "very, very unfair to use our fellow citizens as guinea pigs. We have to find [them] in the laboratory." Two days following, Pusztai was suspended and forced to retire. He was reinstated after an group of 20

Time in industrial society revolves around the fast pace of industrial innovation and the discipline of competition. Time is compressed in the development and commercialization of new technologies where history becomes shorter and is framed around the timeframes of technological development. Capital accumulation strategies in industrial society are directed toward profit maximization in the short-term such that in the race to commercialize products of genetic engineering there is no time for long-term risk examinations. Even inside public institutions with explicit mandates to assess risk, the pressure to quickly approve genetically engineered products is compromising safety reviews. (I will discuss the compliance of government in conforming to industrial time when I examine the impact of this pressure on the review process for rBGH.) Beck and Adam refer to this as "organized irresponsibility." (Beck 1992, Adam 1998,) The invisibility and long latency periods of risk present moral and political problems. (Adam 1998, Shrader-Frechette 1993:189)

Genetic engineering is designed to facilitate the restructuring of agriculture for globalized production across time and space. The globalizing industrial agri-food system is based in industrial time that crosses over seasons and bioregions. Agri-food production is designed for distance and durability (Friedman 1993) and the development of genetic engineering reflects these goals.¹⁸ Calgene Fresh Inc., for example, has designed the "Flavr

scientists from around the world came forward in support of his method and conclusions. ("Top researchers back suspended lab whistleblower," *The Guardian*, 12 February 1999)

¹⁸ Designing food to cross boundaries of time and space is implicated in the manufacture of contemporary food hazards. (Adam 1998:17) Genetic engineering is proposed as one means of fighting food-born illnesses such as *E-coli* or 'hamburger disease,' (Canadian Biotechnology Strategy 1998:19) illustrating Beck's argument that risks create new market opportunities. One test for harmful food-born bacteria uses the same enzymes that cause fireflies to glow in the dark: "genes that cause luminescence have been spliced into a harmless virus which in turn causes any dangerous bacteria that it infects, such as *Salmonella*, to glow. The glowing bacteria can be seen and counted through the use of detection instruments called biosensors." (Ag-West Biotech Inc. Winter 1999: 4) "FightBac" is a 40-organization initiative launched in Canada in 1998 to promote public awareness of harmful food bacteria. Instead of offering an analysis of the production related causes of these dangers, the campaign diverts attention from process related questions and places

Savr" tomato to survive long journeys from the field to market and an extended life on grocery store shelves. The Flavr Savr tomato promises "summertime taste year round." (*Produce Merchandising* December 1994) The tomato is developed to slow down the rate at which it softens while ripening so that, rather than picking green tomatoes off the vine and having them ripen enroute to market, the tomato can be vine-ripened and then transported. In order to slow the natural softening process Calgene scientists isolated and copied the gene that they identified as causing the tomato to soften and then inserted it backwards into the tomato DNA.¹⁹

In industrial time, innovation and the introduction of new technologies is seen as inevitable. The abandonment of new technologies decided through democratic deliberation over socio-economic impacts and ethical issues is neither possible nor desirable. But just as the introduction of new technologies is inevitable in industrial time, the consequent risks of introduction are irreversible in natural time. Irreversibility is a final expression of the defiance of time boundaries by genetically engineered organisms. Once genetically altered organisms are released into the environment they cannot be controlled or recalled. Organisms have a life of their own and can crossbreed, reproduce, and mutate. These risks, outside the control of institutions and science, become the burden of ecosystems and future generations to assume over time.

responsibility instead on individual consumers to prevent food borne illnesses by, for example, washing their hands before handling food in their kitchens. As seen in the government householder "Food Safety and You," this tactic has since been developed in full to divert public attention away from their safety questions related to genetically engineered foods.

¹⁹ The Flavr Savr tomato met with poor consumer reception, driving Calgene close to bankruptcy in the summer of 1995. Monsanto soon purchased 49.9 per cent of Calgene stock. (Tokar 1996:8)

Across Boundaries of Place

As well as crossing boundaries of time, new risks in the risk society cross boundaries of place. Risks are not restricted by place but cross regional and national boundaries with the possibility of creating global conditions of fear. Genetic engineering enables the direct transfer of genes across space, across both species and kingdom barriers. The environmental release of organisms carrying "exotic" or foreign genes is fraught with danger and a major fear associated with the introduction of genetically engineered plants is the ability of those plants to cross-pollinate or out-cross, spreading outside the fields where they are planted and becoming contaminants or "genetic pollution."²⁰ The biotech industry argues that, "there is no greater possibility of genes from genetically-altered plants being passed on to natural plant resources than from conventionally-bred crops."²¹ (Ag-West Biotech Inc. and Canadian Saskatchewan Agriculture Green Plan Agreement 1996: 9) This argument dismisses outright that genetic engineering creates new organisms and it fails to acknowledge the potential for catastrophe.

Industry denies that cross-pollination is a significant risk and yet Monsanto's own attempts to control the planting of their genetically engineered seed through grower contracts are being defeated by cross-pollination. Canadian farmer Percy Schmeiser, former mayor of Bruno, Saskatchewan, is being charged by Monsanto with illegally planting the company's *Roundup Ready Canola*, a plant which Schmeiser insists grows on his land unwanted.

²⁰ Agriculture Canada has been authorizing field trials of genetically engineered crops since 1988.

²¹ The genome is in a constant state of flux because, through the movement of viruses or parasites, genes can jump between organisms that do not interbreed. Gene jumping of this kind, otherwise known as "fluid genome processes," are rare however and are subject to certain controls within organisms. (Ho 1998:51)

Schmeiser speculates that the seed blew from seed trucks travelling on nearby roads.²²

(*Washington Post* 3 February 1999) Canola is particularly prone to cross-pollination because of its many wild relatives. In October 1998 the British government forced Monsanto to destroy an trial site of herbicide-resistant canola after it pollinated nearby plants. (*New Scientist* 31 October 1998: 39) Shipments of Canadian canola seed sold to the European market as free of genetic engineering were recently found to be contaminated with *Roundup Ready* genes as a result of outcrossing, despite the use of proscribed buffer zones.

In addition to cross-pollination there are concerns that the release of crops engineered to be insect resistant will result in the rapid spread of insect resistance to pesticides. The soil bacteria *Bacillus thuringiensis* (Bt) is an important non-chemical pesticide used topically by organic farmers. The gene for the Bt toxin is now widely used to engineer insect resistance into many crops including potato and corn. Insect resistance to Bt that was previously thought impossible is now considered a serious threat and there are cases where resistance has already developed. (National Agriculture Environment Committee January 1999:11, *Food Bytes* 2 March 1999) The new use of Bt as a transgene creates entirely new conditions of insect exposure to the toxin where soil ecosystems and insect populations are exposed to the Bt toxin at a high and consistent level through the growing season.²³ While genetically engineered plants have already been released into the environment, mechanisms to control the spread of resistance are still being developed.

²² Mike Crawley, an ecologist from Imperial College London, found that the distribution of feral canola around a London motorway matches the transit routes of seed trucks. (*New Scientist* 31 October 1998: 40)

²³ There is a high level of expression of traits in genetically engineered crops. Corporations are now developing technologies to restrict the expression of genes to certain plant tissues where the Bt toxin, for example, would not be expressed through the whole plant but only through the leaves.

The Bt toxin gene is harmful to the Lepidoptera class of insects and while it is successful in disabling target pests there is evidence that Bt crops also harm non-target or "beneficial" insects such as the monarch butterfly. Non-target insects are effected through the food chain in exchanges not investigated in environmental assessments. The movement of the toxin through the food chain offers one example of complex interactions outside the laboratory environment and of conditions across time and space that lead to new questions regarding the character of risk and our ability to assess risks.

The inability of risk to be limited in terms of time and place is an expression of the conflict between the assumptions of possibilities for control that form the basis of genetic engineering, and the reality of uncertainty or chaos and complexity in nature. The conflicts that result from the imposition of industrial time on natural states of uncertainty and complexity will lead to unintended consequences with potentially disastrous effects. We know that cross-pollination and the development of insect resistance are inevitable and will change the environment and realities of food production. There is no way to predict the full ecological consequences of introducing new living organisms.

2: The Capitalist Underpinnings of the Risk Society: Innovation for Growth

2.a: Dynamics of Innovation and Risk Manufacture

A political economy analysis of risk manufacture can make the risks of the risk society visible through an inquiry into the social relations in processes of risk manufacture. Such an examination of scientific and industrial processes reveals the capitalist underpinnings of the risk society. The tremendous capitalist appetite for innovation driven by the profit motive is at

the centre of risk manufacture. I use the dynamic of innovation for profit as a starting point for my examination of the risks of genetic engineering and the place of these in the risk society.

Innovation is a core stimulus of capitalist development. Schumpeterian theorizing of capitalism as an evolutionary process is helpful in exploring the role of innovation in capitalist development and explaining the role that genetic engineering is expected to play in economic growth. The perpetual cycle of innovation creates new products and processes that replace others, continually revolutionizing the economic structure from within in an organic process that Schumpeter (1943) describes as "creative destruction." The logic of perpetually "improving" products and production processes, including those of nature, guides capital investment in genetic engineering technologies. Schumpeter argues that, "the fundamental impulse that sets and keeps the capitalist engine in motion comes from the new consumers' goods, the new methods of production or transportation, the new markets, the new forms of industrial organization that capitalist enterprise creates." (1943: 83) The development of new products allows for expanded production and the creation of new markets. The science of genetic engineering promises limitless "inventions" that will allow for new accumulation strategies and a new level of capital penetration in agriculture, following the now well-established globalized processes of industrialization in agriculture, processes that I will discuss later in this section.

Innovation is assumed to be a tool of "progress" in a risk-benefit analysis that is shaped by faith in scientific "advancement," acceptance of the imperative of competition, and imposition of the idea of perpetual growth and technological progress as an inevitability. Economic growth is determined to be a social good and value. Risks of new technologies are judged in relation to this economic benefit where risks are trade-offs, one social good for another. Defining economic benefit is critical to the development of a risk-benefit analysis of

genetic engineering that balances the need to protect environmental and health safety with the goal of fostering innovation for industrial growth.

Genetic engineering has outstanding potential as an engine of ongoing processes of creative destruction. Genetic engineering is described by the biotechnology industry and the Canadian government as an "enabling technology," so called because it can be applied to innovations in the medical, agricultural, forestry, environmental management, and military industries, among others. Much like the introduction of information technology, genetic engineering holds potential for changing production processes in sectors across the economy. Genetic engineering promises new products and processes, new markets, and new jobs, all of which fit into the powerful discourse of economic growth. In the 1998 report of the Canadian Biotechnology Strategy, the government stated that, "many people see biotechnology as the next important "change maker" after the convergence of information, computer and telecommunications technologies, which have transformed our lives." (Canadian Biotechnology Strategy 1998:2) Because the potential applications are so many, the introduction of genetic engineering could change every aspect of food production, resulting in widespread restructuring and a deeper penetration of capital in agriculture.

The dynamic of innovation in industrial society is a fast-paced development of new technologies that will contribute to increased efficiency and competitive advantage. Schumpeter describes competition as an ever-present threat that disciplines before it attacks. Ongoing processes of industrialization in agriculture are supported by the discourses of competition and efficiency. (Schumpeter 1943: 85) The goal of efficiency for competitive advantage serves to justify capitalist consumption and perpetual innovation. Industry presses on with the introduction of new technologies arguing that this progress is inevitable. It is these

capitalist impulses towards innovation that underlie the risk manufacture that leads us into the risk society.

The marketplace is appealed to as the central organizing principle in industrial society where market forces and the logic of free enterprise propel and regulate technological restructuring. The economy is disembedded from society and mystified as a powerful external force rather than understood as a product of human agency sustained by social institutions. (Friedman 1993: 218) Harriet Friedman argues that, "in the language of adjustment now prevailing, it is not the economy that must be shaped to socially defined needs, but society that must adjust to the supposed "laws" of competition, productivity." (1993: 217) The subordination of society to market forces allows for the introduction of new technologies without democratic deliberation. Beck argues that the risk society has appeared without our noticing and argues that this slide into a new epoch was unintentional; "high-speed industrial dynamism is sliding into a new society without the primeval explosion of a revolution, bypassing political debates and decisions in parliaments and governments." (Beck 1994: 2-3) This, he argues, contradicts the democratic self-understanding of our society.

In the next section I examine the risks of genetic engineering through inquiring into their place in the history of agricultural industrialization and the rise of agribusiness. Though they have been sold on the promise of security, these industrialization processes have manufactured risk. The risks of the risk society present new market opportunities (Beck 1992:23) as new risks offer opportunities to create solutions in the form of technological fixes. Food and environmental insecurity present important opportunities to manufacture and sell technical solutions, here in the form of genetic engineering. Agricultural technology can be seen as wrapped up in its own cycle of creative destruction where, as established technologies fail, new technologies are developed and sold in their place. The dynamic of innovation in the

development of the modern agricultural economy has led to increasing dominance of transnationals over industrialization processes where benefits to corporations are accrued through the development of farmer dependence on corporate inputs. Through a political economy analysis that examines ownership structures and social relations in agricultural production I will argue that genetic engineering fits securely into a history of industrialization processes in agriculture that manufacture risk and serve to highlight the capitalist underpinnings of the risk society.

2.b: Genetic Engineering: Towards Further Industrialization of Agriculture

The innovations and profit maximization strategies of transnational corporations dominate the continuing development of agri-food systems world-wide. The transnational chemical and pharmaceutical corporations that are developing products of genetic engineering have a long-term vision for the place of their investments in the future of globalizing agriculture. This vision has a history through the industrialization of agriculture that introduces new social relations into food production through new ownership structures and distribution of risks and benefits. Through this section I argue that corporate ownership is a central factor in the manufacture of risk.

Corporate strategies have transformed farming into agri-food production such that the current system focuses on food, or industry and services, rather than on agriculture. (Friedman 1993) Farming itself accounts for only about 10 per cent of the value added in the agri-food system, with 25 per cent of the food dollar paying for farm inputs and the remaining 65 percent gained by transportation, processing, and marketing that convert farm products into consumer commodities. (Lewontin 1998: 74) The corporate vision for genetic engineering includes

farmer dependence on capital-intensive inputs in order to secure market expansion in the inputs sector. Farmers are increasingly proletarianized as their control over the means of production or place in the production chain is constrained by technological interventions and the tempo of industrial food production. (Lewontin 1998: 75) Though farmers are increasingly shut out of decision-making in industrialized agri-food systems it is farmers who bare the greatest risks in food production.

Genetic engineering in agriculture will facilitate a continuing adjustment of agriculture and agri-food toward greater concentration and consolidation. There is a general loss of small and medium sized farms in North America and a reduction of farm income as well as a long-term decline in the farm population and agricultural labour force. The number of farms in Canada and the United States has decreased as farm size has increased. In 1998 the 22,000 largest farms in the United States (6 per cent of the total number) received close to 60 per cent of total farm receipts. (Magdoff *et al.* 1998:7) Since the early 1980s the number of broiler, hog, and dairy farmers has declined at a rate of about 4.0 to 4.5 per cent per year. Monsanto argues that US agriculture has been and continues to be a success story overall, "even if the Market has been meting out its discipline within the industry over time." (Monsanto 1994:7) In other words, the costs and risks of technological change in agriculture are squeezing out small farms unable to compete with larger operations. The success story of US agriculture belongs to agribusiness.²⁴

Concerns about the socio-economic effects of introducing new technologies into agriculture are well known and industry replies with the following:

²⁴ The Canadian Biotechnology Strategy anticipates public concern for the impact of genetic engineering on the future of small farms and argues that, "all Canadians - producers and consumers across the country, including people in smaller communities and rural areas - will benefit from the new transformation." (Canadian Biotechnology Strategy 1998: 2)

Proponents of biotech counter that we can't ignore promising new technology simply because of the problems associated with its introduction. Although there may be difficult changes as the food industry adjusts to inputs from biotechnology, such changes come with any technological innovation. Historically, they [opponents to genetic engineering] argue, many innovations are initially destructive to jobs and markets. But eventually, they result in more and better new jobs and markets of generally higher quality than those they displace. While biotechnology could be used to enhance corporate food monopolies, it also offers options to help diversify and stabilize the farm economy. Agbiotech can contribute to more self-reliance for farmers and consumers in both the industrial and developing nations. (Ag-West Biotech Inc. *A Biotech Primer*)

In the next section I look at the Green Revolution as an example of a commercial project to create markets for capital-intensive farm inputs that, rather than contributing to farmer self-reliance, has created dependence - a dependence that I argue genetic engineering will reinforce and recreate. I will argue that the creation of dependence is part of the manufacture of risk, both social and physical, through the history of industrialization in agriculture.

2.c: From "Green Revolution" to "Biorevolution:" Developing Dependence and Manufacturing Risk

The so-called Green Revolution of the 1960's and 70's describes a period of intensive restructuring in agriculture through the introduction of high-yield crop varieties and accompanying chemical inputs. A whole production or "development" paradigm was exported with the "Green Revolution." Development promised self-sufficiency in food production to nations across the world and though it delivered high yields in the short term, these yields ultimately bore costs and risks in the long term through the creation of new structures of dependency. The sketch of the Green Revolution provides an initial identification of the

primary set of actors that promote, protect, and benefit from genetic engineering. The history of these actors, their accumulation strategies, and their relations in the Green Revolution places genetic engineering in a particular time and place and brings to light a specific corporate vision for the future of world agriculture. The transnational corporations that dominate the "Life Sciences Industry" have an established history in globalizing industrialized agriculture from the Green Revolution to the present. In this section I examine the corporate vision for the role of genetic engineering in agriculture by contrasting the promises of innovation in the Green Revolution with the realities (of risk manufacture), and look to the social relations embedded in the science and politics of the Green Revolution. These relations are the foundation of the emerging biotechnology industry. Similarly the dynamics of innovation and competition that pushed the Green Revolution forward highlight those that are driving genetic engineering.

The development of the industrial agricultural inputs sector was the cornerstone of the Green Revolution and the need to secure continued and increasing control over this sector is driving the development of genetic engineering. Innovations relating to the seed were the centre of the Green Revolution and chemical and pharmaceutical corporations began investing heavily in the seed industry. The seed is a central site of contestation in agricultural restructuring, then and now, as control over the seed translates into control over food production. The hybridization of seed in the Green Revolution opened up new possibilities for capital accumulation in agriculture just as the technologies of genetic engineering now offer. (Kloppenborg 1988, Shiva 1991)

The Green Revolution was based on new high-yield varieties of plants or "miracle seeds" that were developed by northern and international research institutes and exported by transnational corporations with the support of northern governments. High yields were not intrinsic to the seeds themselves but were a function of the capital-intensive inputs applied to

them. (Shiva 1993:42, Doyle 1986) The high-yield varieties were only one part of a development package that included chemical fertilizers, herbicides, and insecticides, machinery, irrigation technologies, and water supply. The adoption of the new seeds was therefore costly for small farmers and resulted in a precarious dependence on imported inputs. The paradox of the Green Revolution is that as the hybridized seeds provided higher yields, they also created scarcity. (Yapa 1993)

The Green Revolution was based on the introduction of a few genetically uniform plants, the monocropping of which displaced local agricultural systems and indigenous plant varieties. Monocultures increased farmer vulnerability to crop failure; in the Philippines where almost 90 per cent of the country's farms were sown with five expensive high yielding seeds, the harvest was nearly eliminated when the hybrids were attacked by a pest in the 1970s. (Dixit 1994:14) Unheard of until now, farmer suicides have become epidemic in India in what Vandana Shiva argues is an indication of the tremendous stress placed on Indian farmers by conditions of industrial agriculture. (Shiva 1998) The indebtedness that is leading farmers to take their own lives, often by poisoning themselves with pesticides, is a devastating illustration of the potentially crushing risks of high-technology adoption that may be borne by farmers. Shiva argues that control over nature and control over people were essential elements of the centralized and centralizing strategy of the Green Revolution. (Shiva 1991: 15) Vandana Shiva and Henk Hobbelen agree that the adoption of genetic engineering will reinforce the top-down approach of the Green Revolution. (Shiva 1991:224, Hobbelen 1991:17)

The Green Revolution was an attempt to export the capital-intensive model of northern industrialized agri-food production in order to expand input markets. In December 1969 the Green Revolution was presented to the US Congress as a powerful tool of American foreign policy that could provide market prospects for the pesticide, seed and tractor industries. (Yapa

1993: 257)

The development of genetic engineering is aimed at replicating the capital-intensive model of the Green Revolution by replacing high-yield varieties with new seeds. Research into genetic engineering is focussed on the further development of, and increased monopoly over, the industrial inputs sector through the introduction of new technological packages. The single largest area of research in the field of agricultural biotechnology, well over 50 per cent, is in the development of herbicide tolerant plants. Of the 31 genetically engineered plants registered in Canada by January 1999, 25 were designed for herbicide tolerance. Herbicide tolerant plants are designed to tolerate brand-name chemical herbicides, allowing for more intensive and frequent applications of herbicides.²⁵ Herbicide tolerant crops are designed to secure a captive market for corporate chemicals products such that Monsanto has developed *Roundup- Ready* canola, soy and cotton varieties that are resistant to its brand-name herbicide *Roundup*, the largest selling herbicide in the world.²⁶ In 1996 the *Wall Street Journal* reported that, "since farmers will be able to spray Roundup more liberally than ever, some on Wall Street say Monsanto's agricultural-products division could post annual profit gains of 25% for the next four years." (*St. Louis Post Dispatch* October 24 1996)

In order to secure farmers' return to the seed market each year Monsanto requires growers who buy their genetically engineered seed to sign a contract that makes it illegal for them to save and replant seed. The contract also grants Monsanto the right of surveillance over the farmer's property (In the case of *Roundup Ready Canola* a farmer's fields may be inspected

²⁵ Pesticides are too strong to apply to crops at early stages of planting. The application of broad-spectrum herbicides, of which *Roundup* is one, kills all plants indiscriminately.

²⁶ Sales of Monsanto's herbicide *Roundup* amount to 17 per cent of the company's total annual sales. (Middendorf *et al.* 1998) Monsanto's patent on *Roundup* is nearing expiration and the company is desperate to secure a market share for its brand-name product.

for up to three years after the initial purchase and sowing of the seed).²⁷ (Monsanto, *Roundup Ready Growers Agreement*) Monsanto is aggressively pursuing this strategy to control the use of its seed by suing farmers who break their contracts. Monsanto has gone so far as to establish telephone hot-lines where farmers can inform on the activities of their neighbours, advertising: "when a farmer saves seed and replants Monsanto patented biotech seed, he understands that what he is doing is wrong." (Monsanto quoted by Lewontin 1998: 80)

In a final attempt to enforce their patent rights and prevent seed-saving, Monsanto, through a prospective \$1 billion-plus acquisition of Delta and Pine Land Company, was to acquire property rights over the "Terminator Technology."²⁸ The Terminator Technology designs plants to become sterile late in their first growing season, rendering the saving and replanting of seed fruitless. Every major agribusiness company is now developing a version of the "suicide seed."²⁹ Responding to criticism of the Terminator Technology, Monsanto's CEO Robert Shapiro repeated the argument that industry uses to justify patent rights: "one of the hardest issues in biotech has always been, given you're investing all this money, will you get paid for the product?" (*St Louis Post-Dispatch* 13 January 1999)

Investments in the seed industry by chemical and pharmaceutical multinationals have escalated since the Green Revolution such that at least five of the pesticide industry's top ten corporations now dominate international plant breeding. Of 1,500 seed companies in 1995, 24 held a combined market share of more than 50 percent. (Dawkins 1997: 25) Eight of these

²⁷ In mid-western United States, Monsanto hired Pinkerton investigators to track illegal farmer seed-saving. (Rural Advancement Foundation International March/April 1998)

²⁸ The name "Terminator Technology" was coined by Pat Mooney of the Rural Advancement Foundation International, a civil society organization that researches the "Life Sciences" industry.

²⁹ The Terminator Technology is not yet on the market and there is world-wide opposition to its commercialization. A ban on this technology has been endorsed by the research centres of the CGIAR. Recognizing that the terminator technology was becoming a dramatic rallying point for

corporations were transnationals. In 1998, 10 biotechnology companies controlled 37 per cent of the global seed market.

The predominance of research into herbicide-resistant crops contradicts the promise that genetic engineering will feed the world and protect the environment.³⁰ Research into herbicide tolerance has taken priority over research directed, for example, at overcoming hardships of farming on marginal lands or in difficult climates. Herbicide tolerant crops directly benefit transnational chemical manufacturers and reinforce farmer dependence on expensive chemical inputs. The capital intensive model of the Green Revolution is repeated with genetic engineering and is justified on the same grounds of the need to *provide* food for peoples in developing countries. (See Monsanto 1994b) The corporate actors and interests that developed the technologies of the Green Revolution are many of the same that are founding the biotechnology industry. The same transnational corporations that globalized their operations through the Green Revolution are now taking control over this newest wave of innovation in order to secure and expand their markets and realize further growth.

2.d: The "Biotechnology Bubble": High-Risk Technology as High Financial Risk

The dynamic of innovation for profit drives the development of genetic engineering but the speed of this development is not risk-free for investors. The viability of the biotechnology industry is challenged by the unpredictability of the science where both physical and social

anti- biotechnology sentiment and a growing movement, Rockefeller spoke directly with the CEO of Monsanto, Robert Shapiro, to convince him to put aside the technology.

³⁰ Ag-West Biotech Inc. argues that, "the technologies of the Green Revolution have achieved their desired results and can no longer be expected to deliver large yield increases...A second Green Revolution is needed...a more environmentally friendly Green Revolution." (Ag-West Biotech Inc. January 1997: 2)

risks may translate into risks to profits. Monopoly over all aspects of food production and the concentration of operations are strategies to defy these financial risks.

The biotechnology industry was launched with escalating hype and unending promise. No other industry has been launched with such vigour before real products were clearly identified. Formed in 1976, Genentech was the first genetic engineering firm to sell stocks to the public. In an overvaluation of the immediate potential of biotechnology, sales in Genentech stock broke the then Wall Street record - without the company having any products to offer the market.³¹ (Ono 1991:19, Perlas 1994:33)

The new industry quickly became the domain of large multinational investors. In the 1980s the venture capitalists who were the first to finance small biotechnology enterprises began withdrawing their investments because of the long lead time to commercialization, and multinational chemical and pharmaceutical corporations able to provide "patient capital" took their place in bankrolling genetic engineering. Successive waves of corporate take-overs were described in *The Economist* as, "the death of a dream for entrepreneurial success and the competition of independent small biotech firms."³² (quoted in Hobbelink 1991: 30) As early as 1991 Henk Hobbelink observed that, "the pace of the concentration process among the largest agrochemical, seed, drug and food houses is astonishing." (Hobbelink 1991:43) The concentration of biotechnology within the hands of transnationals was concurrent with a take-over wave amongst the big companies themselves, a wave that continues into 2000.

³¹ On October 18, 1980 when Genentech stock went public, share prices rose from US\$35 to \$89 in 20 minutes. (*Management Today* June 1994: 56)

³² The story of Genentech highlights the domination of the Life Sciences industry by transnational corporations. Shares in Genentech were acquired by Monsanto who in 1979 bought the rights to rBGH from the company for \$990,000. (Tokar 1996) Genetech's total sales rose from \$90 million to \$400 million between 1985 and 1989 (Hobbelink 1991:30) and in 1993 60 per cent of Genentech was purchased by the pharmaceutical giant Hoffman-LaRoche of Switzerland for \$2.1 billion. (Mooney 1996:143)

Investments in genetic engineering by chemical and pharmaceutical transnationals can be understood as a defensive manoeuvre in anticipation of the new technology displacing markets for "conventional" chemical inputs. Chemical and pharmaceutical transnationals have been compelled by their domination over the agricultural inputs sector to invest in genetic engineering as the next wave of technological innovation. Monsanto, only recently the second largest chemical corporation in the United States, separated its chemical component in order to focus investments on genetic engineering and reinvent itself as a "Life Sciences" company. Monsanto's confident investment in genetic engineering has been a major force in launching the new "Life Science Industry." The corporation has positioned itself to secure monopolies over some of the newest and potentially deepest technological changes in agriculture. The economic viability of genetic engineering is however not assured and Monsanto's investments may yet prove to be an ambitious and premature gamble on an unstable and dangerous science.

Genetic engineering is an unproven technology that is emerging without a secure market. The science of genetic engineering has not matured on the land as any technology in agriculture should, but was born, literally, on Wall Street and is what Vandana Shiva calls a "Wall Street science." (Shiva 1998) Money is the driving force behind the rush to commercialize biotechnologies and the powerful possibilities for profit and the need to recoup investment costs have distracted attention from some of the high risks involved in applying genetic engineering to agricultural production. The unpredictable behaviour of living organisms presents a challenge to investors. Increased animal ill health with the use of recombinant Bovine Growth Hormone or the unexpected "boll-drop" of Monsanto's cotton in

dry climates are examples of expensive set-backs that may lead farmers to abandon biotechnologies, and shareholders to question the future of their investments.³³

Mae-Wan Ho argues that promises for the commercial success of genetic engineering are unfounded and calls the prevalence of these claims the "biotechnology bubble." (Ho *et al.* 1998) For Ho, the instability of investments in genetic engineering is directly related to the instability of the science. Ho observes that, "billions have already been invested, and companies are desperate to recoup their losses before the whole enterprise collapses." (Ho *et al.* 1998: 147) Most recently the introduction of genetic engineering faces major challenges from citizen protest and consumer mistrust.

The capital invested in the research and development of genetically engineered products is huge and the stakes in commercialization are correspondingly high. Recombinant Bovine Growth Hormone (rBGH) is estimated to have cost 1.5 billion US to develop and the annual profits for Monsanto from rBGH sales in the United States alone is projected to be \$300-500 million. (Canadian Institute for Environmental Law and Policy 1995) Monsanto refuses to release data on the rate of rBGH adoption in the United States but it is estimated that as few as 4 percent of US farmers are using rBGH.

The intensity of capital invested in genetic engineering has itself become a tool in industry attempts to reify the technology and establish its centrality in the future of agriculture and economic progress. *Genetic Engineering News* is an industry magazine published in the United States that features a yearly report of "Molecular Millionaires" that lists 100 millionaires who have investments in biotechnological/pharmaceutical stock (In 1998 the value of these stocks totalled \$1.76 billion). (*Genetic Engineering News* 1 April 1998) This parading

³³ In 1997 farmers were compensated by Monsanto when cotton bolls dropped from genetically engineered cotton plants. (Stienbrecher 1998:18)

of wealth is a tactic used to inspire confidence in the future of genetic engineering as a strategy of capital accumulation and to foster the belief that, because this investment has taken place, the industry is already a success and technology adoption is inevitable.

The perpetual cycle of creative destruction is insecure for corporations investing in new technologies. In chapters three and four I will argue that the desperation and determination of transnationals to commercialize products of genetic engineering quickly for maximum profit is reflected in corporate strategies to secure government product approval.

Investments in genetic engineering are spiralling in a race to commercialize technologies that are poised to become the future of agri-food production. But the success of genetic engineering in agriculture is not assured and, as I will argue, industry efforts to secure its future by commercializing products quickly are increasing the risks of the technology and enhancing lay mistrust. Genetic engineering is a new technology that creates new risks and presents institutions with new challenges in risk assessment and regulation. In the next section I argue that lay mistrust in science presents a challenge to expert risk assessment and to the success of a “science-based” regulation of genetic engineering. I examine the features of this mistrust and introduce social risk as an aspect of risk manufacture that is not accounted for in risk assessment.

3: Recognizing Lay Mistrust and the Manufacture of Social Risk: Challenges to Risk Management in the Risk Society

The risks of genetic engineering and the character of risks in the risk society pose challenges to risk assessment. Drawing on the work of Brian Wynne and Ulrich Beck I discuss the social as well as physical nature of risk. In this section I examine lay mistrust in science and expert-based risk assessments and the challenges posed by lay-expert conflict over risk

evaluations. I outline possible causes of lay mistrust in science and genetic engineering and suggest some of the implications of such mistrust for government and industry strategies to regulate, particularly through the use of science. I argue that lay mistrust of science and institutional regulation of risk is actually enhanced by the privileging of scientific criteria in risk regulation.

Mistrust of science is widespread and powerful in the lives of lay peoples and their shared experiences of risk and yet lay trust is often assumed.³⁴ Lay critiques of expert knowledges exist in many forms and have histories and cultures of their own. Mistrust in science, institutions, and social actors is a central aspect of conflict over risk where expert knowledge becomes a core of conflict as well as a party to risk manufacture.

Expert knowledge is a source of lay mistrust for a number of reasons.³⁵ Firstly, lay mistrust of science is partially fed by unrealistic expectations of science, expectations that are unwittingly fed by scientists themselves. (Wynne) The limitations of scientific risk assessment are rarely acknowledged, especially when enrolled in policy-making processes that expect and demand certainty. Science is unable to overcome uncertainty and provide the proof that is expected in risk assessment. Officials in the US Environmental Protection Agency (EPA) have stated that, "due to the many sources of uncertainty inherent in [risk] analyses, any risk results should not be interpreted as precise measures of risk." (Reichhardt 1996:12) And yet precision is what policy-makers expect from science. As I will discuss in chapter three, the use of science in policy processes often reinforces the myth of the unlimited capacity of science to

³⁴ Brian Wynne criticizes risk literature as well as Beck's work on the risk society for not recognizing existing lay mistrust in institutions and institutional definitions of risk. (Wynne)

³⁵ Analysis of power differentials is generally glossed over in risk literature (distinct from risk society literature) where voluntary and involuntary risk are not distinguished. Lay evaluations of risk are often dismissed as irrational or inconsistent because this analysis of social relations and lay mistrust in social actors is missing.

produce "facts." Toxicologist Christopher Wilkenson, a consultant to pesticide companies and former member of the EPA's Scientific Advisory Panel, cautions that, "the basic problem is that questions being asked in relation to chronic health effects such as cancer far exceed the capacities of the science." (quoted in Goldman and Wiles 1994:16) The qualitatively new risks of genetic engineering create even greater challenges to the use of science in risk assessment.

Secondly, lay-expert conflicts over risk often involve conflicting values and world views. Lay calculations of risk often employ dramatically different criteria from those used by experts, leading to profoundly different evaluations of risk and conclusions about the acceptability of risk. (Perrow 1984) The differing criteria employed by lay peoples and experts in their respective risk evaluations is a source of conflict and mistrust. Lay peoples are inclined to assess risk in terms of moral and social criteria, not just scientific or technical calculations. Accounting for possible impacts on future generations and the extension of probability into the future is a moral issue that comes into play in lay evaluations. Experts often discount temporally or spatially distant risks in what Shrader-Frechette argues is an unethical "isolationist strategy." (Shrader- Frechette 1991)

Risk assessment is a determination of the probability of harm but this calculation of frequency is largely irrelevant to lay peoples who generally place a greater importance on the type and degree of risk. A deciding factor in lay risk evaluation of nuclear power, for example, is what Perrow calls the "disaster factor." (1984) The disaster factor allows that while the chances of nuclear "accidents" may be slim (as the nuclear industry and scientists maintain), accident would mean catastrophe and this risk, though small, is often unacceptable to lay peoples. Lay judgement of the potential for disaster confounds experts who have established their calculations based on probability.

Industry's response to the "disaster factor" is to dismiss and belittle fear.³⁶ In response to lay conclusions that risks are unacceptable, the expert response is often to simply discount concern as irrational fear and offer reassurances and an appeal to "trust us." This response does not address the cause of lay mistrust and can compound rather than overcome it. Instead of dismissing lay evaluations as irrational, Beck argues that, "the growing awareness of risks must be reconstructed as a struggle among rationality claims, some competing and some overlapping." (1992: 59) Similarly, John Adams (1995) sees that, rather than irrationality, a world of plural rationalities characterizes debates over risks. Perrow argues that experts function on the basis of their ideal of an absolute rationality that comes into direct conflict with the bounded rationality or social and cultural rationality of the public at large. Science therefore cannot be relied on to resolve conflicts over risks. Beck argues that the "essential and momentous consequence" is that, "in definitions of risk the *science's monopoly on rationality is broken*." (1992:29)

Thirdly, mistrust in science is connected to scientific method and tools that achieve distance and are key in the manufacture of risk. The scientific method is based in tools of separation that achieve decontextualization. Scientific experimentation demands objectification and removal from context to allow quantification and prediction.³⁷ These methods are a source of both physical and social risk. They are also a source of inaccuracy in scientific risk assessment. Separation from context results in conclusions drawn from experiences that are different from lay contextually based knowledge. Barbara Adam argues that, "freedom from context is one of the greatest achievements of science and

³⁶ Douglas Powell and William Leiss (1997) argue that lay fear is result of failed institutional risk communications.

³⁷ Feminist analysis critiques decontextualization as part of the violence of scientific method. (Merchant 1980, Shiva 1995)

industrialization" (1998: 149) but as she and Beck argue, the victories of science are also the source of its failures. In real world applications of technologies such as genetic engineering, decontextualization has potentially catastrophic consequences.

The limitations of expert knowledge that are born of decontextualization are revealed when scientific knowledge that is developed in the closed system of the laboratory or test site is applied in the open system reality of the farm. The risks of genetic engineering such as, for example, cross pollination as seen in the case of canola or the risks of animal ill-health associated with rBGH, can be seen as a partial consequence of scientific design that is divorced from real world contexts. The social context of the farm can reveal naive assumptions about real world conditions. These assumptions have translated into applications of agricultural technologies that place farmers, the wider public, and the environment at risk. The inadequate and faulty risk assessments of the health effects of pesticide use is one example that illustrates how scientific assumptions about farm conditions can conflict with the social reality and knowledge of farmers. Expert assessments of the safety of the pesticide 2,4,5-T rested on assumptions of its ideal field application that contradicted the knowledge and experience of farmers.³⁸ (Wynne 1989:36, Irwin 1995) The introduction of technologies developed without consideration of the complex and varied contexts of use creates social and physical risk. Research into chemical inputs is still largely carried out in tightly controlled and uniform circumstances, without farmer participation.

Risk is enhanced by the imposition of meanings and definitions that are developed through expert-based risk assessment and operationalized through regulation. Wynne argues that, "risk is assumed to have an intrinsic, objective natural meaning that everyone should

share, rather than a meaning that has been created and imposed by particular dominant social institutions with their own interests and anxieties, and that systematically conceals certain issues and questions from public attention" (1992: 284); "Science is not meaning free or meaning neutral, it is dripping with impoverished and expropriated meanings, and ones in which there is no longer ordinary participation and access." (Wynne 1996b: 58) The imposition of these meanings constitute threats to social identity. Wynne argues that threats to social identity are the core of conflicts over risk and he introduces the concept of social risk to describe these effects. Wynne argues that, "through their rationalist discourses, modern expert institutions and their 'natural' cultural responses to risks in the idiom of scientific risk management, *tacitly and furtively impose prescriptive models of the human and the social upon lay people, and these are implicitly found wanting in human terms.*" (1996b: 57) Wynne argues that it is the value commitments created or represented by technologies rather than the impacts of technologies that dominate conflict over risk. Risk evaluation should focus therefore on value commitments as well as specific effects.

Expert risk determinations are unconscious answers to the question "how do we want to live?" and a fundamental inadequacy of expert risk determination and source of lay mistrust is the inability of science to answer this question. Beck argues that, "there are no expert solutions in risk discourse because experts can only supply factual information and are never able to assess which solutions are culturally acceptable." (Beck) The exclusion of lay knowledge and criteria in risk evaluation is the outcome of a number of intersecting practices. Neil Postman (1993) argues that theory of science, by definition, gives little weight to information that falls outside the constraints of science. Postman argues that our technological

³⁸ 2,4,5-T is one of two herbicides used in the defoliant Agent Orange that was deployed as a combat tool in the Vietnam War. Monsanto Company was one of the primary manufacturers of

culture is one whose available theories do not offer guidance about what is acceptable information in the moral domain. (1993: 79) Ulrich Beck argues that democratic control of risk is only possible if we can gain, "the competence to make our own judgements through a culturally created perceptibility of hazard." (quoted in Adam 1998:197)

Social risk is constituted in struggles over evaluations of risk that form a contestation over knowledge and meaning. Social risk is formed in the imposition of conceptions of human- nature relations and can be understood as a powerful force propelling critiques of modernization toward the transformation of industrial society. Genetic engineering forms a colonizing knowledge that is defined largely through commercial purpose where the conception of life in terms of a genetic code and the manipulation of life-forms through genetic engineering conflicts with traditional knowledges and imposes a new world view. The scientific paradigm and structure of ownership impose a social ordering in a commercial project of control that offers a particular answer to the question of how we want to live. Genetic engineering is a project of control and an expert based knowledge that is subject to a high degree of lay mistrust, at multiple levels. This mistrust is expressed in various critiques of genetic engineering.

Genetic engineering in agriculture cannot be separated from applications in medicine and other sectors that have opened all life, including human life, to redesign and reconstruction. Monsanto describes biotechnology as a "weapon in the war against weeds and insects" (Monsanto, *Common Ground*: 8) but a similar war is being waged by science and commerce against disease and undesirable traits in humans. The \$35 million Human Genome Diversity Project aims to chart all human genes for the purpose of developing new pharmaceutical drugs and therapies. In the United States, scientists at the National Institutes of

the chemical.

Health are searching for the gene responsible for a predisposition to violence in the "Violence Initiative Project," an overtly racist and classist project that targets inner-city youth. Genetic technologies also have military applications. Promises for genetic engineering as the key to a better world, offering salvation from world hunger and environmental degradation, contradict these applications and engender further mistrust.

Social actors engaged in the pursuit of science for profit already face a high degree of lay mistrust. The biotechnology industry widely recognizes mistrust in corporations, large multinationals in particular, as a problem in selling the advantages of genetic engineering. In the next chapter I will examine industry attempts to overcome this mistrust by enrolling trusted actors, including government regulators, into corporate communications strategies.

In discussing lay mistrust of social actors, Wynne pinpoints the broader issue as one of how authority is generated and maintained. (1992: 276) As Perrow argues, "ultimately, the issue is not risk, but power; the power to impose risks on the many for the benefit of the few." (1984: 306) The use of scientific criteria in regulation to the exclusion of socio-economic and ethical criteria achieves a review of the physical risks of agricultural biotechnology alone. The privileging of science may be seen as a coercive tactic to avoid debate. It imposes definitions of risk that conflict with lay values and may form a threat to social identity. A debate over the physical risks of genetic engineering is more easily controlled by industry and government than is any regarding social risk. In the next chapters I will explore how government and industry attempt to construct regulatory authority based in science and the privileged consideration of technical issues and expert knowledge. The resulting constraints on risk evaluation form a basis of lay mistrust and heightened lay-expert conflict.

Risk discourse fails to include lay knowledge and public concerns. Rather than attributing this to "congenital expert arrogance or even conspiracy," Wynne's analysis

pinpoints, "the institutional structures of decision making within which scientific experts naturally operate." (1992:286) Wynne highlights, "the unconscious social visions shaping different models of technology and risk" rather than "the deliberate and conscious social visions that engineers and others have as the social templates for their technical programmes." (Wynne 1995: 29) The structural role of scientists in systems of decision-making is implicated as well as the narrowness of the scientific education. Social models and assumptions are usually inadvertent and implicit in technical analysis and form the underlying source of disagreement.

In the case of the regulation of genetic engineering I argue that science-based regulation is not just a failure of risk assessment to include lay knowledges and public concerns but is a deliberate structural and discursive strategy to exclude. In the next chapter I will examine the appeal of science to the state in its attempts to normalise and manage risks. Lay mistrust presents a challenge to this strategy of science based risk regulation.

Conclusion

In this chapter I have introduced the risks of genetic engineering as risks of a qualitatively new type. I have examined genetic engineering in terms of its physical risks and the logic of profit maximization that drives its production. I argue that the physical and social risks of genetic engineering are its defining features and that these need to be made visible through various means including a political economy analysis of the source of risk as well as an incorporation of lay criteria and knowledge in risk evaluation. Science is centrally implicated in the manufacture of risk and yet institutions of industrial society continue to use

science in risk assessment. In the next chapter I examine the appeal of using science in policy making and the construction science based regulation in risk management.

Chapter Three

A Failed Response to Risk: The Appeal of “Science-Based” Regulation in Response to Risk

Introduction

In this chapter I argue that the rhetoric and structures of the science based regulation of genetic engineering serve both purposes of promoting innovation and legitimating the introduction of new genetic technologies. I argue that science based regulation is employed and appealed to by both government and industry to these ends. I will explore reasons why the state values science in decision-making processes, though the complex realities of its use in public policy disappoint and contradict expectations. I argue that science based regulation is used in response to the challenges of risk in attempts to normalize and manage risk.

1. Role of the State in Promoting Innovation: Defining Benefit

As I discussed in chapter two, innovation is viewed as a core stimulus of capitalist development. In this section I examine the role that the state is expected and asked to play in promoting innovation. The regulatory responsibilities of the state relating to health and safety can conflict with this role and, as I argue in chapter four, protecting human health and environmental safety is increasingly subordinated in risk regulation to the goal of promoting innovation. The state has an important role to play in the administration of the economy and pursues this in partnership with industry. The state has a role to play in providing or

guaranteeing a market for products and in underwriting the costs of product development.

(Galbraith 1967) Industry demands support from national governments in the form of financial incentives including tax breaks, loans, favourable property rights regimes, research and human resource development and infrastructure, in order to create conditions favourable to industry growth.

Structural competitiveness driven by innovation is becoming central to the successful performance of the economic functions of the contemporary capitalist state and heightened international competition for advantage in new and emerging industries is exerting pressure on governments to yield to industry demands. Bob Jessop argues that, "advanced capitalist economies must move up the technological hierarchy and specialize in the new core technologies if they are to maintain employment and growth." (1993:13) Jessop describes a critical trend in the rise of new core technologies as motive and carrier forces of economic expansion and argues that, "many are so knowledge - and capital -intensive that their development demands extensive collaboration (especially at precompetitive stages) among diverse interests (firms, institutes of higher education, public and private research laboratories, venture capital concerns, public finance bodies, etc.)." (1993: 12-13) State action is required to guide the development of technologies and widen their application to promote competitiveness; "States have a key role here in promoting innovative capacities, technical competence, and technology transfer so that as many firms and sectors as possible benefit from the new technological opportunities created by research and development activities undertaken in specific parts of the economy." (Jessop 1993:13)

Jessop describes a form of state regulation that he argues is best suited to accommodating the new economic demands of competition. In opposition to the regime of the Keynesian Welfare State (KWS) that supported Fordist production, a Schumpeterian Workfare

State (SWS) is emerging to meet the demands of flexibility in the period of transition from Fordist to post-Fordist production. The priority of the SWS is to promote innovation and structural competitiveness in economic (and social) policy and is distinctive because of this "explicit, strategically self-conscious concern with the many and varied conditions which make for structural competitiveness in open economies." (Jessop 1993:18)

Increasingly the regulatory environment is seen as an important factor in creating environments supportive of innovation, and regulation is being shaped according to this priority. Richard Paton of the Treasury Board argues that, "regulatory issues are an important component of how this country is seen internationally as a good place to do business, thus offering accessibility to markets, getting products to the market, being able to work across the country, without having to go through several different regulatory regimes and dealing with the costs that this incurs." (quoted in Mehta 1995:12)

In the next chapter I outline industry arguments for efficiency and competitiveness in regulation and examine the role of science based regulation in meeting this goal. The regulatory system has become a site of contestation because of this potential and because of increasing conflict between demands made on the state to promote innovation and the state's continuing responsibility to protect and promote human and environmental health. As described by Agriculture Canada in early materials on their regulation of genetic engineering, "the role of the regulator is to balance public concern for safety with those of industries that wish to use technology to create national prosperity." (Agriculture and Agri-Food Canada 15 March 1995)

In addition to promoting innovation, the state plays an important role in legitimating accumulation strategies and the introduction of new technologies. Having accepted the economic benefits of developing the new biotechnology industry, the government is left with the task, in

addition to developing a business-friendly regulatory system and commercializing products in a timely fashion, of communicating these benefits and legitimating state support for their development. As I will discuss in the next chapter, industry explicitly argues for the role that it expects and demands government, and regulators in particular, to fulfil in legitimating genetic engineering. In chapter four I will discuss how this role is picked up by the Canadian government through the commitments of regulatory agencies and staff to communicating their role in reviewing genetically engineered products for safety. As John Kenneth Galbraith argues, "when investment in technological-development is very high, a wrong technical judgement or a failure in persuading consumers to buy the product can be extremely expensive. The cost and associated risk can be greatly reduced if the state pays for more exalted technical development or guarantees a market for the technically advanced product." (Galbraith 1967:17) In the case of genetic technologies, the Canadian government aims to minimize the financial risks of commercialization to private corporations by legitimating genetic engineering to the public, and, as I will discuss in chapter four, creating an "efficient" and predictable product approval process. Both of these goals depend on the construction of a science based regulation.

Through the regulation of genetically engineered products the state defines genetic engineering, its risks and benefits, and determines what is acceptable risk. The fundamental question remains however: how can institutions that are central to risk manufacture, regulate risk? Institutions of industrial society continue to legitimate the manufacture of risk, even as they regulate for public safety. In the next section I outline the commitment that the Canadian government has made to promoting growth in the biotechnology industry. I then explore why science is appealed to by the state in response to risk. I argue that the privileging of science in policy-making compounds the institutional crisis that is the risk society.

2. The Canadian Biotechnology Strategy: Promoting Industry Growth

The Canadian government has accepted a central role in supporting biotechnology innovation and the emerging biotechnology industry in Canada. There was an early government commitment to a high level of assistance to the industry through mechanisms such as infrastructure development, including research funds and partnerships. Subsidies to corporations have continued and increased through various government initiatives. The demonstrated commitment of the government to the industry has influenced the development of regulation. In the next chapter I will discuss how this has translated into a direct conflict inside regulatory agencies where government both promotes and regulates genetic engineering, ultimately enrolling the regulatory system in legitimization strategies. Having decided to support innovation in genetic engineering, the government accepts the economic benefits and constructs acceptable risk for the Canadian public accordingly.

The Canadian government is persuaded by the potential economic benefit of biotechnological innovation and is caught up in a race to compete for advantage in the emerging international industry. According to the Canadian Biotechnology Strategy (CBS), "national governments are targeting biotechnology as a strategic enabling technology to support growth and international competitiveness. As a result, the Canadian biotechnology industry faces formidable competition from American, German and other companies that have benefited from major biotechnology and related government initiatives in their countries." (Canadian Biotechnology Strategy 1998:5)

In 1983 the federal government made its first financial commitment to the development of a Canadian biotechnology industry. This commitment made Saskatoon a North American plant biotechnology research centre, one of five Canadian government biotechnology

"Networks of Centers of Excellence." (KPMG 1994: 11) That same year the National Biotechnology Advisory Committee (NBAC) was established by Industry Canada in partnership with industry and academia as a consultative body to advise and direct the government in the development of biotechnology - research and development and human resources in particular. (Canada, Workshop 1993:4) In 1993, speaking about the collaboration of university researchers and the support to the industry - both financial and otherwise - from the Canadian government, Richard Mahoney, the then CEO and Chairman of Monsanto, stated that, "this focus and exercise of political will in biotechnology has been an incredible achievement- rarely if ever duplicated in peacetime." (Mahoney 1993:2) By 1994 the federal government had invested over \$22 million in the biotechnology industry. (KPMG 1994: 11)

The government is building research partnerships with industry to support corporate initiatives and fund government endeavours. In 1995 Agriculture and Agri-Food Canada created the "Matching Investment Initiative" whereby the department matches industry financing of agricultural research, "to ensure that the Canadian industry benefits from access to the latest technology available." (Saskatoon Research Center May 1998) Each of the research programs at the Agriculture Canada Saskatoon Research Center advertises this initiative: "Our objective is to carry out research which can be readily transferred to the client for the generation of new business and economic growth in Canada." (Saskatoon Research Center May 1998)

Saskatchewan is the world center of canola engineering and the federal government has pledged to build upon this success. "Canadian agriculture needs to make sure it stays in the driver's seat regarding innovations in biotechnology," argued Dr. Murray McLaughlin, president of Ag-West Biotech Inc., a non-profit industry lobby that focuses on strengthening the biotechnology industry in Saskatchewan. (*Ontario Farmer* March 15, 1994) The Canadian

government now advertises "well-established ag-biotech clusters" across the country, existing in each of the ten provinces. ("Investing in Canada's Dynamic Agricultural Biotechnology Sector," Government of Canada, 1998) In the 1997 Speech from the Throne, the federal government declared that biotechnology was an important sector for future jobs and economic growth, and in the 1999 Federal Budget the Liberal government allocated \$55 billion dollars over three years to the Canadian Biotechnology Strategy for research and industrial application of biotechnologies, "to make Canada a world leader in biotechnology." (Canadian Biotechnology Strategy February 1998, Federal Budget 1999)

In a Industry Canada initiative NBAC was replaced by the Canadian Biotechnology Strategy (CBS). (The House of Commons Standing Committee on the Environment and Sustainable Development had argued in 1996 that, "the focus of NBAC is too narrowly directed to the commercial aspects of biotechnology and, moreover, does not have the independence from government departments that the Committee feels is necessary to deal with the problems and controversies that continually beset biotechnology." (Standing Committee on Environment and Sustainable Development November 1996: 37) The Canadian Biotechnology Strategy is a project of Industry Canada that aims to address a broad range of issues that have an impact on the industry, including public awareness and ethical concerns. The purpose of the CBS is to coordinate government support for the biotechnology industry and promote its competitive position. The point of origin for the Canadian Biotechnology Strategy is the Canadian government's commitment to biotechnology as a core new technology.

Canada has more biotechnology companies per capita than any other country, 26 per cent of which focus on agriculture and agri-food. (Canadian Biotechnology Strategy 1998:5,19) The Canadian Biotechnology Strategy argues that, "industry experts expect Canada to double its

current exports of agricultural products to \$40 billion by 2005. Biotechnology will play a significant part in achieving these export goals." (Canadian Biotechnology Strategy 1998:19)

Economic development goals, including the powerful appeal of job creation, dominate arguments for the imperative to press forward with support for genetic engineering. In early 1999 the Government of Manitoba announced that Monsanto will build its new crop development center on the University of Manitoba campus. The \$10 million dollar center will create "30 new technology jobs over next two years." (Government of Manitoba 10 March 1999) The provincial government is contributing \$1 million to the center. Said Premier Gary Filmon, "we're very pleased Monsanto chose Manitoba for this project. Not only will it provide new high tech jobs, it is expected to infuse about 12.5 million into the provincial economy, through spinoff opportunities." (Government of Manitoba 10 March 1999)

Having made a substantial financial investment in the development of the biotechnology industry, the government is confronted with the challenge of regulating the technology to realize expected benefit, an increasingly complex and controversial task. In 1988, NBAC outlined criteria needed for regulation formation, arguing that, "the development of an appropriate regulatory system which covers environmental introduction and use of such products will, in large measure, determine whether the commercial benefits from the substantial private and public investments which have been made to date will be reaped in Canada." (1988: 3) As I will explore through this chapter and the next, these criteria have shaped a regulatory framework that creates a restrictive definition of genetic engineering. The definition is constructed through a science based regulation that serves to promote innovation and legitimate genetic engineering.

3. Science Based Regulation As State Response to Risk

In this section I explore the use of science as an institutional response to the challenges of risk regulation. I discuss some of the reasons why the state values science in policy decision-making processes generally and, in particular, towards the goals of promoting innovation and legitimating the regulation and introduction of new technologies. I discuss some of the complex realities of the use of science in policy making and pressures under which science is practised. These realities reveal policy making as an unavoidably political process.

Liora Slater (1988) uses the term "mandated science" to refer to the role of science and scientists in policy making. The mandate to develop recommendations or decisions for public policy exerts a pressure on science that is reflected in the activities of scientists, their work and its interpretation. (Salter 1988: 3) Salter examines this pressure, not in terms of politics corrupting science, but as constraints upon the role of science and scientists acting in the "special world" of policy making. Such constraints are felt by both scientists and government. Science is a particular knowledge seeking strategy that has a critical role to play in protecting human health and the environment. At the same time mandated science is idealized as a public enterprise that is value-free and able to reach credible conclusions that are independent of how they are used. The ideal offers advantages for decision-makers, and is necessary to assert if science is used to justify government decisions, but the realities of science in policy making processes are complex and contradict these expectations.

Science is expected to provide of a degree of certainty upon which policy decisions can be based. The production of "facts" is valuable for decision makers but the limitations of science in producing certainty are rarely recognized. In the 1998 Public Policy Forum "Round Table Discussion on the Credibility and Acceptability of Science Advice for Decision-

Making," officials from government departments, including Health Canada, agreed that because, "the perception that scientists have established truth exists in the public and often in the political community as well," it is important to recognize and communicate the "evolving nature of scientific knowledge."³⁹ (Public Policy Forum 1998: 6) According to the round table report, participants argued that, "there is an urgent need to establish more realistic expectations with respect to scientific advice." (Public Policy Forum 1998: 6)

The authority of science is largely derived from the myth of its value-neutrality or objectivity which allows for the construction of "facts." Theodore Porter (1995) argues that bureaucracies often appeal to this authority in attempts to legitimate policy making processes that have no public mandate. Policy decisions based on science may be less open to challenge as, "objectivity as impersonality is often conflated with objectivity as truth." (Porter 1995) State institutions may appeal to the objectivity of science in response to internal disciplinary weakness or external regulatory pressures in order to meet the demands for impartiality and fairness that are associated with political democracy. Science and quantification is a way of making decisions without seeming to decide. In this way, science and the discovery of facts can be used to depoliticize decisions and minimise the responsibility of decision makers.

Despite attempts to rely solely on scientific criteria, however, decisions about risk are inherently political. The science basis of regulation claims value-neutrality but non-scientific

³⁹ The Public Policy Forum workshop was attended by many people who are active in a network promoting the science basis of regulation as a means of inspiring trust in the safety of genetic engineering. Alan Nymark, Associate Deputy Minister of Health Canada, and Ian Shugart, Visiting Assistant Deputy Minister of the Health Protection Branch, Health Canada, were both implicated, in a case that I will discuss in the next section, by department scientists in pressuring for the approval of rBGH, against the recommendations of those scientists. The Deputy Minister of Health Canada, David Dodge, participated in the forum only a month after testifying at the Senate Standing Committee on Agriculture and Forestry regarding these conflicts inside Health Canada over the scientific evaluation of rBGH. The forum round table was also attended by Ronald L. Doering of the Canadian Food Inspection Agency and by Laurie Curry, Vice President, Public Policy and Scientific Affairs, Food & Consumer Products Manufacturers. Curry is deeply engaged in developing communications strategies that focus on using the science-based review of genetically engineered products in response to consumer concerns about genetically engineered foods.

interests are always at play in regulatory processes. Alan Irwin (1989) argues that it is necessary to view risk decisions as unavoidably social as well as technical in character. Judging acceptable risk is most obviously a political decision and must be structured, through democratic processes, by this recognition. Ultimately it is politics rather than science that decides acceptable risk. (Macilwain 1996:11) The report of the Public Policy Forum round table concluded that, "in the end the judgement on the acceptability of a given level of risk must be part of the political decision process, clearly separated from the role of the science advice process." (1998:8) Salter (1988) argues however that scientific and policy issues are so closely entwined that they cannot be separated. The political nature of risk assessments and policy decisions must be explicitly recognized by regulatory agencies and the role of ethical considerations needs to be acknowledged. As was articulated in the Round Table report:

The recognition that non-science issues often play a predominant role in what may appear to be science-based decisions needs to be better understood and communicated. The example of cloning was used as an illustration. Although sometimes perceived as principally an issue of science, both in terms of capability and of consequences, the key decisions are almost entirely determined by ethical rather than scientific considerations. (Public Policy Forum 1998:14)

The use of science in policy making processes can also offer a veil of objectivity (Porter 1995) that can mask the political nature of decisions generally or be used in direct ways to cover the manipulation of science and scientific results. Participants at the round table agreed that, "science must remain true to its own principles if it is to be a useful tool for public policy. 'Managing' the science to fit the needs of a policy decision would diminish both the science and the policy." (Public Policy Forum 1998: 6) They argue that, "where political accountability is very prominent, the need to have the scientific expertise close at hand and clearly unaffected by commercial interests was seen as important." (Public Policy Forum 1998:7) In the next section I will show how this advice is relevant to the use of science in Health Canada's review

of rBGH. In the last section of this chapter I examine its relevance in examining international regulation of genetic engineering.

The ability of institutions of industrial society to manage risk is challenged in the risk society. Faced with risks that challenge the very basis of industrial society, institutions only deny and attempt to manage or legitimate risks. To manage risks, institutions turn to science and a dependency on technical risk assessment, defining risk as a technical problem that, with enough time and resources, scientific study can overcome. The response of the state to the challenges posed in the risk society is to reduce risk to technical calculations. Science is privileged in the regulation of genetic engineering in an attempt to normalize the risks of genetic engineering. The regulation of products of genetic engineering is pursued as if science could calculate and manage risks. The discussion of genetic engineering in terms of safety and efficacy assumes that risks can be calculated and, in this way, science based regulation portrays a sense of security in the ability of science and experts to provide certainty, as well as in the ability of institutions of industrial society to use these tools to successfully manage risk.

The construction of the regulation of genetic engineering in scientific terms reifies genetic engineering, giving a false natural status to the technology itself and validating it as a viable technological fix. The doctrine of technical fixes works to avoid social negotiation by redefining social uncertainties as technical. (Wynne 1987: 103) Brian Wynne argues that in constructing the decision issues as one of objective discovery rather than social commitment, opponents to a technology and their concerns are constructed as factually wrong or irrational. (Wynne 1992: 277) The use of scientific criteria in risk assessment thus becomes a powerful tool of legitimation that works to privilege expert knowledge above lay knowledge and exclude social and ethical concerns.

Through the central use of science, the state defines risk based on the same rationality from which risks were manufactured. Szerszynski *et al.* (1996) identify a process that they observe in the European Union's environmental regulation in which complex risks are reduced to technical issues and challenges for science. They refer to this as a "technologization" of policy concerns where the discourse of technological fix is applied to environmental issues and evacuates discussions of their social and cultural meaning. They argue that through this process the "very vocabularies that threaten the lifeworld" are being employed by governments to address ecological destruction.

Ulrich Beck argues that in the risk society, "the legal order no longer guarantees social peace, because it generalizes and legitimizes the threats to life." (1996: 14) Regulating risk has become a part of normalizing risk in industrial society where, "concretely, it is not rule-breaking but the rules themselves which 'normalize' the death of species, rivers or lakes." (Beck 1996: 12) Beck argues that, "all these agencies and regulations can play their role, and all the valid agreements can be honoured, without this resulting in any security." (1996: 12) Institutions attempt to legitimate and normalize risk as security fictions break down.

What is referred to as an ecological crisis then, is better understood as an institutional crisis where the risks of the risk society are an expression, not of ecological failure, but of the failure of institutions of industrial capitalism. Institutions of industrial society continue to produce and legitimate risks which they cannot control. The failures of attempts to control or manage risk reveal an inability of the state to maintain security fictions when faced with the risks of the risk society. In response to risk the state appeals to science in regulation, both to promote innovation and to legitimate the introduction of new technologies with their accompanying risks. Unable or unwilling to acknowledge the role of science in risk manufacture, the complex realities of using science in decision-making processes, and the

political nature of risk evaluation and risk decisions, institutions of industrial society attempt to regulate risk through the same paradigm and discourse of science that is implicated in risk manufacture.

In the next section I highlight some of the struggles around the use of science in Health Canada's review of the genetically engineered drug Bovine Growth Hormone (rBGH). The details that emerged regarding this review offer a unique window into the complexities of using science in regulation. They illustrate some of the ways in which science can be used to facilitate speedy product commercialization and otherwise serve industry interests. They illuminate some industry access points to regulators and some of the ways in which industry influence can be manifest in regulation.

4. Political Realities of Science in Policy Making: Struggles Inside Health Canada

Through the course of the review of rBGH, dynamics internal to Health Canada, including the working relationships of scientists and managers, and external pressures on the department enhanced existing constraints on the use of science in regulation. These pressures produced powerful new relationships and structural and discursive circumstances that, according to a number of scientists in the Bureau of Veterinary Drugs, Health Canada, compromised rigorous safety review. In 1997 six scientific evaluators who work in the Bureau of Veterinary Drugs of the Health Protection Branch, Health Canada filed a grievance with their union, the Professional Institute of the Public Service (PIPS), complaining that they were being harassed by their managers to approve drugs, including rBGH, that were of questionable safety. The testimony of the scientists at their grievance hearing and the subsequent testimony of three of the six at hearings of the Standing Senate Committee on Agriculture and Forestry

offer a window into the workings of regulatory review in general, and some of the pressures in regulation of genetically engineered products in particular - a perspective on the science and its role from the scientific evaluators themselves.

Scientists in the Bureau of Veterinary Drugs (BVD) described the most immediate and troubling constraints on their work as a direct result of industry influence in the department. In 1996 Health Canada introduced a program of cost recovery that requires product manufacturers to pay a portion, between 70 and 90 per cent, of the costs of each product review.⁴⁰ The cost recovery program created a new relationship between industry and government departments such that private companies now pay for the review of their products. The "Quality Initiative" of the Drugs and Medical Devices Programme of the Health Protection Branch informs scientific evaluators that: "Your client is the direct recipient of your services. In many cases this is the person or company who pays for the service."⁴¹ (Drugs and Medical Devices Programme, February 1997) In testimony at her grievance hearing, BVD scientific evaluator Dr. Margaret Haydon argued that the pressure from pharmaceutical corporations to approve drugs quickly became more acute after cost recovery measures came into effect. (PSSRB hearings 1998) Dr. Haydon alleged that one of her managers repeatedly threatened that she could be subject to personal suit by a particular manufacturer if she held up product review. (PSSRB Hearing 1998) At least one company has written to managers of the Health Protection Branch demanding that, as a paying client, the review of their drug be expedited. Industry representatives, through participation in a Joint Management Program Advisory

⁴⁰ Dr. Haydon argued that the budget of the Bureau of Veterinary Drugs was reduced in anticipation of income from the cost-recovery program. (PSSRB Hearing 1998)

⁴¹ This document was submitted by Dr. Michelle Brill-Edwards as part of her resignation letter from the Drugs Directorate of Health Canada. Dr. Brill-Edwards quit her work as a drug evaluator because of the degree of industry influence within the department that she felt was directly compromising her work and public safety. She is now a member of a small pressure group called the Alliance for Public Accountability.

Committee, have access to the names of the scientists who are reviewing their products. The result has been letters written to department managers asking that individual scientists be removed from their review cases for working too slowly.

In Health Canada, scientists evaluate corporately owned data. This private ownership has a profound effect on the review process, in particular on the relationships between scientific evaluators and product manufacturers or "proponents." The conception of mandated science as an intrinsically public enterprise is altered when access to information is restricted. (Salter 1988: 189) Intellectual property rights protect product information and the classification of product data as trade secrets has enhanced the ability of industry to restrict access to research data, even from the scientists evaluating products for approval. In the case of rBGH, all product related files were locked away from scientific evaluators in the Bureau of Veterinary Drugs and controlled by one manager, obstructing the scientists' work. (PSSRB Hearing 1998) Private control over product data also restricts the access of politicians and the public to this information. The need to protect trade secrets was used by managers in Health Canada as a justification of their censorship of information on rBGH that was requested by the Senate agriculture committee.⁴² A leaked document from the Minister of Health's office revealed that department officials were concerned about what Monsanto lawyers in St. Louis and its Government Relations representatives in Ottawa would think if confidential information came out in the Senate hearings. (*The Globe and Mail* October 1998) Managers apparently prepared to "engineer" the appearance of the BVD scientists in order to prevent this from happening.

In the 1998 union grievance hearing, six BVD scientists testified that they were under constant pressure from department managers to approve products quickly. They alleged that

their requests for further data from proponents were suppressed and that their safety concerns were ignored. Five of the six scientists testified that they were moved to another division and assigned to areas outside their expertise in retaliation for their mounting complaints about the review process. Managers argued that these were not "transfers" but "temporary reassignments" that were necessary to deal with a backlog of review cases. The scientists maintain however that this was an effort to undermine their review of rBGH. Managers characterised the problems in the department as interpersonal conflicts but the scientists argued that the disagreement was not just over the science but also over the goals of management. Managers wanted to approve products quickly for the satisfaction of corporate clients and this compromised the rigour of scientists in reviewing product safety in the public interest.⁴³ There was a distinct lack of trust between scientists and upper management inside the BVD. The details of review inside Health Canada expose a troublesome relationship between industry and regulatory agencies. In chapter five I will explore this case further in that, after ten years of public protest, Health Canada managers were forced to announce rejection of Monsanto's submission for approval of rBGH.

In response to the ongoing conflicts over rBGH review inside Health Canada, the department engaged two independent scientific panels to review the available data. Health Canada requested the Royal Society of Physicians and Surgeons and the Canadian Veterinary Medical Association to form panels to assess the human and animal safety of rBGH

⁴² When the Standing Senate Committee on Agriculture and Forestry requested a copy of an internal Health Canada analysis of rBGH, the "Gaps Analysis Report," they received a version that was more heavily censored than a copy of the report later received through an Access to Information Request.

⁴³ In response to the grievances filed by the scientists the department contracted consultants KPMG to survey staff and study relationships inside the bureau. The KPMG report concluded that interpersonal problems were the source of conflicts over review cases and blamed "a clique of troublemakers" for disturbing the business of the bureau. Dr. Haydon and the other scientists who filed the grievance viewed this as a reference to them and, as the report was circulated to all staff in the BVD, they saw this as an intimidation tactic.

respectively. Dr. Margaret Haydon argued that it was "interesting and unusual that the external panel, the Canadian Veterinary Medical Association, has been asked to review the drug. We still have not completed the review that appears in our bureau." (Senate testimony October 20, 1998)

The Royal College of Physicians and Surgeons of Canada (RCPSC) described their mandated from Health Canada as follows:

In approaching the RCPSC with a request that an expert panel be convened, Health Canada stated that "it is essential that *public confidence* in the safety of the milk supply be assured at all times. In cases where scientists within the health department lack consensus on matters of drug safety and where there is substantial controversy in the international scientific community about the safety and efficacy of a veterinary drug, then, the creation of an external expert advisory committee to provide independent advice to Health Canada is appropriate." (Royal College of Physicians and Surgeons of Canada 1999)(emphasis added)

The RCPSC notes that the selection of panel members was based on their suggestions and those of Health Canada. The RCPSC panel included a consultant to Monsanto who, in 1994, co-authored an article recommending approval of rBGH. (*Toronto Star* 24 September 1998)

Department memos show that through telephone conversations and meetings, Monsanto officials volunteered input into panel proceedings. A memo from Dr. Ian Alexander of Health Canada, regarding a telephone conversation with Dr. Kowalczyk, Regulatory Affairs, Monsanto Company, notes that Dr. Kowalczyk suggested agenda items for an upcoming meeting with Health Canada that included a discussion item on the independent panels. The memo states that, "they [Monsanto] would have some suggestions based on experience in the U.S." (Health Canada 1998) Monsanto and BVD officials also met to discuss the work of the external panels. Monsanto officials suggested specific scientific studies that the department could bring to the attention of the panel. (Health Canada 1998)

The RCPSC panel concluded that, "adequate data have been provided to the Bureau of Veterinary Drugs to permit reasonable decisions to be made about the human safety of meat, milk, and dairy products derived from Canadian dairy cattle treated with Nutrilac (rbST)." (Royal College of Physicians and Surgeons of Canada 1999) The report of the Canadian Veterinary Medical Association panel validated the concerns of the BVD scientists, concluding that rBGH resulted in animal ill-health. The panel conclusions gave Health Canada an opportunity to use a scientific justification to deny Monsanto market approval of rBGH, "at this time." As I will discuss in the next section, this scientific justification is necessitated by Canadian government obligations in international trade agreements. With a scientific reasoning in hand the government did not need to acknowledge the impact of public protest on the review process and their decision to refuse rBGH.

In the next section I look at the construction of a science basis in international regulation of genetic engineering. Regulation developed through international trading regimes coordinates the policy response to risk across nation states and imposes the discipline of a science based regulation on risk decisions.

5. A Science-Based Regulation Constitutionalized in International Trade Regimes

The use of scientific criteria in national regulatory regimes for the purposes of commercialization and legitimation is replicated in, and reinforced through, international regulation as outlined in multilateral trade agreements. In the North American Free Trade Agreement and the World Trade Organization, scientific criteria is explicitly privileged above other considerations in the establishment of food and environmental safety regulations. Negotiated by national governments and transnational corporations at a time when products of

genetic engineering were being developed and readied for commercialization, the establishment of a science basis for regulation in international regimes supports the introduction of these products into markets across the world.⁴⁴

Rules established through international trading regimes challenge domestic risk regulation by working to restrict policy choices at the nation-state level. International trade agreements essentially "constitutionalize" approaches to policy making.⁴⁵ (Robinson 1993) Harriet Friedman and Philip McMichael argue that a transition from national to international regulation is clear in the agricultural sector. (Friedman 1993, McMichael 1994) The use of scientific criteria in deciding food safety standards is necessary to permit international harmonization and a rule based trading system, something that would not be possible with decision making based on non-scientific concerns. Heather Menzies argues that with Free Trade there is a "new thrust of regulation away from social and political issues toward narrowly technical, economic ones." (Menzies 1996: 16)

Sanitary and phytosanitary (SPS) measures are those taken by governments for the protection of humans, animals and plants from pests, diseases, and contaminants. The SPS measures established through the World Trade Organization (WTO) are based solely on scientific assessment: "Members shall ensure that any sanitary and phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles, and is not maintained without sufficient scientific evidence." The WTO defines the scientific basis broadly as a reason based on data or information derived using

⁴⁴ Liora Salter argues that people are generally reassured when told that standards conform to those determined internationally, that, "it is almost as a matter of faith that international standards are accepted as sufficient for public safety." (Salter 1988:67) The Canadian government now makes sure to describe its regulatory framework as based on internationally recognized principles (This is a response to criticism of the use of the concept substantial equivalence that I will examine in chapter four).

scientific methods. The SPS measures of both the North American Free Trade Agreement and the WTO detail that national governments can only reject genetically engineered products based on scientific concerns and evidence. This constraint was outlined in early Canadian government consultations on the regulation of genetic engineering. (Canada, Workshop 1993:18) The science basis is enforced to ensure that political considerations are not used to reach decisions that violate the principle of non-discrimination and create what the WTO would rule as unfair trading practices. The SPS measures are designed to enforce the principle of non-discrimination where, "the SPS agreement explicitly recognizes the right of governments to take measures to protect human, animal and plant health and do not unjustifiably discriminate among foreign sources of supply." (World Trade Organization Secretariat 1995:6)

The WTO itself does not establish standards or guidelines on SPS matters but defers to the work of other international bodies. The Codex Alimentarius Commission is a joint body of the United Nations Food and Agriculture Organization and the World Health Organization that was established to set food safety standards for voluntary adoption by national governments. The Codex now serves as a reference in WTO trade disputes pertaining to food and food safety. As described by the Canadian Office of the Codex Contact, "countries which establish requirements that are more stringent than the standards, guidelines and recommendations developed by Codex could be required to provide justification for their higher standards if a trade dispute arises." (Office of the Codex Contact 1998) The explicit purpose of food safety standard harmonization in Codex, since its formation in 1956, is to facilitate international trade. Codex formerly recognizes the importance of standards for trade relationships and sets its standards accordingly. (Salter 1988: 68) As Salter argues, Codex standards are primarily

⁴⁵ Goldman and Wagner argue that the WTO decision on Hormones in meat ruled on procedure which is outside the authority of the SPS measures and the dispute panels. (Goldman and Wagner)

connected to export decisions and are "anything but symbolic in their importance. They have a direct effect upon the profit levels of major corporations." (Salter 1988: 89) The trend toward downward harmonization of standards is established through Codex and is the general outcome of policy-making through trading regimes.

The project of harmonizing standards is only possible based on scientific criteria, as opposed to social and ethical considerations. At the 1995 meeting of Codex, the delegation of officials from the United States, with support from the Canadian government delegation, succeeded in pushing for agreement that Codex standards be based solely on science. (Leonard 1995:4) Patrick McCabe of the Animal Health Institute, a U.S. trade organization representing manufacturers of veterinary drugs, argued that, "Codex standards should be based on science and not socio-economic factors." (Avery 1993) In a letter written to Europe's Agriculture Commissioner, the then U.S. Agriculture Secretary, argued that the prospective European Union moratorium on rBGH would "contravene our mutual objective of achieving international harmonization in this sensitive area of food safety. It would also add fuel to the fires of those who wish to have public policy decisions made on the basis of emotion and political pressure." (quoted in Ritchie 1993:185) The non-governmental consumer advocacy organization Consumers International argues that science is necessary but not sufficient for the determination of food safety standards and that "other factors" play an unrecognized role in Codex decision making and will inevitably continue to do so. (Consumers International 1998). The Codex Alimentarius Commission is presently debating the role of "other factors" in its decision-making processes.

National policies can be challenged by WTO member countries in a threat that takes the form of a new discipline over policy making. Concerns over Canada's obligations in trade agreements were raised in parliamentary debate over the ability of the government to reject

rBGH.⁴⁶ Trade challenges are mediated by dispute panels through which the WTO permits trade experts to second guess the sufficiency of the scientific evidence underlying food safety standards. (Goldman and Wiles 1994) No expertise in food safety is required for panel membership; qualifications for service on panels include past service on a panel, past representation of a country before a trade institution or tribunal, past service as a senior trade policy official of a member country, and teaching experience or publishing on international trade law or policy. (Goldman and Wiles 1994: 80) Dispute panels can chose to seek scientific advice and convene technical expert groups but the examples of international deliberations over food safety in the WTO with the case of the beef hormone (Goldman and Wagner October 31 1997), and in the Codex Commission with the case of rBGH, make clear the fundamental political nature of decisions as well as the potential for manipulation of science and scientific panels at the international level.

National governments can engage international processes to create conditions to press decisions that they have no mandate to take domestically. The Canadian government used Codex proceedings to forward approval of rBGH. At the 1995 meeting Canada joined the US and other countries in supporting the approval of rBGH even though this was not Canada's position domestically. (Leonard 1995) Member of the Codex Delegation, Dr. Sol Gunner, then Director General of the Health Protection Branch, had earlier testified before a House of Commons committee that Health Canada had not established the safety of rBGH for human consumption. (Council of Canadians September 11 1995) The Canadian government is also implicated in attempts to manipulate the "independent" scientific panel formed in Codex to make recommendations regarding the safety of rBGH. The Joint Expert Committee on Food

⁴⁶ In the 1994 hearings of the House of Commons Standing Committee on Agriculture and Agri-Food, Members of Parliament asked witnesses about the possible implications in NAFTA of a decision in Canada to reject rBGH.

Additives (JECFA) was formed in 1987 to advise Codex on acceptable residues of veterinary drugs in food and as early as 1992 was asked to assess rBGH for human health effects. Health Canada officials, under advisement from Monsanto representatives, prepared to delay any decision on approving rBGH until the JECFA had ruled on human safety. According to Michelle Brill-Edwards, it is a breach of the Food and Drugs Act to delay decisions if the department had concluded its review. (Senate testimony December 7, 1998) It was only when Health Canada faced unprecedented public scrutiny, including the revelation of this planned delay, that it, before JECFA reached its conclusions, rejected rBGH.

Examination of the work of the "independent" scientific panel of the JECFA offers an important illustration of the possible manipulation of science for predetermined policy outcomes. John Verrel, member of the UK Food Ethics Council, argues that in the case of JECFA's inquiries into rBGH, "there is a lack of transparency and an apparently secretive operation that allows the distortion of scientific evidence for what can only be regarded in this case...as politico-economic expediency." (Senate testimony November 17, 1998) Verrel argues that the committee consistently disregarded important emerging scientific evidence about the effects of rBGH on human health, in particular the much discussed possible link to cancer.

The meeting of the JECFA was dominated by officials from the U.S. Food and Drug Association (FDA) - the FDA having approved rBGH in 1994. Proceedings of JECFA are confidential and committee members are not permitted to discuss their work outside proceedings. Documents from Health Canada received through Access to Information reveal however that a JECFA panel member and employee of the FDA,⁴⁷ sent confidential committee documents to Monsanto months ahead of the JECFA meeting that was to make

⁴⁷ The FDA employee, Dr. Nick Webber, reports to Dr. Margaret Miller who is an ex-employee of Monsanto and another JECFA panel member. (Consumers International 1999)

recommendations regarding the safety of rBGH for regulatory approval (Monsanto officials then passed the documents to Health Canada officials). The exchange of restricted documents reveals a high level of collaboration between FDA officials, Monsanto representatives, and Canadian government officials for the purposes of manipulating panel proceedings such that the scientific evidence would support conclusions of the safety of rBGH.

The construction of a science based regulation internationally serves the same purposes - to promote innovation and legitimate regulatory decisions - as the similar construction in Canadian regulation. The use of science in international bodies mirrors the use of science in Canadian regulation and the review of rBGH in particular. Risk decisions are political in nature and the manipulation of scientific processes and results warns of the need for a critique of the authority of science as well as a recognition of the political nature of decision making.

6. A Science-Based Regulation in Defence of Genetic Engineering

The culmination of efforts to establish science-based regulation and use "sound science" to legitimate the approval of genetically engineered foods can be seen in the adoption of this discourse in government defense of its policies relating to genetic engineering. In replying to challenging questions about the Ministry's acceptance of the benefits of genetic engineering and the government's seemingly inadequate regulation of risks, Minister of Agriculture, Lyle Vanclief, relied heavily (almost exclusively) on the science basis of review. Vanclief was interviewed in the last episode of the 1999 CBC radio series "A Field of Genes," an unprecedented week-long exploration of the issues of genetic engineering in agriculture. Vanclief's appearance was the most high-profile government defense of biotechnology in Canada to date. The Minister repeated industry rhetoric in his justification of the government's

approach to genetic engineering and used the science-basis of regulation to legitimate the Canadian approval of genetically engineered foods.

Vanciel reiterated the prevailing assurance that Canada's regulatory system is "one of the best in the world" and serves as a model for other countries. (Canadian Broadcasting Corporation May 7, 1999) The Minister refused to acknowledge that genetic engineering resulted in significantly altered foods but chose to represent transgenic foods as foods different only as varieties of apples and potatoes are different, "there's certainly a difference between a Macintosh apple and a Red Delicious apple," he argued, eluding to traditional plant breeding or natural evolutionary differences within species.

Faced with the question of Agriculture Canada's role in promoting genetic engineering the Minister replied, "I am not a promoter of biotechnology. I'm a promoter of anything that we can do that is based on sound science." He argued, "I can assure you that we have the most sound regulatory process for the review of the science, based, as I said, on the review of that, on national and international expert advice. I don't know how much further anybody can go on that, and then science... scientists from a broad diversity of disciplines review that. And if there's any question whatsoever in the validity of that, if all of the answers are not given by that, then the product is not registered."

Mirroring an earlier interview with a Monsanto representative in the same CBC series, the Minister stated that, "There is no such thing as 100 per cent confident in...absolutely never. We can base it on the best science today, and then what you do is if science changes tomorrow, if the science changes next week, you review that." The Minister acknowledged that, "Nobody knows, for example, what is going to happen...20 years down the road, 10 years down the road." but continued, "As I go back to the same thing I said at the beginning, we have to base the decisions based on the most sound science and the best science we have available today. If

science changes then we have to...and we always do review any decisions that have been made in the past."

When asked, "In your mind, whose interests come first, the biotech companies, or the people?" the Minister managed to hesitate: "the safety...neither one...well, the people. It's the safety of the results of anything that's requested for the people." Confronted with the question of how the Canadian government was planning to cope with the controversy over genetic engineering in Europe that could affect Canadian exports the Minister responded, "we make and we base decisions based on science rather than based on emotion" and continued that, "through the WTO, for example, they cannot continue to do that unless they can demonstrate that the science is not sound."

Conclusion

It is politics rather than science which determines national policy outcomes. In this chapter I have discussed the paradox of the state appealing to science in regulation when science cannot match the ideal nor fulfil expectations. The political nature of risk regulation and the limitations of science must be recognized but this has implications for the use of science in policy making and threatens the construction of "science based" regulation. In chapter four I discuss the construction of science based regulation as a political process over which certain actors have powerful influence. Through an examination of the regulatory framework I further explore ways in which the science basis promotes and legitimates genetic engineering. In chapter five I suggest that lay risk evaluation can be a powerful force in defying the restrictive definitions of genetic engineering that are built through the science basis.

Chapter Four

A Limited Set of Actors and Universe of Political Discourse: Behind a “Science Based” Regulation of Genetic Engineering

Introduction

In this chapter I use the concepts of the policy community and universe of political discourse to examine the actors and interests that are influential in formulating the science based regulation of genetic engineering in Canada. The policy community constructs the universe of political discourse that I argue is dominated by five major themes, all of which support industry demands of regulation. I argue that examining the interests and power relations in the formulation of regulation will help make the role of regulation in risk manufacture visible. In this chapter I explore some of the forces in the formulation of regulation and argue that the strategy of science based regulation benefits specific members of the policy community.

The argument presented in chapter three that science based regulation is enrolled in state strategies to promote regulation and legitimate the introduction of genetic engineering is elaborated on. In this chapter I sketch the structure of the regulatory framework for genetic engineering in Canada. The framework accommodates a science-based regulation through concepts and mechanisms that narrowly define genetic engineering and its risks. The examination of the influence of the policy community and the universe of political discourse over the formation of regulation connects back to my analysis of the capitalist underpinnings of the risk society where the drive for innovation is centrally implicated in risk manufacture.

1. Examining the Policy Community: A Limited Set of Actors

The concept of the policy community enables an identification of actors who are engaged in policy formation, the relations between those actors, and their power relative to one another, at a particular time and place. The policy community is an analytical tool for understanding the role of pressure groups in policy making processes in relation to the state, where the public can be divided into two parts: the general public and the special public or policy community. (Pross 1986) The policy community has a dominant voice in determining government decisions in a specific field of public policy. It is populated by government agencies, pressure groups, journalists, and individuals, including academics. According to Paul Pross, the policy community is composed of the “subgovernment” and the attentive public, the subgovernment being a small group of people that can include ministers, senior government officials, and representatives from a few interest groups. The attentive public may or may not emerge as a voice in the policy community. The lead government agency or agencies for the policy area sit at the center of the subgovernment and the relationship most significant to any group in the policy community is that between it and the lead agency. (Pross 1986: 131)

Members of the subgovernment are in a position to regulate the flow of information to government and to the public, secure the success or failure of government programs, and confer legitimacy on public policies. In order to fulfil these potential roles, members must be ready to frequently contribute advice to policy officials, serve on advisory committees, represent their interests to the public, and co-ordinate with other groups. The policy community acquires its dominant voice as a result of its functional responsibilities, its vested interests, and its specialized knowledge. Membership in the policy community requires a high level of

organizational resources where, as Pross argues, "only those with a vital interest and resources to sustain full membership in the sub-government attempt to become full members." (Pross 1986:113) The policy community is part of the communications network that links government to the community at large.

The most prominent members of the policy community are not primarily interested in making or reformulating policy. The policy community is, instead, a protective device that limits rather than expands opportunities for the public at large to achieve major policy changes. Pross argues that, "the goal of the sub-government is to keep policy-making at the routine or technical level, thereby minimizing interference." (Pross 1986: 107) As I will discuss later in this chapter, the regulatory framework for genetic engineering reflects a desire to protect existing structures and approaches in regulation. This policy direction is determined by the policy community and the universe of political discourse that the policy community constructs, rather than through mechanisms of parliamentary democracy.

Industry actors are the most powerful pressure groups in the subgovernment and dominate the small circle of actors. Industry exercises a great deal of influence over regulatory formation and regulatory practice. Corporations and industry groups are conferred the status of legitimate actors in the policy community and have numerous exclusive access points to lead government agencies. These actors, and their rhetoric, come together in culturally and politically powerful ways to shape the universe of political discourse. Industry lobby groups or business interest associations enjoy a type and degree of access to the policy community that corresponds to their financial resources and level of organization. Corporate actors in the policy community also work to promote industry interests outside government and with the public. Corporate actors are engaged in both direct policy advocacy and more indirect shaping of the universe of political discourse. Industry influence over the universe of political discourse

complements industry activities in policy advocacy and secures access to the policy community. Industry demands and the language used to articulate those demands is directly reflected in government regulation of genetic engineering and government communications.

In 1998 the Industrial Biotechnology Association of Canada (IBAC) merged with the Canadian Institute of Biotechnology to become BIOTECCanada, the central industry lobby in Canada. IBAC activities focussed on "developing collaborative approaches with the federal authorities in order to create a reasonable regulatory environment," (Roger Perrault quoted in KPMG 1994:8) BIOTECCanada Chair, Mr. Dobson of AgrEvo, states that the group's purpose is "to work with government to generate an effective regulatory and financially competitive business environment ensuring Canadians have access to safe and effective agricultural biotechnology products." BIOTECCanada has 115 lobbyists registered to lobby 16 government institutions. (Kneen July 2000) ⁴⁸

There are six government departments that have varying roles and responsibilities in the regulation of genetic engineering. Many of these were consolidated in the 1997 creation of the Canadian Food Inspection Agency (CFIA). Agriculture Canada, which is responsible for the CFIA, is the lead agency in the regulation of genetically engineered products for use in agriculture. It is Health Canada however that reviews food products and veterinary drugs for human safety. Health Canada's product review evaluates scientific data for the satisfaction of three criteria: human health safety, animal health safety, and product efficacy (meaning that the drug in question does what it is intended to do and satisfies manufacturing requirements).

Health Canada issues a Notice of Compliance that grants market approval for a product once all

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Industry Canada is a dues-paying member of BIOTECCanada. The department renewed its membership after the annual fees of \$6,500 were cut to \$1000 in response to requests from Dr. George Michaliszyn, Director of the Bio-

the assessment criteria are satisfied. The CFIA conducts environmental assessments while Environment Canada regulates under the authority of the Canadian Environmental Protection Act. In addition, Industry Canada plays a role and the Department of Fisheries and Oceans have emerging responsibilities.

Grace Skogstad argues that financial and other elements of agriculture policy are now significantly shaped by departments whose primary mandate is not agriculture. In the era of free trade non-producer agri-food interests or "new state actors, notably those responsible for trade matters" have considerable influence over the policy agenda. (Skogstad 1996: 161) As I will discuss later in this chapter, the mandate of the CFIA and its regulatory practice reflect this influence.

Public protest can, however, occasionally take policy out of the hands of the subgovernment and into those of actors at the highest political levels. (Pross 1986) In chapter five I will examine this circumstance in the case of rBGH where the protest of diverse actors in the attentive public took the issue out of the hands of the policy community and beyond the parameters of the universe of political discourse, changing the policy outcome from that desired by actors in the policy community. In the next section I examine the universe of political discourse that the policy community constructs to support their work in promoting innovation and legitimating genetic engineering.

2. Constructing Regulation: Themes that Dominate the Universe of Political Discourse

The concept of the universe of political discourse, developed by Jane Jenson, is an approach to examining the construction of language and possibilities in political struggle. The concept offers a research strategy for analysing how actors and discourse, in a particular time and place, shape policy. (Lindquist 1996) The universe of political discourse sets the parameters of political action through processes that limit the set of actors who are accorded status as legitimate participants, the range of issues considered within the realm of political debate, the policy alternatives considered feasible for implementation, and the alliance strategies available for achieving change. (Jenson 1986:26) In her development of the concept, Jane Jenson takes account of unequal power relations among actors and argues that, in capitalist society, the universe of political discourse will be unequally structured. The universe of political discourse is constructed by actors in the policy community and takes shape through a number of processes and relationships. In a mutually reinforcing relationship, the universe of political discourse further limits the set of actors who have access to the policy community. An examination of the universe of political discourse can shed light on the power of interests in the policy community to construct a climate favourable to their demands.

I argue that the universe of political discourse influential over the formation of regulation of genetic engineering in agriculture is dominated by five broad themes that emerge from a neo-liberal analysis of economic development: survival in international competition, market regulation, harmonization, efficiency, and “balance.” These themes are influential in shaping regulatory structures and practice that prioritize the promotion of innovation and allow for the uncontested introduction of genetic engineering into our food system. The five themes create a climate that supports and legitimates industry demands for regulation. They are used to

support the goals of promoting innovation and legitimating genetic engineering and work to limit the range of issues debated as well as the policy alternatives considered. They work to define the benefits of genetic engineering in terms of economic growth and they reinforce the rhetoric of an imperative to press forward with genetic engineering as a new core technology. The themes emerge through industry studies and briefs to government and are reflected in, and developed through, government policy papers, discussions and, finally, are expressed through the structure of the regulatory framework. They are expressed and developed in a broader discourse of globalization that has gained cultural and political power, taking shape through a number of national and international processes. The themes allow for the scientific basis of the regulatory system and are used to legitimate this system.

My examination of the themes and arguments that dominate the universe of political discourse is influenced by an analysis of regulatory debate undertaken by Steve Tombs and Dave Whyte. Tombs and Whyte (1998) highlight the role of dominant themes in their analysis of industry influence in a struggle over regulating the UK offshore oil industry. They argue that the oil industry created a new set of "commercial realities" by successfully arguing that the industry could not survive international competition without government assistance. These new realities, they argue, proved to be a powerful propaganda tool in the creation of a regulatory environment that was more suited to "the corporate goal of ever increasing profit margins and limiting policy alternatives." (1998:86) The arguments put forward by the UK oil industry that the pressures of international competition required new regulatory conditions are mirrored in those used by the biotechnology industry to shape regulation in Canada.

The desire to develop a strong domestic biotechnology industry is a driving force behind the Canadian governments' decisions regarding regulation of genetic engineering. These decisions rest largely on a language of corporate survival in market competition. This discourse

of surviving competition is led by threats of capital flight that have been, and continue to be, employed by industry to warn against restrictive or burdensome government regulation. In a presentation at York University in 1993 the then Chairman and CEO of Monsanto congratulated the Canadian government on its review of products in a muted warning: "Our regulatory systems - not known for speed on either side of the 48th parallel - even approved some new, biotech-based pharmaceuticals and field testing of agricultural products - while in Europe, these sciences were stifled, indeed driven to North America, Hoechst and BASF moved their research programs to America - after an unfriendly reception in Germany." (Mahoney 1993:2) In relation to the review of the Canadian Environmental Protection Act, the Industrial Biotechnology Association of Canada was explicit that, "if Canada subjects firms to the uncertainties of socio-economic assessments, we can expect an outflow of R&D investment for biotechnology." (Industrial Biotechnology Association of Canada 1994:9)

In June 1995 *The Globe and Mail* reported that the two manufacturers of rBGH products, Monsanto and Eli Lilly,⁴⁹ threatened to pull some of their research investments out of Canada if the moratorium on the use or sale rBGH was extended by parliament.⁵⁰ (27 June 1995) Eli Lilly marketing representative, Terry Clark, stated that any further delay would send, "a very, very negative message to future Canadian research and development by our company" and Jean Skotnecki of the Canadian Animal Health Institute, a trade association representing

⁴⁹ Eli Lilly later withdrew its submission to Health Canada for approval of its rBGH product pending the outcome of Monsanto's.

⁵⁰ Following its hearings, the House of Commons Standing Committee on Agriculture and Agri-Food recommended a moratorium on the use or sale of rBGH in Canada to allow for further study of the issues. With intense public pressure mounting against the introduction of rBGH, the government responded with a "voluntary moratorium" that it negotiated with the product manufacturers.

A 1994 KPMG report made industry views on this matter clear and clarifies the purpose of the negotiated delay as far as industry was concerned: "A small number of vocal parliamentarians recently prompted the Standing Committee on Agriculture and Agri-food in the House of Commons to recommend a one-year moratorium on the use of BST, to allow further study. The industry has countered with a suggested period of time for raising public awareness, and this

agricultural and chemical companies, argued that a moratorium on rBGH could trigger a "domino effect" with US based companies pulling research investments out of Canada. (*Globe and Mail* June 27, 1995) Wayne Easter, a member of the House of Commons Standing Committee on Agriculture and Agri-food that recommended the delay, responded: "what they're saying is blackmail, nothing less." (*Globe and Mail* June 27, 1995) The government has however largely accepted the strength of the arguments behind such threats. The warning of capital flight if uncertainty continued was repeated by the Deputy Minister of Health Canada, David Dodge, in 1998 Senate hearings on rBGH. (Senate testimony December 7, 1998)

Secondly, regulation of genetic engineering is shaped by an appeal to market regulation. The biotechnology industry stresses self-regulation or regulation through the market as its ideal, particularly in relation to the undesirable spectre of interference from the consideration of non-technical issues. Industry argues that the marketplace is the most appropriate place to deal with any socio-economic issues that arise with the introduction of new technologies; "in western economies, the free market is the mechanism that determines the socio-economic impacts of technology." (Industrial Biotechnology Association of Canada 1994:9) Industry uses the "free market" as a key legitimating concept in strategies to exclude considerations of ethics and socio-economic impacts. The Industrial Biotechnology Association of Canada argues that, "the government has generally not intervened to assess the socio-economic impacts of technology even when these are pervasive and have a major impact, e.g. computers operating in real time. Most governments understand that the marketplace should decide the merits of new products." (Industrial Biotechnology Association of Canada 1994:9) Monsanto argues that, "the marketplace is the most effective and efficient mechanism for measuring the 'value' of a

is under active consideration. The biotechnology industry believes government acquiescence to such public-interest pressure could send an unwelcome signal to potential investors in Canadian biotechnology." (KPMG 1994:6-7)

product."⁵¹ Industry warns that social regulation would allow irrational public fears to retard economic progress; as Monsanto argues, "for many all change is bad. Some oppose all new technology as if the best future is some bucolic re-creation of the past that never actually existed." (Monsanto 1994:8)

Thirdly, harmonization consistently appears as a key consideration in, and goal of, regulatory reform. Harmonizing standards across countries will assist corporations in meeting requirements for submissions to regulatory agencies. Industry consultants KPMG argue for example, that, "a regulatory system that is consistent with US practice, is essential to attract foreign investment and partners in a highly competitive global marketplace." (KPMG 1994:9) As I discussed in chapter three, harmonization is a goal of international regulation and requires that standards be based on scientific criteria.

Fourthly, the demand for "efficiency" in review is pervasive and persistent. Efficiency is portrayed as the key to surviving market competition and as a goal against which regulation for health and safety must be balanced. Demands for efficiency are tied to cost and time-saving measures that can constitute deregulation and be used to justify removing regulatory obstacles to commercialization.

Finally, the theme of "balance" appears in government discourse generally and in policy documents regarding the regulation and communication issues of genetic engineering in particular. The notion of balance is used in several ways to assist the promotion and legitimation of genetic engineering and to create a climate supportive of articulating the other

⁵¹ While arguing that the social value of products should be determined through the marketplace rather than through regulation, Monsanto adamantly opposes labelling genetically engineered foods as unnecessary, expensive and impractical. Paradoxically, the industry is lobbying for the labelling of foods that are genetically engineered for specific nutritional or medicinal advantages - foods known as "functional foods" or nutraceuticals. The company wrote to the Canadian Government that, "Monsanto believes in the consumers right to access to information. This will best managed through a communications program rather than labelling." (Monsanto 1994)

themes of the universe of political discourse. Balance surfaces in government and industry discourse as a concept that places economic competitiveness as an equally important goal to that of public safety. This serves to undermine public safety as a legitimate priority in its own right and opens this goal up for negotiation.

Jerry Ravetz and Jennifer Brown assume the benefits of genetic engineering and argue that the "recognized task in the case of biotechnology is to strike a reasonable balance, always improving in the light of experience, between technical progress and environmental safety." (1989: 72) Though arguing for balance in regulation, Ravetz and Brown add that, "perhaps the one thing of which we can be certain, is that there will be surprises for us when micro-organisms are released into the environment." (1989: 71) The notion of balance here implies that environmental safety is negotiable, even where there is a recognition of risk. The implications of Ravetz and Brown's argument is that acceptable risk is determined in relation to the unquestioned benefits of "technical progress."

The consequence of the balance that is sought between the goals of industry growth and product safety is a justification of regulatory structures and practices that undermine rigorous review and compromise human health and environmental safety. In this framing of product review, the high stakes of future development in biotechnology and economic growth in general are expected to be considered. Through the review of rBGH managers in the Health Protection Branch of Health Canada expressed their desire to balance the two goals of encouraging economic development and promoting public safety. Though the mandate of the branch is explicitly and exclusively health protection, the Director General, George Paterson expressed his concern that the prolonged and controversial review of rBGH could have a negative effect on the acceptability of other biotechnology products. (Paterson 1996) Similarly

an interdepartmental group that included Health Canada spent time considered the impact that labelling rBGH would have on the dairy industry. (*Ottawa Citizen*)

The notion of balance is also used to describe the ideal and responsible government approach to communications about genetic engineering. Balance has become a virtue in much the same way as efficiency is accepted as a public good. Balance is however a vague concept that can be, and is in this case, defined for purposes of limiting the set of actors in the policy community and the issues and policy alternatives considered (constructing the universe of political discourse). I argue that the concept is used to shut down a plurality of critical perspectives. The government encourages balanced dialogue around genetic engineering and this framing is central in defining the parameters of "stakeholder" consultations and circumscribing the inclusion of non-scientific criteria in debate, processes that I will discuss in the last section of this chapter. A balancing act between polar perspectives has become the basis of rhetoric that aims to silence critical voices that could tip the balance away from concern for industrial growth, in favour of safety concerns and social and ethical questions. There is no room for "extreme" positions in the space that "balance" constructs.

In the universe of political discourse so constructed the values of balance and efficiency are eclipsing a primary commitment in regulation to the protection of human health and environmental safety. The themes of market regulation, survival in international competition, and international harmonization are industry goals that have been accepted in arguments for accommodating new "commercial realities" in regulation. They are reflected in the regulatory framework for genetic engineering in agriculture and in the rhetoric that is used to describe and legitimate this framework. The five themes that dominate the universe of political discourse influence the conditions under which genetic engineering is regulated and serve to promote science-based regulation as a means to further restrict the set of actors and issues discussed. In

the next section I examine how the themes of the universe of political discourse support industry demands for science based regulation. I will then examine how the government's commitment to the themes are translated by the policy community into regulatory structure.

3. The Appeal of the Science-Basis: Efficient Review and Competitive Advantage

In this section I examine industry demands for a “science-based” regulation of genetic engineering and inquire into industry's intentions for the science basis. I argue that science-based regulation is constructed by industry and government to support the speedy commercialization of products of genetic engineering. The construction of a science based review is an industry strategy to establish a predictable and efficient product approval process that will assist long-term corporate planning for the research and development of genetic engineering. As well as a key mechanism in fulfilling the state's role in promoting innovation, science based regulation is used for legitimization purposes.

Industry actors present several arguments for efficiency in product review, all of which are anchored in the rhetoric of their need to survive international competition. Regulatory review is the means by which products are assessed for safety and efficacy and rejected or approved for market, a process that industry often refers to as the “approval process.” (see KPMG 1994: 9) Efficient regulation facilitates the introduction of products onto the market. Industry argues that any delays in the approval process will result in expensive setbacks for manufacturers and constitute a serious threat to Canada's competitive position in the international market for biotechnology. Delayed approval translates into lost profits and, for corporations that want to recoup intensive research and development costs, immediate market access is important, especially as other manufacturers race to prepare competing products.

Acceptance of industry's argument that efficient and predictable regulation has a central role to play in supporting innovation and competition and thus in encouraging industry growth is prompting governments around the world to remove regulatory "obstacles" to commercialization.

The regulatory system itself has become an important component of industry and government efforts to build comparative advantage internationally. Bill Jarvis (1998) describes the transformation of science-based regulatory agencies and their functions into an emerging domain of economic potential. Jarvis argues that the economic opportunity represented by the "business" of regulation may be seen as the creation of a new economic sector: "the international regulatory services sector as a commercial enterprise." (1998: 19, 7) The Canadian government states its goal of becoming a "provider of first choice of regulatory services," and advertises that, "international companies investing in Canada's ag-biotech sector will find...a predictable and effective regulatory environment." ("Investing in Canada's Dynamic Agricultural Biotechnology Sector," Government of Canada, 1998)

The goal of efficiency in regulation is eclipsing safety as a priority. In 1996 the House of Commons Standing Committee on the Environment and Sustainable Development reordered priorities in regulation, stating that their principle concern in "this complicated debate over biotechnology and genetic engineering" was that the technology be "utilized and applied in a manner that is *efficient, safe and ethically acceptable*." (The House of Commons Standing Committee on the Environment and Sustainable Development November 1996: 30)(emphasis added) The Canadian Biotechnology Strategy (CBS) makes clear the government's priority "to identify options to make the regulatory system more efficient, effective, responsive and predictable." (1998: 14) The CBS proposes using tools such as international benchmarking to achieve efficiency and predictability.

Three focus areas for regulation were identified by Health Canada in their 1995 review of the Food and Drugs Act: health and safety, protection against consumer fraud, and competitiveness of the industry. In addition to these, there were three factors identified as enhancing competitiveness: simplification, responsiveness, and harmonization. (Health Canada April 1995: I-1) In its review of the act, Health Canada stated that, "This approach is consistent with the objective of the Regulatory Review as reiterated in the Federal Regulatory Plan 1994, that is: 'to reduce the regulatory burden on Canadian business and individuals.'" (Health Canada April 1995: I-1) Health Canada continued that, "to accomplish this goal, the President of Treasury Board recognized that workable alternatives to regulation and partnerships with other governments and the private sector would be important elements in achieving more efficient regulation." (Health Canada April 1995: I-1)

Industry argues that only a science-based review offers the stability and security of an efficient and predictable review process. Predictability is achieved through a privileging of scientific criteria and technical risk assessment models above the more unpredictable factors of non-scientific considerations such as socio-economic or ethical concerns. Corporations argue that they need to know that their products will be reviewed within the expected time-frame. Through the 1990s the approval of rBGH by Health Canada was continually delayed because of public protest over unresolved safety concerns as well as socio-economic and ethical concerns. (Sharratt in print) In testimony at 1998 Senate hearings regarding rBGH review, Monsanto Canada's Vice-President of Government and Public Affairs, Ray Mowling, argued that, "the uncertainty that surrounds the approval process is disconcerting for us and does not bode well for others seeking approval for new technologies." (Senate testimony December 7 1998) Mowling quoted the earlier testimony of the Deputy Minister of Health Canada, David Dodge, concerning the need to establish predictability in review: "[the review process] is compromised

in Canada and if developers of these products feel that it is compromised in Canada, then unfortunately they will not bother to come here because we are 2 per cent of the world market. Citizens and farmers will not have available those particular products which are available in other countries." (Senate testimony December 7 1998) The Agricultural Institute of Canada, a professional association of agronomists whose foundation includes Monsanto Canada and Ag-West Biotech Inc., argues that, "Canada's system for regulating the products of food biotechnology is viewed around the world as a model to be emulated. By using science as the basis of regulation, we are well-positioned to meet the challenges of the future." (Agricultural Institute of Canada, August 1998)

Science-based regulation is the Canadian government's commitment to industry that social and ethical concerns will not interfere in product review. The science-based regulation achieves an exclusion of non-scientific criteria from the review process in an explicit industry strategy to reduce unpredictable elements, elements of public attention and public protest. The Industrial Biotechnology Association of Canada (IBAC) argued that the inclusion of socio-economic considerations in risk evaluations of genetic engineering is one means of "inviting opposition to biotechnology." (Industrial Biotechnology Association of Canada 1994:8) Murray McLaughlin, in his capacity as president of Ag-West Biotech Inc., argued that, "science must continue to be the basis of regulations. Other issues are too variable and could be used by industry opponents to hold up the approval of new products indefinitely." (Ag-West Biotech Inc. June 3 1995) Similarly, industry consultants KPMG argue that, "The industry feels that the *licensing and approval process* is absolutely critical to the future development and growth of the industry, and should focus on a science-based approach rather than one that is weighted by social and political concerns." (KPMG 1994: 26) (emphasis added) An approach that is "weighted" by non-scientific concerns is one that may permit public participation and the

articulation of public or lay concerns in regulation and policy making. The science basis is an attempt to silence voices in critique by delegitimizing lay interventions as irrational, irrelevant, and unnecessarily disruptive.

In the introduction to the report of a 1993 government initiated "stakeholder" workshop on the regulation of genetic engineering, Agriculture and Agri-food Canada stated that, "to date, consultation on draft guidelines has focussed primarily on receiving technical and scientific input from the scientific community. The department recognizes the importance of ensuring that all interested parties have a chance to comment and become involved in the development of guidelines." And yet the summary of opening remarks by the then Assistant Deputy Minister of the Research Branch, Dr. Brian Morrissey, reports that he stressed that the consultation would focus on the "scientific data requirements to assess the safety of genetically engineered products". (Canada, Workshop 1993:1) It was at this same workshop that Murray McLaughlin of Ag-West Biotech Inc. argued that, "science-based regulation, and sensitivity to public concerns, are key to a good climate for investment in biotechnology." (Canada, Workshop 1993:21) Demands for science based regulation were developed and pressed for by industry in early stages of regulation formation, through forums including this workshop.

The efforts of the policy community to construct a science based regulation culminate in the use of regulation for legitimization purposes. Government regulation is central to industry strategies for assuring the successful commercialization of genetic technologies, of which public confidence and acceptance is key. The biotechnology industry is enrolling government regulation and regulatory agencies in risk communication strategies in an approach that reveals a fear of heightened lay mistrust in corporate communications.⁵² There is a recognition that

⁵² This is a recent recognition of lay mistrust that is reflected in changing corporate communications strategies. The language used to promote genetic engineering and the claims for the science as the solution to world problems of

public fear could defeat this technology; as Rick Walter, past president of the Canadian Institute of Biotechnology, argued, "it is the public, the consumer - the poorly informed and uninitiated average individual that holds the key to our future. This may not be comforting but this is reality. To ensure eventual economic success, everything we do must be dominated by the spectre of public acceptance." (Walter 1995) Industry is thus engaged in an active campaign to change public "perceptions" of the risks of genetic engineering by promoting the benefits of biotechnology while encouraging trust in scientific advancement and government regulation.

Industry argues that it is the responsibility of regulators to communicate the role that they play in assuring food safety. (See Joyce Groote quoted on CBC 1999) The industry has begun to look toward regulators as trusted spokespersons who can assure the public of the safety of genetic engineering. The government, primarily through the staff in the CFIA, has taken on this role. The Guelph Food Technology Centre argues that, "one of the most important subjective influences on the acceptability of a factual message is the trustworthiness (or lack!) of the industry and its spokespeople. Biotechnology will first be judged, not on current facts or objective benefits of the product, but rather on whether or not the consumer sees it as being represented by "good" people." (Guelph Food Technology Centre 1997) Europe's leading biotechnology lobby group, EuropaBio, hired the public relations firm Burston Marsteller⁵³ to investigate strategies for communicating the safety and value of genetic engineering to the public. In the "communications program" that they developed Burston Marsteller argue that the message of biotechnology safety is best heard from regulators; "the industry must accept that it

hunger and environmental degradation have generally been toned down since the early 1990's. Companies have conducted a number of public opinion surveys and public relations analyses that guide their strategies.

⁵³ Burston Marsteller, a "single worldwide team of public affairs specialists" represented the corporation Babcock and Wilcox following the Three Mile Island nuclear accident and Union Carbide after the Bhopal disaster in India. They were also a part of management of advice over the outbreak of BSE or 'mad cow disease' in the United Kingdom.

is those charged with the public trust in this area - politicians and regulators - to assure the public that bio-industry products are safe." (Burston Marsteller 1997) Burston Marsteller argue that, "where safety is concerned there is no substitute for credible public regulators. It thus must become a strategic objective of this campaign to help build that credibility." (quoted in *The Guardian* August 6 1997)

According to the Canadian Biotechnology Strategy, participants in their consultations stressed using "credible sources such as government, health care professionals, scientists, educators and NGOs to convey information." (Canadian Biotechnology Strategy 1998: 14) Participants also apparently recommended "increasing the visibility of regulatory processes, providing support for the communication of regulatory matters, including risks and benefits, to the public to "de-mystify" regulatory operations, and better explaining of how they function and protect the public interest." (Canadian Biotechnology Strategy 1998: 14) The work of the Canadian Biotechnology Strategy makes it clear that building public confidence in the regulatory process and in genetic engineering is a priority in government communications with the public. They argue that partnership with industry can facilitate this:

Several challenges need to be addressed by industry and government working together. One involves building public confidence, including determining the public's information needs and the role that industry and other stakeholders can play in satisfying those needs, and providing clear, timely information on regulatory processes, decisions, enforcement activities and other matters. (Canadian Biotechnology Strategy 1998: 19)

In 1996, five Monsanto representatives (two from Canada and three from the United States) met with five officials from the Bureau of Veterinary Drugs, including the Director General of Health Canada, to discuss the development of government communications materials on rBGH. Health Canada's minutes of the meeting outline the plan as follows:

R. Mowling [Regulatory Affairs, Monsanto Canada] indicated that the Canadian Consumer has no context to make decisions. Monsanto and R. Mowling have been active in working in the area of consumer education on biotechnology. Agriculture and Agri-Food Canada is one of the main contacts for public reaction concerning biotechnology. The issue of preparation of Question and Answers for BST [rBGH] was discussed. Monsanto will work with Margaret Kenny's group in AAFC [the Office of Biotechnology, now in the CFIA] to prepare generic questions and answers relative to biotechnology and rBST. ("Record of Meeting Between Monsanto Inc. and the Bureau of Veterinary Drugs" September 26 1996: 3)

Later that month BVD officials were still discussing "consumer perception issues" with Ray Mowling and scheduling further meetings to address these concerns. (Access to Info Ian Alexander memo to Yong, Landry, Malik 09/20/96 "Meeting with Monsanto")

As well as developing communications materials with government, industry is relying on regulatory approval itself to communicate the safety of genetically engineered products. Ag-West Biotech Inc. argues that, "an appreciation of Canada's high regulatory standards is particularly important to the development of the agbiotech industry." (Ag-West Biotech Inc. June 1995: 1) When confronted with public concerns about the risks of genetic engineering the Canadian biotechnology industry as well as grocery stores and food companies repeat the assurance that the Canadian regulatory system is one of the safest in the world.

The reference to science based review is a part of industry strategies to overcome lay mistrust and critical risk evaluation. The science basis relies heavily on the authority and credibility of science to legitimate product approvals. The science-based review serves to legitimate product approval as the outcome of an objective and authoritative expert technical risk assessment that produces non-negotiable facts. In their attempts to enrol regulatory institutions in risk communication, industry is relying however on a lay trust in science and institutions that is no longer assured in the risk society. An appeal to science in facilitating commercialization and public acceptance actually serves to further undermine public trust in

regulatory institutions. While relying on regulatory approval to communicate safety and inspire trust, the biotechnology industry also demands a speedy product review and a contradiction arises between the need to inspire public confidence in the regulatory system and satisfy industry demands for speedy review. In the next section I examine how the definitions of genetic engineering built through a “science based” regulatory framework facilitate the fast approval of genetically engineered products.

4. A Restrictive Regulatory Framework: Limiting the Range of Issues and Accommodating the Science Basis

In this section I examine the framework for regulating genetic engineering that is designed to support the development of the biotechnology industry. It was designed in consultation with industry actors and is maintained through a regulation of products that is co-managed by government departments and private corporations. The regulatory framework was developed through consideration of the goals that I have identified as themes dominating the universe of political discourse. The framework is the clearest expression of the policy direction taken by the Canadian government regarding the introduction of genetic engineering in agriculture. It encourages the speedy commercialization of products through a number of concepts and mechanisms that support, and are enhanced by, a science basis.

The Canadian framework for regulating products of genetic engineering in agriculture serves to limit the range of issues and policy alternatives considered in the universe of political discourse. The framework does not consider genetic engineering as a new technology for the purposes of risk assessment but achieves the primary concern of the policy community: protection of the status quo. The government refuses to acknowledge the process of genetic

engineering as distinct from other technologies in food production and restricts risk analysis accordingly. The framework relies on conventional risk assessment models and excludes possible roles for non-scientific considerations. The science basis needs to be understood in terms of the concepts and mechanisms that build a regulatory framework that overwhelmingly accepts the benefits of genetic engineering while refusing to acknowledge qualitatively new risks. The definition of genetic engineering as traditional plant breeding is operationalized through the framework and defines the parameters within which scientific criteria are applied. There are five significant ways in which the regulatory framework presents obstacles to a review of genetic engineering that could consider the complex nature and breadth of its risks.

Firstly, Canadian government regulation of "novel foods" is based on the pre-existing framework for regulation of "conventional technology."⁵⁴ This commitment to the existing framework was outlined in the 1993 Canadian Federal Regulatory Framework which stressed the key principle, to avoid duplication, of using existing laws and regulatory departments. In 1995 Agriculture and Agri-Food Canada stated four guiding principles determining the department's approach to biotechnology regulation; the first of these was the directive to build on existing legislation and areas of responsibility.⁵⁵ (Canada, BioInfo 1995:2) This approach prioritizes rationalization in regulation and is based on the assumption that existing regulatory mechanisms and scientific knowledge are appropriate and sufficient to review products of genetic engineering. The existing framework fails to recognize the profound differences of genetic engineering from other technologies employed in agriculture, and regulatory agencies remain blind therefore to the possibilities of risk that are consequent to these differences.

⁵⁴ The term "conventional technology" is used to refer to industrial agriculture technologies such as chemical pesticides.

⁵⁵ This approach follows that taken by the United States Food and Drug Administration and approved through "fast track" in Congress.

By employing the review system that was established for conventional technology, industry and government have avoided the ordeal of creating new regulatory mechanisms and new legislation. (See Holleborn quoted in Kneen 1999:135) Debate over new regulation for genetic engineering could have become a focal point for public deliberation over a potentially controversial new technology and attracted a level of public attention to genetic engineering that has, until very recently, been largely avoided in Canada. Even if uncontroversial, the creation of a new regulatory framework would have resulted in a delay in the commercialization of new products.

Secondly, the Canadian government regulates genetic engineering on a case-by-case or product-by-product basis. The case-by-case basis ensures that it is the products of genetic engineering rather than the processes that are reviewed. Product based regulation is an assessment of risk that discounts the production process as a source of risk (Product assessment is most importantly developed through the use of the concept of substantial equivalence which that I will discuss below). As Paul Mayers, then Acting Chief in the Bureau of Microbial Hazards, Health Canada stated, "we recognize that the application of biotechnology as just a technology doesn't bring with it any unique risk."⁵⁶ (House of Commons Committee on the Environment and Sustainable Development, Wednesday June 5, 1996) The system is thereby narrowed to technical models of risk assessment that exclude possible broader examinations of the risks and benefits of new production processes. A KPMG report states that, "Industry believes this emphasis on process as well as product places the industry at a commercial disadvantage." (KPMG 1994:9)

Through this approach to regulation, each new product that is approved for use in Canada becomes a benchmark by which other products are judged. In this way, as Joyce Tait

and Les Levidow argue, "the regulatory system is built up slowly, in a piecemeal fashion, as new generations of product and process exhibit different hazards." (Tait and Levidow 1992: 221) Product based regulation is reactive because new policies and safety assessments are established only as new health and safety effects become apparent and evidence mounts. (Levidow 1992) This contrasts with a proactive regulation or regulation that rests on the precautionary principle. The precautionary principle allows for controls to be implemented without having to wait for scientific proof of harm. Prevention is thus pursued at the source (or process) of risk manufacture rather than the impact. Goldman and Wagner define the precautionary principle as based on the premise that "science does not always provide the information or insights necessary to take protective action effectively or in a timely manner and that undesirable and potentially irreversible effects may result if action is not taken until science does provide such insights." (Goldman and Wagner 1996: 9) The application of the precautionary principle acknowledges complexity and uncertainty in contrast with product based regulation that assumes adequate knowledge exists to enable identification and control of risks.

Thirdly, the review of genetically engineered products is based on the twin concepts of "familiarity" and "substantial equivalence."⁵⁷ Through these concepts products are evaluated in comparison with existing crops and foods using past experience with traditional breeding as the acceptable baseline. The concept of "familiarity" is used to establish that adequate knowledge exists to enable a comparison of the new product with products that are already on the market. The new product is then compared to approved products using the concept of "substantial

⁵⁶ Paul Mayers is a central public spokesperson for Health Canada on genetic engineering.

⁵⁷ The concept of substantial equivalence was first introduced in 1993 by the Organization for Economic Cooperation and Development and was endorsed by the United Nations Food and Agriculture Organization and the World Health Organization in 1996.

equivalence.”⁵⁸ (Canada, Workshop. 1993: 11) If a product is deemed substantially equivalent then there are no further requirements for risk assessment and therefore no risk management component is involved. (Canada, Workshop 1993: 12) Health Canada describes the system in the following way: "The safety assessment approach of comparing novel foods with non-modified counterparts is referred to as the concept of 'substantial equivalence'. This approach allows regulatory agencies to include in their consideration, the substantial history of information related to foods which have long been safely consumed in the human diet."⁵⁹ (Health Canada web site) No genetically engineered product has been found substantially different by Canadian regulatory authorities.

The concept of substantial equivalence defines genetic engineering as an extension of traditional plant breeding and allows products to be evaluated for safety without considering potential new risks. In Health Canada's "Frequently Asked Questions," the department asks, "How is the potential for long term effects of genetically modified foods on humans considered in the safety assessment approach?" and answers that long term testing is unnecessary: "Given that the application of genetic modification does not introduce unique risks, the potential for long term effects of these foods are no different than that for conventional foods which have been safely part of the Canadian diet for a long time. Therefore there is no current evidence to indicate that long term studies are needed to ensure the safety of foods produced using this technology." (Health Canada website) Millstone *et al.* argue that, "substantial equivalence is a

⁵⁸ "Familiarity" is defined by Agriculture and Agri-Food Canada as the knowledge of the characteristics of a plant species and experience with the use of that plant species in Canada." Substantial equivalence" is defined as the equivalence of a novel trait within a particular plant species, in terms of its specific use and safety to the environment and human health, to those in that same species, that are in use and generally considered as safe in Canada, based on valid scientific rationale. (Regulatory Directive 94-08, "Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits," Agriculture and Agri-Food Canada, 16 December 1994)

pseudo-scientific concept because it is a commercial and political judgement masquerading as if it were scientific. It is, moreover, inherently anti-scientific because it was created primarily to provide an excuse for not requiring biochemical or toxicological tests. It therefore serves to discourage and inhibit potentially informative scientific research...the concept of substantial equivalence is being misapplied, even on its own terms, within the regulatory process."

(Millstone et al., 1999: 526)

The concepts of familiarity and substantial equivalence are based on the premise that we have enough knowledge to compare products of genetic engineering to others and that this comparison is sufficient for risk assessment. Familiarity and substantial equivalence serve therefore to allay fears of genetic engineering as a new and different science with risks of a qualitatively new character. Les Levidow argues then that the two concepts "can serve as an implicit policy instrument for defining evidence of safety, and for portraying some GMOs [Genetically Modified Organisms] as normal products." (Levidow *et al.* 1996: 146-147)

The regulatory framework is a product approval process that, as a primary expression of policy, amounts to an acceptance of genetic engineering through the gradual commercialization of products, one by one. Product by product approval facilitates market access by quietly introducing new products onto the marketplace, unnamed. Regulation is segmented through a case-by-case risk assessment. This approach is an attempt to minimize the responsibility of the government for decisions that determine the future of the technology. The framework is designed to privilege scientific criteria and restrict opportunities for non- scientific criteria as well as opportunities to consider the technology as a whole. The framework achieves a technologization of policy where regulating genetic engineering is defined as a technical issue

⁵⁹ The phrase "safety assessment approach" emerged in government communications to clarify their approach to regulation. It is a response, in particular, to critiques that Health Canada does none of its own testing (The Minister

alone. As well as excluding non-scientific criteria, the regulatory framework constrains the use of science itself. The framework constructs a definition of genetic engineering that denies its qualitatively new risks.

Industry influence over regulation is powerful and is shaped through many processes. The problems of accountability and capture of regulatory agencies can be partly accounted for in an analysis of the internal dynamics of regulatory agencies. For Liora Salter this relationship is best described as one of co-management between government and industry, a relationship of reciprocity or mutuality between government agencies and industry, the regulator and the regulated industry. (Salter 1993) Such a relationship with industry is required for the agency to carry out its mandate and at the same time it undermines the capacity of the agency to fulfil the terms of this mandate. Health Canada, for example, negotiates relationships with product manufacturers on a daily basis through a review process that demands industry-government co-operation over corporate data submission. The process opens up important points of access to department officials. Industry has direct access to government agencies through the demands of a review process that requires constant communication and exchange of information. Salter argues that, "the regulator who follows a strategy of co-management is unlikely to be sensitive to non-industry interests and constituencies, and unlikely to find its interpretation of the public interest supported among the wider public." (Salter 1993) The relationship of co-management structures regulatory practice such that industry plays a central role in the implementation of the regulatory framework.

The details of Health Canada's review of rBGH reveal how a relationship of co-management can compromise product review. This was also clear in the case of another product review where Monsanto and Health Canada brokered a private deal to enable

of Health Allan Rock was quoted in the media as insisting that Health Canada did test).

the approval of two varieties of Monsanto's genetically engineered potatoes. (*Ottawa Citizen* 30 November 1999) In exchange for Monsanto's co-operation in supplying test data (the company had resisted supplying all of the data requested), Health Canada and the CFIA "agreed to a 30-day turnaround for reviewing the information provided." (*Ottawa Citizen* 30 November 1999) Former Health Canada drug evaluator Michelle Brill-Edwards argues that, "these kinds of meetings go on all the time and it's almost never captured because people are careful not to let this kind of thing be known." (*Ottawa Citizen* 30 November 1999)

Lastly, the regulatory framework is conditioned by the important and contradictory roles that departments and agencies regulating genetic engineering play in promoting the technology. The conflict between promotion and regulation underlies the regulatory framework that accepts the benefits of genetic engineering and inhibits evaluation of the risks of genetic engineering outside a comparison to known risks. Liora Salter argues that the conflict between regulatory responsibilities and promotional roles is endemic to the structure of regulatory agencies. (Salter 1993) The conflict is acute, however, in the regulation of a technology that is viewed by government as a new and dynamic "change making" technology and the basis of a potentially strong and competitive domestic industry.

In 1996 the House of Commons Standing Committee on the Environment and Sustainable Development examined what it saw as two possible paths for the future of biotechnology regulation in Canada: improving the existing system or fundamentally changing the system. The committee recommended that NBAC carry out a study of the advisability and utility of a "transgenics agency" to regulate genetic engineering in Canada. The committee argued that the creation of a separate agency could resolve the

conflict of government departments simultaneously promoting and regulating genetic engineering. The committee also argued that, "implicit in this recommendation is the need for a comprehensive examination and evaluation of the comparative advantages and disadvantages of the product-orientated and process-oriented regulatory approaches for biotechnology and other potential regulatory approaches." (Standing Committee on Environment and Sustainable Development November 1996:40) The recommendation was rejected outright by the Government which replied only that the regulatory process is "*based on sound science* and the generally accepted premise that products rather than technology are the subject of regulation." (Canada, Government Response 5)(emphasis added)

The conflict between regulation and promotion, however, threatened the credibility of regulatory agencies such that in 1997 the Federal Government restructured responsibilities by creating the Canadian Food Inspection Agency (CFIA). Despite promising to resolve the ongoing conflict, the mandate of the CFIA included the primary goal of promoting trade and commerce. Efficiency and cost-cutting concerns were paramount in the formation of the CFIA. In CFIA fact sheets, the question: "Will public health and safety be improved in this consolidation?" is answered in terms relating less to food safety and more to service delivery: "Food safety remains the number one priority of government. The consolidation of inspection and related services at the federal level coupled with the reinforcement of food safety policy and standard setting responsibilities at Health Canada will allow for resources to be better aligned against priority areas and hence result in a more efficient and effective system."(CFIA website) Elizabeth Moore and Grace Skogstad argue that the new

system is more market driven and sensitive to international pressures. (Moore and Skogstad 1998)

The CFIA reports to the Minister of Agriculture and Agri-Food rather than to the Minister of Health and, as Brewster Kneen observes, the Office of Biotechnology which was the center of the promoter-regulator conflict, was transferred directly from Agriculture Canada to the new agency, with the same offices, personnel, and phone numbers. (Kneen 1999: 130) The creation of the CFIA as "Canada's lead agency responsible for the regulation of agricultural products" may be advertised as an attempt to overcome the conflict of roles and activities in both promotion and regulation but Kneen argues that the establishment of the separate agency is a strategy to distract the public from the departments where the significant policy decisions continue to be made and the conflict of promoter and regulator is maintained.

The conflict between promotion and regulatory activities inside the CFIA underlies review practice and the structure of the regulatory framework. CFIA officials are actively engaged in public communications efforts to legitimate genetic engineering as the output of a science based safety assessment. The regulatory framework excludes social and ethical questions altogether. The government has constructed fora outside of the regulatory process in order to address social and ethical concerns. In the next section I examine the use of stakeholder consultations and expert committees as mechanisms to legitimate genetic engineering and its regulation.

5. Legitimation Outside Science-Based Regulation: Segregating Non-Technical Concerns

The persistence and power of social and ethical concerns challenge the success of using science based regulation in promotion and legitimation of genetic engineering. In this section I briefly look at government construction of stakeholder consultations and expert committees as additional legitimation tools. The construction of stakeholder participation and “expert” advice is an attempt to manage dissenting voices and contain the role of non-scientific issues, silencing both and circumscribing the policy community and universe of political discourse. I argue that the Canadian government has engaged both stakeholder consultations and expert committees in order to further segregate and marginalize social and ethical considerations and lay participation and knowledge in risk assessment.

In order to protect the status quo, members of the policy community restrict and obstruct the articulation of concerns from actors outside the community. I argue that stakeholder consultations and expert committees are employed as tactics to constrain public debate over genetic engineering. Through a reliance on technical definitions of risk and expert knowledge, the science based regulation of genetic engineering excludes non-scientific questions and lay participation. In order to further control the role of such considerations in risk assessment and policy making, the Canadian government has constructed fora outside the review process. The state can claim to be addressing non-scientific considerations while defining the narrow parameters within which they can be engaged. Through such fora the government defines inclusion and invites dialogue on its own terms. In this section I will discuss how the controlled environments of consultations and expert committees are used

by the government to reinforce its approach to genetic engineering, legitimate its policy decisions, and further restrict public debate.

The design of government consultations has successfully constructed public involvement in policy making as “stakeholder” participation. The term “stakeholder” describes and circumscribes participation. The stakeholders in this policy field have been defined, as actors both inside and outside the policy community, to include the agricultural industry (producers, manufacturers, processors, distributors), consumer and environmental interest groups, other government departments (both provincial and federal) and scientists (from academia and industry). The category of stakeholder separates people in terms of their areas of interest. The existence of pressure groups enables the government to define potentially divisive questions as technical issues where they can be defused piecemeal by officials and interest group representatives. (Pross 1986: 208) Dividing issues around genetic engineering into stakeholder interests contributes to a fragmentation of the issues such that the overarching value commitments of the technology are not evaluated and the fundamental social and ethical questions remain unaddressed. As the Agricultural Institute of Canada argues:

Biotechnology is not a single technology, nor even a single branch of science; it is part of many existing and emerging disciplines. It may be more convenient to view biotechnology as a series of sub-disciplines where different tools have applications in different areas. Therefore, any discussion of the role of biotechnology should be in the context of a specific platform or area of application. *This will result in a more tangible and scientifically-defined dialogue.* (Agricultural Institute of Canada 1998) (emphasis added)

Stakeholder consultations played an early, if small, role in contributing to the universe of political discourse and legitimating the regulatory formation. In 1988 the National

Biotechnology Advisory Committee argued that, "The system should be "open" to allow the public and members of special interest groups to participate in the process through, for instance, advisory committees." (National Biotechnology Advisory Committee 1988:14)

Consultations served to limit the set of actors conferred legitimacy, the issues and policy alternatives considered, and possible alliance strategies, and, as I will discuss, have since been used in government communication strategies to legitimate the regulatory framework and policy making processes.

Stakeholder status for consultative purposes is conferred according to the interests of actors and their ability to participate. In stakeholder consultations barriers to entry are similar to those that exclude actors from the policy community. While industry is classified as one of many stakeholders, industry actors have status and resources that permit central and consistent participation in a wide variety of consultation processes. This access complements the place of industry actors in the policy community and their activities in daily regulatory practice. Early government consultations on genetic engineering, including a workshop held in 1993 and one in 1994, were dominated by industry actors.

In the case of genetic engineering, the government has actively supported the participation of one group, the Consumers Association of Canada (CAC), to counterbalance the dominance of industry interests.⁶⁰ The CAC is the only organization outside of industry associations that has consistently participated in stakeholder consultations and similar government meetings. Throughout their enrolment in consultation processes however the CAC has argued against the mandatory labelling of genetically engineered foods. Their position is

⁶⁰ Until 1999 there were only a small number of interest groups and individuals who were engaged in research and advocacy around genetic engineering, most notably the Canadian Institute for Environmental Law and Policy. The government turned towards the Consumers Association of Canada as a group with the potential for broad representation.

contrary to those of all other public advocacy groups that have since emerged to speak on this issue and to all public opinion polls conducted since 1994. The CAC argues that labelling is only one way, an inadequate method, of giving consumers information they need and that resources should be spent on means outside labelling. In the 1993 government workshop, the Consumers Association was reported to have argued that regulatory decision-making needs to be "*balanced and be based on scientific methods*." (Canada, Workshop 1993:17) (emphasis added) The CAC also articulated their concern over the regulatory structure that, "competitiveness in the marketplace not be needlessly affected." (Canada, Workshop 1993:17)

Stakeholder consultations have allowed for the creation of alliance strategies between the Consumers Association of Canada and government departments and industry groups that have proved useful to both in promoting genetic engineering. The Consumers Association has endorsed, edited, and co-produced various communications materials on genetic engineering with government and industry, the Consumers Association is a partner with BIOTEC Canada, for example, in the Food Biotechnology Communications Network that provides consumers with information on genetic engineering in lieu of product labelling. The participation of the CAC and the contribution of their "middle position" is used to legitimate the government's approach to regulation.

The close relationship of the CAC with industry and their continued unlikely position against labelling has undermined the group's credibility and some of their usefulness, to government in particular, as a legitimating agency. With a new level of public awareness and new actors and issues active in highlighting social and ethical issues relating to genetic engineering, the government has recently sought to expand its enrolment of actors in its legitimization strategies. Renowned Canadian author and critic of genetic engineering, Brewster Kneen, argues that his participation in the 1993 government consultation is now being used by

Canadian Food Inspection Agency officials as a part of a network of biotechnology supporters in efforts to legitimate regulation formation. (Kneen April 2000) In separate public presentations across the country, Mary Lou Garr of AGCare (a producer organization that supports the use of genetic engineering), Dale Adolph of the Canola Council of Canada, and Stephen Yarrow of the CFIA have all referred specifically to Kneen's consultation participation to demonstrate the legitimacy of regulatory formation processes.⁶¹ (This is a response to growing critiques of the regulatory framework and the use of the concept of substantial equivalence in particular.) Kneen describes the group that came together for the 1993 workshop as "essentially self-selected."⁶² (Kneen April 2000) He argues that, "the consultation, like the second one a year later, did not reach a consensus, although industry and government voices have presented the pro-industry outcome ever since as if there had been." (Kneen April 2000)

Stakeholder consultations are bound by the parameters of the regulatory framework and by government commitments to genetic engineering and the biotechnology industry. Participation is limited from the outset by the government's commitment to the future of genetic engineering as a new core technology. The construction of stakeholder consultations therefore limits the policy alternatives that may be considered. Policy options are considered in relation to the framework that accepts the benefits of biotechnology and promotes the development of the industry. This commitment is made explicit in consultation frameworks and mandates, as can be seen in the case in the Canadian Biotechnology Strategy. Stakeholders are expected to participate within the bounds of the framework and conform to its aims. The

⁶¹ Yarrow apparently had repeated this at several public meetings. Kneen argues that, "it was no longer possible to avoid drawing the conclusion that this little script had been photocopied and sent around to all industry flacks from some central propaganda agency." (Kneen April 2000)

⁶² Kneen continues that, "I was there only because I insisted on being present as one of the very few members of the public who had any idea of what was going on in Ottawa...I did this on my own time, and at my own expense." (Kneen April 2000)

stakeholder construction further marginalizes less powerful interests and critical positions that diverge from the universe of political discourse.

In response to the recommendations of the House of Commons Standing Committee on the Environment and Sustainable Development that ethical concerns need to be engaged, the government framed the consideration of ethical questions in terms of the goal of economic growth and the inevitability of genetic engineering:

The government believes that biotechnology is a critical emerging technology for Canada in terms of potential economic and societal value...*Given that this technology is and will continue to be a part of Canadian life*, the government recognizes that it needs the best possible advice on issues relating to the impact of this technology. The government is in agreement with the Standing Committee that addressing ethical considerations is critical for the public good and for the development of a vibrant Canadian biotechnology industry. (Government Response to Third Report 1)

In seeking this advice, the Canadian Biotechnology Strategy argues that, "advisory committees are increasingly the way of the future in biotechnology." (Canadian Biotechnology Strategy 1998: 7) The use of expert committees relegates even ethical concerns to the domain of "experts." The use of expert committees is an expression of the government's unwillingness to open genetic engineering to public debate and lay risk evaluation. It also signals a change in tactic as the use of stakeholder consultations becomes problematic, the more groups that are engaged in the issue and demand involvement.

The new Canadian Biotechnology Strategy has created a Canadian Biotechnology Advisory Committee (CBAC) of 12-20 appointed experts, "to advise ministers on the ethical, social, economic, scientific, regulatory, environmental and health aspects of biotechnology. The committee will advise on policy directions but will not arbitrate regulatory decisions. It will also examine the potential benefits and risks of emerging biotechnologies." (Canadian Biotechnology Strategy 1998) CBAC has designed what it calls a "two-pronged approach to

engaging Canadians in biotechnology discussions." Firstly, CBAC will "ensure that citizens have *factual, balanced information* available to them by publishing studies and reports on specific topics of interest." Secondly, it will give Canadians an opportunity to express their views on specific issues through public consultations.

In this case "citizenship" only begins when "expertise" has set the agenda. (Irwin 1995: 78) The public is characterized as "ignorant" and can therefore be excluded. This highly restrictive concept of citizenship is legitimated by the presentation of risk issues as technical. Charging committees with the mandate to provide advice to the government asks lay people to contribute in limited ways and essentially asks lay people to trust that the experts are taking care of these issues. Rick Walter, past president of the Canadian Institute of Biotechnology, argued that, "*the existence of bio-ethics committees and other research controls* must be advertised to offer assurances that human health and environmental safety is being protected." (Walter 1995) Such committees delegitimize lay participation in debate on these issues and marginalize lay knowledge in even social and ethical questions.

Where the need to address non-technical issues is recognized by the state, the state responds with structures that confine lay participation and knowledges to a narrow framework over which experts are given ultimate authority and responsibility. Expert advice is solicited on how to handle troublesome lay critique and risk evaluation without engaging in public debate.

Conclusion

The science based regulation of genetic engineering is a construction of the policy community and a universe of political discourse that promotes innovation as a key stimulus in economic growth. Genetic engineering is defined through the regulatory framework as an

extension of traditional plant breeding in an approach that refuses to acknowledge the possibilities of qualitatively new risks. Through this definition and through conditions of co-management with industry, the regulatory framework facilitates the uncontested commercialization of genetically engineered products in agriculture. Government regulation is the centerpiece of legitimation strategies that are aimed at assuring lay peoples of its safety. Conditions of lay mistrust in members of the policy community and the science that is appealed to in regulation may however undermine the success of this strategy. In the next chapter I will look at the case of lay protest over the review of rBGH that suggests possibilities for lay risk evaluation forcing policy making outside the policy community and changing policy outcomes.

Chapter Five

Risk Made Visible: Possibilities for Lay Risk Evaluation

Introduction

In this chapter I argue that lay knowledge has the potential to render the risks of the risk society visible. I argue that lay risk evaluation challenges the state to democratize technology decision making. The validation of lay knowledge in risk evaluation would include the legitimization of social and ethical considerations that serve as a direct challenge to the restriction of risk regulation to technical questions and expert knowledge. The application of lay knowledge in risk evaluation may break open the universe of political discourse that surrounds genetic engineering with the result of opening up the set of actors considered legitimate in the policy community, introducing new policy options, widening the range of issues discussed, and making new alliance strategies possible. I argue that the validation of lay criteria in risk evaluation may result in the abandonment of genetic engineering becoming a policy option.

Not all issues are resolved in the policy community and in the second section of this chapter I discuss the ways in which resistance to rBGH in Canada took the issue outside the policy community and the confines of the universe of political discourse, overthrowing these constraints, including those imposed by the regulatory framework, to present a formidable challenge to science-based regulation. I suggest that this case offers an important illustration of some possibilities for lay risk evaluation in making risk visible. In this case, lay risk evaluation widened policy options to include the abandonment of rBGH and forced this policy outcome. I suggest that lay risk evaluation and diverse public protest, emerging in new spaces of resistance, can disrupt the

power of the policy community and the universe of political discourse to allow for consideration of abandonment as a policy alternative.

1. Ecological Crisis as Institutional Crisis: Lay Knowledge and Prospects for Democracy in Technology Decision Making

Ecological crisis in the risk society needs to be understood as an institutional crisis where the institutions of industrial society continue to manufacture and legitimate risks that they can neither control nor manage. Faced with risks that cross boundaries of time and space, threatening future generations and creating global conditions of fear, institutions are faced with deep moral questions about the effects of risk decisions. The state continues to attempt to manage risks through the use of science but, confronted with complex risks like those of genetic engineering, conventional scientific risk assessment models are revealed as inadequate and risk enhancing. In this section I argue that the centrality of social and ethical criteria to lay risk evaluation threatens the technologization of risk assessment and may thus render risk visible.

I have argued through this thesis that the science based regulation of genetic engineering is constructed to conceal risk for the purposes of promoting innovation and legitimating the introduction of genetic engineering. To protect the status quo the policy community resists recognizing the qualitatively new risks of genetic engineering and works instead to protect and promote its interests by denying and concealing risk. For this purpose, risk is defined as a technical issue and the domain of experts. The potential of lay risk evaluation to introduce non-technical criteria is a threat to the policy community and its domination over the universe of political discourse. In asserting ethical and social considerations in the regulation of genetic engineering lay risk evaluation may open up new policy options.

I do not have the space here to suggest ways in which lay knowledge can be incorporated into risk evaluation or possible forms for co-operation between lay and scientific knowledge. I do however suggest that given the Canadian government's commitment to the biotechnology industry and its defence of the regulatory framework, the recognition of lay knowledge can only happen through public protest.

The character of lay knowledge presents significant challenges to the structure of risk regulation. Lay knowledges have a character very different from scientific knowledge. Lay knowledge is often tacit and cannot be codified. It cannot necessarily be shared and stored in the form of words and symbols. Hillary Wainwright argues that confronted with the character of lay knowledge, the usefulness and practicality of conventional bureaucratic hierarchies break down. (Wainwright 1993:120) The legitimization of local and diverse knowledges in risk evaluation requires a democratization of technology decision making.

Lay evaluation of risk engages social and ethical criteria. The validation of lay knowledge and lay criteria is therefore a direct challenge to attempts to restrict risk evaluation to scientific criteria and expert knowledge. Lay knowledge challenges the confinement of policy discussions to technical and expert language, and the defining of risk through non- scientific criteria and vocabularies challenges the defining power of the policy community. Lay knowledge threatens to reject the rhetoric of technology fix and processes that technologize policy concerns. The application of lay social and ethical criteria in risk evaluation has therefore the potential to break apart the narrow definitions of risk and restrictive definitions of genetic engineering that are constructed through science based regulation. Lay critique of science challenges the successful use of science based regulation in strategies to legitimate genetic engineering. The power of lay critique lies in an evaluation of the value commitments embodied in new technologies where the

introduction of new technologies may threaten social identities and constitute a source of social risk.

Lay knowledges can also serve as a powerful countervailing force to the argument that there are no alternatives. The biotechnology industry argues that we have no choice but to press ahead with genetic engineering; precaution is characterized as an immoral response to risk. The CEO of Dupont describes our "choice" regarding the future of genetic engineering as follows: "What we decide will have a direct impact on whether we can achieve the larger goal of creating a sustainable global economy or if we will let the next few generations try to make their way in a world of collapsing ecosystems." (Holliday 1999) But diverse ways of knowing open up possibilities for the consideration of new policy options and new approaches to defining problems and seeking their solutions. The central consideration of social and ethical considerations in lay risk-benefit evaluation may conclude that not only is abandonment possible, it is desirable and even necessary.

The universe of political discourse that promotes a future propelled by innovation also constructs regulation according to "the goal of becoming a technically advanced nation." (National Biotechnology Advisory Committee 1988:4) But rather than accepting innovation as the engine of economic growth lay criteria may introduce the consideration of social need in the design and introduction of new technologies and the recognition that scientific advancement and economic development are not ends in themselves. Lay critique allows that innovation can be directed towards specific goals that are socially determined.

A political economy analysis of the actors and interests promoting genetic engineering suggests that a reordering of priorities in risk regulation can only happen through public protest and public debate. The insertion of lay criteria and language in risk evaluation has the potential to take risk evaluation of genetic engineering outside the policy community and the universe of

political discourse. Richard Mahoney, former CEO of Monsanto argues: "The biotech race can be won-and I'm confident it will be-because it must be...Biotechnology is the battleground upon which all future technology battles will be fought. This time we must succeed. We must not let our lead slip away because of bad public policy." (Mahoney 1993:8- 9) An analysis of the actors engaged in waging the battle for the future of genetic engineering may also make risk visible.

In the next and final section I look at lay evaluation of the risks of rBGH. In this case public protest successfully challenged the definitions of genetic engineering that were constructed by the policy community. The universe of political discourse that was built by the policy community to support the commercialization of this product was altered through lay interventions and public protest such that the policy outcome was changed. Lay risk evaluation proved to be a formidable power in opposition to the interests of the policy community. This case suggests the application of lay knowledges may successfully challenge the construction of science based regulation.

2. The Review of Bovine Growth Hormone: Moving Outside the Policy Community and Universe of Political Discourse

Experience in Canada already shows that policy outcomes regarding the introduction of genetically engineered products can be altered through public debate and protest. The veterinary drug recombinant Bovine Growth Hormone was ready to be the first genetically engineered food product to enter the Canadian market until public debate stalled its approval and ultimately forced its rejection by Health Canada. In the case of public debate over rBGH, lay participation proved a powerful force in risk evaluation that included a critique of science, an evaluation of social risk,

and an analysis of actor interest and industrial social relations behind promotion of the product. All of these aspects of lay risk evaluation contributed to rendering the risks of rBGH visible.

Not all issues are resolved within the policy community. Some issues are too important to be left to the policy community and are addressed instead by the political leadership and full-dress debate. (Pross 1986) In this section I examine public protest in the review of Bovine Growth Hormone as an illustration of the potential for policy outcomes to be determined outside the policy community. The power of lay risk evaluation and lay protest over the review of rBGH offers insights into possibilities for the role of lay knowledge and participation in risk evaluation of genetic engineering. I argue that the conflict over the introduction of rBGH made risk visible, defeating attempts by the policy community to deny and conceal the character of risk.

The prospective introduction of rBGH into Canada became the subject of public and media scrutiny through the period beginning November 1988 through to January 1999, when Health Canada announced its decision to reject Monsanto's submission for approval of their rBGH product. The department's rejection of rBGH was the outcome of intensive public debate and public protest. In this case, members of the attentive public acted as counterbalancing voices to that of the policy community. Lay voices were heard throughout the review of rBGH as pressure groups and lay peoples articulated concerns in fora that were not constructed by the policy community. Protest to rBGH was the representation of lay critique in the attentive public that was powerful enough to overthrow the monopoly of members of the policy community and overturn the intended policy outcome of product approval. In this case the attentive public clearly pushed genetic engineering out of the constraints that were built by regulatory structures and the universe of political discourse. New issues and policy options were pushed to the fore, new actors influenced debate, and new alliance strategies were formed. The attentive public moved the issues

of rBGH into a public space where lay risk evaluation defied industry and government definitions of the product.

Definitions were highly contested in the struggle over rBGH, just as they are in risk evaluation of genetic engineering generally. Monsanto attempted to change the name of Bovine Growth Hormone to recombinant bovine somatotropin (rbST) in an effort to define the product in scientific terms and keep the language out of the public's reach. Kneen argues that this was an attempt to sanitize the product. (Kneen 1999:90) In contrast, the term Bovine Growth Hormone offered a clear and transparent description of the drug and its functions that lay people could understand. Popular use of the term facilitated communication and helped demystify the product, giving lay people a sense that they could talk about the drug and, with the help of farmers and other actors, understand both its potential effects and its value commitments.

Trust was a central issue in the struggle over rBGH. A high level of lay mistrust in government departments and corporate actors encouraged scrutiny and lay critique. Canada's regulatory systems were facing a crisis of trust resulting from the failure of the blood supply system and health risks associated with the silicone breast implants that Health Canada had approved for safe use. Monsanto's conduct through the review of rBGH added to existing lay mistrust of corporate actors generally and this company in particular. Monsanto recognized the problem of trust and proposed the following approach to overcoming public risk perception problems:

We must unite to educate and re-establish public faith in food production technology. We must help those producers trapped in the past, or in ignorance, not to fall off the back end of the technology treadmill. And, we must stop those who make a profession of misleading the public about food technology. (Monsanto Company, "The US Dairy Industry: A Vision for the Future," October 1994: 58)

But with the Canadian market and the future of other markets at stake in this review, Monsanto employed a number of tactics that undermined public trust and invited lay criticism.⁶³

Farmer knowledge emerged as a powerful counterbalancing voice to that of Monsanto and Health Canada. As members of the policy community continued to fail in their efforts to win the trust of lay peoples, farmers looked to their own knowledge and, in response, consumers turned to farmers. The articulation of farmer views concerning the ethical issues of animal welfare and the socio-economic effects of introducing the product onto the market was key in raising the profile of critique. Richard Lloyd of the National Farmers Union argues that farmers understand animal comfort as a critical component of successful dairying. (Lloyd 1999: interview) Farmer experience teaches that forcing a dairy cow to higher milk production would put stress on the cow's system, leading to animal health problems. Lloyd argues that farmers did not want to treat their cows in the way that use of the hormone demanded. rBGH needs to be injected into cows twice a week and the complications of the drug include mastitis, a painful udder infection that requires treatment with antibiotics. Dairy farmer Lorraine Lapointe argued, "Cows need to be healthy. Why would a processor buy milk from unhealthy cows?"⁶⁴ (Lapointe 1999: interview) Animal health concerns also led to questions about human health concerns where, for example, the use of antibiotics would increase antibiotic levels in milk and could contribute to the development of antibiotic resistance in humans.)

⁶³ In 1994 CTV program *The Fifth Estate* reported an alleged bribe attempt of Health Canada officials by Monsanto representatives, an allegation that was repeated in 1998 Senate hearings by a scientist who witnessed the exchange. It was also alleged that Monsanto was failing to report cases of animal health problems in the United States to the FDA. Monsanto released a list to the House of Commons agriculture committee of countries where their product was approved but the information was incorrect.

⁶⁴ Lorraine Lapointe successfully filed a complaint with the Food Products Marketing Commission when milk from test herds was put onto the market by the Ontario Milk Marketing Commission without notification. to processors and county milk committees.

For farmers, rBGH was an issue of animal welfare and financial risk. As Lloyd argued, "It is hard to find a dairy farmer who wants their industry to start using these injected synthetic hormones. They are, of course, worried about the threat to their incomes if milk consumption drops because of an erosion in consumer confidence in dairy products' safety. But the issue of the health problems to their cows is equally important." (Lloyd 1995: interview) In this instance rBGH was critiqued as a threat to the social identity of farmers. Farmers rejected the relationship to their animals and farming practice that the use of rBGH would impose. As far as the National Farmers Union was concerned, farmers did not view their cows in the same way that Monsanto did. Farmers evaluated the technology based on its value commitments in addition to its specific effects.

Monsanto attempted to define animal health problems like mastitis as a result, not of the drug, but of bad farm management practices. Monsanto argued that rBGH was just another tool for farmers and that successful and efficient farmers could mitigate any animal health risks.⁶⁵ The NFU intervened to critique this analysis and argue that the product was harmful to dairy cows and, moreover, that the product was not needed by farmers and would not contribute to the Canadian dairy industry. Farmers introduced a risk-benefit evaluation that included an analysis of the social purpose of the technology, its socio-economic effects, animal welfare concerns, and milk quality and safety for human consumption.

rBGH was approved for use in the United States in 1994. According to documents obtained by the Wisconsin Farmers Union through a freedom of information request, in less than a year over 800 farmers reported health problems with their cows. (Wisconsin Farmers Union March 14 1995) Monsanto's response to farmers' reports of animal health problems was to dismiss their experiences. Monsanto tried to isolate farmers and blame their management

skills for any animal health problems. A Florida farmer found one or two new cases of mastitis in his herd each day and stated that, "Monsanto tried to make me feel incompetent, so I kept quiet and figured I should try to solve this thing on my own." (Kneen 1994: 2) Dairy farmer Jay Livingston of Lisbon, New York, described his experience with the company as follows:

"When we started to develop problems, Monsanto came out to the farm and told us we were the only ones having problems. They blamed us and had every excuse from here to hell and back, but totally rejected that BST had any relationship to our problems." (Wisconsin Farmers Union March 14 1995) In the face of corporate arrogance and intimidation tactics farmers insisted that their knowledge of dairying correctly identified risk.

The active participation of farmers in the Canadian debate over rBGH propelled the issues into the public eye, the media, and parliament. Politicians could not delegitimize the voice of farmers but, in fact, benefited from association with it. The National Farmers Union is rarely influential over farm policy and never fully represented in the policy community. Member of Parliament Wayne Easter was past president of the NFU and when he took government office he brought the issues of rBGH, and the work of the NFU, to the attention the House of Commons Standing Committee on Agriculture and Agri-Food. The extensive investigative research conducted by Richard Lloyd and others in the NFU was a powerful advantage that, with access to this parliamentary committee and the support of key committee members, put the group at the center of the debate.

There was tremendous power in the coming together of consumers and farmers over this issue. The debate allowed for the creation of new alliance strategies that included the animal rights group the Animal Alliance of Canada joining with the National Farmers Union and the Council of Canadians for a one day lobby of members of parliament. The Council of Canadians is

⁶⁵ Animal health risks were clearly identified on the product label that the FDA approved.

a national citizen advocacy group that formed over the struggle against Free Trade and, in this debate, served to bring disparate community voices together. The Council compiled a list of over 300 groups across the country who opposed rBGH including school boards, municipal health boards, women's organizations, and environmental groups. The Council and the NFU organized the gathering of thousands of signatures on petitions that were collected by local people in their communities. (Sharratt in print) This was in addition postcards sent to the Minister of Health that began, "I want to continue to trust Canadian milk.."

Richard Lloyd argues that by the middle of 1995 - seven years after testing of rBGH began in Canada and one and a half years after rBGH was expected to be approved in Canada - rBGH was at the top of the parliamentary agenda and the debate had reached the Prime Minister's Office. (Lloyd 1995: interview) The attentive public forced policy community members to meet the hectic agenda of media and parliament. An attentive public pushed rBGH out of the hands of the policy community and onto the parliamentary agenda at several points. The role of parliamentarians, both House members and Senators, indicates important possibilities for the role of parliament in public debate and public policy development. When no one in Parliament was familiar enough with rBGH to speak on the issues, information was gathered and competence created through parliamentary committee hearings. In the case of rBGH, committee hearings of both the House of Commons Standing Committee on Agriculture and Agri-Food (1994) and the Standing Senate Committee on Agriculture and Forestry (1998) were important fora for the articulation of voices outside the policy community. Hearings created opportunities for media and public education through the scrutiny of evidence presented by a wide variety of witnesses that including academics, scientists, farmers, and representatives of citizen interest groups. The hearings created an important space for resistance.

Scientific evaluators inside the Bureau of Veterinary Drugs in the Health Protection Branch of Health Canada emerged through Senate committee hearings as highly trusted and influential individuals. Public protest created a safe space for the scientists to speak up about their own concerns and committee hearings provided a safe forum.⁶⁶ The scientists had constructed a safe place for the articulation of some of their concerns through their union grievance hearing. Members of the public, non-governmental organizations, and journalists were all present at these hearings and the scientists subsequently testified in front of the Senate agriculture committee. In addition to their resistance inside the department, the scientists also organised a public conference on food safety through their union. The conference brought together scientists in the Canadian public service with independent scientists from the US and the UK, politicians, members of citizen advocacy groups and the public, with members of the policy community including department officials. The forum examined the science and social issues of the use of veterinary hormones and antibiotics and explored the question of mandated science as a public enterprise. Scientists were highly trusted because of the risks that they took to articulate their concerns and their clear identification of these with the public interest.

Through the various efforts of members of the attentive public to insert critical voices into the review of rBGH it became apparent that there are few mechanisms for Canadians to debate the merits of new technologies. Brewster Kneen argues that there is a total absence in Canada of any tradition of public policy debate concerning either agriculture or technology; "not only is there no tradition of debate, there are no mechanisms or fora in which debate and policy formation might take place" (Kneen 1999: 120) Kneen argues that, "the public must create the structures for debating and forming public policy democratically, and for holding the government

⁶⁶ The Senate Standing Committee on Procedures has since heard testimony from Dr. Shiv Chopra that he was subject to further disciplinary action as a result of his appearance at the Senate committee hearings.

accountable - to the public rather than to just a diminishing handful of transnational corporations." (Kneen 1999:154-5) The rejection of rBGH demonstrated that the public could take control of the discourse of regulation and intercept the intentions of the policy community. The introduction of new technologies into our economy and society is not inevitable but can be decided through public debate and public protest.

Conclusion

The review process for genetically engineered products is a central site of contest over the defining of genetic engineering and its risks. The regulatory system is the greatest expression of Canadian government policy on genetic engineering and is the place where this policy is most directly operationalized. It is the process through which products enter the market place and is an immediate target of pressure group activity as well as central site of lay mistrust and critique.

Regulation of genetic engineering is constructed as “science based” in order to retain control over risk evaluation. The science based regulation of genetic engineering is designed to facilitate the speedy commercialization of products of genetic engineering and is constructed to promote innovation and legitimate genetic engineering. The regulation of genetic engineering is a technologized product review that defines the issues as technical rather than social or ethical. The case-by-case or product-by-product review permits a deliberately fragmented approach to defining risks away from the production process or source of risk. This approach works to deny and conceal the qualitatively new risks of genetic engineering.

The science based regulation of genetic engineering is constructed by a small circle of actors in a policy community that is dominated by corporate interests. The policy community constructs a universe of political discourse that works to restrict public debate and create a climate favourable to promoting genetic engineering. The universe of political discourse constructs the risks and benefits of genetic engineering in terms of economic progress. A political economy analysis of actors and interests in the development and commercialization of genetic engineering contributes to efforts to make risk visible.

The construction of science based regulation is a part of the larger project of control that is genetic engineering. The science based regulation excludes non-technical considerations in risk

evaluation and marginalizes non-scientific or non-expert knowledges. It engages the same rationality and language in risk regulation that is implicated in risk manufacture. Ultimately the construction of science based regulation is itself a source of risk.

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