

**Recombinant Bovine Somatotropin: Challenging Canada's Science-based
Regulatory System and the Emergence of Post-Normal Science**

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By

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ABSTRACT

Recombinant Bovine Somatotropin (rBST) is a biotechnology for increasing milk production in dairy cattle. The purpose of this research was to investigate and to build a better understanding of the complexities and controversies around this product in Canada. To accomplish this, I examined the Standing Senate Committee on Agriculture and Forestry's inquiry into rBST and the drug approval process. I compared and contrasted the testimony of witnesses and Senators and I uncovered emerging issues, patterns, and themes. This research was an exploratory and qualitative exercise that analyzed how the participants of this Senate inquiry conceptualized and contested the meaning of science, safety, and the state's regulatory functions.

This research revealed several commonalities between Health Canada management, the human safety panel, and industry representatives. These witnesses argued that the drug approval process must be efficient, standard-driven, and based upon available scientific studies. These witnesses stated that they had confidence in the neutrality and competency of internal standard setting-agencies. They emphasized transparency rather than public participation in the drug approval process. Health and safety were conceptualized as static phenomena to be measured and evaluated by experts.

In contrast, Health Canada employees had several commonalities with the Senators, dairy representatives, and witnesses from citizen interest groups. Their testimony supports the argument that health and safety are dynamic social constructs. These actors transformed the boundaries of science to accommodate their precautionary framing of safety. They highlighted several problems with Canada's science-based regulatory framework and demanded that they have a decisive voice in the rBST

decision. They challenged the hegemony of industrial capitalism by combining both scientific and lay knowledge to expose the limits and contradictions of industrialized agriculture.

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DEDICATION

This work is dedicated in loving memory to my Uncle Ken. Thank you so much for showing me to respect nature and teaching me to see the good in everybody.

I miss you everyday.

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Chapter One: Introduction

1.1 Description of the Problem

Recombinant bovine somatotropin (rBST) is a genetically engineered drug to increase milk productivity in dairy cattle. In 1990, the Monsanto Corporation sought to have their rBST product (trade name Nutrilac) approved for sale and use in Canada. Health Canada, the government agency responsible for licensing this drug, was severely criticized for its handling of this drug. Ultimately, Health Canada took nine years to decide the fate of Monsanto's rBST submission, and in 1999 decided not to approve it for use in Canada.

The rBST case challenged the credibility of Health Canada because not only was there a lack of scientific consensus on rBST's safety but also because this drug came to symbolize broader economic, political, and social issues. Canada's dairy industry was concerned over rBST's socio-economic impacts. Many dairy producers perceived the economic benefits proposed by Monsanto as risks. These risks included a further decline of smaller family dairy farms, decreased consumer confidence, and a further drop in export milk prices due to adding more milk to an existing oversupply. With the benefits of rBST blurred, many Canadians also questioned whether or not any risk to human health would be worth taking. The rBST controversy is a debate about the extent to which science alone should judge the acceptability of this drug (MacDonald 2001; Mills 2002; and Jones 2001).

rBST was one of the first major genetically engineered products introduced to Canada's regulatory system. In many respects, Canadians perceived rBST as a test case for the adequacy of Canada's regulatory system to handle the predicted flood of genetically engineered products to come. As one of the first genetically engineered products, rBST was arguably a test case for industry's success in getting genetically engineered products on the market. Turner (2001b) suggests that Health Canada's decision to ban rBST perhaps blunted Monsanto's and other corporation's commercial pursuit of biotechnologies. Whether or not this single case blunted corporate investments into biotechnologies is debatable, but nonetheless this case study demonstrates the impact of this single drug on much larger questions about the state's regulatory agencies and the political economy in which they operate.

Canada's experience with rBST reveals much about the appropriateness and applicability of the insights of post-normal science as a tool for explaining regulatory debates. The Senate inquiry allows for an excellent examination of this because it is a situation where participants struggle with trying to use the traditional model of scientific inquiry in order to make a decision about an anything but "normal" product. The rBST Senate inquiry highlighted the presence of the following four dimensions contributing to the complexity around rBST: uncertain facts, disputed values, high decision stakes, and urgent decisions.

1.2 Purpose and Objectives

There are clearly defined testing procedures a veterinary drug must undergo to be deemed acceptable in the marketplace (MacDonald 2001). Quantitative investigations into degrees and probabilities of harm and injury are key activities in deciding courses of

action to take with veterinary drugs. The rBST case however, challenged Health Canada's science-based regulatory mandates for assessing and approving veterinary drugs in unique ways (MacDonald 2001, Mills 2002, and Jones 2001).

Although there were many different actors testifying and raising different issues at the Senate inquiry, I have decided to limit my focus to issues specific to Health Canada's roles, responsibilities, credibility, and capabilities. There are two primary levels of analysis research takes. At one level, this research is concerned with identifying and examining the differences and similarities within Health Canada with respect to how new veterinary drugs are treated. At a second level, this research explores the expectations, interpretations, and criticism of non-Health Canada participants, including the Senators, in regards to Health Canada's performance at the Senate inquiry, as well as the events prior to this inquiry.

More specifically the objectives of this research are:

1. To explore the meanings and values that Health Canada actors attribute to the science-based decision making process for approving veterinary drugs.
Furthermore, to explore how politics, economics, and social dynamics are interfaced with these scientific evaluations.
2. To identify where Health Canada actors turn for information and advice when making judgments regarding the risks and benefits of rBST, and to uncover the motives for their choices.
3. To examine the interpretations formed and areas of contestation raised by non-Health Canada witnesses in reaction to the different actors within Health Canada.
More specifically, to compare and contrast the representations of the risks and

benefits of rBST between non-Health Canada witnesses and Health Canada witnesses.

4. To isolate the institutional barriers Health Canada witnesses identify and struggle with in an effort to make what they deem as the best possible regulatory decision.

This research is an exploration into the difficulties Health Canada's management and rank-and-file scientists encountered when making a regulatory decision on Nutrilac, Monsanto's trade name for their rBST product. As well this research explores the reactions of other witnesses to Health Canada's handling of the rBST file. The primary objective is to examine discursive practices and the maintenance of and resistance to the practices and ways of thinking within Health Canada. In order to provide insight into this, I have chosen to conduct a discourse analysis of the Standing Senate Committee on Agriculture and Forestry inquiry into rBST and the drug approval process. The Senate inquiry began on 14 June 1998 with a total of eight different sessions with the last session on 13 May 1999.

This research aims to demonstrate that the authority of scientific knowledge is not absolute, but rather that such authority is contingent upon a variety of discursive practices. More specifically, this research will uncover the discursive means by which actors construct meanings of the risks and benefits of rBST. Moreover, this research will highlight important barriers to consensus and satisfactory closures due to differences in risk perceptions and representations among the regulator, the regulated, and other affected parties.

This research examines the discourses of Health Canada personnel at the Senate inquiry with the intent of uncovering whether the basic tenets of post-normal science are

being posed in an informal sense and the resistance to such a possibility. In order to provide insight into this, I have chosen to employ Foucault's theoretical approach on discourse, knowledge and power, and Antonio Gramsci's theory of hegemony.

1.3. Methods

Discourse analysis is the means by which I identify and analyze themes and issues in the Senate inquiry. Before I discuss the specific methods and procedures used, it is imperative to provide a general introduction to the meaning and significance of discourse.

To provide a broad definition, discourse is a "bounded body of knowledge and associated practices, a particular identifiable way of giving meaning to reality via words or imagery" (Lupton 1999: 15). Discourse is grounded in language use and is a way people interpret information and construct coherent understanding and accounts of events and phenomena (Dryzek 1997).

According to Black (2002) discourses perform three functions. Discourses are constitutive, functional, and coordinative. Discourses can be viewed as a mirror on reality. Discourses, or the way we construct knowledge, is based on reality. Discourses, several scholars (e.g. Black 2002, Fairclough 1992) argue are more than mere reflections, but also a constructive force shaping (if not creating) reality. Discourse builds objects, identities, relationships, and ideas. Black (2002) describes discourse as having a functional purpose to achieve certain ends. Lastly, Black (2002: 165) asserts that discourse requires and produces coordination for creating meaning and "shared senses" of social life.

According to O'Mahony and Skillington (1999), ideologies are activated through discourses in various roles: explanatory, evaluative, orientative, and the pragmatic. These roles give actors an ideological programme for social and political action. O'Mahony and Skillington (1999) also argue that how an actor presents issues is not only contingent upon immediate factors but also wider cultural and social systems of meaning.

Foucault builds upon this general sense of discourse with the insight that discourses are historically specific ways of defining knowledge and truth (Carabine 2001). Power is central to Foucault's understanding of discourse as he argued, "There can be no possible exercise of power without a certain economy of discourses of truth which operates through and on the basis of this association" (Foucault 1980: 93). Power is implicated in discourses by setting limits and establishing procedures to what can be said, by whom, and when (Fairclough 1992).

Discourses are more than resources enabling a researcher to describe the attitudes and perspectives of social actors; they are in and of themselves topics of inquiry (Gilbert and Mulkay 1984). According to Gilbert and Mulkay (1984) discourse analysis is different from traditional social inquiry where a researcher collects participant statements in order to assemble an account of what happened. Discourse analysis instead studies statements and actions of participants in order to uncover how discourse is organized in contextually appropriate or inappropriate ways (Gilbert and Mulkay 1984). I elaborate on the above by applying O'Mahony and Skillington's (1999: 100) contention that "scientific disputes are not resolved simply by reference to scientific 'facts', but by the adoption of rhetorical strategies that weave together ideological elements in a manner designed to shape public discourse and gain legitimation."

My research is concerned with variability of expert discourses and Foucault has a particular appeal because of his emphasis on the discontinuities of discourses. The discontinuous and fragmentary nature of a discourse is, according to Foucault, of equal importance if not more than its continuities. Foucault poses an interesting question that guides my analysis: “How is it that at certain moments and at certain orders of knowledge, there are sudden take-offs, these hastenings of evolution, these transformations which fail to correspond to the calm, continuist image that is normally accredited (Rabinow 1984:112).” In other words, do the discourses of Health Canada representatives represent a take-off from normal science?

I began my data analysis by reading the entire Senate transcripts in order to gain an understanding of the major topics, themes, and issues discussed. There are a lot of different perspectives on a wide variety of topics throughout the Senate inquiry. Therefore, I chose to focus on four specific issues characteristic of “post-normal” controversies; Mastitis, Canada’s dairy industry, regulatory environments and the future of Monsanto and industry in Canada, and rBST and Canada’s international competitiveness and trade. I then proceeded to isolate excerpts from the transcripts. Following this, I read the excerpts in order to gain a more in-depth look paying close attention to the three levels of discourse analysis, as described by Fairclough (1992).

Fairclough’s first level of discourse analysis is “Discourse as Text”. This level is primarily concerned with textual features (e.g. language use and language forms). In this level, Fairclough identifies four main aspects to consider when doing discourse analysis: vocabulary, grammar, cohesion, and text structure.

Vocabulary examines words within a text and their meanings. A speaker is faced with many possible combinations of words to choose from when constructing his/her

statements. However, the words a speaker chooses is not arbitrary in that words are selected (consciously and unconsciously) to convey a certain image. As Fairclough (1992) asserts, the words a speaker uses are socially variable and socially contested as words and their meanings have wider social and cultural significance. Moreover, words are not static or one-dimensional. The meaning of a word can be highly variable, dependant upon its context, and subject to rapid change.

In contrast grammar focuses upon how words are combined to form clauses and sentences. Fairclough (1992) divides grammar analysis into three dimensions: transitivity, theme, and modality. Transitivity examines agency, causality, and the attribution of responsibility. Transitivity includes looking at whether sentences are active or passive. Nominalization, turning processes and activities into nouns, is a key to examining the omission of agents and participants.

Other considerations include looking at what process types are dominant. Process types refer to how an actor represents social events. Fairclough (1992) states that the main process types in English include: action, event, relational, and mental. Action processes can be both direct (an agent is acting upon a goal) or indirect (there is an agent and an action; however there is no explicit goal). For example, the statement “the teacher scolded Paul” is an example of a direct action process type. Whereas the statement “the teacher was scolding” is an example of an indirect action process. Event process types, by contrast involve an event and a goal. An example of an event process would be “Paul was scolded” Emphasis in event process types focus on explaining what happened. Relational process types are clauses representing relations of being and becoming or having possession. “Paul is scolded” is an example of a relational process type. Lastly, mental processes are representations of social events stressing states of

cognition such as “I think, I know, I feel”. The clause “Paul knows he deserved to be scolded” is an example of a mental process type.

“Discursive practice” is the second level of Fairclough’s model. Discursive practice “draws upon conventions which naturalize power relations and ideologies and these conventions themselves and the ways in which they are articulated, are a focus of struggle” (Fairclough 1992: 71). This dimension involves examining how a text is produced, interpreted, and consumed. Fairclough calls attention to the socio-cognitive process of how a text is produced and interpreted. These socio-cognitive aspects include internalized social structures, norms and conventions and past experiences and events influencing how a text (any spoken or written utterance) is produced by an actor and how others may interpret a text (Fairclough 1992). Fairclough (1992) also emphasizes how text production and interpretation is constrained by the social context and social practices within which it is situated. Fairclough identifies intertextuality as the most significant feature to investigate in this dimension. Basically, intertextuality refers to a text incorporating past texts. A text may incorporate other texts explicitly or implicitly for a variety of purposes such as integration, contradiction, and irony (Fairclough 1992).

Fairclough’s “discourse representation” was an invaluable tool in my research. Discourse representation is a form of intertextuality in which a speaker is usually explicitly reporting on what others have said previously. Fairclough divides discourse representation into two types: direct and indirect. Direct representations use quotation marks (e.g. “she said “I am warning you””). Indirect representations replace quotations by taking the represented discourse and making it a subordinate clause using ‘that’ to the reporting clause (e.g. “She warned them that drinking and driving is dangerous”). The choices a speaker makes when integrating other texts is important because these

instances reveal what a speaker declares as worthy, valid, and legitimate knowledge. Discourse representations are cues to the distance or affinity the speaker wishes to establish with other participants. As Fairclough (1992: 107) explains “There is an explicit boundary between the ‘voice’ of the being reported and the ‘voice’ of the reporter and direct discourse is often said to use the exact words of the person being reported.” With indirect representations, the voice of the reporter and the reported are less clear. As well, direct discourse representations stress the time and place of the original when the text was produced, whereas with indirect discourse representations a shift to the past tense occurs.

Fairclough’s third dimension is ‘discourse as social practice’. This dimension focuses upon ideological and hegemonic properties and effects. The central tasks of analyzing this dimension are to provide explanations for how social and hegemonic relations and structures constitute discourses and how discourses transform social and hegemonic relations and structures.

1.4 Outline of Thesis

The remainder of this thesis is divided into four chapters. In Chapter Two, I provide a broad analysis of the conventional and dominant approaches of the state with respect to risk issues. I begin with an introduction into the need for government action with new technologies and the appeals to science-based regulations to fulfill this need. I then proceed to review literature identifying problems with science in regulatory and policy matters. The second half of this chapter examines Canada’s regulatory confusion and conflict with Monsanto’s rBST submission. This chapter concludes with an overview of the uncertainty and high decision-stakes associated with making a

regulatory decision on rBST. In Chapter Three, I elaborate on the post-normal environment surrounding rBST identified in Chapter Two, through an exclusive examination of how the features of post-normal science (uncertainty of facts, disputed values, high decision-stakes, and the need for a decision) were constructed and communicated in the Senate inquiry. In Chapter Four, I discuss my findings in terms of the inclusion/exclusion of extended facts and the encouragement of extended communities participating in a decision to accept or reject approval. In Chapter Five, I conclude this thesis with a follow up of developments within Health Canada since the Senate inquiry. Conclusions drawn from this study are presented at the end of this chapter.

Chapter Two: Technology, Risk, and Regulation

2.1 Introduction

Over the past few decades there has been heightened public awareness and concern over risks. This heightened awareness has put new pressures on governments and industry to respond to risk issues with more transparency, precaution, and accountability. It is in this atmosphere that rBST entered Canada's regulatory arena. The main purpose of this chapter is to provide a background into key events (both domestically and internationally) leading up to the Senate inquiry. The focus of this chapter is to identify the key social, economic, and political contexts directly related to rBST, as well as to identify pressures for change facing Canada's regulatory institutions. This chapter is an exploration of the concept of risk and the dominant and alternative frameworks for its understanding and management. I first explore the character of formal technical models and why they are so dominant in state regulatory activities. I then proceed to challenge the dominance of these models by exploring constructionist accounts of risk knowledge and the problems the state encounters using formal technical models to assess and subsequently manage risks.

2.2 Technology and Risk

Technology is a hallmark of modernity and promises to liberate humanity from nature by mastering it (Delanty 1999). Delanty (1999: 38) further notes that technology "was simply part of the grand narrative of progress and enlightenment." It is important,

that we make note of his use of the word “was.” Over the last four decades, the general public and some experts have been questioning the costs and benefits of technologies to our health, environment, lifestyle, and socio-economic well being.

Recently, there has been a proliferation of discussion and concern over risks from experts and the public (Lupton 1999). Industrial development and technological innovations are two driving forces for this increased interest. We are confronted with many different types of risks. There are risks to human health, to environmental sustainability, to our economic survival, and to our values and ethics. This marked interest is reflected in increased media attention and increased litigation and regulation (Nelkin 1984). Anthony Giddens termed this prominence of risk as “risk culture”

Giddens (1991: 3-4) asserts:

Modernity is a risk culture. I do not mean by this that social life is inherently more risky than it used to be; for most people that is not the case. Rather, the concept of risk becomes fundamental to the way both lay actors and technical specialists organize the social world. Modernity reduces the overall riskiness of certain areas and modes of life, yet at the same time introduces new risk parameters largely or completely unknown to previous areas.

Originally risk was a neutral term indicating a wager between individuals after considering the chances of costs and benefits (Gabe 1995). Risk could therefore be defined simply as a probability of an event occurring. However, this basic definition does not really clarify what a risk is because there are many chance events not considered as a risk. According to Gabe (1995), the term risk almost always carries an image of negative or adverse consequences (Gabe 1995). Thus, a more precise definition of risk could make exclusive reference to risk as a probability of a negative or adverse consequence.

These types of definitions do not capture the essence of what risk can mean. As Kemshall (2000) argues it is difficult to provide a concise, all encompassing, and universal definition of risk because every risk issue is diverse and far from uniform. Risks are dynamic social concepts and whether a risk is chosen or not, familiar or unfamiliar, or has devastating or minimal consequences as well as being what is impacted, and who benefits and who loses impacts how people respond to risks.

2.3 The State and Science-based Regulations

Citizens entrust their governments to assess and make decisions about risks on their behalf. The state is a central player in creating policies and enforcing regulations to protect the health and safety of citizens, protect the environment, and achieve economic growth and stability. Black (2002: 170) describes regulation as a “process involving the sustained and focused attempt to alter the behaviors of others according to identified purposes with the intention of producing broadly identified outcome or outcomes which may involve mechanisms of standard-setting, information gathering, and behavior modification.” Regulations exist out of some recognized need for protection, improvement, and/or stability. Jasanoff describes regulation as a contract requiring society and the state to agree to accept the costs, risks, and benefits of technologies (Jasanoff cited in Mills 2002: 12). Regulations are rife with controversies and conflict, especially when there are diverse interests, values, and meanings surrounding new technologies.

Regulation involves losing certain freedoms such as the freedom to engage in particular behaviors, to consume certain products, or to sell and market a product. These costs of regulation are justified on the basis that the public needs to be safe and healthy.

Regulatory decisions are complex and difficult, with potentially far reaching impacts. There are serious consequences when regulatory agencies underestimate or misinterpret potential hazards. As well, there are political, economic, and social consequences accompanying regulatory choices. For instance, imposing strict regulatory standards can stifle economic innovation and perhaps loss of the ability for Canadian markets to compete at the global level, and on the other side there is an overwhelming demand for precautionary measures to ensure safety and well-being.

In order to balance the loss of freedoms, political demands and safety demands associated with regulation, government agencies depend upon traditional or 'normal science' to inform policies and regulatory decisions. The state seeks legitimacy through science-based regulations (Doern and Reed 2001, Nelkin 1975, and De Marchi and Ravetz 1999). Science-based regulatory agencies, primarily and sometimes exclusively, rely on the natural sciences to make or at least justify regulatory actions (Jarvis 2001). Scientific knowledge is privileged knowledge because science claims to discover facts objectively, systematically, rigorously, and rationally. Basing decisions on science presumably leads to fair, effective, and efficient policy and regulatory choices. Science is embedded with the assumption that it will put an end to irrational and value-driven arguments.

Science is also a powerful institution with prestige and status, setting standards and boundaries of what is and is not acceptable knowledge and practice. As

Kloppenburg articulates:

Despite the existence of many valid forms of knowledge, science has achieved the status of the modern epistemic hegemon, that standard against which all other knowledge claims are compared to (Kloppenburg 1992:98 cited in Beckie 2000).

The state enjoys a certain comfort level by justifying its decisions on technical grounds. In framing technology choices as a technical issue, the state can to a degree insulate itself from the rocky political terrain of values, beliefs, emotions, and ideologies. Science is presumed to discover irrefutable 'hard' facts'. As Dorothy Nelkin (1975: 36) states:

Science... is widely regarded as a means by which to de-politicize public issues. The increasing use of expertise is often associated with the 'end of ideology'; politics, it is claimed, will become less important as scientists are able to define constraints and provide rational policy choices.

Jasanoff (1995) notes that regulatory agencies are public and contentious by nature. Regulatory agencies are frequently accused of being incompetent or subordinating science to achieving political ends. In response to these two frequent charges, Jasanoff (1995) observes, regulatory agencies insist that autonomous and independent science will put their critics at ease. In an effort to appear credible and trustworthy, science-based regulatory agencies often seek to persuade their constituents that their decisions are entirely based upon theoretically sound, independent, methodologically rigorous, and objective science. This argument leaves science to scientists and political, economic, and social issues to be resolved elsewhere. Such separation of science and society is a dominant feature of science-based regulations.

2.4 The Conventional Model of Regulating Risks and Managing Technology

Scientific risk analyses are typically premised upon some variation of positivism. Mathematical calculations are utilized to predict the probability and severity of technological impacts. The use of mathematical calculations leads to the assumption that risks are manageable and can be brought within safe levels. Although risks are seen as

manageable this is qualified by the assertion that nothing can be guaranteed completely safe (Lidskog 1996). Webler et al (1992) argue that the contention that risks are manageable, and nothing is guaranteed safe, restricts technical experts to bring the consequences within 'safe' levels and considerations such as who is at risk, the type of risk, and the social context in which exposure occurs becomes less relevant (Webler et al 1992).

Simplicity is a characteristic of normal science because it reduces complex phenomenon into discrete and manageable units for analysis. Normal science has difficulties in comprehending the totality of systems.

2.5 Problems with and Alternatives to the Conventional Model

According to Frewer (2001) it is not surprising or unusual that different stakeholders have different agendas when it comes to assessing and managing risks. Frewer (2001) expands this point to argue that failure to recognize or acknowledge the different agendas stakeholders bring to a risk issue will result in failure to achieve a consensus dialogue. Frewer (2001) cites a study by Scholderer et al (2000) in which consensus about risk analysis failed to emerge not because of technical disagreements but because individual members of stakeholder groups did not start discussions with similar representations of the nature of potential risks. For instance, scientists were concerned with risk estimate while members of civil society groups were concerned with technical limitations, voluntary exposure and consumer choice. As Frewer (2001: 223) articulates "Understanding how different groups represent objects and issues may assist our understanding of how institutions 'learn' to develop new forms of mediation and regulation in response to public concern about risks."

The current alignment of the state and science in settling risk controversies is far from perfect. The relationship between science and politics is a delicate relationship. The state requires scientists to provide certainties and committed conclusions of which science is often unable to provide (Garvin 2001 and Mehta 2001).

There are unique differences and challenges facing regulatory scientists making it imperative to examine how regulatory research is carried out. The challenges and uniqueness of regulatory science deserves special consideration because the rules that apply to normal science do not apply to the social, political, and economics impacts of any regulatory decision. There are other unique features of scientific knowledge in regulatory decision-making. For instance, scientists work with material protected by commercial secrecy and the normal process of peer review- a characteristic of normal science- is hindered (Irwin et al 1997).

In addition, there are ethical obligations, time limits, financial limitations and other methodological difficulties that scientists, in particular regulatory scientists, encounter while trying to achieve certainty in their findings. There are ethical guidelines preventing scientists from conducting certain experiments on humans, so they have to use lab animals. Extrapolating the results of experiments to the human population compromises the certainty of findings. To obtain certainty of the distributions and impacts of risks can require long periods of experimentation and testing. However, regulatory scientists often are not accorded such an opportunity for several reasons due to obligations to come to a decision within a certain time frame. There may be limited studies thus limiting the ability to achieve absolute or near absolute certainty. As well, financial resources compromise available labour, equipment, and other needs to increase certainty levels.

Committing to conclusions is difficult for scientists for several reasons. The epistemological and methodological foundations of science lead scientists to work in explicitly the realm of probabilities. Science has to continue to alter, if not challenge, existing scientific findings. With the evolving character of science what may be held as true today may not be so later on. Scientists working in regulatory agencies have tremendous responsibilities because their work can affect the health and safety of whole nations, and generations yet to come.

Garvin (2001) sees a growth of interest in how knowledge and evidence is utilized. In particular, there is growing concern over how different actors construct and define usable knowledge in risk-based controversies. Conflicts can and do arise because of differences in how actors construct and define knowledge. Garvin (2001) argues that scientists, policy-makers, and the public use different language and unique discourses and conventions for constructing knowledge and persuasive arguments.

Several commentators of the differences between public and expert understanding of risks have concentrated their efforts to examine differences between how expert and the lay public assess risks (e.g. Powell and Leiss 1997). Such differences include that experts typically deny the possibility that something is one hundred per cent safe. The public demands “yes” and “no” answers. However, experts speak in probabilistic terms in which there are no certainties. Another noted difference is that experts look at population averages, whereas the public sees risks in terms of personal consequences. Powell and Leiss (1997) also note that experts tend to view a death as a death, where as the public is concerned with how one dies. The public judges risk in terms of whether or not it is involuntary or voluntary. Yet experts are generally not concerned with such issues or feel it is out of their domain as risk assessors (Jones

2001). These differences, Leiss and Powell (1997) argue are barriers to effective risk communication.

There have been substantially different explanations proposed for how and why discrepancies exist between expert risk assessments and public assessments. There are two general positions within this literature. One position maintains that experts produce objective measures of risks while the public is treated as ignorant, misinformed, or irrational. This position generally maintains the idea that obstacles to risk reduction and risk elimination will be removed through educating and correcting the public.

Trust is an essential component for achieving publicly acceptance about risks. Irwin and Wynne (1995) argue that in addition to rhetoric claims about the superiority of the scientific world view, science is also dependent upon building social processes of trust. To place trust in another individual or institution involves a willingness to put oneself in a vulnerable position. Trust is a complex concept with many dimensions. The dimensions of trust include perceptions of competence, objectivity, fairness, consistency, and values and interests of those who are to be trusted. These dimensions are not mutually exclusive and one feature may take prominence in how risk controversies are played out. For instance, objectivity may initially be a prerequisite for making a publicly acceptable decision. However, objectivity may become less relevant when individuals perceive their interests and values clashing with a particular decision reached. This heavy reliance upon technical expertise, especially by the state, has been labeled by some as anti-democratic (Freidson 1986).

The sociology of scientific knowledge has provided much insight into social constructionist arguments of scientific knowledge. Although approaches are diverse, proponents of social constructionist theories share the common goal of challenging the

objective claims of science. Some commentators restrict values to only influencing the uses to which science is put while others argue that the very epistemological and methodological basis of science is value-laden and subjective. Several authors within the social constructionist school argue that science is no different than other types of knowledge and therefore should not be perceived as more valuable. Science is often perceived as valuable and is often privileged in comparison to other forms of knowledge because of specific historical and cultural developments in western society (Garvin 2001).

Social constructionism essentially argues that finding the real objective measure of risks is an extremely difficult, if not impossible, task to the point where even the most ideal scientific study is biased and context dependent. This position sometimes takes the argument that scientific knowledge is limited and that new knowledge- and hence new solutions- needs to be integrated in risk management planning.

Technical experts have assumptions about the social context of the risks they are investigating (Wynne 1989, Carter 1995). The social assumptions that guide expert risk assessments can result in different judgments about risks, even with the utilization of standard methods. Wynne (1989) argues that unearthing the social assumptions that guide technical risk assessment is an essential starting point for understanding the gaps that form between expert and public risk perceptions that are often irresolvable in a risk controversy.

Given the identified problems with technical risk assessment, it is too simplistic and naïve to conclude that science is not needed for managing risks. Science is a persuasive force in our lives and we enjoy a certain comfort level in using science to assess risk levels and to remove scientific risk assessment from government policy and

regulatory standards would certainly be met with public opposition. I have taken the position that scientific risk assessment can be most useful and insightful, and rather than proposing to eliminate scientific risk assessment it should be enriched with other perceptions, knowledge, and experiences.

2.5.1 Post-Normal Science

Post-normal science developed in growing reaction to the changing policy and regulatory contexts in which science is situated. This changing context involves uncertainties, disputed values, high decision stakes, and urgent decisions (Ravetz 1999). A typical reaction is that such factors are not the concern of science but of politics. However, Ravetz (1999) argues that this position is problematic because science is thrown into resolving political disputes. Science is supposed to reduce complexities in order to make political decisions. However; complexity is increased as science is used as a strategic resource of political action (Von Schomberg 1995). Thus, scientists are placed in this research to be more than sources of objective facts. Scientists are also sources for political and economic manipulation.

The biggest challenge to achieving post-normal science is that it runs against the dominant model of regulation in which the discovery of the “facts” will produce the best possible decision. Rather than entering into regulatory controversies in search of discovering which expert is more technically correct or more incorrect, post-normal science is about answering these two questions simultaneously: Who is more technically correct, and which expert evaluations are to be accepted for respecting values, communities, and economic and political interests?

Traditional science is about asking what/how and how/why questions. “What if” questions are typical in the very beginning of research before problems are defined and hypotheses are formed. By contrast, post-normal science takes the question “what if” as its leading question throughout all stages of inquiry.

Post-normal science argues that value commitments and uncertainty are factors always present when decisions regarding risks are made. De Marchi and Ravetz (1999) argue that science must be complemented with other considerations. These scholars assert that even scientists themselves are requesting new information and other types of knowledge as they begin to realize the limitations of science for providing the necessary information for making the best policy or regulatory choices.

Tierney (1999) argues that closer attention to the role of the state in the creation and allocation of risk is required. Tierney calls for a more critical examination of the state’s involvement in risk controversies because the state is more than a reducer or eliminator of risk. The state sometimes is either a passive bystander or a facilitator in the creation of risks and the unequal distribution of risks and benefits. The state, Tierney (1999) argues, should be viewed as an autonomous actor pursuing its own interests and creating hazards in the process. Tierney (1999) argues that sociologists need to pay greater attention to the states pivotal role in the political economy for promoting economic expansion and favourable conditions for business.

Hegemony is a key theoretical concept of this research. Hegemony is conceptualized in this research as a privileging of one ideology over another. Ideology in this sense is understood to mean a “set of patterns or set of ideas, assumptions, beliefs, values, or interpretations of the world by which a culture or group operates” (Foss 1996: 291). Foss (1996: 291) argues that ideologies are not always fully articulated or

apparent, such as “process is more important than product,” “competition produces superior achievements,” “men are more important than women,” and “the collective good is more important than the welfare of the individual.” These ideologies are sometimes constructed as superior and hence hegemonic.

Antonio Gramsci argued that hegemonic ideologies are unstable and contradictions emerge. The unstable and contradictory properties of hegemonies allow for counter-hegemonies or alternative knowledge to challenge and resist oppressive power relations (Beckie 2000). The concept of hegemony is not restrictive in the sense that it allows for analysis of deviances within, and not just across, social groups such as the case of rBST where scientists depending on their personal beliefs, experiences, and position within Health Canada have differing value judgments.

Hegemony is a pivotal concept to post-normal science because the authority of experts is increasingly challenged in science policy related fields (Ravetz 1999). Post-normal science requires not only the trust of laypersons in regards to experts but also depends upon laypersons trusting experts to contribute to issues outside of their expertise.

2.6 The Canadian Experience with rBST

2.6.1 Profile of Monsanto and its rBST Product

On a global scale, the Monsanto Chemical Corporation is the second largest manufacturer of agricultural chemicals and one of the largest seed producers (Canadian Broadcasting Corporation 1999). Canadians had been introduced to the Monsanto Corporation before the rBST submission. The Monsanto Corporation has had several

controversial products (e.g. PCB, Agent Orange, aspartame) compromising their credibility and trustworthiness internationally and in Canada.

In the 1920s and 1930s French and Russian scientists experimented with extracting bovine somatotropin (BST) from the pituitary glands of slaughtered cattle and administered it to dairy cows. They discovered that administering extra BST into dairy cows increased milk production and extended lactation cycles. BST is a non-steroidal protein hormone found naturally in dairy cattle and is primarily responsible for regulating lactation and promoting growth. Naturally occurring BST is not viable as a production aid because it requires a large number of slaughtered cattle to produce a single dose. The development of recombinant DNA technology, however, allowed scientists to inexpensively mass produce synthetic BST known as recombinant bovine somatotropin (rBST). In the 1980s several companies (Upjohn, Eli Lilly, Elanco, and Monsanto) developed recombinant bovine somatotropin products.

Monsanto's rBST product (Nutrilac) is at the center of this Canadian regulatory controversy even though there were several other rBST products reviewed by Health Canada. Elanco Canada submitted a new drug submission two years before Monsanto's 1990 submission. Monsanto became the leader in pushing for approval of rBST and Elanco Canada put their application on hold and waited for Monsanto's regulatory outcome. This turned out to be a strategic decision for Elanco, as Monsanto's Nutrilac application spent nine years under review, ultimately ending in a failure to receive a notice of compliance- the final hurdle in getting a pharmaceutical to market.

2.6.2 Health Canada and its Regulatory Mandates

Health Canada is a science-based regulatory agency meaning that its decisions are justified on the basis of technical expert inputs and scientific experimentation. Canadians demand scientific assurances about the products they consume and have characteristically granted their regulatory agencies considerable power to act on their behalf. However, science-based regulatory regimes are increasingly under pressure to adapt to globalization, fiscal constraint, and diminished public confidence (Jarvis in Doern and Reed 2001). Canadian regulatory agencies assume the role of the exclusive protector of the public interest (Hoberg 1994 cited in Turner 2001a). These agencies make decisions behind closed doors. These two defining features of Canada's regulatory process are contingent upon high levels of public trust in Health Canada. There were several high profile controversies other than the rBST case threatening the level of trust needed to sustain Health Canada's role of exclusive protector of public health and safety.

Mills (2002) argues that Canada's regulatory system is not conducive for scientists to challenge existing scientific knowledge or to broadly conceptualize health. Mills (2002) further explains that a combination of industry both creating data and paying for its evaluation, the creation of the Joint Management Advisory Committee (a committee composed of managers and industry representatives), time constraints, and regulators' understanding of corporate requirements are pressures placing regulatory scientists in a difficult position.

In 1993-1994, the Canadian federal government initiated the Programme Review in an effort to cut costs by privatization, harmonization, and deregulation. The Programme Review also brought in a new market-based paradigm of risk regulation

(Turner 2001b). Doern and Reed (2001) describe this market-based regulatory paradigm as one in which there is a greater reliance on industry's scientific reviews and a decreased need for in-house science. Cost-recovery is emphasized and there is a greater emphasis on post-approval monitoring. Regulatory departments have had their budgets cut as well (Doern and Reed 2001).

In these times of financial constraints and scientific uncertainty, government policy and regulatory agencies are demanding from science a more principled, efficient, and effective approach to risk assessment and management (Doern and Reed 2001). Canada's drug approval system is one that has become heavily dependant upon science to provide the knowledge for decision-making.

The federal government has made a commitment to foster the growth of biotechnology industries in Canada. This commitment is a subject of controversy as some argue that the government cannot regulate the risks of biotechnology and put the health and safety of Canadians at top priority while strategizing for biotech industry growth. The Canadian government serves two contradictory roles: that of innovation promoter and regulator.

The Bureau of Veterinary Drugs of Health Canada's Health Protection Branch was responsible for evaluating and approving veterinary drugs such as rBST. The Bureau of Veterinary Drugs has two divisions within it: the Human Safety Division examines human health aspects of veterinary drugs and the Pharmaceutical Assessment Division reviews animal safety and efficacy aspects. The normal protocol for a new veterinary drug to be approved for sale and use in Canada involves the manufacturer submitting details of the drugs ingredients, manufacturing equipment, and methods. The manufacturer must also submit satisfactory scientific studies demonstrating their

products efficacy, stability, and safety for humans and animals. If the Bureau of Veterinary Drugs is unsatisfied, it can request the manufacturer to submit more studies. A notice of compliance may be issued once a product meets these requirements.

rBST was one of the first major genetically engineered products introduced to Canada's regulatory system. In many respects, Canadians perceived rBST as test case for the adequacy of Canada's regulatory system to handle the predicted flood of genetically engineered products to come. As well, as one of the first genetically engineered products, rBST was arguably a test case for industry's success in getting genetically engineered products on the market. Turner (2001b) suggests that Health Canada's decision to ban rBST perhaps blunted Monsanto's and other corporations' commercial pursuit of biotechnologies. Whether or not this single case blunted corporate investments into biotechnologies is debatable, but nonetheless this case study demonstrates the explosion of this single drug into much larger questions of the state's regulatory agencies and the political economy.

The Canadian experience with rBST is one fraught with disagreement, controversy, and confusion. The first controversy surrounding rBST occurred in 1989, when several local newspapers reported the milk from rBST test herds was added to the milk supply (Leiss and Powell 1997). According to Leiss and Powell (1997) even though Health Canada had cleared rBST treated milk for human consumption, the Canadian public objected.

In March of 1994, concerns over rBST's economic impacts on Canadian dairy farming prompted the House of Commons Standing Committee on Agriculture and Agri-Food to hold public hearings. This committee heard from Monsanto, dairy farmer groups, dairy industry representatives, and consumer groups. This committee

recommended further investigation into the costs and benefits of rBST for the Canadian dairy industry and greater transparency in the review process. However, the House of Commons committee hearings, according to Mills (2002), did not provide a clear resolution. Mills (2002) argued that socio-economic concerns officially remained outside of the regulatory review, the existing regulatory process was maintained, and that transparency was never accomplished.

The House of Commons inquiry established an rBST task force, comprised of representatives from Monsanto, Eli Lilly, the dairy industry, and the Canadian government (Mills 2002). The task force reviewed the socio-economic impacts on Canada's dairy industry, consumer reactions, the impact on genetic evaluation programs, and consumer reactions in the United States (Turner 2001a). The task force recommended further scientific studies and investigation into rBST's potential socio-economic impacts. Consequently, a one-year moratorium on rBST was initiated. The overall result of this task force, according to Turner (2001a) was a favourable assessment for approval, and a setback for anti-rBST groups.

Several commentators have addressed how rBST is a struggle over defining what is "natural". Proponents of rBST who took on the route to persuade others that rBST is identical - or at the very least very similar - to BST essentially did so to persuade others that rBST is natural and therefore must be safe. Similarly, some proponents of rBST also presented the argument that rBST is simply a tool to enhance nature. Turner (2001b) notes the struggle to define rBST as natural or conversely unnatural emerged in American science in the early 1990s.

In November 1998, Health Canada established two independent expert advisory panels. Health Canada established these panels in order to break the scientific deadlock

on rBST within the department. The regulatory decision became contingent upon the conclusions of these two expert panels. One panel, operating under the Royal College of Physicians and Surgeons, examined human health issues with rBST. The other panel, established by the Canadian Veterinary Medical Association, examined animal health and safety aspects of rBST.

In the face of tensions surrounding rBST, the Standing Senate Committee of Agriculture and Forestry began a public inquiry into rBST on 4 June 1998. Credibility and responsibility issues of Health Canada, as well as persistent scientific uncertainty and economic concerns, were the topics of most interest. Discussion and debate regarding risk analysis, public participation, the precautionary principle, and the influence of international regulatory bodies also took place within the Senate inquiry (Turner 2001b).

2.6.3 Human Health and rBST Milk

The impacts of consuming milk from rBST treated cows on human health and safety is one of the top concerns with this product. To question the safety of rBST milk was to question the safety and goodness of natural non-rBST treated milk, a food that symbolizes what is natural, nutritious, and wholesome. In an effort to persuade critics of rBST's safety, proponents of this drug stressed the similarity of rBST and BST. This debate often centered on comparing the amino acid composition of each. Monsanto's Nutrilac differs by one amino acid in a chain of 191 in comparison with BST (Jones 2001). Only Upjohn's rBST product is considered identical to BST (Mills 2002).

Monsanto argued that because rBST is a protein it will be digested and impossible for rBST to enter the human blood stream where residues could cause harm.

This assumption, Jones (1999) speculates is the reason why Man Sen Yong, the Chief of the Human Safety Division, gave rBST human safety clearance in 1990.

Health Canada again declared rBST safe for humans in 1995 by issuing an Experimental Studies Certificate. Further, human safety confirmations included United States Food and Drug Administration approval for Monsanto's rBST product (U.S trade name Posilac) in 1993. As well, on 5 March 1998, The Joint Expert Committee on Food Additives (JECFA) found that rBST presented no human health concerns with rBST (Jones 2001). The significance of this is that JECFA advises the Codex Alimentarius Committee, a U.N. agency of the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) which sets international food safety standards, and whose judgments are used to settle what might be discriminatory trade practices when a country refuses to import a product for human health reasons.

However, human safety concerns persisted inside Health Canada. Scientists within the Human Safety Division dissented from Health Canada's earlier declaration of rBST's safety. These scientists requested the establishment of an internal review team to re-examine human safety data and to locate procedural and scientific gaps in the literature (Turner 2001b). Management agreed and established the "gaps analysis team." The gaps analysis team consisted of four scientists from the Bureau's Human Safety Division, a scientist from the Therapeutic Products Division, and another scientist from the Chemical Health Hazard Assessment Division (Mills 2002).

The 'gaps analysis' team was divided as the two non- Bureau of Veterinary Drugs scientists felt the other members were too concerned with internal conflicts. However, the team did report two deficiencies in the scientific literature. The gaps analysis team discovered that when looking at the raw data of Monsanto's 90-day rat

study, a study submitted as evidence for rBST's safety, that 20-30% of the rats developed antibodies to rBST, a feature not mentioned in Monsanto's summary (Jones 2001). The presence of rBST in the digestive tract of rats was another deficiency uncovered.

Insulin-like growth factor (IGF-1), a byproduct of lactation found in milk emerged as a major human health concern among the scientific community. Both administered rBST and a cow's own BST produce IGF-1. However, in the mid 1990's scientists studied IGF-1 and implicated IGF-1 with tumors growth and certain types of cancer.

According to Mills (2002) there was little disagreement among scientists that the existing scientific evidence proved rBST milk is unsafe for human consumption. However, the scientific community was divided over the need for more research and the discrepancies between scientists' expectations and the need for further investigation (Mills 2002).

2.6.4 Animal Health and Safety

The Bureau of Veterinary Drugs is required to demonstrate that a new veterinary drug is safe for treated animals under the Food and Drug Act. There is several animal health issues associated with rBST. These include mastitis, reproductive problems, culling, and lameness. As well, the implications of animal health problems were addressed in terms of its direct and indirect affects on human health.

In 1990, six months after receiving Monsanto's Nutrilac submission, evaluators within the Pharmaceutical Assessment Division declared the submission incomplete for animal health (Turner 2001b).

Although human health issues received greater attention and debate than animal health risks, it was animal health reasons cited as the reason to reject a notice of compliance. The animal safety expert panel reported a 25% increase in clinical mastitis, an increased risk of non-pregnancy, a 50% increased risk of lameness, and a 20-25% increase in culling (Turner 2001b).

2.6.5 Canada's Dairy Industry

In 1970 the Canadian Milk Supply Management system was established. The supply management system works to protect against oversupply through quotas. Farmers must buy or sell quotas. The quota is a contract of how much product the farmer will deliver. Supply management ensures that supply meets demand. The supply management system also restricts imports in order to protect Canada's dairy industry from international competition. Up until 1995, import restrictions were accomplished through imposing import quotas on dairy products. However, in 1993 Canada signed a World Trade Agreement under the General Agreement on Tariffs and Trade (GATT) that no longer permitted import quotas (Boyd 1999). Import quotas were consequently replaced by tariffs. Tariffs were supposed to be reduced and eliminated with NAFTA, however, in July 1996 a trade panel ruled in favour of Canada to maintain high tariffs (Mills 2002).

Over the past three decades, the demographics of Canada's dairy farms have changed. In 1971, there were approximately 145,000 dairy farms (Boyd 1999). In 1983, the number of dairy farms was 49,936 (Canadian Dairy Industry Profile, Agriculture and Agri-Food Canada 2004). By 1996, there were a reported 30,900 dairy farms (Boyd

1999). In 2003, the number of farms decreased further to 17,931 (Canadian Dairy Industry Profile, Agriculture and Agri-Food Canada 2004).

Although the number of farms has substantially decreased, the average size of a dairy farm increased. In 1996, the average number of cows per dairy farm was 35 and in 2002, the average size was 60, a change of 71 per cent (Canadian Dairy Industry Profile, Agriculture and Agri-Food Canada 2004).

Over the last three decades, there has been a decline in the overall number of cows in Canada. In 1971 Canada had approximately 2.3 million dairy cows (Boyd 1999). In 1983 there were approximately 1.7 million dairy cows (Canadian Dairy Industry Profile, Agriculture and Agri-Food Canada 2004). In 1996, the number dropped to 1.2 million (Boyd 1999). The latest available data from 2003 reports just over a million dairy cows.

Despite fewer cows in Canada, milk production has continued to climb, both in terms of volume of milk produced per farm and overall. In 1983, the total volume of milk produced in Canada was at 72.3 million hectoliters and in 2003 the total volume of milk produced was at 74.5 million hectoliters (Canadian Dairy Industry Profile, Agriculture and Agri-Food Canada 2004).

2.6.6 Scandal, Conspiracy, Cover-up: Health Canada and its Relationship with Industry

Health Canada's handling of rBST is dramatic with allegations of corruption, scandal, and cover-up. Beginning in 1997, Health Canada was finding itself immersed in a public confidence crisis over rBST. Over the next two years a spotlight was cast intermittently on the internal problems and credibility and accountability lapses within

Health Canada. Rank-and-file scientists within the Bureau of Veterinary Drugs came forward with damaging allegations of cover-ups, intimidation, and scandal within the ranks of Health Canada management. They told stories of management putting pressure on them to approve drugs, rBST included, despite lingering doubts of their safety. Internal conflict between managers and employees also included high turn over rates and accounts of racism (Turner 2001b).

Further damaging and scandalous allegations followed. Margaret Haydon, a support scientist for review of rBST within the Bureau of Veterinary Drugs, alleged that rBST documents were stolen from her locked cabinet. She also told about Monsanto attempting to bribe her with \$1 million in research funding. Top health officials were also accused of trying to suppress a report criticizing Health Canada's handling of rBST (Canadian Broadcasting Corporation 1999).

2.7 Summary

In this chapter, I provided a brief review of the social scientific literature on risk, technology, and regulation. I described the dominant model of risk regulation in which decisions must be justified with science and political, economic, and social issues, if they are addressed; they are addressed separately from science. However, there are several compelling arguments that scientific knowledge embodies many assumptions and values of the social context in which risks exist. Upon reviewing this general literature, it became apparent that there is a need and a demand for alternative models for regulating risks. Post-normal science is one alternative that I focused upon in this chapter. Post-normal science maintains that science is important but that science can be

improved through increased participation of a variety of experts and laypersons and embracing other types of knowledge.

In the second part of this chapter, I described rBST, Monsanto, and Health Canada's responsibility. I provided a history of rBST in Canada and the controversies that accumulated throughout the nine years it took to make a decision. I also examined the financial restraints and restructuring of Health Canada that has made science-based decisions even more problematic and controversial.

I also provided a background of the structure of the Canadian dairy industry and its transformation towards industrialization and intensification. The Canadian dairy industry has been through profound transformations because of science and technology. Cows are producing significantly more and there is a surplus of milk. Social and economic changes have occurred as a result of science and technology. The trend is towards fewer but larger dairy farms and family farms are struggling to exist.

Chapter Three: Post-normal Science and the Senate Inquiry

3.1 Introduction

In the previous chapter, I reviewed the literature on the dominance of normal science in regulatory matters and reviewed the challenges of this traditional science in regulatory decision-making. I then provided a background on rBST in Canada to uncover the complexities and points of contention leading up to the Senate inquiry.

In this chapter, I examine the contents of the Senate inquiry with an in-depth look at how the uncertainty of facts, disputed values, high decision stakes, and the urgency/need for a decision were presented, constructed and negotiated. More specifically, I examine how mastitis, an infection of the udder in cows, was addressed by participants in the Senate inquiry to represent the uncertainty of facts aspect of this post-normal regulatory situation. Secondly, I examine how consumer reactions to rBST, and biotechnology in general, emerged as a dispute over defining health, safety, and benefits. I examine the different values witnesses and Senators placed on consumer reactions and the option of labeling rBST treated milk. Thirdly, I investigate discussions around proprietary information and confidentiality of manufacturer's data and the problems of this policy in terms of public participation and consultation. This section includes a presentation of what is at stake if the drug approval process releases information to the public and the larger scientific community. In the last section, I provide insights into the ways witnesses and Senators discussed and debated the urgency and/or need for a

decision because of Canada's trade agreements and the need for economic development through scientific and technological innovations.

3.2 Mastitis

Throughout the Senate committee considerable discussion was devoted to the certainty and uncertainty of scientific studies on rBST's safety for both humans and animals. There was a variety of experts testifying at the Senate inquiry providing an opportunity to examine the presentation of scientific evidence and subsequently, how both laypersons and experts evaluated such information. I begin this chapter with an exploration of how mastitis was addressed in the Senate inquiry. Mastitis was a concern for many participants because of the potential economic losses of this disease for farmers. As well, witnesses and Senators placed different significance and priority on this issue because of the indirect human health risks associated with increased antibiotic use.

3.2.1 Does rBST Cause Mastitis?

A difficult fact on mastitis is that this condition occurs because of increased milk production with or without the use of rBST. Participants agreed that increased milk production increases the risk of cows developing mastitis. Participants also agreed that rBST increases milk production in dairy cows. However, participants disagreed that rBST could be directly implicated with increased incidences of mastitis as some argued that herd management skills determine mastitis outbreaks.

We have not uncovered anything unusual in our product that does not normally occur in any kind of dairy herd. Everything occurs with the same incidence in cows not supplemented with BST. We receive almost no reports or complaints of Posilac being associated with an increase of something like mastitis, which is probably of most concern to dairy farmers. That has an impact on milk

production (David Kowalczyk, Director, Regulatory Affairs, Monsanto, Senate of Canada 1998a).

But rBST does not give the cow mastitis. Higher levels of milk production require higher levels of food, as Senator Whelan said (Senator Hays speaking to Shiv Chopra, Bureau of Veterinary Drugs evaluator and gaps analysis team member, Senate of Canada 1998b).

The size of the herd would not necessarily make a difference to how you would manage mastitis, because it comes down to keeping your cows clean and your equipment in good working order to try to lower somatic cells so that your cows do not get mastitis. That is no different for a herd of 28 or 280 or 1,200 cows. A larger herd versus a smaller herd would not make that much difference (Linnea Kooistra, Dairy Farmer from Illinois that uses rBST, Senate of Canada 1998g).

Several witnesses stated that Monsanto's own data indicates there is an increased risk of mastitis.

Turning to the mastitis and the increased use of antibiotics, even the Monsanto label warns about all the things that can go wrong with cows using their product (Senator Spivak, Senate of Canada 1998d).

Monsanto reported results from eight trials, which the company interpreted as demonstrating that the use of rBST caused no significant increase in mastitis. Sussex University subsequently found out there was an increase of 19 per cent. A later publication from Monsanto covering 15 trials claimed there was still no adverse effect on clinical mastitis or on somatic cell count, whilst the analysis undertaken by Millstone at Sussex University in the U.K. showed that within the 15 trials the use of rBST increased the incidence of clinical mastitis by approximately 39 per cent. This was using figures they obtained from Monsanto (John Verrall, The Food Ethics Council, Senate of Canada 1998e).

If you look at the situation where there might be a greater incidence of mastitis in cows treated with the hormone, Monsanto's people used a set of data that said there was no difference. They gave this raw data to a group of people working in England who looked at the statistics and said that there is a significant increase in the incidence of mastitis in the treated cows (Ann Oaks, Fellow of the Royal Society of Canada, Senate of Canada 1998e).

Studies other than Monsanto's were also mentioned

The moratorium is being imposed because, as the report says, they are concerned with: 1) increased levels of a hormone called IGF-1 in milk; and 2) increased disease rates in treated cows that lead to increased antibiotic use (Senator Chalifoux discussing the European's Moratorium on rBST with Mr. Collier of Monsanto Senate of Canada 1998a).

Monsanto reported results from eight trials which the company interpreted as demonstrating that the use of rBST caused no significant increase in mastitis. Sussex University have subsequently found that there was an increase of 19 per cent (Senator Taylor, Senate of Canada 1998e).

Margaret Haydon stated that the scientific studies on mastitis that she had reviewed from three different companies - before have been taken off the file in 1994 - were methodologically flawed. She argued that she could not say in a statistically significant manner that mastitis was a concern. However, she did argue that from her past large animal practice experience, she considered mastitis to be a significant concern.

But at that time there were problems with -- as I say, there were three different companies' data that I reviewed -- there were problems with design of studies and this sort of thing, so there were even some studies that I did not receive specific information about how much mastitis had even occurred. Those cows would just disappear from the study, and there was no further explanation or follow-up. In other cases, I sometimes did not even find out what particular bacterial organism or mastitis organism was causing the problem because that work was not provided. So there were all sorts of variations in the amount of data that was supplied, but there certainly appeared to be an increase. I could not say from a statistically significant point of view, because sometimes there were not enough cows in which to determine that; sometimes there were not enough data provided (Margaret Haydon, Bureau of Veterinary Drugs evaluator and gaps analysis team member, Senate of Canada 1998b).

3.2.2 Antibiotic Residues: A Manageable Human Health Concern

Mastitis was implicated as a human health threat because of increased antibiotic use in dairy cattle to treat this disease. Increased antibiotic residues in milk were a human health concern that several participants addressed. There was no scientific consensus on elevated antibiotic residues in milk associated with rBST. Michael Hansen from the Consumer Policy Institute disagreed with JECFA's finding that there were no insignificant changes with antibiotic residue levels after rBST was approved. He cited

flawed experimental design, misinterpretations, and inaccurate reporting as the reasons for this disagreement. Dr. Chopra and Dr. Paterson had different conclusions about the quality of the FDA's post-approval monitoring study of rBST.

Not the way it is being done in the United States right now where there is this study where you give to whatever cows you want to and then you pool the milk and then you look for antibiotic residues and IGF in there. How are you going to determine that? There is no way to have scientific information coming out of that and say everything is all right (Shiv Chopra, Bureau of Veterinary Drugs evaluator and gaps analysis team member, Senate of Canada 1998b).

An important part of our review has been the decision by the U.S. to approve rBST and, as part of that decision, the requirement for post-approval monitoring which occurred from 1994 to 1996. In that, the FDA requested that Monsanto proactively develop an adverse drug experience reporting system, do statistically valid analyses of state antibiotic drug residue data, and do a health evaluation of 28 commercial herds representative of the U.S. dairy industry (George Paterson, Director General, Foods Directorate Health Canada, Senate of Canada 1998a).

3.2.3 Antibiotic Resistance: A Not-so Manageable Human Health Concern

Antibiotic residues in the milk supply were a concern, although some participants argued that antibiotic resistance was a much bigger threat. Monsanto representatives and Health Canada managers presented that antibiotic residue was the primary human health concerns with mastitis while Senators, several witnesses, and Health Canada evaluators argued that antibiotic resistance was a much larger and serious threat. Shiv Chopra had very different descriptions of the antibiotic resistance problem from those of Margaret Haydon, David Dodge, and Dr. Losos. Dr. Chopra's testimony gave a sense of urgency to this problem because he argued that this is a current problem whereas the others presented antibiotic resistance as a potential problem. Dr. Chopra used the pronoun "you" to emphasize to his audience that this is a problem that directly affects them. Margaret Haydon, much like David Dodge and Joseph Losos, described

antibiotic resistance with formal language. Margaret Haydon did claim personal ownership of the antibiotic resistance problem.

The study also says that mastitis in treated cows increases antibiotic use. I am very concerned with this issue. It affects our own health, because it makes us more resistant to antibiotics, and we know that antibiotics are carried through to the milk and the meat (Senator Chalifoux speaking to Mr. Collier, Senate of Canada 1998a).

...and there are issues of antibiotic resistance, which have a direct effect coming out of overproduction of milk, causing mastitis; overuse of antibiotics, causing antibiotic resistance. Fifty per cent of the antibiotics are used -- all antibiotics are used in animals and farm animals, so the spillover effect of that is directly on the humans, because antibiotic resistance is now killing people because you do not have antibiotics to cure people. You go to hospital to get your appendix out, and you pick up an infection and you die because it cannot be treated anymore (Shiv Chopra, Bureau of Veterinary Drugs evaluator and gaps analysis team member, Senate of Canada 1998b).

This is an issue where the whole world is clamouring with fear. Antibiotic resistance is emerging from food-producing animals and affecting human health. People are dying when they go to hospitals because they pick up infections. It is coming from the sub-therapeutic use of antibiotics on the farms (Shiv Chopra, Bureau of Veterinary Drugs evaluator and gaps analysis team member, Senate of Canada 1999c).

It is not a question of residues any more; it is a question of additional use of antibiotics, which poses a danger (Shiv Chopra, Bureau of Veterinary Drugs evaluator and gaps analysis team member, Senate of Canada 1999a).

Of course, my concern is the potential for the increased use of antibiotics promoting increased resistance in the on-farm bacteria. These can have potential human safety effects in the sense that the organisms on the farm may acquire that resistance, as well as the organisms that humans have. There is a transmission of resistance between bacteria (Margaret Haydon, Bureau of Veterinary Drugs evaluator and gaps analysis team member, Senate of Canada 1998b).

This is a very serious problem. It is a classic issue where third parties are affected and where, over time, we could have some serious public health risks through overuse of antibiotics both for animals and for humans. We are working hard on this (David Dodge, Deputy Minister, Health Canada, Senate of Canada 1999c).

3.2.4 Approval Criteria and Action Plans

The following are participant's accounts of what scientists and regulators should consider in regards to rBST and mastitis, antibiotic residues and antibiotic resistance.

With regard to our efficacy review, through research trials and commercial use it must be shown that rBST will result in increased production as measured by the increased weight of milk produced. That milk must be marketable, and the milk from cows treated with antibiotics cannot be sold until the residues of the drugs have dropped to established safe levels. Those are the three main criteria of our efficacy review (George Paterson, Director General, Foods Directorate Health Canada, Senate of Canada 1998a).

Mastitis would be considered in terms of cow health and welfare, but also with regard to using antibiotics, and the antibiotic residues getting into milk (George Paterson, Director General, Foods Directorate Health Canada, Senate of Canada 1998a).

We will be looking at that and trying to determine our best estimate to whether there is an increased risk of mastitis associated with the product. If so, how big an increased risk is it? Is it something of substantial consequence that we need to be concerned about, or is it very small? We will also be addressing that question. I am afraid that I cannot tell you the answers to those questions yet (Ian Dohoo, Chair of the Animal Safety Panel, Senate of Canada 1998d).

The first issue that was of concern was mastitis. JECFA only looks at safety in food, and so the only concern that fell within its purview was that of antibiotic residues, and, to all intents and purposes, there was no increase in antibiotic residues (Jock McLean, Dean of Faculty of Applied Science and Pro Vice Chancellor, Division of Science, Swinburne University of Technology, and former JECFA advisor, Senate of Canada 1998d).

Monsanto witnesses, dairy representatives, and Ian Dohoo from the animal safety expert panel dismissed antibiotic residues getting into the milk supply as a problem because of the stringent testing procedures to control for antibiotic residue levels in milk, mandatory withdrawal times, and fines if a farmer's milk has antibiotic levels above an established maximum.

There was also some discussion this morning about antibiotic residues. I can assure you that every load of milk in Canada is tested for residues. It is not just a Mickey Mouse test. The milk is broadly screened for a wide range of antibiotics,

and the penalties are severe. There is no risk to the milk supply in this country (Robert Bell, Monsanto witness and veterinarian, Senate of Canada 1998g).

Antibiotics are checked on every load. When a tanker load arrives at the dairy, there is a check on the full tanker load. If that tanker is found to contain an unacceptable antibiotic level, then that tanker is disposed of. They then go to the particular vials that made up that load. That producer is then found. He is responsible for the full tanker load of milk. I am talking about \$17,000 or \$18,000 for one tanker load. He does not get paid for his milk, plus he is responsible for everyone else's milk on that truck. That is quite an incentive to ensure that that does not happen. That is done on every load in this country (Baron Blois, President of the Dairy Farmers of Canada, Senate of Canada 1998d).

There are serious consequences for producers who let antibiotic residues enter into the food chain now. In addition to the penalties associated with being detected, if the truckload of milk is found to have residues, they must pay for the whole truckload (Ian Dohoo, Senate of Canada 1998c).

Health Canada management did not offer any specifics about what would be considered with regards to the antibiotic resistance issue. Mr. Dodge invited Senator Spivak to attend a stakeholder meeting on antibiotics and the food supply. Dr. Losos, the Assistant Deputy Minister of the Health Protection Branch, referred to the importance of surveillance programs and the resources of private industry.

We have a two-pronged program in the Health Protection Branch, one with the foods program looking at feeds. We are working with the European Union and the Americans and with other countries who are equally concerned. We know that the incidence of antibiotic resistance is intolerable. The second important stream is antibiotic resistance in humans in hospitals, post-surgery, in intensive care and elsewhere. We have intensive surveillance programs across the country with a number of professional associations. Private industry cannot put enough resources into research for new antibiotics. We know this is an important area and we are giving it priority (Joseph Losos, Assistant Deputy Minister of the Health Protection Branch, Health Canada, Senate of Canada 1999d).

Michael Hansen, a research associate from The Consumers Union, argued that effort is needed to stop the growth of antibiotic resistance.

Therefore, while I do agree that the amount of antibiotics that will be in the milk will be marginal compared to the overuse that is occurring in human and animal medicine, part of the way to control antibiotic resistance is through thousands of

small increments, from doctors exercising restraint in prescribing antibiotics for respiratory ailments, to reductions of the animal feed uses. Since the only purpose of rBGH is to increase milk outputs, and since there is no therapeutic use, we do not think we should tolerate any increase in antibiotic use whatsoever through this drug. That will be a very small step. The antibiotic resistance issue is one to which rBGH will contribute, however small that contribution may be, and that must be stopped (Michael Hansen, Consumer Policy Institute of the Consumers Union, Senate of Canada 1999a).

3.2.5 Decisions and Uncertainty

The following passage from David Dodge the Deputy Minister of Health Canada is significant because he framed the willingness to accept the risks of uncertainty as a “judgment call”, presupposing the existence of choice. The significance of which is that he is recognizing post-normal insights that “we must make hard policy decisions where our scientific inputs are irremediably soft” (Ravetz 1999: 649).

That is the evolution of science and knowledge over time. We are always working with a degree of uncertainty. The difficult job -- such as you had when you were Minister of Agriculture or such as Mr. Rock has as Minister of Health today -- is to weigh the benefits of proceeding even though things are not absolutely certain. Things will never be certain, but we weigh the benefits of proceeding against the potential costs and risks. That is a very difficult job. In the end, that cannot be delegated. It is a difficult judgment call (David Dodge, Deputy Minister, Health Canada, Senate of Canada 1999d).

There were no witnesses arguing that it is possible to assess the health and safety risks with absolute certainty. Several participants noted that decisions must be made with some uncertainty.

When a submission is at stake, the decision to approve or not approve the product must be taken at some point. It is not uncommon for regulatory agencies to have to make such decisions in the face of some uncertainty (Thea Mueller, Bureau of Pharmaceutical Assessment, Therapeutic Products Directorate evaluator and gaps analysis team member, Bureau of Pharmaceutical Assessment, Therapeutic Products Directorate evaluator and gaps analysis team member, Senate of Canada 1998b).

Senator Whelan said earlier that it is hard to prove that something does not happen. That is true. However, that is the basis of the scientific method. This sort

of uncertainty is what scientists deal with all the time.... We are always dealing with probabilities. We will never prove with 100 per cent certainty that rBST, or some of the other biological substances that result from the use of rBST, are absolutely safe. It cannot be done. If that is the standard that we have to achieve, there is no point in starting. We must deal with what science always deals with: probabilities. That is certainly what the human safety panel will do (Stuart McLeod, Human Safety Panel, Senate of Canada 1998d).

When we come to the issue of safety, nothing is absolutely guaranteed under any circumstances. If we wanted to aim for absolute safety, then we would spend all of our budget ensuring that, and there would be nothing left for the important issues. Absolute safety is not achievable. The safety levels that are associated with treatment with BST do not warrant our going any further in trying to ensure safety there, but rather putting resources into other areas (Jock McLean, Dean of Faculty of Applied Science and Pro Vice Chancellor, Division of Science, Swinburne University of Technology, and former JECFA advisor, Senate of Canada 1998d).

3.3 Consumers, the Dairy Industry, and the Drug Approval Process

In this section, I examine the contributions of dairy producers and processors, Monsanto representatives, Senators, citizen groups' representatives, and Health Canada officials in regard to the rights of consumers and farmers to decide the fate of this product. The purpose of this discussion is to illustrate further the diversity of values and interests in rBST. I then proceed to examine testimony concerned with whether or not these socio-economic issues have a place in Health Canada's decision-making. I argue that there is an overwhelming tendency to try and keep science separate from these other concerns; however, the socio-economics and political factors of rBST were not always separable from the science of health and safety.

3.3.1 Consumer Trust and the Dairy Industry

Dairy farmers and dairy processors expressed considerable concerns over rBST and consumer reactions on the dairy industry. Dairy representatives argued that

consumer confidence in the wholesomeness and purity of milk must be maintained.

They argued negative consumer reactions will hurt them financially. In addition to the economic consequences, dairy farmer and dairy processor witnesses also argued that they owe their consumers the best possible product out of a sense of pride and obligation.

Our livelihood depends on their confidence in dairy foods as nutritious, wholesome, tasty, and, most of all, safe (Tim Finkle, vice-president of the National Dairy Council of Canada, Senate of Canada 1998c).

These latter campaigns generated in excess of several thousand complaints. In the history of the National Dairy Council of Canada, founded 80 years ago, we have no record of any similar crisis of such magnitude. If a consumer has taken the time to write, fax or call us and our member companies, we must respond to them. We cannot afford to dismiss so many complaints (Tim Finkle, vice-president of the National Dairy Council of Canada, Senate of Canada 1998c).

It would be crazy, and it would be silly economics, to spend millions of dollars promoting the product on the one hand, and lose consumer confidence on the other. We have said all along that the approval process for this product must be seen by the public to be very credible (Baron Blois, President, Dairy Farmers of Canada, Senate of Canada 1998c).

It is true that the studies from the petitioner say otherwise, but other studies do not really demonstrate the cost effectiveness. This is not our major concern. Our major concern is how the consumer will react to all of this? Our client is the consumer. For the petitioner, the client is the milk producer. The petitioner is very little concerned with the rest of the chain. Even if Health Canada approves the hormone, we do not yet know how we will react. We hope that Health Canada will have a credible process and will do its job in reassuring the public sufficiently to dispense with labeling (Lise Beauchamp, agriculture specialist, a dairy producer from Quebec, and a board member on the Dairy Farmers of Canada, Senate of Canada 1998c).

We have become even more aware of the massive resistance to this product among Canadian farmers and consumers from coast to coast, and of the incontestable scientific, economic and humanitarian reasons for that resistance (Peter Dowling, Member of the National Farmers Union National Executive and a Dairy Farmer, Senate of Canada 1998d).

George Paterson, Director General of the Foods Directorate at Health Canada

indicated a drop in milk consumption was not anticipated with the introduction of rBST:

Milk consumption is not part of our review per se, but I will give you some information on it which was gathered in the U.S. before and after the approval of rBST. Basically, it shows that before approval 15 to 60 per cent of consumers would avoid or reduce consumption of milk. Post-approval data does not seem to support that (George Paterson, Director General, Foods Directorate Health Canada Senate of Canada 1998a).

Senators and witnesses against rBST's approval used the lack of knowledge about the affects of rBST on children to advance their position against rBST's approval. Milk served as a particularly powerful cultural symbol. The focus on children consuming milk served as a persuasive argument because of the difficulty of challenging the common-sense belief, and the health professional endorsements, that children must consume milk in order to grow up healthy and strong.

It forced me to fight a battle. You could say I was fighting a battle for my children. I did not want my children or anyone else's children in Canada to be exposed to this (Lorraine Lapointe, Dairy Farmer, Past Director of the Ontario Milk Marketing Board, Senate of Canada 1998d).

Consumers will then not have the choice that was being spoken about this morning. If they did have the choice, who would be paying for that choice? It would be the people who had the concerns. That is usually how the scenario plays out. They would end up having to pay more for their milk and their children may not get enough milk (Peter Dowling, Member of the National Farmers Union National Executive and a Dairy Farmer, Senate of Canada 1998d).

Also, the gaps analysis talked about the impact on neonates, but as I understand the JECFA assessment, that issue was never examined. We know that issue is important because children drink more milk, and based on their size, any intake has a greater impact than it would on adults (Senator Spivak, Senate of Canada 1998f).

I am concerned in these hearings about the cost benefits of this. I was in the garage one day where I usually have my car repaired, and a guy walked up to me and said, "I have seen you on TV. You are looking at that thing that they give to cows for milk. I am worried. I have three children. If I feel that this might not be tested fully and not good for the children, they will not drink milk anymore." If the children stop drinking milk, it will certainly have an effect on their health and their development (Senator Robichaud, Senate of Canada 1999a).

Before I ask you a couple of questions, I should reveal my own personal bias. I have been pretty strongly against this all along. Last night, my youngest son informed me that if this is ever introduced into the milk pool in Canada, not another drop of milk will go into their house, ever. There is a predisposition to breast cancer in his wife's family. They are not even going to think about risking it (Senator Milne, Senate of Canada 1998e).

Baron Blois, the President of the Dairy Farmers of Canada, focused his testimony on Health Canada and the drug approval process. He argued that the “drug approval process is paramount” and consumers must be assured the process is credible otherwise the Dairy Farmers of Canada will hold Health Canada responsible for their losses (Baron Blois, President of the Dairy Farmers of Canada, Senate of Canada 1998c). He stated that the Dairy Farmers of Canada would wait for a credible decision and then they would begin addressing consumer concerns and labeling.

First, I go back to what I said originally. We must have a credible process of approval before that discussion with the consumer even begins (Baron Blois, President of the Dairy Farmers of Canada, Senate of Canada 1998c).

Meanwhile other dairy representatives and Senator Whelan stressed that farmers must make a firm commitment against rBST in Canada.

My concern has been that the Dairy Farmers of Canada has not taken a strong enough stand. You have not said anything in your paper about the fact that we have built a record of performance across this nation without using any of these artificial hormones (Senator Whelan, Senate of Canada 1998c).

There are many arguments against using rBST. The number one argument against it is that consumers do not want it... Consumers have told us that if rBST is used in Canada, they will stop drinking milk (Tim Finkle, vice-president of the National Dairy Council of Canada, Senate of Canada 1998c).

3.3.2 Consumer Choice and Labeling

The option of providing consumers with a choice between rBST derived milk and non-rBST milk was discussed several times throughout the inquiry. The following is a range of perspectives on labeling that participants offered:

...in certain products, they (Canadians) will still want to exercise choice about whether they want to consume that product. That is particularly important in something which is as pervasive a product as milk. Senator Fairbairn mentioned that earlier (Ian Shugart, Visiting Assistant Deputy Minister, HPB Transition, Health Canada, Senate of Canada 1998d).

In other words, they would be interested in having the milk labeled. I think a lot of consumers would want to know what they are drinking (Senator Spivak speaking to Mr. Blois, President, Dairy Farmers of Canada, Senate of Canada 1998c).

If Health Canada, based on that rat study, says it is safe, mothers might want to be extra cautious. Surely they have the right to know. If we do not label it, they will not be able to determine whether they should give their children milk which has rBST in it or does not have rBST. I think that is another very important issue you might want to address in your review of the department (Senator Spivak, Senate of Canada 1998d).

We hope that Health Canada will have a credible process and will do its job in reassuring the public sufficiently to dispense with labeling (Lise Beauchamp, Senate of Canada 1998c).

Several witnesses argued that the costs of segregating milk, separate pick-up runs, and the cost of separate labeling makes labeling too costly.

Common sense dictates that consumers must be heard and, therefore, offered a choice of milk with or without rBST. Offering this choice will increase the cost of milk due to segregation at pickup, delivery, and processing. These added costs should not be borne by consumers, but must be absorbed by farmers wishing to use rBST on their herds. We will not accept the American response to the introduction of rBST under any circumstances. In that country, consumers paid a premium for milk produced without the assistance of rBST (Tim Finkle, vice-president of the National Dairy Council of Canada, Senate of Canada 19998c).

I heard a representative from Monsanto at the hearing say to the media that, "We believe that consumers should have a choice. We will champion that. Well, yes in Canada there is a problem about pooling, but we will help them manage it

(Lorraine Lapointe, Dairy Farmer, Past Director of the Ontario Milk Marketing Board, Senate of Canada 1998d).

In contrast Robert Bell of Monsanto did not see segregating milk as a problem.

He pointed out that organic milk is offered in Ontario.

From the processing standpoint, one of the issues was the question of choice. Now we are starting to get that. Organic milk is now available in Ontario. That is what the processor was concerned about, separating out milk supplies (Robert Bell, Monsanto witness and veterinarian, Senate of Canada 1998a).

Shiv Chopra did not support labeling. He stated “You are looking at the entire population. Children, pregnant women and old people will be consuming, and they are not making any choice. Labeling does not help” (Shiv Chopra, Bureau of Veterinary Drugs evaluator and gaps analysis team member, Senate of Canada 1999a). Angela Rickman of the Sierra Club gave a unique spin to the debate on labeling:

Labeling of GM food is essential, but we should revisit the implicit assumption that if Monsanto made it, it must be good for us. In a democracy, the public has the right to determine which technologies are used in their communities and, similarly, which drugs. We do not want the safety of our food determined by large, unaccountable multinationals like Coca-Cola and Monsanto. We do not want Canada arguing against the precautionary principle in setting food standards and WTO challenges (Angela Rickman, Deputy Director, Sierra Club, Senate of Canada 1999b).

3.3.3 Benefits and Risks

Witnesses from the National Farmer’s Union, the gaps analysis team, consumer and citizen group representatives, and Senators put forth that rBST is both unwanted and unneeded. This lack of benefits as Jones (1999) also identified was a major obstacle for Monsanto’s success in getting Nutrilac approved. These arguments involved defining health and safety as prevention and avoidance rather than management and surveillance of dangers.

Do we just grab onto anything that any company brings forward, requesting to sell it to farmers? Are we going to inject this hormone into cows to produce more milk just so that farmers can make more money? We talk about economics, but social and economic concerns are combined. I do not care what you said in the press release; you cannot separate them from one another (Senator Whelan, Senate of Canada 1998d).

Farmers, consumers and processors do not want it. When we say that, the question that comes back is who does want it (Peter Dowling, Member of the National Farmers Union National Executive and a Dairy Farmer, Senate of Canada 1998d).

We are always over quota. Our cows will produce. With good management, you do not need a drug to make those cows milk. That is how strongly I feel. There are many efficient farmers in our area. They do not want it. The consumers do not want it. The processors do not want it. Who really wants it? There has been much time and money spent on discussing this subject today for so few farmers. How many dairy farmers are there in Canada? Not many, compared to the money that is being spent on a product that we do not want and we do not need. We can produce the milk (Lorraine Lapointe, Dairy Farmer, Past Director of the Ontario Milk Marketing Board, Senate of Canada 1998d).

Why would they introduce a product that is not curing anything, with those ramifications? Again, we repeat the list over and over. No one wants it. Why are we spending all this time and money on rBST? Why have I devoted 10 years of my life fighting this? Mrs. Lapointe and our organization have also devoted 10 years to this fight. It is clear to us that we do not need this (Richard Lloyd, National Farmers Union, Senate of Canada 1998d).

We are not going to feed the world with this drug. I guarantee you that. These are the same folks that brought us the "Green Revolution." We have many fewer farmers now than we did 20 or 30 years ago. We have more people going to bed hungry than ever before in the history of the world, so I do not think that this is about feeding the world (Anthony Pollina, Senior Policy Advisor, Vermont Public Interest Research Group, Senate of Canada 1998g).

This section reviews testimony of witnesses and Senators who argued that because rBST is a production drug with no therapeutic benefits Health Canada must take this under consideration in the decision.

Risks to human health include the fact that rBST is a non-therapeutic drug which is unnecessary. It does not improve the milk or the cows. It does not have any nutritional attributes (Peter Dowling, Member of the National Farmers Union National Executive and a Dairy Farmer, Senate of Canada 1998d).

As you know, rBGH is a production drug. It is not a therapeutic drug. It does nothing for society, whatsoever. It does not cure disease; it does not benefit consumers or society. Its only purpose is to force cows to make more milk. Given this complete lack of benefit, there should be absolutely no risk at all to consumers from its use (Anthony Pollina, Senior Policy Advisor, Vermont Public Interest Research Group, Senate of Canada, 1998g).

... the criteria of safety, quality and efficacy as is used on therapeutic products is, to my way of thinking and to many people's way of thinking, inadequate for the non-therapeutic application (John Verrall, Senate of Canada 1998f).

It is risk assessment, not risk management. Under risk management, I believe I would absolutely agree to it when you have a drug that might prevent something like cancer and that would be beneficial to mankind. However, here you have this whole other class of drugs, and that is quite a different proposition (Senator Spivak speaking to Len Ritter, a former Health Canada, Senate of Canada 1999c).

As a non-scientist, I would say that you are on the side of safety, particularly when you are talking about a production drug. If this drug were going to cure AIDS or cure a headache, for that matter, you would be willing to suffer side effects. You take your allergy medicine, you get drowsy, and that is okay. There is a reason for the side effect. However, in the case of a production drug, there is no reason for there to be any risk to anyone, the cow or the consumer, because there are no benefits (Anthony Pollina, Senior Policy Advisor, Vermont Public Interest Research Group, Senate of Canada 1998g).

What is the benefit to the consumer? If the consumer benefit is small, then the risk should be actually negligible or zero. Why should they be exposed to any kind of risk if there is no benefit, the milk is not of greater nutritional quality, or even like more of a social benefit or more people being able to have access to it because it becomes cheaper or whatever? So you have to look at all of these complex issues that are very interrelated in order to come up with the answer to should additional studies be required (Thea Mueller, Bureau of Pharmaceutical Assessment, Therapeutic Products Directorate evaluator and gaps analysis team member, Senate of Canada 1998b).

In contrast, there were participants that argued rBST should not be considered special.

We should be cautious with regard to introducing substances into commerce, whether they are therapeutic drugs or non-therapeutic drugs, and regardless of whether or not they have this commercial interest. I believe we should be careful, period. I would not attach any specific limitation on that concern. It is an appropriate concern for all substances at all times, not just in this particular case (Len Ritter, former Health Canada Manager and Codex Advisor, Senate of Canada 1999c).

That does not mean that it is absolutely safe. It means that given current methods it is impossible to prove danger. You must contrast that with all sorts of other products, as Dr. Pollak has pointed out, that are in common use and that are known to be dangerous. We cannot apply an unfair standard to the bovine growth hormone or to other similar biotechnology products (Jock McLean, Dean of Faculty of Applied Science and Pro Vice Chancellor, Division of Science, Swinburne University of Technology, and former JECFA advisor, Senate of Canada 1999a).

The review process involves several areas: manufacturing, human safety, animal safety and efficacy. In general, requirements for a drug are similar, whether they are for a therapeutic drug or a production drug. In other words, you have to make sure that that product will be safe. We want to make sure that the standards of manufacturing will be met -- that the product is stable, potent, and will meet the standard requirements (Ian Alexander, Drug Evaluator, Bureau of Veterinary Drugs, Health Canada, Senate of Canada 1998f).

This debate became much more complicated because of the charges made that the normal scientific review had not even been done (i.e. long-term toxicology studies). The central debate over the inclusion of additional considerations often revolved around divergent values regarding the obligations of Health Canada to Monsanto, and to industry in general.

3.4 Decision-stakes and the Regulatory Climate for Industry

In this section, I analyze the testimony about industry expectations of and demands from the drug approval process and what is seen as at stake if Canada does not encourage companies to locate here. This section is reviewed with the intention of looking at the way participants in the Senate inquiry determined how the drug approval process should consider commercial concerns. I begin this section with a brief introduction from representatives of Monsanto and Jean Szkotnicki, President of the Canadian Animal Health Institute.

Manufacturer's data submitted for evaluation is considered proprietary information and therefore the manufacturer is not required to make all their research public. I explore this topic with testimony describing this policy and why it is necessary. I then proceed to review challenges to this policy and examine what participants identified as problems with proprietary information and the consequences if this confidentiality is compromised. I also provide an examination of two different and conflicting interpretations over the restriction of what employees within Health Canada can or cannot say.

This issue speaks directly to the heart of balancing private and public interests. The decisions stakes that I examine are the challenges of Health Canada achieving democratic accountability while providing a favourable climate for commercial ventures.

3.4.1 Industry Representatives and their Problems with and Expectations for the Drug Approval Process

Two industry representatives stressed that Health Canada's decisions must be based exclusively upon scientific evidence. Jean Szkotnicki, President of the Canadian Animal Health Institute stated:

I am here to support a science-based approval process for all animal pharmaceuticals... Canada is increasingly becoming the last jurisdiction approached with a new drug submission because Bureau of Veterinary Drugs is viewed as highly unpredictable (Jean Szkotnicki, President of Canadian Animal Health Institute, Senate of Canada 1998g).

Ray Mowling, Monsanto's vice-president of Government and Public Affairs supported this position and described Monsanto's experience with the drug approval process as:

This particular process with this product has become unpredictable for us.....My company and others like us -- anybody who is trying to have a technology approved --need to know what kind of a process we must work with (Ray

Mowling, Vice- president of Government and Public Affairs, Monsanto, Senate of Canada 1998g).

The uncertainty that surrounds the approval process is disconcerting for us and does not bode well for others seeking approval for new technologies (Ray Mowling, Vice- president of Government and Public Affairs, Monsanto, Senate of Canada 1998g).

Next, I would like to discuss the critical path of BST in the Canadian review process. It is our intent to continue to encourage and support a review that is based on strong scientific evidence and the weight of scientific findings (Ray Mowling, Vice- president of Government and Public Affairs, Monsanto, Senate of Canada 1998b).

Finally, I will address why the science-based regulatory process must be allowed to continue until it reaches a science-based conclusion. Sound, extensive, in-depth research into the safety and efficacies of BST must be the basis for the decisions to be made by Canadian reviewers in deciding whether they will approve BST for use and sale in Canada. Should the product be registered, farmers and veterinarians can clearly voice their thoughts by either buying it or not. If there is no demand, the product will not be used. Any other approach may set an unacceptable precedent, implying that approval of a human or animal product is not based on scientific findings (Ray Mowling, Vice- president of Government and Public Affairs, Monsanto, Senate of Canada 1998b).

In the above section, it is clear that industry representatives Jean Szkotnicki and Ray Mowling argued that a regulatory environment must accommodate industry through predictability and timeliness. The decision to reject or issue a notice of compliance became more than a safety decision or even an agricultural decision. The decision-stakes erupted into issues over what kind of regulatory environment do we need in order to invite companies to submit products for approval and otherwise invest in Canada's biotechnology strategy. Here are some comments made by witnesses in regards to the need for companies and their (bio)technologies to invest in Canada.

These increased review times mean our veterinarians and food animal producers do not have access to safe and effective animal pharmaceuticals at the same time as other countries, many of which we compete with globally (Jean Szkotnicki, President of Canadian Animal Health Institute, Senate of Canada 1998g).

We need to be fair to the companies that do great work. Each one of us in this room benefits from a standard of living that we would not have if it were not for some of these scientific developments. I know that as a farmer. I would go as far as to say that if you removed many of the advantages that we have because of scientific research, probably half of the world would starve. I think Senator Whelan might question that (Senator Gustafson, Senate of Canada 1998d).

How do you deal with those people who say they have a right to sell this product; that this is not a totalitarian state so you cannot interfere with their rights and freedoms? This is what it boils down to (Michael Pollak, Human Safety Panel, Human Safety Panel, Senate of Canada 1999a).

Robert Bell of Monsanto stressed that the market can and should dictate the benefit of this drug for farmers. He also stressed that the approval process must be determined by science.

Ultimately, based on the science review of products, they will individually decide whether they will use a product or not. I am all for a scientific review of a product. After that, let us stand behind our scientific review process and allow those individual producers to decide whether to use that product (Robert Bell Monsanto witness and veterinarian, Senate of Canada 1998g).

If a product passes the hurdles on a scientific basis, it is up to every individual farmer to decide whether to use this product or not. The farmers will ultimately decide. I have no problem with that. That is fair and honest (Robert Bell Monsanto witness and veterinarian, Senate of Canada 1998g).

Several Health Canada managers also stressed that it is in the public's best interest to make decisions on the basis of scientific evidence.

There are two issues of balance here. One is the scientific implications for human and animal health. That is the job of our department. We may have to make some changes to the way we go about it, but that is our job. We then go beyond that. Some of these new developments have very important ethical, social, and economic implications. The Health Protection Branch is not the place where economic and social implications can be brought to bear. We then come to another question that will have to put back before Parliament as the work that Ian Shugart is heading in terms of the renewal of the Health Protection Branch moves forward. How can economic, social, and ethical interests be brought to bear in the process? One does not want the science and the objective impacts on human and animal health to be coloured by those considerations. One wants clean advice as to the safety aspects, and then one wants to be able to deal with some of these things outside of that with respect to the other issues (David Dodge, Deputy Minister, Health Canada, Senate of Canada 1998d).

We are struggling with the important question of how to introduce into the regulatory and the decision-making process factors other than safety and efficacy. Clearly the science is responsible for dealing with those issues, but society is raising other issues-ethical questions, social questions, cultural questions, and the like (Ian Shughart, Assistant Deputy Minister, HPB Transition, Health Canada, Senate of Canada 1998d).

These passages maintain the dominant position that science is responsible for safety and efficacy evaluations implying that laypersons are not to be involved in the assessment of these regulatory requirements. Furthermore, they did not acknowledge that science itself might be raising ethical, social, and cultural questions.

Several Senators and witnesses asked if socio-economic issues are considered in the review process and several others argued that these issues should be addressed.

The whole dairy industry is very much protected by the marketing board concept, which tells us at this point in time that we do not need to compete with the Americans or we do not need to compete economically because of the protections that are in place. I see that changing over time, and there may be a change of position on this issue because of economic reality. Have you given any thought to that (Senator Gustafson, Senate of Canada 1998d).

Senator, both Mr. Nymark and I, in former capacities, spent a lot of time worrying about those issues. I do not think it is appropriate for either of us in our capacities as deputy and associate ministers of health to deal with that (David Dodge, Deputy Minister, Health Canada, Senate of Canada 1998d).

Health Canada does not look at the economic benefits, et cetera, or at the damage that this drug can do to the whole history of the super dairy herds of the world, which have not used this kind of injection to make a cow give more milk. You do not look at that part of it at all (Senator Whelan, Senate of Canada 1998a).

3.4.2 Proprietary Information for the Public Good

Mr. Dodge spoke the most about proprietary information. He and Joseph Losos argued that proprietary information exists to benefit Canadians. Mr. Dodge argued that intellectual propriety rights were created and chosen by governments for the collective

good. This collective good is conceptualized as benefiting from the leading-edge research and products of proprietary information without the public's money.

We must remember that intellectual property rights, unlike human rights, were created by governments for the collective good in order to encourage research (David Dodge, Deputy Minister, Health Canada, Senate of Canada, 1998d).

...essentially we rely on the protection provided to intellectual property through patents to provide the stimulus for research which has benefited us all (David Dodge, Deputy Minister, Health Canada, Senate of Canada 1998d).

First, it is undoubtedly true that over the last half century we have moved, not just in Canada but around the world, in a number of areas to strengthen patent protection and intellectual property protection in order to encourage research. We do less ourselves with money commissioned publicly. We have chosen to use the tool of creating intellectual property rights to get the work done, as opposed to having government agencies do it themselves (David Dodge, Deputy Minister, Health Canada, Senate of Canada 1999d).

Finally, let me address the competitive aspect. This is fundamentally a very difficult issue. It is not driven so much by the corporations. We have set up in the western world -- and we are part of that system -- a system to try to drive research that does not require all that research to be done by public money. We use the patent mechanism to do it (David Dodge, Deputy Minister, Health Canada, Senate of Canada 1998d).

3.4.3 Proprietary Information: Restricting Access and Corruption

Participants argued that proprietary protections compromise access to the manufacturer's data and unacceptably close the drug approval process to public and outside expert scrutiny.

Proprietary information was, in fact, what I was alluding to and that is, of course, a double-edged sword for us. We would certainly like to get as much information as we can to the public. On the other hand, the companies submit information to us under Canada's agreements and regulations (Joseph Losos, Assistant Deputy Minister, Health Protection Branch, Department of Health Canada, Senate of Canada 1998f).

Protecting commercial information, not only was identified as a significant challenge to a transparent drug approval process and public participation, but a challenge for Health Canada employees as well.

...managers decide to whom we will talk, what meetings we will attend, what scientific conferences we will attend, what papers we can write and where we can write them, and whether we can speak, or whatever. There is complete control over the system under the term "confidentiality of proprietary rights (Shiv Chopra speaking to Senator Kinsella, Bureau of Veterinary Drugs evaluator and gaps analysis team member, Senate of Canada 1999b).

We must also look at the ability of civil servants to protect the public interest. The scientists from within Health Canada who have testified before this committee have taken brave steps to inform the public about their important concerns, and their actions can probably politely be described as "career limiting moves." Frankly, I do not know how they have had and continue to have the courage, the perseverance, and the bravery to do what they have done. The gag order which now prevents them from speaking in a publicly about their experiences and concerns does not serve the public interest. We believe it should be removed immediately (Jo Dufay, Campaign Coordinator, Council of Canadians, Panel on Continuing Concerns, Senate of Canada 1999b).

The information they supply to us and the FDA and authorities in other countries is proprietary information. That makes life extraordinarily difficult. It is not like science back at the university where you are dealing with everything on the public record, in essence. You are dealing with proprietary information that has been put together. The great difficulty we all have is how, given the background against which we are working, we provide a light into the system which does not compromise that proprietary information (David Dodge, Deputy Minister, Health Canada, Senate of Canada 1998d).

3.4.4 The Stakes of Releasing Proprietary Information

Participants agreed that proprietary information complicates transparency and public participation and that there are consequences for regulators. Health Canada managers disagreed with their employees and several Senators disagreed on the severity of these complications and challenges, as well as whether or not proprietary protections should be removed. Health Canada managers, David Dodge and Joseph Losos, as well as Ray Mowling argued that Canadians will suffer if confidential information is released

because manufacturers will apply to have their products approved for sale and use in Canada:

If it 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 (David Dodge, Deputy Minister, Health Canada, Senate of Canada 1998d).

The rules on inventions and the work that goes into them will benefit inventors, like Canadian academics, entrepreneurs or companies like ours. If data is released -- and, again, this was referenced this morning -- anyone can use it. We need rules in line with other countries, or as Dr. Losos said, the developments will go elsewhere (Ray Mowling, Vice-President of Government and Public Affairs, Monsanto, Senate of Canada 1998g).

If we compromise them, we may find, as I believe Mr. Dodge commented at the last hearing, that companies are reluctant to submit applications in Canada (Joseph Losos, Assistant Deputy Minister of the Health Protection Branch, Senate of Canada 1998f).

Michèle Brill-Edwards, from the Alliance for Public Accountability and a former Health Canada manager argued that proprietary restrictions must be removed:

Second, because we will have more products coming up for approval and because we will not have more resources to deal with that, the privilege of secrecy that has heretofore been accorded to manufacturers must be dropped. If we do not have sufficient reviewer resources to allow reviewers adequate time to review material in depth, then there is no way that material should remain secret and unavailable to anyone else who may choose to take the time to review it (Michèle Brill-Edwards, Alliance for Public Accountability, Senate of Canada 1998g).

3.5 Trade and the Need for a Regulatory Decision

The Senate inquiry extended beyond concerns of rBST's safety, consumer reactions, and domestic economic impacts to include discussion and debate over Canada's trade obligations and global competition. In this section, I examine the demand for a decision in regards to Canada's trade obligations and the international competitiveness of Canada's dairy industry. With this issue, I explore the different

descriptions participants gave of Codex Alimentarius and JECFA. I then examine the confusion and controversy surrounding the power of Codex Alimentarius to overrule if Canada decided to reject a notice of compliance because of human health concerns. I present testimony that emphasizes the importance of examining the conflicts of interest of international standard setting bodies and evidence by showing that who and where the science is done is of importance for reasons related to the value of sovereign decision making and the precautionary principle.

3.5.1 Descriptions of the Codex Alimentarius Commission and the Joint Expert Committee on Food Additives

George Paterson described Codex's review of JECFA's human safety evaluations on rBST as a source of confidence for Health Canada's review and decision:

There are two main routes that we are taking to get further confidence in our review. One is our internal gap analysis. The second is the expert panels. A third route might also be the fact that the Joint Expert Committee on Food Additives re-evaluated its opinion, and came out with a conclusion in February of this year. That then must go to the Codex Committee on Residues of Veterinary Drugs in Food. That committee will meet in September, which is also when our panels are scheduled to submit their findings. These are two watershed events; the Codex committee meeting in terms of discussing and reviewing the JECFA report, and our own expert panels coming in with their reports (George Paterson, Director General, Foods Directorate Health Canada, Senate of Canada 1998a).

Senator Kinsella asked Len Ritter how important is Codex and he responded "I should like to think that it is very important (Len Ritter, former Deputy Minister of the Bureau of Veterinary Drugs, Senate of Canada 1999c David Dodge also gave a positive description of Codex.

That is right. The purpose of the Codex is to provide the best international scientific basis for all of us to make national decisions. That is helpful, and especially helpful in a world where we have some strong trading partners and we are trying to find some way to ensure that no abuse is made of science, that

health and safety issues are foremost (David Dodge, Deputy Minister, Health Canada, Senate of Canada 1999d).

Jock McLean, a former JECFA advisor that Health Canada asked to testify at the Senate inquiry, argued that JECFA is a separate and independent body from the Codex Alimentarius Commission but that the Codex Alimentarius does use JECFA's expert evaluations.

JECFA gives advice to, but is independent of, Codex Alimentarius. There are a number of international organizations that actually use the results of JECFA independent of the Codex process. JECFA publishes all its work in the open literature, and those publications that relate to BST are now in the open literature. The most recent volume appeared last week (Jock McLean, Dean of Faculty of Applied Science and Pro Vice Chancellor, Division of Science, Swinburne University of Technology, and former JECFA advisor, Senate of Canada 1998d).

Scientists, Health Canada witnesses, Monsanto witnesses, and those from the Sierra Club and the Council of Canadians also knew that Codex Alimentarius is separate from JECFA:

I share your concern about Codex itself, but the expert committee is a very separate group that is composed of regulatory scientists from around the world. For example, this last JECFA, which convened in February, is composed of approximately 40 regulatory scientists from around the world, including Canada. That is different from looking at Codex itself (David Kowalczyk, Senate of Canada 1998a).

However, Senators were unfamiliar with Codex and JECFA's formal relationship:

The question to be asked is: What good are our reviews if the Codex Alimentarius -- I think that is it; I can never pronounce that -- says this is great? And that is binding now on Canada. And it turns out that the JECFA also based its findings on summaries that had nothing to do with raw data (Senator Spivak, Senate of Canada 1998b).

I thought you were part of it (Senator Whelan speaking to Jock McLean, Senate of Canada 1998d).

There was also considerable confusion as to whether or not Codex could overrule a decision to reject approval because of human safety risks.

In fact, I think I prefaced my comments by saying that I am not a lawyer and I am not here representing any WHO, WTO or United Nations panel. My understanding is exactly as you have just articulated; that is, that standards established by the Codex Alimentarius Commission are used as reference points by the WTO in arbitrating disputes between countries. The extent to which those standards that the WTO may refer to have legal meaning is a matter for interpretation by an appropriately qualified trade lawyer, which I am not (Len Ritter, former Deputy Minister of the Bureau of Veterinary Drugs, Senate of Canada 1999c).

My understanding of the Codex Alimentarius decisions is that while they may necessarily be binding, they can be used in dispute settlement mechanisms. If the Codex Alimentarius, for example, says that rBST is perfectly safe and should be used forthwith, and then Canada decides not to use it, then Monsanto can sue the Canadian government for loss of profit, as has already happened with Ethyl Corp. and the MMT issue. Is this assumption correct (Senator Spivak speaking to Dr. Losos, Senate of Canada 1998d).

Are you saying that if the Codex Alimentarius deems that rBST is safe for use and the Canadian government then chooses to say that it is not prepared to license rBST, then Monsanto has no basis on which to sue the government for lost profits and opportunities under the WTO process (Senator Spivak, Senate of Canada 1998d).

In response to Senator Spivak's question George Paterson responded:

Not being an international lawyer, I will be careful how I respond to that question. As long as Canada, as a sovereign nation, had a justifiable rationale -- in other words, the health and safety risk assessment was rigorous and valid -- then, no, there would be no basis (George Paterson, Director General, Foods Directorate Health Canada, Senate of Canada 1998d).

3.5.2 Criticisms of Codex Alimentarius and JECFA

Several witnesses and Senators expressed concerns over the power of Codex to challenge a decision to reject rBST's approval. Participants criticized Codex because of the lack of access and transparency of this body. As well, several participants identified Codex as a threat to sovereignty to keep rBST out of Canada.

Senator Hays mentioned Codex. I am sure that you are aware that I have strong reservations about Codex and how it operates. People are making decisions on behalf of the rest of society, and the rest of society does not know what they are doing. I thought you would be aware of all these things when Codex, this great

secret body, is going to make a decision on whether food is safe for us. I have strong reservations about Codex, and I do not mind telling you that (Senator Whelan, Senate of Canada 1998a).

Surely you are not telling me that a strictly undemocratic and bureaucratic decision will be made, and that will be it. When we talked about Codex, they had nothing to say about that. Someone represents Codex and makes a decision on behalf of Canada, but parliamentarians do not know anything about it (Senator Whelan, Senate of Canada 1998a).

While most Canadians have never heard of Codex Alimentarius, it is likely to have a more decisive role in setting safety standards, including pesticide residues, than the Canadian government (Angela Rickman, Deputy Director, Sierra Club, Senate of Canada 1999b).

Several witnesses and Senators also criticized Codex and JECFA for being composed primarily and/or exclusively of industry representatives.

By the 1991 Codex meeting, there are more representatives of giant TNCs than from government -- 140 from corporations and only 105 from government. Coca-Cola alone sent 18, so concerned were they with food safety. Unilever sent nine representatives, and Monsanto sent eight. While Codex was initially supposed to concentrate on food safety standards for the developing world, industrialized countries quickly dominated the process with TNCs and their delegations. At the 1993 meeting, Coca-Cola had the largest delegation, followed by Nestle. In fact, 48 countries had fewer representatives than Coca-Cola and Nestle, including wealthy industrialized countries like Switzerland, the UK, and Australia (Angela Rickman, Deputy Director, Sierra Club, Senate of Canada 1999b).

You are not going to impress me by quoting WHO or FAO. I was associated with them for 12 years and I know how they operate. They operate on grants and their decisions sometimes depend on who pays their bills. As far as that goes, I have as much respect for some of their decisions as hell would have for a snowball. Do not try to impress me with them because I know how they work. Do not try to impress me, if you are going to go that far, with Codex because I know how they work. The big companies sit behind them and tell them what to do (Senator Whelan, Senate of Canada 1998a).

In this era of globalization, however, we seem to be getting away from the idea that we can do things in a different way here (Senator Whelan, Senate of Canada 1999d).

3.6 Summary

In this chapter, I examined four specific topics of the Senate inquiry. Each of these four topics revealed the trouble and conflict with the prevailing assumptions that health and safety are pre-defined entities that can be measured objectively and independently of their social context. The dominant science-based decision-making was unable to capture the broad and sometimes conflicting meanings of health and safety that participants offered throughout the Senate proceedings. Nor did the Health Canada employees, several Senators, the dairy representatives, and the citizen group representatives have confidence in the scientific evidence to address and anticipate the social context in which this technology would be released. Participants recognized that science does and should play a role in the decision; however, the difficulty is that participants had different ideas on what exactly constitutes sound science and what standards of evidence to use.

The troubles and conflicts with science included methodological errors and inconsistencies, distorted and incorrect reporting, and misinterpretations. Science also found itself in a predicament over who should be paying for approval data and the composition of international and arms-length expert bodies. Participants of the inquiry differentiated between good science and bad science. Management, industry representatives, the human safety panel, Jock McLean, and Len Ritter defined good science as objective, standard-driven, and efficient. While the majority of the other witnesses also described good science as objective they also defined good science as comprehensive and embracing the precautionary principle. The debates over Codex Alimentarius and JECFA particularly revealed the conflict with these two different meanings of good science because if Health Canada were to disallow rBST their

decision could be challenged on the basis that it was not scientific. Although science is required by federal and national law and trade to justify a decision, these opponents to rBST's approval reconstructed the meaning of science and safety. In the following chapter, I review these reconstructions of science and safety and the cultural, economic, symbolic, technical, and structural resources participants used in the process.

Chapter Four: Extending Participation and Using Extended Facts

4.1 Introduction

In the preceding chapter I examined the testimony of witnesses and Senators about four specific issues that complicated the possibility of making a decision on rBST. These four issues demonstrated that the rBST debate was complex with no simple resolution, because of persistent uncertainties and its potential to cause social, political, and economic instability.

Post-normal science is a project as much as it is a theory and takes as its foundation that improving risk management is contingent upon understanding the “essential complexities of the task”(De Marchi and Ravetz 1999: 744). Understanding the complexities of risk management is in turn about employing extended facts and encouraging the participation of extended peer communities. This chapter examines Health Canada use and response to extended facts from such actors. As well this chapter examines Health Canada perceptions on who is legitimately qualified to contribute to rBST decision-making and in what capacity.

I begin this chapter with an examination of the reactions of the Senate participants towards Health Canada witnesses. I examine the division between Health Canada managers and employees and the subsequent alliances that formed with other witnesses and Senators. These alliances, although composed of different actors with unique interests and backgrounds, utilized similar and/or compatible discursive

strategies in an effort to advance their position on rBST's approval or rejection. More specifically, I examine the critical negotiation and reconstruction of the meaning of science, health, and governance that occurred in the Senate inquiry.

4.2 Discourse Coalitions

4.2.1 Reactions to Health Canada Witnesses

There were several instances in which participants criticized Health Canada managers.

Honourable senators, this morning I was quite upset that the first panel seemed to be very arrogant in providing you the proper information. (Jo Dufay, Campaign Coordinator, Council of Canadians, Panel on Continuing Concerns, Senate of Canada 1999b)

The question is, why should we trust you? When we look at the real world, as Senator Gustafson has, we see that there are five or six companies that have said quite openly that they want to control the world's food production. People who have worked for them are on Codex, JECFA, and your human health external panel. That has happened... Why should we trust you? Senator Hays has put forward the essential question. The public needs to trust you. You should not be talking about stakeholders and public relations... Your job is to ensure that you are protecting human health. There is another branch of government that looks after industry (Senator Spivak, Senate of Canada 1999d).

We have studied the responses from the senior managers in Health Canada. Nothing they have said, quite frankly, reassures the public that they can be trusted, or that they have been part of a solution to these disturbing problems. In the words of Helen Forsey, there was nothing real in what they said. Instead, it was like a sparring match, scoring points; truth and falsehood were merely incidental (Kathleen Connors, Chairperson, Canadian Health Coalition, President, National Federation of Nurses, Senate of Canada 1998g).

Bias in health and management, and bias in policy and management, have been introduced through the government appointment to senior positions in Health Canada generally, and the Health Protection Branch in particular, of unqualified managers who are hostile to the department's legal mandate (Michael McBane, National Coordinator, Canadian Health Coalition, Senate of Canada 1998g).

Likewise, their managers must render decisions on the information brought forward to them by their reviewers with due diligence. If we look at the BST

process, we see that that due diligence has not been served. Let me remind you that, when we speak of due diligence, we are including the necessity for the reviewers to maintain independence and for the review process to be independent. It is not acceptable to introduce an unseen bias into the evaluation of a drug (Michèle Brill-Edwards, Alliance for Public Accountability, Senate of Canada 1998g).

Positive comments about Health Canada managers included:

In the course of the review of these programs, we have made a number of recommendations. I have been impressed over the last year by the openness and cooperation of the management, and by their enthusiasm in implementing these various changes (Yves Morin, Vice-Chair, Science Advisory Board, Health Canada, Senate of Canada 1998d).

I would like to thank Dr. George Paterson for the openness I have found in trying to deal with Health Canada, because we have been writing them letters for the past year. Apparently, they were good enough to go into the gaps analysis report. You are missing a few that were written since the report's publication, and we will supply them to you (Victor Daniel, Toronto, Co-Chairman, Toronto Food Policy Council, Senate of Canada 1999b).

The gaps analysis team received mixed reactions. Dr. Ritter, a former Deputy Minister of the Bureau of Veterinary Drugs, testified that he found the gaps analysis report unprofessional because it contains unsubstantiated personal attacks.

Moreover, I referred to the "gaps report" earlier. If you have not had the distinction of being referred to as a bozo, then I am one up on you. I certainly find that kind of commentary to be entirely inappropriate. I consider it to be reprehensible. Although I have not taken legal action, I think it is very unfortunate that otherwise well-intentioned scientists would reduce the level of conversation to the point that it becomes a personal attack. It undermines the credibility of what they are setting out to do. It becomes a personal vendetta and that is unfortunate (Len Ritter, former Deputy Minister of the Bureau of Veterinary Drugs, Senate of Canada 1999c).

The members of the gaps analysis team were also criticized as acting irresponsibly by causing unnecessary alarm.

We do not want to have a weak Health Protection Branch that does not stand up to big, bad companies. However, we also do not want to have alarmist people coming around and scaring the population where there is no need for fear (Michael Pollak, Human Safety Panel, Senate of Canada 1999a).

I require that the scientists touch all their bases in their analysis. I found some of the testimony of last week disturbing because it inappropriately attacks the integrity of the branch and its scientists and creates anxiety in the public, which is totally inappropriate (Joseph Losos, Assistant Deputy Minister of the Health Protection Branch, Senate of Canada 1998d).

Conversely, several participants had favourable comments about the gaps analysis team.

The scientists who went public with criticism of this review are heroes (Bill von Meyer, independent toxicologist, Senate of Canada 1999a).

First, I agree with the prior witness this morning that the Health Canada scientists who did not rubber-stamp the application from Monsanto could be described as heroes. There was enough cause for reasonable concern that they were correct in saying that this is not a rubber stamp issue and that it requires further thought (Michael Pollak, Human Safety Panel, Senate of Canada 1999a).

Finally, I refer to my question or suggestion to you. I would like to, on behalf of the group here and particularly the people of Canada, congratulate you for appearing here today because it took a lot of courage. On behalf of the group here -- and, in particular, on behalf of the people of Canada -- I should like to congratulate you for appearing here today. It took a lot of courage to do so. It is not something that is easy to do, particularly when three of you took the oath. It is very unusual for that to occur (Senator Stratton, Senate of Canada 1998b).

4.2.2 Divisions within Health Canada

The Senate committee inquiry revealed divisions between Health Canada's management and the Bureau of Veterinary Drugs' evaluators. Health Canada management witnesses included both scientists and non-scientists, while employees were all scientists, which indicated that the rBST controversy was more than a case of scientists verses laypersons. Managers and evaluators were divided not just over technical issues but also over different values, beliefs, and interests. These differences manifested themselves in different interpretations over the adequacy and conclusiveness of the scientific literature, job expectations, and obligations to industry, consumers,

citizens, and farmers. While management and employees agreed that Health Canada's prime objective is health and safety, there was disagreement over what factors should or should not be considered in deciding rBST's regulatory fate.

The divisions between Health Canada managers and employees were a part of a larger division between those espousing the necessity for, benefits of, and requirements for objective analysis and rational decision-making and those that demand social and economic impacts be taken into consideration. The case of rBST demonstrated that different values, interests, experiences, and beliefs produced different conceptualizations of the public's best interest. This lack of consensus on the meaning of public interest produced instances where participants, including scientists framed their arguments with appeals to beliefs, values, and interests rather than trying to appear as objective and neutral. As well, there were participants striving for an appearance of objectivity that met with limited success to be persuasive and appear as competent and trustworthy. These moments Ravetz (1999: 648) would argue challenge "the previous belief that scientists could and should provide certain, objective factual information for decision-makers." He further comments that this belief is "increasingly recognized as simplistic and immature."

4.2.3 Power Struggles and Discourse Coalitions

An easily identifiable power struggle to emerge within the Senate proceeding is that between employees and management. Within this struggle, there was a fight for greater autonomy and authority for Health Canada employees. Throughout the Senate proceedings there were numerous instances in which the internal conflicts within this agency were highlight. These internal conflicts included allegations of corruption and

examples of management as serving the needs of industry over the interests of Canadians. Other internal conflicts they identified included manager's training and experience as not relevant to health and safety but business, racism, the loss of freedom to speak in public, and excessive reprimands. Witnesses Thea Muller and Mark Feeley, the two non BVD members of the gaps analysis team criticized the first gaps analysis report because:

“First, the scientific issues dealing with the human safety, the animal safety and efficacy, have become intertwined with the internal conflict that the rBST submissions have generated within the Bureau of Veterinary Drugs. The scientific issues are quite distinct from the internal BVD conflicts. Each is equally important but each should be examined in its own right (Thea Mueller , Bureau of Pharmaceutical Assessment, Therapeutic Products Directorate evaluator and gaps analysis team member, Senate of Canada 1998b).

However, Dr. Chopra was adamant that the internal problems within the department are negatively impacting the quality of regulatory decisions. Shiv Chopra responded stating:

My colleague Dr. Mueller talks about the conflict. Conflict is not peripheral to this. Rather, rBST and other drugs have been central to the conflict. The conflict was not that we were unhappy with our own personal jobs, our promotions or anything like that. The conflict was that our concern at the BVD, particularly in the Human Safety Division, has been that we have been pressured and coerced to pass drugs of questionable safety, including rBST (Shiv Chopra, Bureau of Veterinary Drugs evaluator and gaps analysis team member, Senate of Canada 1998b).

The Senate inquiry was a struggle for opponents to rBST's approval to resist the dominant political and economic forces defining safety, food, and agriculture. These dominant forces were identified as foreign and corporate control over Canada's agriculture sector, food sources, and regulatory agencies. The contradictions to emerge within the dominant scientific and industrial model of economic growth included risks to health, economic independence, and citizens' ability to decide which technologies they want in their communities.

I adopted O'Mahony and Skillington's concept of discourse coalition to describe the alliances between diverse actors that emerged to challenge, reconstruct, or reinforce the hegemony of industrial capitalism and science. O'Mahony and Skillington (1999:102) describe discourse coalition as:

complex intersections of social meaning-making practices...the concept of coalition does not presuppose a strongly unified and fixed alliance in which coalition members can be subsumed within one cultural framework over time.

They further add that solidarity between actors within a discourse coalition is contingent upon the specific issue at hand as actors may disagree on other issues.

The concept of discourse coalition is utilized in my research to capture how participants combined and rearticulated ideas, resources, arguments, and knowledge to their advantage. Murphy (2001) provides a useful description of how actors produce competing rhetorical positions to their advantage. Murphy (200: 280) states that "how a social problem is defined - as primarily economic, political, or scientific - affects what resources figure into the solution.

4.3 Competing and Compatible Meanings of Health and Safety

4.3.1 Sources of Knowledge on Health and Safety

Health Canada witnesses showed that there are many different possible sources of knowledge on the health and safety of rBST. I have divided these sources in two types: formal and informal. Formal sources included manufacturer's data, studies on other rBST products, other countries' evaluations, and published literature. The formal sources management turned towards the two external panel's conclusions, JECFA, Codex Alimentarius, Food and Drug Administration (F.D.A) and the U.S Post Approval Monitoring Program (PAMP, manufacturer's data in an effort to demonstrate the breadth

of scientific studies and to use as examples of expert affirmations of rBST's human and animal safety and efficacy. Evaluators turned towards these same sources of information, however, they criticized these sources for inconsistencies, assumptions, and validity of data. Informal sources included past work experiences, personal experiences, and tradition. Dr. Chopra and Mr. Dodge were the two Health Canada witnesses that shared their personal feelings and experiences that impacted how they approached assessing rBST.

The decreased in-house science capacity and increased reliance upon manufacturer's data was more of a concern for Senators that it was for Health Canada representatives.

Whole departments and areas have been closed down. You would not know about it. It comes under "normal cuts" and "budgetary planning" and so on. Science is thoroughly compromised. We do not care if Canada does not do any science, but science that is concerned with public safety cannot be jeopardized (Shiv Chopra, Bureau of Veterinary Drugs evaluator and gaps analysis team member, Senate of Canada 1999b).

I think it is a fact, though, in the regulatory field, that we place quite a large reliance, or heavy reliance, on data generated by the manufacturer. And I was reading Senator Whelan's skepticism regarding this data, but there are checks and balances that we can use. We can ask the company to design the studies in such a way that we can determine, or have a fair level of confidence, that the data is a true reflection of the situation (Thea Mueller, Bureau of Pharmaceutical Assessment, Therapeutic Products Directorate evaluator and gaps analysis team member, Senate of Canada 1998b).

That is true. That is how our process works. We work on an honour system. The companies provide the data. We, unlike the United States, are not inclined to do the studies here in Canada under our supervision simply because it is expeditious and expedient, because we are a small country. If we had those kinds of requirements, no manufacturer will come to sell in our country. So therefore, we are willing to receive data from anywhere in the world, on the honour system, and we are simply the auditors of science and data are given to us and we evaluate and we argue on that, and we ask the company to, if necessary, go back and produce more (Shiv Chopra, Bureau of Veterinary Drugs evaluator and gaps analysis team member, Senate of Canada 1998d).

4.3.2 Uncertainty v. Best Available Science

Uncertainty was a central preoccupation of those participants with doubts of rBST's safety and opposed to rBST's approval. Jones and Salter (2003:21) argue that "uncertainty itself is central to the discursive currency of political debates about the governance of genetic technologies." Uncertainties because of expert disagreements provide public interest groups strategies for resistance and influence (Murphy 2001).

The certainty and uncertainty of technical evidence is a major point of disagreement among both scientists and laypersons. There is significant amount of testimony dedicated to challenging opposing scientific viewpoints based on methods used, experimental design, and reporting of results. Uncertainty of technical evidence, for instance, is expressed in terms of accuracy, reliability, validity, controls, and replicability. However, the uncertainty of technical evidence was not limited to discussion of available studies but also the need for more research.

Participants of the Senate inquiry had different and sometimes competing understandings of uncertainty. Uncertainty was expressed as a "gap" in knowledge. Uncertainties were argued to be inevitable and decisions must be made with some uncertainty. Uncertainties also arose from the lack of mutual understanding on what constitutes safety, economic success, and government responsibilities. While there were several health uncertainties identified based on a lack of adequate scientific investigation and long-term studies, the uncertainty of the drug approval process was also identified as a significant issue for Monsanto and Health Canada managers.

Senior managers constructed the goal of the regulatory process as consistency through applying best available science. Senior managers stressed decisions must be

made on the current state of scientific evidence, whereas Dr. Chopra stressed that we must be certain that the risks are fully known before approval is given.

Our job, to the best of our ability, is to ensure that the food or drugs they take or the goods they use are indeed as safe as we know how to make them given current science (David Dodge, Deputy Minister, Health Canada, Senate of Canada 1998d).

I will make recommendations on the basis of the best science available (David Dodge, Deputy Minister, Health Canada, Senate of Canada 1999d).

The latest piece is the MacLeod panel piece, and it confirmed our previous work. You will notice that I am not using the term "perfectly safe" because no one can ever guarantee that anything is absolutely, perfectly safe. For humans, the McLeod panel says BST, given the best scientific knowledge available, poses no significant risks. That is not saying that it is absolutely safe. One should be quite careful in one's use of language (David Dodge, Deputy Minister, Health Canada, Senate of Canada 1999d).

Yes, we did. Where is the evidence? No evidence was tabled; it was alleged evidence. We were basing our opinion on the most up-to-date scientific evidence we believed to be available. If no firm evidence was tabled or put into the record, then it was just pure supposition (George Paterson, Director General, Foods Directorate Health Canada, Senate of Canada 1998a).

What we scientists have to do, in weighing the risks and benefits, is to somehow gaze into the future, into the unknown territory, so we are changing the existing risk/benefit method by which we have been doing up to now, that you first know the risk and, once that risk is eliminated, then you can proceed. Here we are taking a risk that we do not know. Therefore, that is the kind of thing that has happened with blood and breast implants and other situation (Shiv Chopra, Bureau of Veterinary Drugs evaluator and gaps analysis team member, Senate of Canada 1998b).

4.3.3 Precautionary Framing verses Consistency

The difficulty of reaching consensus and negotiating satisfactory closure resided in the need for both consistency and flexibility in regulatory decision-making. This difficulty is apparent in the Senate proceedings on rBST and the drug approval process. The position of Health Canada managers rests upon presenting rBST as similar to any other drug up for review. They extended this position and argued that if Health Canada

imposes higher than 'normal' standards for rBST's approval than all products, including human therapeutic drug submissions, must be evaluated with a higher standard and Canadians will suffer. However, members of the gaps analysis team argued that because of the lack of benefit of rBST, extra measures must be taken to ensure safety. The position of management is compatible with industry and the external human safety panel. The employees within Health Canada shared the position that the lack of benefits of rBST warrants assurances of zero or minimal risk with the several Senators and witnesses who opposed rBST's approval and safety claims.

I require that (Health Canada programs) aspire to achieve the level of scientific excellence required and demanded of such an organization, that they have in place the capacity and the networks to assess absolutely all of the knowledge available on whatever subject they are managing, that they have the management processes and mechanisms in place to ensure that their work is effective, efficient and standard-driven, and that there are mechanisms in place to address all differences of scientific opinion to allow for the proper scientific challenge. We welcome proper scientific challenge and we want to ensure that expert review, both internally and externally, is fully utilized in our health protection role (Joseph Losos, Assistant Deputy Minister of the Health Protection Branch, Senate of Canada 1998d).

Our goal is to have an effective public health partnership where information is gathered, analyzed and used, with good, common standards, strong privacy protection and a good system for setting priorities and evaluating the results. We share that challenge with every jurisdiction in the world (Ian Shughart, Visiting Assistant Deputy Minister, HPB Transition, Health Canada, Senate of Canada 1998d).

Many witnesses stressed the importance of Health Canada utilizing the precautionary principle in the case of rBST. It is interesting that to some the precautionary principle was not new to Canada's regulatory approach, while others argued that it is new and needs to be further explored, and then implemented.

That sets in perspective how chilling it is to hear senior management refer to health regulations as "old-fashioned." As a precautionary principle, an ounce of prevention should never be old-fashioned (Michael MacBane National Coordinator, Canadian Health Coalition, Senate of Canada 1998g).

We must prevent illness. It is chilling to realize that if the proper regulatory mechanism does not exist for Canadians, we will create illness rather than prevent it. The precautionary principle must be first and foremost... I think Canada could be sitting on several Ford Pintos that will blow up in our face if we do not ensure that the Health Protection Branch effectively does the job it was established to do; that is, utilizing the precautionary principle as the first line of defense in protecting public health and safety (Kathleen Connors, Chairperson, Canadian Health Coalition, President, National Federation of Nurses Unions, Senate of Canada 1998g).

The Canadian public does not care about efficiency and timeliness. They care that what comes out of the end of the pipe is absolutely safe. Whether they know what it means or not, they are interested in the precautionary principle (Senator Spivak Senate of Canada 1999d).

We had a large-scale staff meeting where we invited Justice Krever to talk to us and discuss how we could adjust our programs to specifically address and embody the precautionary principle. It has implications on policy and on organizational structure eventually, as that is the way that we will be moving. We do not have a final answer as to how that precautionary principle will work (Joseph Losos, Assistant Deputy Minister, Health Protection Branch, Senate of Canada 1998d).

The Senate inquiry highlighted the fact that health and safety are not absolute but highly variable concepts as different people and groups had different perceptions of what constitutes safety. In many instances safety is portrayed as a matter of science (Ravetz 2002). However, Ravetz argues that safety is a broader concept than just estimates and probabilities of harm. Science, according to Ravetz (2002) has sanitized safety, reducing it to mere probabilities and estimates of harm. Ravetz (2002) notes the public is concerned with more than estimates and probabilities. Safety judgments, argues Ravetz (2002: 262), “need bear little relation to the magnitude of risk.”

4.4 Negotiating and (Re)constructing Science

There is a long list of positions one can assume when evaluating risks. Whether a person searches for proof of harm, or just doubts of a product’s safety, can contribute to

different judgments. Whether one starts with the assumption that a product is safe or starts with the assumption that a product is hazardous is also a factor in different conclusions about the same product. Even more broadly, focusing on what is known about a product's health risks or focusing on what is not known can radically produce differing interpretations about the costs, risks, and benefits of a product. Significantly, different definitions of costs and benefits contribute to disagreements among people. As well, there is the inevitable dilemma of deciding which evidence best predicts the future. From this list, I have introduced only a fraction of the problems rBST and other products can present to regulatory agencies.

Barnes (1999: 60) suggests that “controversies involving technical expertise may involve chronic conflict not just between incompatible technical analysis but also how far technical analysis is appropriate.” He (1999: 61) further adds that “if the limits of technical expertise are to be clearly drawn, then a method of delineating them is required, and this itself may become a contested matter.” The rBST case demonstrated that what is technical or scientific and what is political, economic, or social is subject to construction and negotiation. However, I also add to Barnes' insight, in that the rBST case also is about challenging who has a legitimate voice in this redefinition.

Furthermore, the rBST case is a struggle to have laypersons contribute to technical expertise as well as the struggle for scientists to move into a previously restricted area and engage in dialogue about social values, ethics, politics, and economics of technologies.

4.4.2 Challenging the Authority of Expertise

Post-normal science is about changing and challenging the exclusive authority and power of expertise. Ravetz (1999) argues that counter-expertise is growing in that public interest groups and advocacy groups are capable of engaging in critical dialogue with official experts. Counter-expertise in the case of rBST was not limited to those with formal scientific training. Counter-expertise also emerged from laypersons that cited references to scientific studies they had come across and compared their knowledge to that of experts.

Honourable senators, I am proud to be a dairy farmer. Ours is a family farm. Our son and daughter have recently taken over the farm. There is no way that a growth hormone will ever be used on our farm. Even if it is approved and declared to be "safe" it will never be used on our farm (Joyce Hutchings, Dairy Farmer and member of the National Farmers Union, Senate of Canada 1998d).

Scientific studies and consumer research over the past decade have confirmed the wisdom of our opposition to this product. The recent events and disclosures, stemming largely from the work of this committee, have further reinforced our position (Peter Dowling, Member of the National Farmers Union National Executive and a Dairy Farmer, Senate of Canada 1998d).

They are really trying to redefine what a healthy cow is. They are basically trying to convince all of us that as long as a cow is giving milk, it must be healthy. Farmers recognize what an unhealthy cow is. Monsanto has a very different image as to what a healthy cow is and they are redefining the approval process. They are redefining risk and manageable risk as opposed to safety. I think they are trying to redefine what a healthy cow is (Anthony Pollina, Senior Policy Advisor, Vermont Public Interest Research Group, Senate of Canada 1998g).

4.4.3 Public Participation

Post-normal science stresses increased public participation as not only necessary for achieving democratically accountable decisions but also for achieving quality decisions. Descriptions of a quality decision are resisted and/or neglected in the literature on post-normal science because quality is a highly variable concept among

people and its conceptualization is dependant upon social context and people's interests and values.

Health Canada's employees scarcely discussed public participation in the drug approval process and commented more on the transparency of the drug approval process. In contrast, management commented significantly more on both transparency and public participation. In the second last Senate meeting Steve Hindle, the President of the Professional Institute of the Public Service of Canada, which is the union of the gaps analysis team members stated that:

The Institute continues to be very supportive of what the scientists are doing in their professional life, and also very supportive of their efforts to ensure that there is adequate public debate about the management of science within Health Canada (Steve Hindle, President of the Professional Institute of the Public Service of Canada, Senate of Canada 1999c).

He described the work of the gaps analysis team members as not just a matter of disgruntled workers desperately seeking more autonomy and greater authority for themselves but seeking to expose to the public the corruption within Health Canada's management. This statement presupposes that employees within Health Canada have similar demands and values in regards to the drug approval process with the Canadian public.

Transparency, consultation and participation were three key terms in discussions around Health Canada's drug approval process and the department's communication with the Canadian public. Health Canada managers had several similarities and assumptions built into their descriptions of public involvement in regulatory decision-making.

One of the grave problems that has accumulated over time is that the whole process of the branch and this particular part of the branch has indeed been a bit of a black box. There is no really good public window looking in on how the

decisions are made and no opportunity for outside comment at the end of the process before a product is given approval for sale in Canada. This is a real problem. It is a problem that we face not just in Canada, but one faced around the world (David Dodge, Deputy Minister, Health Canada, Senate of Canada 1998d).

As far as dealing with these various stakeholders, I do not feel at all threatened by them being part of the process. The client is the Canadian public. It all stops with me, and that is the bottom line. If these stakeholders include the consumer groups, the advocacy groups, and the industry groups, that is all right. Let them come. They can discuss and lobby me. I am lobbied by dozens of these people a day. ... Their involvement does not necessarily mean that we are being unduly influenced by either side. The bottom line is that we are the backdrop for health and safety. That is the only reason we are there (Joseph Losos, Assistant Deputy Minister, Health Protection Branch, Senate of Canada 1999d).

Dryzek (1997: 75) describes the discourse of administrative rationalism as built on the premise that the public interest is a unitary concept in which the “discovery and application of the public interest is itself a technical procedure.” He also argues that administrative rationalism enlists and organizes scientific and technical experts into “the bureaucratic hierarchy of the state” (Dryzek 1997: 73). Administrative rationalist discourse emphasizes the role of the expert rather than the citizen. This model was altered in the Senate inquiry as citizens, farmers, Senators, and laypersons stated which experts they trusted and did not trust. They demanded a voice on which expert advice Health Canada ought to depend upon.

Senior officials at Health Canada overall emphasized the importance of international bodies such as Codex and JECFA as well as other countries, largely the United States, evaluations and approval status of rBST. The use of external panels, other country’s evaluations, and international experts are examples of extending the peer community by bringing in more expert opinions. This is a foundation of post-normal science. However, there was conflict over the department’s use of these bodies for several reasons such as the inability to apply the precautionary principle, sovereignty,

and independence of these organizations and other countries drug approval processes. This conflict is important because it highlights that if post-normal science is to produce democratically accountable and quality decisions, the background and composition of extended peer communities must be in line with the values and interests of Canadians.

Consequently, a challenge with post-normal science is that by bringing in more 'players' there is also the increased risk that there is an imbalance in terms of representing a diversity of perspectives, experiences, and interests. As well, the operations and decisions of these extended peer communities also pose challenges in terms of citizens accessing and engaging in dialogue with these expert bodies.

Post-normal science requires increased public and expert participation and considering extended facts. However, the pragmatics of doing so is potentially difficult both logistically and financially. As Senator Stratton stated to Mr. Dodge:

You said you were addressing the process by which you will handle these new biotech ideas that will be coming across your plate in the future in ever increasing numbers. The last thing we want, and I am sure the last thing you want, is an ongoing process where every time a new product goes for approval we have this kind of hearing. This is really not the way to go (Senator Stratton, Senate of Canada 1998d).

It is difficult to argue who from Health Canada is or is not a post-normalist. Dr. Chopra does bring in what can be defined as post-normal insights. However, one glaring instance emerges in his testimony that reinforces the dominance of scientific expertise in resolving regulatory issues. Dr. Chopra gave considerable testimony admonishing senior managers if their specific training and background is not in science.

Those are our concerns, people who are in the science and who are being told by people who are not scientists -- they are saying we have to move on post-thalidomide. We have to have new things, we have to make money, and those kinds of concerns. We just are unable to deal with it any more. Mr. Dodge and Dr. Lachance, in another department, also talk about the qualifications of the people in Health Canada who supervise us. They claim that the authorities who

are supervising us are also scientists. That is a patently false statement. There is not a single veterinarian in the department above us (Shiv Chopra, Bureau of Veterinary Drugs evaluator and gaps analysis team member, Senate of Canada 1999b).

4.5 National Identity, Government Duty, and Sovereignty

Throughout the Senate Proceedings emerged themes about national identity, the duty of government, and sovereignty. Shiv Chopra's testimony emphasized that Canadian standards are and should be better and not just the same as other countries. In comparing Canadian milk with U.S milk, he had this to say:

There are other differences. Canadian milk is of a higher quality, if I can be so nationalistic. There are standards that Agriculture Canada here and there are supposed to use. I believe their standard is 750,000 cells. If your milk contains more than 750,000 of these damaged cells in the milk, then that milk should be rejected. I believe in Canada it is 500,000 as the maximum limit, although our farmers try to bring it down to less than 150. These are the kinds of differences that do exist in the U.S. producing patterns and Canadian producing patterns (Shiv Chopra, Bureau of Veterinary Drugs evaluator and gaps analysis team member, Senate of Canada 1998b).

In several instances, Mr. Dodge and Mr. Losos pointed out that the problems identified in the Senate committee are global problems and they stressed that these problems are not unique to Canada.

There is no really good public window looking in on how the decisions are made and no opportunity for outside comment at the end of the process before a product is given approval for sale in Canada. This is a real problem. It is a problem that we face not just in Canada, but one faced around the world (David Dodge, Deputy Minister, Health Canada, Senate of Canada 1998d).

In the Senate proceedings we learn that there is a strong push for Health Canada to return to having complete control over the regulatory process. The reasons for this include the desire or necessity to have a central body to be held responsible if things go wrong (i.e. more risk and economic losses). More precisely, the public acceptance of extended peer community advice depends on having a government agency that is the

principle decision-maker and utilizes the advice of extended peer communities that are not affiliated with industry and utilize the precautionary approach. The credibility of expertise is shifting away from legitimating knowledge based on claims of objectivity but rather on their stake-holder alliances.

If Health Canada is to expand the pool from which technical evidence is selected, there are reasons emanating from the Senate inquiry that Canadians will demand that this government body cannot abdicate its responsibilities in this process of extending peer community participation. As well, the acceptance of extended peer community input is dependant upon public perceptions of credibility, value similarities, and competency. Transparency of this extended participation was also a concern for Senators, citizen interest groups, and Health Canada employees.

4.6 Conclusions

I did not attempt to find the answer as to how the rBST case should have been decided. However, I hope that I have demonstrated that in any instance a neat solution for all affected parties was highly unlikely given the strong opposing viewpoints, definitions, interests, values and stakes with rBST. Post-normal science is about achieving quality decisions. However, quality is in itself a problematic term because of the diverse and sometimes opposing meanings of what is a quality decision. As Ravetz and Funtowicz (1999 642) point out “...there is no monopoly of true interpretations of post-normal science; that would be contradictory to its message.”

The two ideas participants did agree upon is that health and safety is important and that science has a role in determining the health and safety of rBST. Participants however disagreed on what constitutes sound science, what authority should science

have in deciding rBST's approval, the place of socio-economic concerns in the decision-making process, and who should participate in the decision-making and in what capacity. The testimony of Health Canada managers was consistent with the dominant model of regulating risks and managing technology. This dominant model is premised upon the assumption that risks are measurable. Science is conveyed as the only means by which the truth about hazards can be discovered. Scientists must study risks objectively and separate their analysis from the social, economic, and political context surrounding technology. However, the Senate inquiry demonstrated that what is considered as scientific activity was subject to construction and negotiation by both scientists and laypersons. There were critical revisions as to what counts as scientific activity as the boundaries between the technical and safety, economics, and social issues were contested. It is in these boundary negotiations the possibility and necessity for a post-normal science emerged.

In the Senate hearings, the broader commitment of the federal government to promote technological innovation and in particular biotechnology was extensively discussed. Health Canada managers formed an alliance with industry representatives in terms of trying to establish that the regulatory protocol for rBST's approval or rejection must be efficient, standard-driven and a decision must be made with the "best available science."

In contrast, the Health Canada employees found support and an alliance with the dairy industry, most Senators, the citizen interest groups, Bill von Meyer, and John Verrall. This alliance utilized the symbolic power of milk as a nutritious, pure, and wholesome and the importance of milk to children's diet to advance their position. They argued that Canada's dairy industry and the food supply in general must be protected

from foreign control and unaccountable large corporations. This coalition, in particular the dairy farmers and the dairy processors challenged the assumptions of senior managers and Monsanto that the primary goal of dairy farming is economic efficiency.

Chapter Five: Conclusions

5.1 Introduction

The Senate inquiry was a difficult text to examine in terms of obtaining a balanced representation of witnesses and Senators because some witnesses testified more than others, and Senators asked different questions to different witnesses thus affecting the flow of topics discussed. Another short-coming of examining this text is that there were a relatively small number of participants, although the participants that did testify were from diverse backgrounds with different interests. Nonetheless, the Senate inquiry transcripts provided many insights into the controversies of rBST and the inadequacies of Canada's regulatory framework. The Senate inquiry gave way to an interesting and informative study on the troubles of science-based decision-making, and the strategies to improve and democratize the drug approval process.

I begin this chapter with a review of my findings and their implications. In this chapter, I also examine several developments that have taken place since the Senate inquiry and Health Canada's decision to issue a notice of noncompliance. The purpose of this chapter is to examine the legacy of rBST and how Health Canada has responded to the contents of the Senate inquiry. I give some concluding reflections on the areas of post-normal science that need further exploration and clarification.

5.2 Summary of Findings

Incidences of mastitis could ideally be measured and determined if there is an increase that correlates with rBST treatment. However, rBST and the concerns with mastitis was an issue loaded with technical disagreement. There was no consensus among scientists that rBST does or does not directly cause mastitis. Experts debated this seemingly scientific matter focusing on issues of the validity, reliability, and consistency of data.

In addition, in order to draw a conclusion required a value judgment on the capabilities and capacities of dairy farmers to control mastitis outbreaks. Those trying to dismiss mastitis as a concern with rBST argued that good management practices determine mastitis outbreaks. Dairy farmers were reluctant to be labeled as poor managers. Joyce Hutchings described her visit to a New York dairy farm that used rBST and she provided a vivid picture of the losses this farmer and his neighbour endured after treating their cows with rBST. These losses included financial losses due to fines and illness. The farmer that she visited almost lost his farm and his family. She also learned from this farmer that his neighbour's experience was far worse and he was too ashamed to talk about it. Dairy farmers argued that the health of their cows and their farming success includes pride and respect in their communities.

Antibiotic residue was the primary concern with mastitis for dairy farmers, Monsanto witnesses, the human health expert panel, and Health Canada managers perhaps because concern is not as severe, but much more manageable than antibiotic resistance. rBST is only one small contributor to the growing problem of antibiotic resistance. Participants were divided as to whether or not to reject this product, and whether or not this risk is serious enough that all measures must be taken to stop its

spread. Opponents to rBST's approval argued that in order to control this emerging health threat, collective responsibility is required. Health Canada management and Monsanto representatives however, did not see rBST's potential to increase antibiotic use as significant. They argued that even if there is an increase of mastitis with rBST approval it cannot be refused because rBST it is only one contributor to "potential" antibiotic resistance.

Dairy farmers and processors explicitly stated that consumer reactions to rBST milk are their primary concerns. Moreover, labeling was a related topic in which there were arguments both for and against labeling. While consumer choice was argued as a positive idea, and in some instances a consumer right, opponents to labeling typically argued that it is cost-ineffective because of the single pooling and processing system. Witnesses that explicitly expressed that they did not want rBST approved often supported labeling. This contradiction occurs perhaps because these witnesses, prior to a decision, felt they would lose and as a compromise they should at least fight for labeling of rBST milk.

Consumer acceptance and the possibility of labeling milk placed science in a difficult position because of the argument that consumer perceptions are just as important, and formed independently from the "facts" on rBST's safety. One strategy among opponents to rBST's approval was to argue that rBST's approval would cause significant financial losses because of negative consumer reactions. These participants used consumer reactions to their advantage by linking consumer perceptions of health and economics to advance their power. This discursive event was a strategy to resist the dominant economic forces of globalization by transforming the goal of agriculture away

from economic efficiency, as espoused by Monsanto and Health Canada managers, towards a way of life built on community, hard work, and pride in their product.

Labeling could be interpreted as a means to empower consumers by offering them choice. Labeling could be seen as a means to persuade consumers that a product is safe, especially if safety is endorsed by a well-known agency such as Health Canada. How product is labeled, and how much information will fit on a label, were important factors in this debate. As well, the different cost between milk labeled as rBST-derived milk v. non-rBST milk was a concern.

The political economy in which the state and actors are located needs to be acknowledged and critically examined if post-normal science is to develop and flourish. Post-normal science requires a willingness to reach mutual understanding. For example, proprietary information exists so that companies have a greater incentive to develop products and gain profits. In the Senate proceedings managers and industry argued that propriety protections must be in place. However, proprietary information comes at a cost for transparency and access to information for both the public and experts. Proprietary protections were defined by management as a necessity whereas critics of rBST argued proprietary information is a privilege accorded to industry that must be removed.

The powers and trade implications of Codex Alimentarius was a heated debate because it put to the forefront that Canadians have limited power and authority to decide which technologies they want, and to define the health and safety of technological risks. Codex Alimentarius also highlighted significant discrepancies between Health Canada management and the public, Senators, citizen interest groups, and Health Canada employees over the neutrality of this international standard setting and trade-meditating

agency. In an effort to gain legitimacy and power, the latter reconstructed the meaning of sound science as one embracing the precautionary principle.

My findings suggest that it is erroneous to assume that the public interest is a given and that health and safety are static concepts. In order for Health Canada to address the competing and multiple meanings of safety, and the public's interest, the involvement of a diversity of actors early in the drug approval process is needed.

In this thesis I uncovered several tenets of post-normal science to emerge throughout the course of the Senate committee. I have also argued in this thesis that ideology and power are two important factors that need to be examined in an effort to uncover resistance to post-normal science. More specifically, the power of authority of traditional science is struggling as laypersons and even scientists are questioning its claims of objectivity and value- neutrality. Not only did witnesses and Senators question these claims but they raised questions as to whether we should even be using science as a truth arbiter to settle the diverse interests, values and stakes associated with rBST.

According to Ravetz and Funtowicz (1999), post-normal dilemmas are not reducible to either science or politics. I extend this insight by arguing that the boundaries between science and politics, as well as economic and social conditions, were unavoidably blurred in the case of rBST.

Trust is a central theme running throughout the Senate inquiry. The Senate inquiry revealed that science is not just a tool to measure risks, but that science is a social process that builds public trust and confidence. I suggest that further exploration into trust between scientists, policy-makers and the public is crucial. In particular, this research reveals that public trust with extended peer communities involves issues of choice, control, a disassociation with industry, and values similarity like securing and

protecting consumer confidence and promoting the economic sustainability of Canada's dairy industry. To put this more concisely, confidence in technical assessments is only one component of trust

However, participants offered what Gramsci would call counter-hegemonies. Witnesses and Senators identified and critically analyzed the contradictions of industrial capitalism and science's authority and claims of objectivity, neutrality, and ability to discover the full range of risks of rBST.

5.3 Post-rBST

On 14 January 1999 Health Canada closed the rBST file by issuing a notice of noncompliance for Nutrilac. This decision was announced even though the Senate committee had not finished its inquiry. Health Canada closed the rBST file citing the scientific findings of the animal health panel for this decision. Despite that several witnesses expected Monsanto to resubmit Nutrilac for approval, Monsanto has not yet reapplied.

Much has happened since Health Canada issued a notice of noncompliance for Nutrilac. The BVD scientists swore an oath and sought protection from reprimands and threats to their job security. On 14 July 2004 Health Canada terminated these scientists without publicly stating their reasons. These scientists had been in several other high profile cases and their actions clashed with Health Canada (Canadian Broadcasting Corporation, 2004). Media accounts, as well as several citizen interest groups suspected that rBST was a major reason for the termination of these scientists. Support for these scientists after their termination continues. The Council of Canadians (2004) called for an independent and public investigation into why these individuals were terminated.

Similarly the Sierra Club of Canada is seeking legislation to protect “whistle-blowing” employees (2004).

Throughout the Senate inquiry the precautionary principle was extensively debated. Management did not explicitly state that they were against the precautionary principle, rather they stated that the precautionary principle must be implemented before they could use it on the rBST decision. As well, management frequently refused to acknowledge that rBST is different from therapeutic drugs up for approval. Whereas dairy representatives, farmers, Senators, Health Canada employees, and the citizen interest groups argued that rBST is different from therapeutic drugs and therefore extra precautionary measures must be taken. Those advocating a precautionary approach emphasized that proof of harm is not required, just doubt.

Since the Senate proceedings, the Government of Canada has issued the document A Framework for the Application of Precaution in Science-based Decision Making about Risk (2003) to Health Canada and several other government agencies. Upon reviewing this document, I found several differences between this document and my findings. This document defines the application of precaution as “the absence of full scientific certainty shall not be used as a reason for postponing decisions where there is a risk of serious or irreversible harm” (Government of Canada 2003: 2). While the lack of scientific certainty is compatible with the Senate inquiry, this definition is ambiguous because it is in the negative. More concisely, this definition does not say for what reason the absence of certainty could be used. The meaning and focus shifts if I were to translate this definition into the positive such as the absence of full scientific certainty shall be used as a reason for making a decision where there is a risk of serious or irreversible harm. This document advocates applying the precautionary principle

consistently. Managers and industry stressed the need for consistency in the drug approval process, while consistency was not an issue for those advocating the precautionary principle. A difficult challenge therefore is to develop a drug approval that consistently applies the precautionary principle. The process of doing so brings in values, interest, and beliefs to the forefront. This document, does acknowledge that public involvement is an important component for the application of the precautionary principle and this is consistent with my findings.

5.4 Suggestions for Achieving a Post-normal Decision-making Environment

Post-normal science is a potentially useful framework for government agencies to make complex and controversial decisions like whether or not to approve rBST. While the use of extended facts and extended expert and public participation are crucial for produce democratically accountable and precautionary decisions, post-normal science is underdeveloped in terms of its use in decision-making as well as academically the literature typically short and brief. Locating the political economy in which the regulators are situated is one such area in need of greater attention. My research examined that economic interests may prove more of a formidable challenge than post-normal science has currently acknowledged.

Leiss (2001) suggests that governments move away from science and let independent arm's-length panels take care of the science portion of health and safety. Leiss argues that arm's-length expert panels enhance the independence of science and allow governments to more effectively manage risks and make decisions. However, the way the public, Senators, and anti-rBST experts reacted towards the human and animal safety panels challenges the viability of Leiss's arguments. My findings indicate that the

public expects a strong and accountable agency that does in-house science. This resonates with Millstone and Van Zwanenberg's observation that "new kinds of risks emerging in food production chains actually demand greater rather than less reliance on the strong administrative accountability that can be found typical departmental lines of authority" (Doern and Reed 2001:371). As well, in the Senate inquiry both witnesses and Senators questioned the meaning of the independence of science. They argued that there is a shortage of scientists who have not at one point in time consulted with industry.

In conclusion, post-normal science is a useful concept for exploring alternative regulatory arrangements and how decisions can be enhanced both in terms of their democratic accountability and in the reduction of risks. However, there are nonetheless challenges to its realization in regulatory and policy circles. In the case of rBST, these challenges included the dominant belief that decisions must be based on science and that the science must disregard social, economic, and cultural variables. Furthermore, there were high economic stakes that diminished the willingness of actors to engage in dialogue and reach mutual understanding with each other that is required for a truly post-normal decision-making process. Despite these barriers to achieving a post-normal science regulatory framework, this research has demonstrated that both Health Canada scientists and laypersons worked together and challenged the meaning of science in order to accommodate the social and technical complexities surrounding rBST.

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