A Decade Of Regulating Agricultural Biotechnology Liability In Canada: A Case Study From 1994 - 2004

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Abstract

Innovation is the fundamental driver for the advancement of societies. The advent of the Industrial Revolution in the 17th century precipitated a dramatic increase in the rate of innovation. Societies of the time struggled in how to deal with the rapid changes that resulted from these innovations and their application. Present day society is no different.

Innovations in today's society have the ability to be widely adopted and the potential to affect far larger segments of the population that previous innovations. The rapid rise of genetic modification is one such innovation. This innovative technology has been widely adopted by the drug and agriculture industries and as a result, it has impacted all segments of Canadian society.

This thesis examines how Canadian society has dealt with the specific innovation of agricultural biotechnology, or the genetic modification of plants. The commercialization of genetically modified plants has resulted in regulatory challenges for the government, intellectual property and liability concerns for industry and consumer acceptance issues within the general public.

By researching the interaction and relationships between government regulators, private firms and consumer organizations, it is possible to identify how Canada has

reacted to the challenge of regulating agricultural biotechnology. The interdisciplinary framework necessary to accomplish this requires conceptual contributions from economics, political science and sociology.

In the development of the innovation, or innovative product, the regulatory approval process requires a risk analysis for all new plant varieties. This risk analysis process is comprised of risk assessment, risk management and risk communication. This thesis argues that risk and the application of risk analysis is appropriate for pre-commercialization, but once the innovative product is in the marketplace, any failure regarding this product can be viewed as a potential liability.

The management of and communication about liabilities differs from that of risk management and communication. The key theme of this research is to examine how regulators in Canada have attempted to regulate post-commercialization liabilities and to identify what governance structures or institutions are essential for the regulation of post-commercialization liabilities.

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Dedication

I would like to thank my wife, Lanette, for her support and understanding throughout the whole process of this degree.

I would like to thank my Grade 4 teacher Mrs. Rey. Thank you for teaching me that learning was fun and enjoyable, a gift that will last a lifetime.

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List of Acronyms

APHIS	Animal and Plant Health Inspection Service
BIO	Biotechnology Industry Organization
B. napus	*Brassica napus*
B. rapa	*Brassica rapa*
Bt	*Bacillus thuringiensis*
CBAC	Canadian Biotechnology Advisory Committee
CIHR	Canadian Institutes of Health Research
CCC	Canola Council of Canada
CEC	Commission for Environmental Co-operation
CEO	Chief Executive Officer
CFIA	Canadian Food Inspection Agency
Codex	Codex Alimentarius Commission
EPA	Environmental Protection Agency
EU	European Union
FDA	Food and Drug Administration
GM	Genetically Modified
GURTs	Genetic Use Restriction Technologies
HACCP	Hazard Analysis Critical Control Points
HT	Herbicide Tolerant
IPPM	Identity Preserved Production and Marketing
IPRs	Intellectual Property Rights
ISO	International Standards Organization
NAFTA	North American Free Trade Agreement
NGOs	Non-governmental Organizations
NIH	National Institutes of Health
PMPs	Plant Made Pharmaceuticals
PNTs	Plants with Novel Traits
rBST	Recombinant Bovine Somatotrophin
rDNA	Recombinant Deoxyribonucleic Acid
R&D	Research and Development
SWP	Saskatchewan Wheat Pool
TUA	Technology Use Agreement
UGG	United Grain Growers
UK	United Kingdom
USDA	United States Department of Agriculture

Chapter One

Innovation and Agriculture

1.1 Introduction

Innovation is the key driver behind social advancement and change. While it brings beneficial new products and processes to societies, it also can trigger a level of fear and uncertainty. Over time, individual countries and cultures have found a myriad of ways of dealing with the commercialization of new technologies. Commonly, the social acceptance of innovative products that possessed a level of public uncertainty have been managed through the development and implementation of effective regulations. Social trust in government has acted as a facilitating mechanism for the successful commercialization of some innovations and innovative products that are commonplace in today's society.

This thesis argues that the difference between risk and liability is that risk deals with hypothetical possibilities prior to commercialization and liability deals with marketplace externalities in the post-commercialization period. Public policy literature related to the application of liability is very limited and the objective of this research is to review the risk literature and discuss how it can be modified and applied to examine issues of liability resulting from the innovation of agricultural biotechnology.

Legally, a liability results when an obligation is not fulfilled. From this legal perspective, there are only two kinds of liability—criminal and civil. Criminal liability occurs when there has been a criminal act committed, i.e. where someone breaks the law of the land. Civil liability arises when an obligation has not been met by a party and can result in litigation for compensation on behalf of those affected. The application of liability within the context of this research examines how liabilities have been managed and addressed in the post-commercialization period for products resulting from biotechnology.

Before it is possible to discuss the application of liability to agricultural biotechnology, it is important to understand how science has advanced to the point of being able to deliver commercialized products from this innovation. Genomics research is quite recent and new applications of this innovative process are continually being discovered.

It can be claimed that innovation in agriculture has been going on since mankind first domesticated wild plants species. Regardless of when innovation was first applied to plants, mankind has played an important role in the dispersion of some plant varieties around the world (i.e. maize) and has manipulated many plant species to produce greater yields. In North America, for example, most of the plants that are staples in our daily diets have been introduced to this continent from other parts of the world or been enhanced over time to provide greater yields. In short, plant

genetics is a very important area of innovation for commercial agriculture in the modern age.

The birth of modern genetics took place over 50 years ago with the discovery of the double helix in deoxyribonucleic acid (DNA) by Watson and Crick in 1953. This was a substantial news story and received considerable press coverage. As with many discoveries, the vast future potential of the double helix was, to a large degree, grossly under-estimated. The research in this new field continued for the next two decades with minimal public awareness. Thirty years ago, in a California laboratory, the next major innovation in this field of genetics occurred. The extraction and insertion of genes within the genetic code of an organism was accomplished for the first time and the technology known as recombinant DNA (rDNA) was born.

This time the research community had a greater level of understanding about future applications of the technology and a heightened level of concern existed among researchers. There was so much concern that a voluntary research moratorium was enacted by world scientists in 1975 to enable more to be learned about the technology of gene splicing, including the safety of those working in the laboratories. Protecting confidential information was not of prime concern—this process was very transparent, including representatives from the media, scientific magazines and the US federal government. While the issue received press coverage in scientific magazines, it was not viewed by the popular press as a major newsworthy event. Events in society forced scientific stories to the margins of the

popular press—change was happening quickly in many sectors of society and the end result was the marginalization of science.

Research involving genetically engineered viruses and bacteria continued through the 1970s and, by the end of that decade, researchers were beginning to search for ways to apply this technology to plants. Conducting genetic engineering research with plants was more time consuming than working with viruses and bacteria because the genetic code of plants was more complex. The first genetic modification of a plant occurred in 1983, and the research continued rapidly, so that by the end of the decade field trials were already underway with new crop varieties. Following several years of crop trials, a number of these new genetically modified (GM) plants were commercialized in the early and mid 1990s.

The first commercial planting of a GM crop occurred in China in 1992 (James and Krattiger, 1996). This initial planting involved 100 acres of transgenic tobacco and was done for the purpose of seed multiplication. The first commercial acreage of a GM crop for food purposes occurred in 1994—this was in the US by Calgene, with their transgenic, delayed-ripening tomato. The variety, known commercially as FlavrSavr™, was initially produced on an estimated 10,000 acres. In 1995, other crop types were introduced, including cotton, canola, potatoes and maize. James (2003) estimates that in 2003, GM crops were grown on 167 million acres in 18 different countries.

The number of crop kinds that have been genetically modified continues to grow as an increasing number of transgenic fruits, vegetables, spices and flowers are being granted regulatory approval. Many of the new transgenic crop varieties are facing increasingly rigid regulatory standards prior to receiving variety approval. Many of these new regulations attempt to provide a clearer perspective of the risk related to the commercialization of the prospective new transgenic crop variety.

Biotechnology has accelerated the rate of development of new crop varieties. In the past three years an average of 30 new GM varieties have been introduced annually. The rapid adoption of GM varieties and the subsequent diffusion by the seed industry into a wide range of stacked input traits and differentiated novel output traits have fundamentally altered the marketing system for these new plant varieties. Input trait varieties are those that improve the agronomics of the crop, such as through herbicide tolerance, while output trait varieties offer attributes that generate down-stream market value, such as low cholesterol cooking oil.

While the front end of the supply chain (seed development firms and producers) has not viewed the application of biotechnology as a fundamental shift in agricultural practices, the consuming public has. The reasons for this reluctance to accept the products of the innovation of biotechnology are varied and frequently difficult to quantify. Nevertheless, the innovative process is continuing in Canada at a rapid pace and new products and processes are continually being commercialized.

To date, both industry and regulators have managed the risks of commercializing these innovations. The risk evaluation systems operating in most developed (OECD – Organisation for Economic Co-operation and Development) countries are generally scientifically-based processes that combine the identification and characterisation of hazards with assessments of exposure to characterise risk. In essence, they purport to objectively assess the probabilistic outcomes of discrete adverse events, for the most part abstracting from issues related to risk management or risk communications. The practice is that governments establish a risk threshold for products or classes of products that would reject new products with unacceptable risks but would allow those with acceptable impacts to enter the market. The very recent application of liability pertaining to biotechnology may be a substantial challenge that will require considerable time and capital to address satisfactorily.

Risks related to the commercialization of genetically modified crops have been identified by both the private firms involved in the commercialization process and the Canadian regulatory agencies. The Canadian regulatory agency responsible for approving the commercial release of GM plants deemed all GM plant varieties to be plants with novel traits, thereby, subjecting the GM plant applications to additional environmental, allergenicity and toxicity testing. The firms involved in commercializing the initial varieties of GM plants in Canada worked with the regulatory agency to facilitate the development of these additional regulations.

Ultimately, the risk assessment system ought to be designed to make the right decisions; that is accepting safe products and rejecting unsafe products. As with any human system, there is potential for error, especially when a new class of products is being considered where there is no empirical evidence. While the system is and should be designed to avoid making Type 1 errors, i.e. accepting something that is not safe, it has to be mindful of the trap of making Type 2 errors, i.e. rejecting safe products and activities. While we can tally up the cost of Type 1 errors in lost lives or damaged ecosystems, we cannot convincingly estimate the cost of foregone opportunities and all of the attendant benefits that could flow from them. The difficulty is that social amplification of risk significantly raises the potential of making a Type 2 error, thereby diminishing the flow of new and innovative products and progress in a science-based economy.

The application of post-commercialization liability to agriculture is relatively new. Historically, agriculture production was either consumed domestically or exported internationally with little fanfare. In today's marketplace, the production of GM food products has created numerous challenges for both domestic consumption and international exporting. One of the results of this is that on-farm actions have the potential to disrupt established trade patterns. The research for this thesis examines how the agricultural biotechnology industry has worked to ensure that post-commercialization liabilities have been minimized.

1.2 Background

The maturity of an innovation reflects the social comfort of any corresponding liability. Over time, societies accept the potential liabilities of innovations as the comfort level related to the use of the innovation or the innovative product becomes part of the mainstream of the society. Substantial innovations such as those that can be called transformative technologies (i.e. computers) have a major impact on the societies into which they are commercialized and acceptance of the transformative technology is not an instantaneous reaction. Rather, marketplace failures have to be prevented to allow society to appreciate the fact that the transformative technology is one that is beneficial and safe.

The innovation of commercialized transgenic plants is less than a decade old and as a result, society has not defined its comfort zone for liabilities that are arising and that may arise in the future. Many argue that the present array of transgenic innovations is but the trickle prior to the deluge that is coming (James, 2003, CBAC, 2003). If this anticipated deluge of transgenic plant innovations is to have any commercial potential, the present liabilities (both real and hypothetical) will have to be satisfactorily addressed by all transgenic stakeholders.

The application of liability is evolving, especially as it pertains to agriculture. Historically, lawsuits in crop agriculture have been mostly about production externalities, such as aerial spraying. Occasionally, an aerial application of a chemical would be too close to a neighbouring farmer's land and it would drift onto a crop belonging to another farmer. Depending on the crop, the damage could be

substantial. In some instances, the farmer whose crop was adversely affected sued the commercial sprayer of the chemical for damages suffered. Another commonly cited example is the situation where a scrub bull escapes an enclosure and indiscriminately impregnates a neighbour's pure-bred cattle.[1] The relationship between liability and its application to agriculture is explained in greater detail in Chapter Three.

Innovations in agricultural biotechnology over the past decade have fundamentally changed the way that risks from this technology are analyzed and how the resulting liabilities are managed. In the early 1990s, transgenic plants were identified by Agriculture and Agri-Food Canada (in its role as forerunner to the Canadian Food Inspection Agency) as possessing a unique genotype when compared to conventional plant varieties and therefore, were classified as plants with novel traits. These plant varieties were subjected to additional risk reviews and assessments prior to the granting of variety approval. These additional regulations ultimately delivered decisions that worked from the basis that transgenic varieties were substantially equivalent to conventional varieties, and therefore variety approval was given to the new transgenic varieties. However, the science-based risk assessment methods that were used to approve the commercialization of the new plant varieties have not provided the reassurance to a seemingly nervous consuming public about the long-term safety of consuming these GM food products.

[1] For a detailed analysis of how tort law relating to stray animals can be applied to patent rights of transgenic plants, see Kershen, 2004.

Canada is not alone regarding the application of liability to agricultural biotechnology. Other countries with greater levels of consumer concern have begun to address this issue and have either implemented or suggested new actions that need to be taken to resolve how liabilities from agricultural biotechnology will be addressed.

The 2001 New Zealand Royal Commission, that examined the issue of genetic modification as it applied to that country, included a chapter on liability, opening the discussion with the following questions: “Who is, or is not, liable for damage caused by genetic modification? Who should be? To what extent?” (p. 311). This is a very strong statement in that one could perceive that it presupposes that damages from genetic modification are a forgone conclusion. However, the Royal Commission ultimately rejected a special liability regime for transgenic crops, believing instead that any liabilities (should they arise) could be adequately addressed through present legal regimes (i.e. existing tort laws). Ultimately, the Royal Commission, after thorough review of this subject, believed that any potential liabilities from transgenic crops do not differ in nature from existing technologies.

Similarly, the United Kingdom (UK) Agriculture and Environment Biotechnology Commission (2003) recently released a report on co-existence and liability relating to the production of genetically modified (GM) crops in the UK and recommended to the UK government that the UK Environmental Protection Act of 1990 be

amended to provide financial compensation to those harmed by the commercial release of GM crops, "… irrespective of criminal liability." (p. 11)

Meanwhile, the Danish government has proposed a strategy for co-existence of organic and GM crop production, where the onus of responsibility is placed on the producers that adopt GM crop technology (Danish Ministry for Food, Agriculture and Fisheries, 2003). The Danish Minister for Food, Agriculture and Fisheries, was quoted as saying "… it is crucial that the GM farmer shoulders the burden" for ensuring segregation of GM crops. This burden to accept liability from co-mingling of GM crops would be expected to negatively impact the adoption rate of GM crops in Denmark.

The genetic modification of crops has changed the nature of the liability debate and the application of the term. The commercial release of transgenic crops has created a split within large-scale commercial agriculture, not only between countries, but within countries as well. Internationally, there has been a split between European Union (EU) countries and North America (the US and Canada). The EU views transgenic crops as a threat that presents unacceptable liability and will not allow domestic production of transgenic crops for large-scale food consumption, or the importing of many transgenic raw materials or processed food products. North America has approved the commercial release and encouraged wide spread adoption of a variety of transgenic food crops, which, by some estimates, are incorporated into nearly 70% of all processed foods.

These splits within agriculture at both the international and domestic levels give rise to potential liabilities from agricultural innovations. International trade could potentially be damaged should a commodity export be tested and found to contain unacceptable levels for transgenic varieties. Domestic production of quality assured differentiated products (e.g. GM-free and organic) could also be potentially affected by the wide-spread adoption of transgenic crop varieties. Ultimately, one overriding issue is beginning to emerge: is there a liability if a sales market is damaged by co-mingling of genetically modified seeds and, if so, who is liable?

As other countries proceed with legislation regarding liabilities from GM crops, Canada has not been immune from this issue. The Saskatchewan Organic Directorate is seeking legal remedy from Monsanto and Aventis (now Bayer CropScience) for allegedly destroying the ability of Saskatchewan organic farmers to export organic canola due to the commercialization of the two companies GM canola varieties. This case is presently before the court and is the first legal case where producers are suing the developers of innovative crop technologies for potential market losses.

The relationship between liability and agricultural biotechnology will become increasingly important for Canada in 2005, when consideration of liability and redress regarding the transboundary movement of living modified organisms commence under the Biosafety Protocol. There is the concern that this process will be used to erect barriers to the transfer of technology research and development

between developed and developing countries. Canadian participation in this discussion has so far focused on ensuring that the process is an open, inclusive and science-based approach. Canadian delegates to the Biosafety Protocol have acted to ensure that any liability rules or regimes that are proposed are based on realistic probabilities rather than theoretical concerns.

If a rigid liability regime is adopted, either within Canada or internationally, such that liabilities for marketplace externalities are placed upon the innovating firm, then there is the potential for a reduction of research and development, which will lead to fewer innovative products being commercialized. The research for this thesis examines liabilities that have arisen to date in Canada and examines how they have been effectively addressed through existing and evolving mechanisms.

1.3 Research Agenda

Agriculture biotechnology is a transformative technology that has brought considerable change to the way food is produced. Using an institutional/governance approach, the research undertaken for this thesis examines the question of how the regulation of agriculture biotechnology has developed within Canada. The conceptual construct that is developed for this research identifies the major stakeholders and their roles within the agricultural biotechnology system. This conceptual construct is then applied to a variety of actual occurrences within the development of agriculture biotechnology to demonstrate the strengths and weaknesses of different institutions in the regulation of biotechnology.

The research focus of this thesis is to assess the regulation of innovation, specifically the regulation of agricultural biotechnology. Innovation naturally brings change, and change can often instill worry or uncertainty in societies. While innovation produces new products or opportunities to use old products in new applications, it can also produce liabilities. The management of liabilities resulting from innovation is crucial to both the rates of adoption of the innovation and society's acceptance of the innovation.

Historically, many innovations have involved inanimate objects. Innovations in construction, electronics and transportation all provide classic examples. Innovations in these fields created social upheavals in the societies of the time. Technological advances have fostered innovations involving animate objects, such as plants that are consumed as a regular part of our daily diets. Historically, conventional cross breeding of plants was structured to select for traits normally found within the same species. Recent innovations have resulted in transgenic plant varieties where plants contain genes inserted from other plants, animals or microbes.

Regulatory failures or delays increase the likelihood that commercialization will be delayed, creating the potential for negative economic circumstances. Heller (1995) has estimated that a one-year delay in commercializing an innovation reduces the rate of return on investment for the new product by 2.8%, while a two-year delay results in a reduction of 5.2%. Delays can also affect social outcomes. For example, a recent American study of plant biotechnology by Gianessi, *et al*., (2002) found that

current transgenic plants increased yields by four billion pounds annually and reduced pesticide use by 46 million pounds annually. The combined value of these effects was estimated to be US$1.5 billion. Delays in commercialization of transgenic plants would reduce the benefits of higher yields for producers and increase the application of pesticides into the environment. This has the potential to create the scenario where producers are economically worse off and, arguably, those sensitive to pesticides could also be deemed to be worse off.

When a transformative technology affects the market place, the public relies on the government to regulate the changes. Governments have three options when it comes to managing innovation. First, federal regulators can work from existing regulations and make changes and revisions to the existing regulations to try and ensure that no regulatory gaps exist. In terms of time and cost, this method can be extremely efficient. Second, regulators can begin the process of regulating the innovation from scratch, beginning with no regulations and working with industry to develop an entirely new regulatory framework. This method takes more time and money than the first option. The third option available to government is to do nothing, let the industry develop standards for the innovation and only move to regulate if public opinion or market failure dictates the need for government involvement.

Industry can develop industry specific quality assurance standards or codes of practice to ensure the constant delivery of high quality products to the marketplace. Industry standards require a delicate balance. If standards are overly rigorous, they

can act as barriers to entry for new firms, thus preserving the marketplace for larger firms. On the other hand, if industry standards are not rigorous enough, the quality of the product in the marketplace declines and consumers may switch to alternative products, resulting in large losses to the industry.

The role of society in developing regulations for innovation is perhaps the most difficult to identify as representation in society can be very fragmented. The opportunity for society to participate can also be diverse, ranging from participation in Royal Commission hearings to writing letters to local newspapers. The challenge of a science-based regulatory process is that there is no official capacity for the inclusion of comments or concerns from the consuming public. A variety of attempts have been undertaken to incorporate the public's opinion, but few have provided satisfactory results.

This thesis will argue that when an innovative technology enters the marketplace and is not successfully adopted, this is a marketplace failure. This differs from when a company launches a new product that is rejected due to a flaw in the marketing plan, this is a complete inability of the regulators, the industry and society to grasp the potential of the innovation and to co-operate, thereby facilitating the adoption of the innovation.

The research for this thesis has examined the dynamics of the interaction between regulators, industry and society, or what can be identified as the three key stakeholders in the management of innovation.

1.4 Objective of the Study

The objective of this thesis is to examine the dynamics between government regulatory bodies, industry firms and civil society groups pertaining to the innovation of agricultural biotechnology. This objective will be achieved through analysis of the following crucial aspects of institutional governance:

- An analysis of regulatory overlaps that exist between regulatory agencies, private firms and civil society actors, by focusing on institutional governance responses to agricultural biotechnology;

- Identifying gaps within the regulatory framework for agriculture biotechnology, examining the stakeholder responses to these gaps and assessing the success of the response mechanism; and

- Examining the liabilities that have resulted from the above regulatory gaps with a focus on how the liabilities were managed and what the costs, both financial and social, has been to the agricultural biotechnology industry and society in general.

These objectives will be achieved by the use of four articles that have been published in peer review journals. These articles examine different aspects of the dynamics between regulators, private firms and civil society.

The first article examines the dynamics between Canadian regulators and two seed development firms that commercialized the first GM varieties of canola in Canada. This article was published in 2001 in the journal *International Food and Agribusiness Management Review* (Smyth and Phillips, 2001). This article examines the use of identity preserved production and marketing systems for the production of GM canola.

The second article explores the relationship between Canadian regulators and civil society as it pertains to the role of regulators regarding food safety. This article is a combination of two publications. The front end of this article was published in 2002 in the journal *AgBioForum* (Smyth and Phillips, 2002). This portion of the article offers working definitions and a practical taxonomy for the terms identity preservation, segregation and traceability. The remainder of the article was published in 2003 in the journal *Trends in Biotechnology* (Smyth and Phillips, 2003). This section of the article discusses how the increased demand for product differentiation is placing new constraints on the supply chain. It concludes with an assessment that reflects the need for mandatory labeling.

The third article focuses on the interactions between private firms and the larger society. This article was published in 2002 in the journal *Nature Biotechnology* (Smyth, *et al*., 2002). This article addresses how public concerns regarding cross-pollination of GM varieties with conventional varieties could jeopardize the commercialization of future genetically modified crop varieties.

The fourth article provides an examination of the dynamics that exist between regulators, industry and civil society regarding the emerging innovation of plant-made pharmaceuticals. This article was published late in 2004 in the journal *Biotechnology and Genetic Engineering Reviews* (Smyth, *et al*., 2004). The article presents the scale and scope of plant made pharmaceuticals and examines the role of institutional governance within this context.

These four articles highlight the Canadian regulatory response to potential liabilities in agricultural biotechnology. The justification for undertaking such a narrow regulatory analysis is largely due to the fact that large-scale commercial production of GM crops occurs only in Argentina, Canada and the United States. The research for this thesis examines the complete, post-commercialization supply chain and how it relates to liability. This is not possible in Europe due to the moratorium that was enacted in 1998. The only commercial production of GM crops occurring in Europe is for animal feed varieties approved pre-1998 and is contained to Spain and Romania. Simply put, the commercial production of GM crops in Europe has not reached the point where a marketplace liability assessment would be possible.

1.5 Conceptual Constructs

To properly analyze the process of regulating transformative technology change, this thesis uses a framework that focuses on the interactions among the three identified stakeholders. This framework has been carefully developed following a thorough examination of related discipline-specific models from the academic disciplines of economics, political science and sociology. This framework has been structured to highlight areas of regulatory overlap and to identify where regulatory gaps have occurred. The framework focuses on identifying what governance strategies have been adopted by the various stakeholders within agricultural biotechnology and how these stakeholders have managed the liabilities that have resulted over the first decade of commercialized transgenic crop production.

The framework used in this thesis is designed to identify the drivers for the governance strategies and to evaluate the success of these governance strategies in the management of liabilities. Some of the governance strategies adopted for the use of agricultural biotechnology have been very successful at managing liabilities, while other strategies have been ineffective in managing liabilities, which has resulted in costly class action activities.

1.6 Organization of the Research

Chapter 2 provides a review of the existing literature as it relates to this study and summarizes how the most important theories relate to this thesis. The chapter reviews the theoretical contributions regarding institutional approaches to innovation

from the disciplines of economics, political science and sociology. The chapter provides working definitions of institution and risk. The literature reviewed in this chapter is largely neo-institutional and focuses on how innovation theory and models that have been developed to illustrate how innovation relates to governance. One of the objectives of this literature review is to identify formal and informal organizational structures that exist within institutional frameworks.

Chapter 3 presents the framework that is used in the subsequent chapters. The framework identifies the major stakeholders and highlights where regulatory overlaps and gaps have existed within the regulation of agricultural biotechnology. The framework is explained in detail and the importance of institutional actors and their role in relation to governance are highlighted within this discussion. The framework shows how each chapter relates to a specific overlap.

Chapter 4 focuses on the regulatory gap that existed between the canola industry and the federal regulators in Canada at the time of the initial commercialization of GM canola and the challenges that resulted from this gap. When the Canadian Food Inspection Agency (CFIA) approves a new crop variety, there is no consideration given to, or avenue to allow for an analysis of, the impact on present export markets. When GM canola was commercialized, the canola industry faced foreign market concerns and was forced to address the issue of containment to reassure the foreign markets that Canada could and would ensure shipments of GM-free canola. This

chapter examines the non-governmental organization/industry governance mechanisms used to contain GM canola.

Chapter 5 provides a discussion on product differentiation and the effects on consumer labeling. This chapter addresses the overlap between federal regulators and Canadian society. There are a variety of terminologies used to describe product differentiation and this chapter identifies the three options and provides definitions of their use. Following this is an analysis of the non-governmental organization/ regulatory governance structures at the various stages of the supply chain for each system in the marketplace. This analysis is followed by a review of consumer labeling demands and willingness to pay. This section of the chapter compares recent studies on what consumers are demanding when it comes to labeling GM food products with studies on what consumers are willing to pay for information about GM labeling.

Chapter 6 focuses on those transgenic crop liabilities that exist between firms in the industry and society at large. When new technologies are commercialized, regardless of how effective the regulations are, some individuals will deliberately or inadvertently, misappropriate the technology, thus diluting the benefits and creating the potential for liabilities. This chapter identifies where liabilities have developed from the use of GM crops and examines the industry/regulatory governance structures that have developed to manage these liabilities.

Chapter 7 offers an analysis of the challenges of regulating the liabilities from plant made pharmaceuticals. The previous three chapters analyzed the overlaps between the principal stakeholders in situations where there is involvement primarily from two stakeholders. This chapter examines the area of overlap at the center of the framework, where the interests and concerns of all three stakeholders overlap. The prior chapters discussed what regulations were needed and what gaps existed with an existing innovation and Chapter 7 discusses which issues will be important when dealing with a radically new innovative technology. This chapter identifies those gaps that presently exist and discusses how these gaps will need to be addressed by regulation to ensure that the management of liabilities is maintained.

Chapter 8 offers concluding comments on the topic of regulation of liabilities. The first section discusses how the various academic disciplines have grappled with the issue of modeling transformative technologies. The second section presents the strengths and weaknesses of the methodology used in the course of the research. The third section provides a summary of the previous four chapters and presents the major conclusions from the thesis. The fourth section presents some of the limitations of this thesis. The fifth section presents some observations about research extensions that could arise from this thesis.

Chapter 2

Theory and Literature Review

2.1 Introduction

This chapter focuses on the existing theory and literature from the academic disciplines of economics, political science and sociology. Working from an interdisciplinary approach, these academic disciplines each contribute a unique perspective regarding the regulation of innovation. However, none of these disciplines by themselves offer a thorough structure for understanding the broader issue of the impacts that a transformative innovation can have on an entire society. The intent of this chapter is to present and assess the theory and literature from the various academic disciplines and to highlight the strengths and weaknesses of the various structures.

The disciplines of economics, political science and sociology are long-standing disciplines and enjoy rich fields of theory and literature. The challenge of working in research disciplines with an abundance of theories and typologies is to conduct a review that is thorough enough and that ultimately selects theories and typologies that are directly relevant for an examination of the research topic. The use of an institutional/governance research approach provides one potential approach for examining the issue of regulating innovation.

As was identified in Chapter 1, risk deals with pre-commercialization hypothetical issues and liability with post-commercialization challenges. To date, all of the literature on liability comes from the work of legal academics, and while this is important literature, it does not address the issue of how to regulate innovation. The application on the inclusion of liability is addressed in further detail in Chapter 3.

The literature that has been reviewed for this thesis comes from the broad fields of institutional analysis, institutional governance and risk. These topics have an abundance of literature and it is therefore possible to analyze this literature and apply it to the topic of this thesis. The literature that is reviewed in this section examines how the disciplines view institutions and risk.

Table 2.1 helps to demonstrate how the numerous theories, discipline specific typologies and literature references are accommodated in this literature review. It provides discipline specific definitions for institutions and risk. The importance of institutions for this research can best be summarized by North (1990), when he states that "[i]nstitutions are the rules of the game in a society or, more formally, are the humanly devised constraints that shape human interaction. In consequence they structure incentives in human exchange, whether political, social or economic." (p.3) The economic interpretation of institution is one that was developed from the theory relating to transaction cost analysis. From this perspective, an institution is the mechanism that allows a transaction to occur or that facilitates a transaction. The economic definition of risk is taken from the literature related to insurance and more

specifically, how to price insurance to address risk variances. Within the literature, there is a research focus on gambling and the definition of risk is where the probability that the outcome or output of an event (such as the chance of winning from gambling) is lower than the expected value of the same event (the actual winnings).

Table 2.1: Interdisciplinary comparison of definitions for institution and risk

Discipline	Definition of Institution	Definition of Risk
Economics	Williamson: Institutions are the broad framework of markets, hierarchies and hybrids through which a transaction is channeled.	Varian: The probability that the output of an event is lower than the expected value of the same event.
Political Science	Atkinson: Institutions are mechanisms, bundles of rules, through which choices are made and conflicts resolved.	Stanbury: Adverse effects for citizens resulting from inappropriate government actions.
Sociology	Gibbons: Cultural practices that have the greatest impact on society over time and space can be referred to as institutions.	Sandman: Risk is a function of the level of hazard from exposure to a toxin multiplied by the level of public outrage.
Sources: Williamson, 1993; Varian, 1992; Atkinson, 1993; Stanbury, 2000; Gibbons, 1994; and Sandman, 1994.		

The political science definition of institution focuses not on market transactions as economics does, but on the rules and mechanisms that allow choices to be made. Institutions may not necessarily be formally defined or identified, but can also be the informal operating structures. The political science definition of risk is the adverse effects upon populations from inadequate or inappropriate government actions. This means that people within a particular society can be negatively affected as a result of government actions that do not properly address the severity of a situation or event.

Within the realm of sociology, an institution is identified as those cultural events or practices that work to shape or impact a given society (Gibbons, 1994). Unlike the marketplace transactions or the governance structures, this definition focuses on the composition of the society and institutions are those events that, over time, help to define that particular society. The sociological definition of risk is derived from the scientific definition. In science, risk is a function of hazard multiplied by the time of exposure, which allowed scientists to determine the level of risk from working with specific substances. Sociology has more broadly defined risk as a function of hazard multiplied by socially constructed views of exposure or what Sandman calls outrage. In this definition of risk, outrage is a measure of society's concern that an event has occurred.

This table highlights how varied the definitions of these two terms are across the academic disciplines that relate to this research. The economic definitions relate to how transactions are handled and the expected outcome. The political science definitions address how government choices affect citizens. The definitions from sociology focus on how society is heavily involved in defining both terms.

2.2 Institutional Literature

Williamson (1979) drawing on Coase's (1937) theory, developed the analytical framework for transaction cost analysis, stating that the classical "… economic institutions of capitalism are explained by reference to class interests, technology, and/or monopoly power—the transaction cost approach maintains that these

institutions have the main purpose and effect of economizing on transaction costs" (1985, p.1). By economizing, Williamson means that any inefficiencies associated with a transaction are removed, or at least reduced. Williamson (1993) goes on to say that "… transaction cost economics approach to the study of institutions is predominantly concerned with the governance of contractual relations. Governance may be defined as the institutional framework – broadly consisting of markets, hierarchies and hybrids – through which a transaction is channeled" (p.16). This definition of institutions provided by Williamson is widely recognized as a starting point that numerous other researchers have used for their own research on institutional economics.

North (1990) addresses technical and institutional change and attempts to understand the commonalties and differences between the two. North believes that institutional changes are the more complex of the two due to the multifaceted interrelationships that exist with both formal and informal constraints. North observes that a key point is that stakeholders have varying degrees of vested interests in institutional change and will try to influence institutional changes towards their favour.

Picciotto (1995) examines the essential institutional fundamentals required for successful Third World development projects from the perspective of projects undertaken by the World Bank. Picciotto uses examples of Third World development projects to describe what institutional structure and level of operation is required to ensure that resources devoted to projects are utilized in the most

economical manner possible. Specifically, he focuses on the public, private and voluntary sectors and the interaction among these sectors (Figure 2.1). This institutional methodology attempts to provide insights into how these three stakeholders need to come together to foster successful development projects.

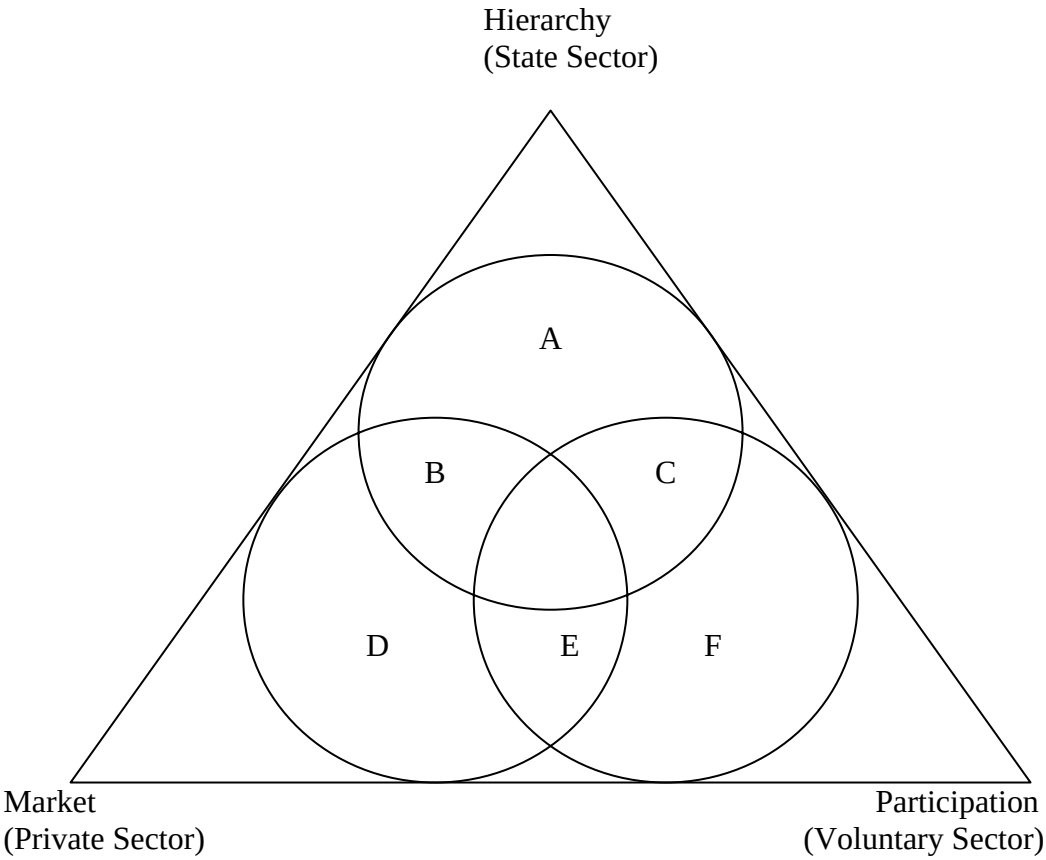
Picciotto discusses how each sector represents different individuals, involves different incentives and is effective in producing goods or attributes with specific characteristics. The government sector produces public goods (A) (e.g. public health and safety), usually characterized by low excludability,[2] low rivalry[3] and low voice,[4] that are involuntarily consumed by all citizens equally. Conversely, the private sector provides market goods (D) (e.g. brands and product specific warranties), that exhibit high excludability, high rivalry and low voice, and are consumed voluntarily by individuals. In contrast, the participation sector specializes in common pool goods (F) (e.g. standards that go beyond regulations but include more than one firm), with low excludability, from low to high rivalry and high voice (e.g. co-ordination).

While discussing the government, private and common pool goods, Picciotto focuses on the relationships that develop in the three areas where overlap occurs. The overlap between government and private goods (B) are deemed to be toll goods and are classified by public or regulated private corporations and can be typified by

[2] Excludability is a circumstance where individual consumers can be excluded without incurring substantial cost.
[3] Non rival, or low substractable, goods are ones where the consumption by one person does not diminish the ability of other persons to benefit from the good.

public utilities. The overlap between private and common pool goods (E) are civil goods. Institutions in this category are non-governmental organizations (NGOs). Examples would be public advocacy groups, professional standards and civic action. The overlap between common pool and government goods (C) are public goods. Institutionally, these are represented by hybrid organizations that are responsible for issues like rural roads.

Figure 2.1: Institutional Design Parameters



Source: Picciotto, 1995.

[4] Voice is the ability of members in a sector to have their opinion heard by those who make decisions.

While Picciotto provides a good model for the assessment of resource utilization, there are two omissions in this model that relate to managing liabilities. The first is that there is no consideration of risk in Picciotto's model. This is important as it deals with how information about a project is communicated to those directly and indirectly affected. Picciotto does not mention how information about the risks and benefits of Third World development projects were communicated to the local populations. This is an unfortunate oversight as communicating the benefits of any project with the local population is an important key to the projects overall success. The second oversight is Picciotto's unexplainable lack of focus on the center of his model, where all three spheres overlap. While all the institutions that play a role in the overlaps identified as B, C and E are thoroughly explained, he offers no insight as to what individuals and institutions are affected in this area. For the purposes of this research, this offers an opportunity to adapt the model illustrated above and to identify what institutional policies and actions are occurring within the center of the model.

2.2.1 Summary

Table 2.2 identifies three key aspects of institutional theory that have made a substantial contribution to the development of this interdisciplinary model. The contributing theories address the importance of the role that institutions have and how institutional constraints affect the transaction costs.

Table 2.2: Critical elements of institutional theory

Research Era	Author	Key concept	Critical theoretical contribution	Implication for model
1970s 1980s	William-son	Transaction cost analysis	Over-regulation of innovation will be viewed as an increased transaction cost, meaning that the regulation is not economically efficient.	This theory can be used to examine whether the stakeholders involved with an innovative technology view proposed regulations as economically efficient.
Early 1990s	North	Informal institution constraints	Formal constraints are easily identified; it is the informal constraints that have an impact on stakeholder relationships.	This theory works well to position the stakeholders and then to identify what informal constraints exist and how they impact each stakeholder.
Mid 1990s	Picciotto	Model of resource utilization	The interaction between public, private and voluntary sectors is essential for successful development projects.	This interaction and the characterization of the actors in the areas of overlap is the key focus of this model.

Williamson's transaction cost analysis theory is a valued contribution to this research as it identifies that regulations are a cost of doing business. This theory can be used to examine the interaction between industry and government in relation to the development of regulations. North's theory regarding informal constraints is important for an analysis of governance institutions as there is considerable difficulty in identifying informal constraints and the working to identify solutions. Picciotto's model of resource utilization is valued because it examines what institutional actors exist within the areas of overlap. This is important for this thesis as regulatory overlap is a key aspect of the research.

2.3 Governance Literature

In an attempt to help students of public policy better understand the process, Dye (1987) compares and contrasts several models of public policy. He explains the concepts of institutionalism, policy behavioural process, group theory, elite theory,

rationalism, incrementalism, game theory and systems theory. In the end, he sets out some general criteria that can allow the user to evaluate the effectiveness of a policy model.

The criteria are:

- it should order and simplify political life so it allows the user to understand the real world relationships;
- it should identify the significant aspects of public policy;
- it should be congruent with reality;
- it has to communicate something meaningful;
- it should direct inquiry and research into public policy; and
- it should suggest an explanation of public policy (Dye, 1987).

As the literature moves through the 1970s and into the 1980s, the emergence of detailed policy analysis models is evident. The work of such academics as Atkinson, Coleman, Doern, Pal and Skogstad have all greatly contributed to the development of this literature. Those within the neo-institutional school of thought argue that while institutions have formal organizational structures, they also have informal organizational dimensions, legal dimensions (i.e. operating rules) and cultural dimensions (i.e. operating norms and values), whereas conventional institutional theorists believe that institutions are bound by more rigid operating protocols. Atkinson (1993) suggests that neo-institutionalism provides for a "… more complete understanding of constraint and creativity" (p. 26). The political realm is largely

about the sources, uses and structures of power through government and public policy. Atkinson goes on to argue that institutions:

> … are mechanisms, bundles of rules, through which choices are made and conflicts resolved. Institutions establish who is permitted to participate, how decision-making is to be accomplished, and what limits (if any) are to be placed on the range of possible outcomes. So, while human beings are central to institutions, institutions represent deliberate attempts to channel and constrain human behaviour (p. 6).

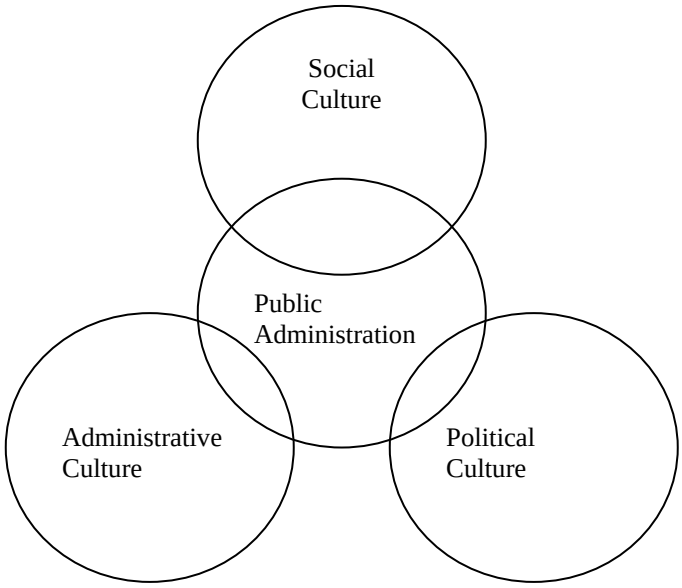
Peters (1989) argues culture is comprised of three distinct spheres: societal; political; and administrative (Figure 2.2). This typology clearly demonstrates the integrated theory concept as all three of these spheres overlap and affect public administration, which is the development and implementation of public policy.

Peters suggests that bureaucracies "… are bound by many thin but strong bonds to their societies and their values" (p. 40). The bond between the political culture and public administration is twofold: first, this bond connects the politicians with the bureaucracy; and second it joins those involved in political parties and organizations to the bureaucracy. Administrative culture is connected to public administration by both formal and informal organizations that are created by a common point of view in an attempt to exert influence on the development of public policy. Public administration is also bound by the cultural values of the particular society.

At any one time, society will have views and opinions on what is acceptable for that society. These values then act as informal boundaries for those in the bureaucracy

developing public policies and regulations. With this model, Peters begins to identify the major stakeholders within a public policy process and attempts to demonstrate how the authority of these stakeholders overlaps with the authority of the other stakeholders to create the concept of an integrated policy development and implementation that presently applies to the regulation of agricultural biotechnology.

Figure 2.2: Culture and Public Administration

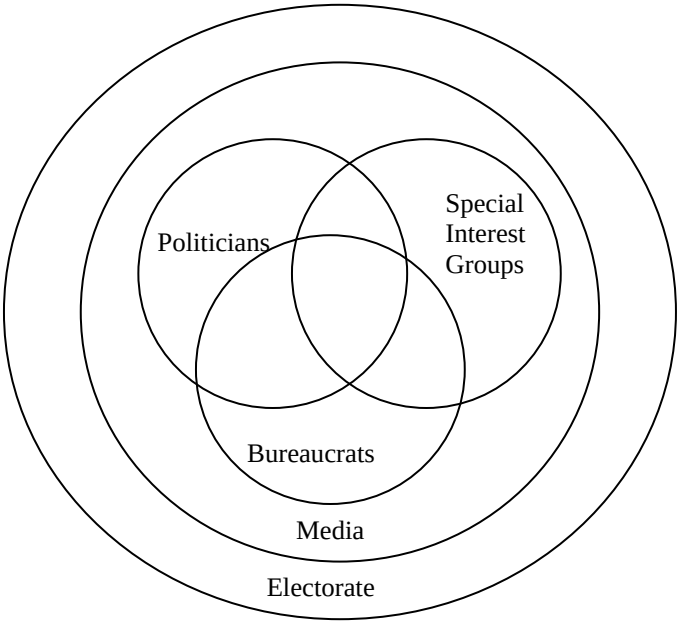


Source: Peters, 1989.

Another conceptualization of political institutions is offered by Brooks. Brooks (1989) works from the public choice model of public policy and argues that this model "… represents an attempt to explain political behaviour, including the policy decisions of governments, in terms of a theory of individual choice developed in microeconomics" (p. 49-50). He notes that none of the stakeholders in this model (Figure 2.3) acts single-mindedly, but rather that each stakeholder works to limit or

restrict the goals of the other stakeholders. The typology shown below focuses on four areas of interplay, the central area where all there inner spheres overlap and the three areas of overlap between two of the stakeholders. The electorate does not participate directly in the public policy formation process, but are important and it is the electorate that chooses the players within the politician sphere. Brooks argues that public policy is a "… continuous and multi-level process of bargaining in which power is based on control over resources that can be used as the basis for profitable exchange" (p. 53).

Figure 2.3: The Policy Process Viewed from the Public Choice Perspective: Four Interrelated Games



Source: Brooks, 1989.

While Brooks goes on to cite some of the short-comings of this model, the concept of the interaction among the three internal stakeholders (i.e. politicians, special

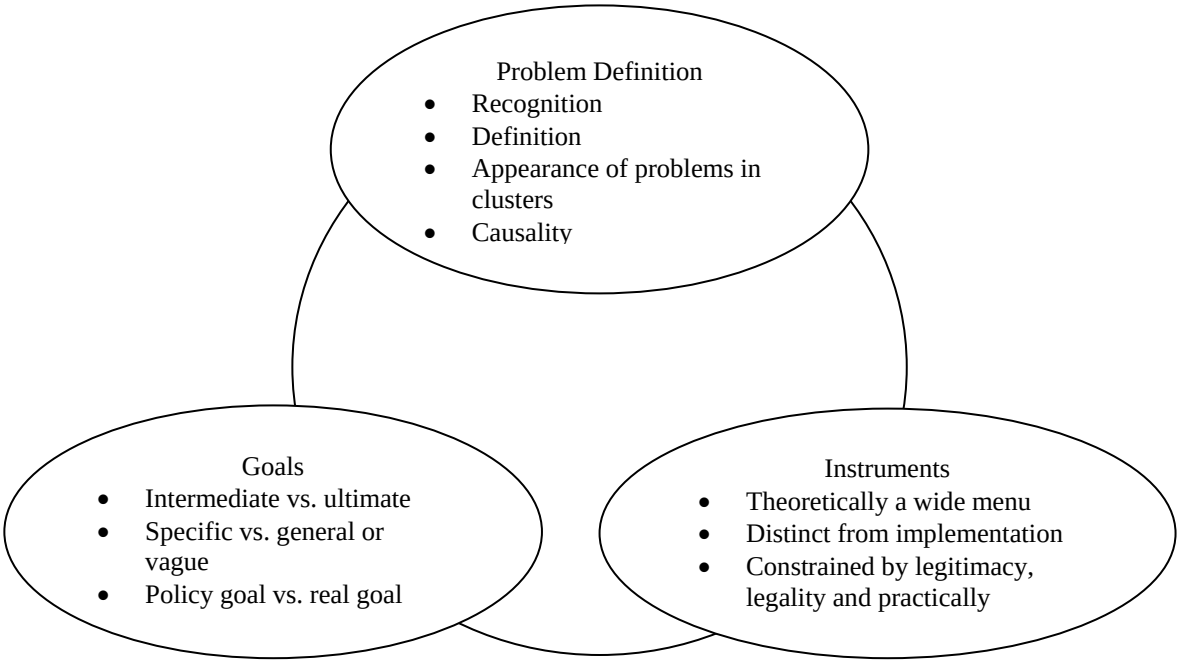
interest groups and bureaucrats), the media and the electorate is an important contributing concept to the development of the methodology for this research. The crucial point from this model is the center where all three stakeholder spheres overlap, as this is where Brooks suggests the key to the decision making process exists.

Coleman and Skogstad (1990) discuss the role of policy networks in relation to the development of public policy. They argue that a government department's or agency's ability to control or limit access to a policy network ultimately dictates the outcome of the policy process. Policy networks then, are those groups of state, society and industry stakeholders that exert the influence they possess in an attempt to create a public policy that is most favourable to their position. They suggest that these relationships are very formal, adversarial and increasingly technocratic. In relation to biotechnology, the latter two relationship characteristics are certainly true, however, it is a difficult argument to say that these relationships are formal in nature. While it is true that the regulatory process is very formal in that the regulations for products of biotechnology have all been codified, the relationship among the stakeholders is presently very informal. This innovation is too new to have developed highly formal policy network relationships.

Pal (1997) takes the work of Coleman and Skogstad and further develops the idea of policy networks and how they relate to public policy analysis. Pal offers five different types of policy networks: pressure pluralist, where groups promote

developed policies rather than participating in the policy development process; clientele pluralist, where the state relies on and even allows associations to participate in policy development; corporate, where groups and the state participate in policy development and implementation; concertation, where state and association are equal partners in the policy process; and state-directed, where the state dominates the policy process. Pal offers a typology that focuses on what considerations go into creating public policy (Figure 2.4).

Figure 2.4: Elements of Policy Content



Source: Pal, 1997.

The above typology shows how the theoretical thinking has become integrated. The typology has three distinct spheres: problem definition; instruments; and goals; and these spheres are connected by an additional loop that ultimately ties the whole

process together. This typology demonstrates how aspects of importance in one sphere spill over and affect aspects of the other two spheres, which is the major focus of this methodology.

The political science literature offers a variety of policy analysis models. Aspects of these typologies that relate to governance and a better understanding of the public policy process have been incorporated into the model developed to examine transformative technologies such as biotechnology.

2.3.1 Summary

The critical aspects of political science theory are highlighted in Table 2.3. The critical contributions of these four authors provide this methodology with a thorough ability to understand the subtleties and nuances of governance and public policy development. Incorporating the concepts from these models has provided this model with the flexibility necessary to identify where communication gaps exist as well as identifying which stakeholders in the regulatory process are capable of exerting the greatest level of influence on decision makers.

A common theme for the theoretical contributions regarding governance theory is the influences that are applied to the policy development process. The contributions from these four authors all examine the decision making process, but each does so from a unique perspective.

Table 2.3: Critical elements of governance theory

Research Era	Author	Key concept	Critical theoretical contribution	Implication for model
Mid 1980s	Dye	Criteria to evaluate effectiveness of policy models	Policy models should reflect reality and communicate something meaningful.	This model represents all stakeholders and addresses the management of liabilities.
Late 1980s	Peters	Culture and public administration model	Administrative, political and social cultures attempt to influence policy.	This model identifies the conflict between science-based and socio-economic based regulations.
Late 1980s	Brooks	Public choice model	The key to the decision making process is the center of stakeholder overlap.	By including the role of industry, this model provides an accurate analysis of interaction within the central overlap.
Late 1990s	Pal	Elements of policy content model	Policy networks have an impact on public policy.	This model concentrates on the relationship of the inner stakeholders by creating areas of overlap to show that the actions of one, directly affect the actions of the others.

Dye examines governance models and suggests that models have to reflect political reality, which is important, since if the model is not representative of reality, the results may be less meaningful. Peters discusses how various cultures attempt to influence policy development. This is important to this thesis given the cultural change regarding the acceptance of biotechnology and GM foods over the past decade. Brooks highlights the importance of overlap and suggests that the areas of overlap are key to the decision making process. There is considerable governance overlap in biotechnology and this is an important contribution to this research. Pal focuses on the importance of policy networks and the impact that the actions of one stakeholder has on the actions of other stakeholders. Pal's research is valuable given

his focus on policy networks and the development of these networks. This research is used to show how policy networks have developed within biotechnology.

2.4 Risk Literature

Shrader-Frechette (1990) has written extensively about risk and has focused on the difference between perceived risks and actual risks. She argues that all risks are perceived, but there are criteria for why some risk perceptions are viewed as more objective than others. She offers eight reasons why actual risks are not typically distinguishable from perceived risks:

i) risk probabilities do not reflect risk frequencies;

ii) actual risk estimates are rough and imprecise;

iii) aspects of hazard, real or perceived, are not quantifiable;

iv) risk is theoretical not a precise empirical confirmation;

v) risk perceptions often affect risk probabilities and it is frequently impossible to distinguish hazards from perceptions;

vi) distinction between actual and perceived risk should not be left to ‘allegedly objective’ experts;

vii) perceived risk is not an erroneous understanding of actual risk; and

viii) there is no distinction because there are only perceived risks.

Ultimately, Shrader-Frechette is arguing that experts are not always right (nor objective) and this is a factor in society's lack of understanding regarding perceptions of risk.

Traditional risk assessment theory suggests that risk is a combination of the level of adverse effects of the agent to other organisms and the length and level of exposure. This can be expressed in the following formula:

RISK = HAZARD x EXPOSURE

If the time of exposure is brief (fractions of a second) or low and the level of hazard is a high dosage, the level of risk would be low or minimal (i.e. receiving an x-ray). Science has used this formula to evaluate whether initial research findings should proceed or be halted. However, scientists who use this formula assume that those involved with the innovation properly understand its uses and applications, and the formula does not factor in human error.

Sandman (1994) has argued that regulators should instead use the following formula for understanding consumer perceptions of risk:

RISK = HAZARD x OUTRAGE

Sandman believes the old formula underestimated the actual level of risk because it ignored outrage. Public concern is focused on whether the risk is acceptable rather than on the scientific perceived level of public risk. This has important implications for risk communication, as food safety institutions must address consumer outrage in their response to the risk assessment. Outrage in relationship to GM foods was that consumers were outraged that it was present, not with the tolerance levels that were established for co-mingling of GM and non-GM products. The challenge of

assessing outrage is how to accommodate outrage when society wants zero risk, which is unachievable.

Publicly managed risk analysis systems are vital to creating trust. Van den Daele, *et al*., (1997) identify three types of risk that affect the safety of products and consumer perceptions of those risks:

- Probabilistic risks involve those theoretically grounded and empirically demonstrated risks related to the product or its technology. The methods and much of the evidence are available in peer-reviewed journals or public records.
- Hypothetical risks, in contrast, involve those possibilities that are grounded in accepted theory but lack empirical experience or evidence that can establish probabilities. Most of these can be identified in academic literature.
- Speculative risks, in contrast to the other two areas, have neither established theory nor experience to back them up. Those speculative risks that have much basis can often be found in working papers or other developing literature. Beyond that, almost any correlation can be made to show the potential for risk, irrespective of whether there is any theoretical basis for the possibility.

Risk assessment systems should be able to effectively handle risk analysis, which is relatively mechanistic, and likely should be able to handle risk management. Risk communication, however, is extremely complex for agricultural biotechnology because of the wide array of speculative issues that science cannot adequately

respond to. In absence of complete certainty about, or at least significant experience with a new technology or product, risk assessment systems must inherently be based on institutional governance approaches that have historically provided trust as a means of providing consumer safety assurance. In turn, trust is instilled as a result of reactions to risk assessments that are carried out by institutions. Trust grows as risk analysis involves elements of social concern and risk management procedures address public concerns. Finally, trust is firmly embedded in the public through the success of the risk communication process that develops over time. Strong institutions are crucial for successful and trustworthy products resulting from transformative innovations.

Stanbury (2000) writes about the regulation of risk from a Canadian perspective and focuses on the Canadian government's risk management activities. He offers eight ‘routine pathologies’ that the government is subjected to:

i) insufficient or poor economic analysis;
ii) no guidance (from the Treasury Board) on the economic value of life;
iii) idiosyncratic or haphazard selection of risks for government action;
iv) “silo management” or a lack of “horizontal mechanisms” to implement a general risk management policy across a score of specialized departments and agencies;
v) government actions being too often based on preference of the most fearful;
vi) one-size-fits-all types of government action to deal with risks;

vii) potential misuse of the precautionary principle; and

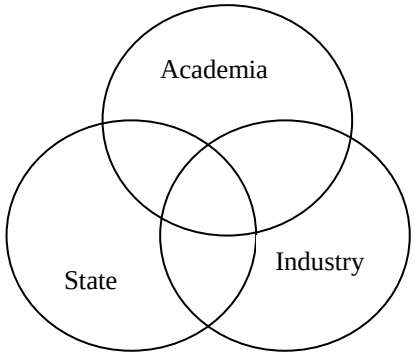
viii) poor risk communication.

These criticisms are leveled against all departments of the Federal Government, not specifically against those involved with the regulation of biotechnology. However they can still be applied to those regulating biotechnology.

Etzkowitz and Leydesdorff provide one possible method of analyzing the interaction among the institutions of academia, industry and the state, which is known as the Triple Helix. The underlying theme of Triple Helix analysis of innovation is to examine the dynamics occurring among the three stakeholders: government; industry; and academia. Most discussions regarding the Triple Helix typology of innovation analysis refer to the third version, or Triple Helix III. The initial typology, Triple Helix I, was a very institutionalized typology, where the relationship between government, industry and academia was largely controlled or directed by the state (Etzkowitz and Leydesdorff, 2000). The Triple Helix II relationship can be described as individual spheres with lines of communication that operate with high levels of mistrust and suspicion. Triple Helix III is the typology that most realistically represents the existing relationships in industrialized economies. In this typology, government, industry and academia are again represented by distinct spheres, but all three spheres overlap each other (Figure 2.5). The center of this typology, where all three spheres overlap, is characterized by

trilateral networks and hybrid organizations (Etzkowitz and Leydesdorff, 2000). Etzkowitz and Leydesdorff argue that the common objective of this typology is "… to realize an innovative environment development, and strategic alliances among firms, government laboratories, and academic research groups" (p. 112). This typology highlights the integration of academia, industry and state and shows the arrangement of innovation analysis that it is designed to identify the dynamics and the impact of these dynamics on the three stakeholders.

Figure 2.5: The Triple Helix Model of University-Industry-Government Relations



Source: Etzkowitz and Leydesdorff, 2000.

There has been very little discussion about the potential role of a fourth helix, which is defined as the public. Baber (2001) briefly mentions the concept of a fourth helix, in suggesting that visiting teams of prominent research scientists in developing countries could be conceived as a fourth helix. In developing this further, Mehta (2002) argues that the regulation of biotechnology has been "… made unnecessarily complex and inherently unstable due to a failure to consult the public early and often

enough” (p. 1). Public acceptance of innovation is crucial to successful commercialization and products sales. Without an accepting public, the full potential of the innovation may not be realized.

This section of literature focuses on risk and discusses the importance of the public's inclusion into decision making processes. The models that have been highlighted in this section focus on the integrated aspect of industry, state and society. When consideration is given to the inclusion of a fourth helix, public opinion, the applicability of these models to this research topic increases dramatically.

2.4.1 Summary

The contribution of these authors and concepts demonstrate the importance for society to have meaningful input into regulatory processes, even though science-based risk assessments processes do not allow for social input. This is not to say that consumers should be allowed to dictate regulations to government and industry, but rather that their concerns and questions be seriously addressed and informative responses provided. While the Canadian regulatory system does not incorporate these social concerns and industry is very opposed to move away from science-based regulation, social concerns can not continue to be outside of the regulatory process. The inclusion of societal actors will distinguish between those actors that have legitimate concerns and those seeking media attention. The action of societal actors with legitimate concerns that are included in preliminary regulatory discussions will increase the transparency of the regulatory process, thereby

providing those who could not find the answer to their questions with factual based information. The critical aspects for the methodology of this thesis from the risk literature are identified in Table 2.4.

Table 2.4: Critical elements of sociology theory

Research Era	Author	Key concept	Critical theoretical contribution	Implication for model
Mid 1990s	Sandman	Importance of outrage	Public is more concerned about the presence of a risk rather than the level of the risk.	This model will allow users to determine what level of liability communication exists within a particular regulatory structure.
Late 1990s	van den Daele	Classifica-tions of risk	Properly managed risk analysis systems are vital to the creation of trust.	This model can be used to identify which stakeholders are legally and contractually responsible for the management of liabilities.
2000s	Etzkowitz and Leydes-dorff	Triple helix model	The dynamics of the interaction between academia, state and industry.	Incorporating the dynamics of these relationships with the dynamics of society are the focus of the model.
Early 2000s	Baber and Mehta	Role of the 4^{th} helix	The ability for societal participants to have their opinions and concerns addressed.	This model incorporates all four helixes; state, industry and society are the three helixes represented in the core of the model while the fourth helix of academics surrounds the inner three.

One unifying theme that reaches across this section of literature are the numerous dynamics of risk and their applicability to the broader society. The ability to perceive risks varies individually and this factor is increasingly important. Present day societies are becoming increasingly concerned about the safety of the food that is consumed on a daily basis and are demanding additional information on the quality of food products.

Sandman identifies that consumers will not be reassured by knowing that a risk may be within a defined tolerance level, but will be outraged that there is a possibility of

the risk even occurring. Van den Daele, *et al*., provide a classification of risks, and this structure is valuable in that it attempts to classify risks into categories that can be responded to by peer reviewed data and those that will have to be addressed through alternative methods. Etzkowitz and Leydesdorff offer a dynamic model that explores the interaction among stakeholders and offers insights into the relationships that exist within the areas of overlap. These insights are an important contribution to this research as one focus of this research is to identify the relationships and the dynamics of these relationships within the regulatory framework for biotechnology in Canada. The recent research by Baber and Mehta regarding a fourth helix is important, as they address one of the shortcomings of the Etzkowitz and Leydesdorff diagram, the non-inclusion of society.

2.5 Conclusions

The combination of these critical theoretical contributions result in a model designed to examine regulatory scenarios for the management of socio-economic liabilities. The fact that there is no common definition of risk or institution within these various literature streams is part of the problem associated with managing liabilities from technology transformations such as agricultural biotechnology. It is possible to view agricultural biotechnology as an institution on its own and all the actors and stakeholders can be positioned within this methodological framework, creating the possibility of developing one definition for institution and liability that can then be used to provide meaningful insight into how the potential for liabilities can be effectively managed by regulation.

Each of the three contributing disciplines has theory and structures for dealing with innovation. Economists offer advice on how firms and industry, together with governments and associations, can develop new, effective supply chains to differentiate products for different markets, at a price premium. Political scientists tend to use biotechnology to illustrate how public regulatory schemes are weakened when they ignore the core principles of effective public policy—transparency, accountability and responsibility. Sociologists suggest that many of the problems and uncertainties around transformative technologies can be moderated through more, new and better communications and debate. The problem is that each provides too narrow a perspective to resolve the problems of transformative technological change.

Ultimately, each of these approaches has some application, but none alone will resolve the challenge of managing liabilities of a transformative technology. Each would manage one or more liabilities of the technology, but often at the expense of creating a new liability. Chapter 3 explores in greater detail how an interdisciplinary approach can be applied to this issue.

The management of liabilities will increase in importance with greater implementation of the BioSafety Protocol. International discussions and consultations will began in the fall of 2004. One option available to stakeholders within agricultural biotechnology is to do nothing and let the existing systems adapt and resolve any liabilities that might arise from the introduction and use of

agricultural biotechnology. Without any further action, disputes about the technology would ultimately land in various administrative tribunals and civil courts. While this approach is often the most appropriate for an incremental technology, it is unlikely to be optimal for a transformative technology such as agricultural biotechnology. The potential impacts of the technology simply span too many domains. The claims and counterclaims will inevitably conflict. This research suggests that new institutions (e.g. new norms, formal and informal policy networks and the fourth helix) will need to be developed to ensure successful management of the use of this technology.

Chapter 3

Conceptual Constructs for this Research Project

3.1 Introduction

This chapter identifies the specific contributions from the previous chapter and demonstrates how the theory and typologies discussed there can be utilized in an interdisciplinary research approach to develop a conceptual construct that is capable of assessing liability in relation to innovation. To demonstrate how these conceptual constructs were developed, the key contributions summarized in Tables 2.2, 2.3 and 2.4 are applied to build, piece by piece, the conceptual construct used for this thesis. The intent is to demonstrate how the theoretical contributions from each academic discipline can be drawn together into a new structure that provides the opportunity to critically assess transformative technologies.

Section 3.2 discusses the legal framework and shows how it is applied to the issue of liability management. This section focuses on the various legal terminologies that can be applied to liability issues concerning transgenic crops. Section 3.3 introduces the concept of socio-economic liability and provides a definition and explanation of this concept. Section 3.4 demonstrates the development of the framework used to examine socio-economic liability. It outlines how the theoretical contributions from Chapter 2 can be drawn together into a single framework for assessing technological

transformations. This process of construction is undertaken step-by-step and highlights what specific contribution has been drawn from the preceding chapter. Section 3.5 shows the final methodology in its entirety and explains the theoretical elements and practical conditions of the framework. This section will provide the details of the framework and identify the key areas that are the focus on this research. Section 3.6 applies this framework to the issue of liability. This section uses the developed framework to visually identify how the subsequent four chapters relate to the methodology and shows the reader what specifically will be addressed in each of the four chapters.

3.2 The Legal Framework to Liability Management

Legally, a liability results when an obligation is not fulfilled or when there is a failure to comply with previously defined requirements. From this legal perspective, there are only two kinds of liability—criminal and civil. Criminal liability occurs when there has been a criminal act committed, i.e. when someone breaks the law of the land. Criminal liability in relation to agricultural biotechnology is not the key issue, as no firm or individual has been tried for a criminal infraction.

Civil liability arises when an obligation has not been met by a party and can result in litigation for compensation on behalf of those affected. Lawsuits from those affected by thalidomide and silicone breast implants are examples of civil liability. The remainder of this section examines the areas of civil liability law that have been

applied to agricultural biotechnology in several court cases. Some of the cases have already been dealt with by the courts and some are still presently before the courts. Varying Statements of Claim filed by plaintiffs have sought damages for negligence, strict liability, nuisance, trespass, and pollution. Various lawsuits have also accused seed development firms of failing to conduct environmental impact assessments prior to the release of transgenic crops. This section examines each of the above concepts and claims.

Negligence

In negligence law, defendants are not responsible for every consequence of a negligent act. In other words, there are limitations on the impacts of a negligent act. The tort of negligence has three key components: the negligent act; causation; and damages. Proof of negligent liability has to include all three components. The focus of this section will be on the first component, the negligent act, as the intent is to provide an analysis of the issue rather than delve into the causation and damages of specific biotechnology cases.

The examination of a negligent act focuses on foreseeability, duty of care and standard of care. The question of foreseeability emanates from the decision of the Privy Council in Overseas Tankship (U.K.) Ltd. v. Morts Dock and Engineering Co. Ltd., The Wagon Mound (No.1) [1961] A.C. 388 (P.C.). Foreseeability in this case was seen to be based on three separate but linkable events. First, when furnace oil was discharged by the boat ‘Wagon Mound’ into the harbour (this case is referred to as the Wagon Mound case), it was foreseeable that this oil would spread. Second, it

was foreseeable that if the oil spread it could be ignited as a result of some unrelated event. Third, when a fire ignited due to some welding that was taking place, it was foreseeable that property damage could be expected. Based upon the Wagon Mound case, it is possible to apply this series of three ‘what-if’ questions to applications of new innovative products or processes.

This series of events could be the justification for asking seed development firms three ‘what-if’ questions regarding the foreseeability of, for example, GM pollen spreading. It would be realistic to pose the following three questions. First, should officials in seed development firms or federal regulatory scientists have known that the pollen from some transgenic plants had the potential to travel great distances? Second, should these officials or scientists have been able to predict that if transgenic plants were widely adopted that the pollen would be widely dispersed? Third, should these officials or scientists have known that the transgenic pollen could land in fields where it was not wanted?

When faced with addressing these questions, the answers are blatantly apparent. The response to the first question can only be affirmative; most farmers know that pollen has the ability to travel great distances. The response to the second question would also be positive, as it is a logical progression from the first question in that if transgenic crops were rapidly and widely adopted, likewise would be the dispersion of pollen. It seems improbable that anyone could argue anything but yes to the third

question, as it would be physically impossible to prevent the transgenic pollen from landing in or on other fields once it had been released.

Based on the above, the biotechnology industry would be wise to concede foreseeability to plaintiffs. This would then shift the key focus of the debate to the issues of duty of care and standard of care. However, the concession of foreseeability would imply that there is a prima facie duty of care owed to the farming community at large. One could successfully argue that there were sufficient data available at the time of variety approval to justify foreseeability.

The focus would then examine whether there were sufficient conditions to establish a duty of care. Osborne (2000) offers a standard definition of what constitutes duty of care. Duty of care is described as "… a question of law which requires the judge to determine if the defendant is under a legal obligation to exercise reasonable care in favour of the plaintiff" (Ch. 2, p. 1). This definition of duty of care is very broad and open to varying interpretations.

The application of duty of care ultimately focuses on two key factors: Who was harmed and what is the nature of the relationship between the party suffering harm and the party causing harm? Those suffering harm can range from a single individual, as in the case of Donaghue v. Stevenson [1932] A.C. 562 (H.L.), or it can be a large group of people, such as the women that suffered from faulty silicone breast implants. While defining who was harmed as it relates to duty of care is rarely

a contentious issue, determining the nature of the relationship is frequently a contentious issue.

In the case of Donaghue v. Stevenson the nature of the relationship was the contentious issue. The facts of this case from the early 1930s are that Mrs. Donaghue and a friend went to a restaurant, where her friend purchased two bottles of ginger beer. The bottles were opaque and Mrs. Donaghue poured some of her beer into a glass and drank this portion of the beer. She then poured the remainder of the bottle into the glass, at which point, the remains of a snail floated in the glass. Mrs. Donaghue became physically ill from consuming the ginger beer. The brewer of the ginger beer, Stevenson, claimed that since Mrs. Donaghue had not purchased the beer directly, there was no duty of care owed to Mrs. Donaghue. The British House of Lords disagreed with this argument and ruled that the "… manufacturer of products does owe a duty to the ultimate consumer to take reasonable care to prevent defects in its products which are likely to cause damage to a person or property" (Osborne, 2000, Ch. 1, p. 1).

More recently, the definition of duty of care has been more narrowly defined by Lord Wilberforce in Anns v. Merton London Borough Council [Note 79: [1978] A.C. 728 (H.L.)]. In this decision he states:

> First one has to ask whether, as between the alleged wrongdoer and the person who has suffered damage there is a sufficient relationship of proximity or neighbourhood such that, in the reasonable contemplation of the former, carelessness on his part may be likely to cause damage to the latter – in which case a prima facie duty of care arises. Secondly, if the first question

> is answered affirmatively, it is necessary to consider whether there are any considerations which ought to negative, or to reduce or limit the scope of the duty or the class of person to whom it is owed or the damages to which a breach of may give rise (Osborne, 2000, Ch. 2, p. 2).

The use of the *Anns dictum* suggests that where there is a relationship and there is reasonable foreseeability of damages, there would be a presumption of a *prima facie* duty of care. The *Anns dictum* also created a process for a more transparent discussion of duty of care issues. Osborne (2000) believes that it was important for two additional reasons. First, it created a presumption of a duty of care in all relationships, giving rise to a reasonable foreseeability of damage to the plaintiff; and second, it placed on the defendant the unenviable and sometimes considerable burden of persuading the court why the plaintiff did not deserve to be protected from his negligent conduct.

While the *Anns dictum* originated in Britain, it is not used by British courts today. However, in Canada the *Anns dictum* has been consistently applied since the mid 1980s. Canadian courts have interpreted the first stage of the Anns test, reasonable foreseeability, as demonstrating that reasonable foreseeability of damage was probable based on the actions of the defendants. As such, there are few issues arising from this stage of the Anns test. The second stage of the Anns test, factors affecting the relationship that may restrict damages, has been widely debated. Osborne believes this stage of the test:

> … permits a full and open debate about the societal costs and benefits of recognising a duty of care. It not only allows the prima facie duty to be negated, but it also allows this duty to be restricted or modified to meet policy concerns. For example, the courts may demand that some additional

> element be found in the relationship, such as reliance by the plaintiff, an assumption of responsibility by the defendant, a specially close relationship, or some other element that defines the relationship more closely than foreseeability, before a duty will be recognised. (Osborne, Ch. 2, pp. 2-3, 2000)

Ultimately, the duty of care as it relates to agriculture can be analyzed using two key concepts. The first concept, as it relates to the introduction of new transgenic crop varieties, would examine whether there is any reasonable foreseeability of harm that may potentially arise from the introduction of a transgenic crop variety into the environment. Secondly, the concept requires consolidation of any policy reasons or considerations that may be applied to reduce or remove the identified damage.

The first concept, reasonable foreseeability, would appear to be part of the regulatory review of the transgenic crop application. A science-based regulatory system examines all aspects for potential environmental harms. The fact that approval is granted for transgenic crop varieties would indicate that the issue of potential liabilities resulting from environmental harm have been analyzed thoroughly and the science of the day had deemed that the production, processing and consumption of the crop type and the resulting food products to be safe. When a new transgenic crop receives variety approval from the federal regulatory agency, the mandate of reasonable foreseeability of harm would appear to have been satisfied. There is a lingering doubt, however, whether theoretical, hypothetical or speculative risks, which usually are not addressed in regulatory systems due to inadequate evidence, might meet the test of foreseeability.

An examination of the second concept suggests there is a need to recognize that the boundaries between the role and authority of Parliament and the role and authority of the judiciary can in some instances become clouded. Some civil society issues can become very contentious due to the debates arising between Parliamentarians and within the professional legal community. However, one issue that the courts have routinely left to the discretion of Parliament is the distribution of wealth. Technological innovations, which frequently redistribute wealth, are thus covered by policy not law.

This preference for choosing technology winners ultimately means that some group in society will lose. This concept is not new to present day innovations (the makers of buggy whips are the classic case of an industry that lost with the introduction of a new innovation, in that case, automobiles). North American society has generally chosen not to financially compensate industries or individuals that suffer financial loss due to innovation commercializations. Biotechnology companies can argue that they have properly followed all regulations relating to the commercialization of transgenic crop varieties and any losses in the agriculture industry are unfortunate but not their fault. Based on previous innovations, losers in agriculture could be expected, but North American policy (and even society at large) does not call for financial remuneration to flow to those that are adversely affected economically by the introduction of GM crops.

Those firms that have commercialized transgenic crops in North America can legitimately state that they have followed the federal regulatory process. Duty of care issues that fall into the socio-economic category may well be rejected by the judicial system given that there are no federal regulatory structures in place in North America that would justify their inclusion. Courts that are faced with tort cases claiming large financial damages due to the introduction of transgenic crop technology may decide that they do not want to rule on the re-distribution of wealth resulting from this technology and may instead suggest that this is a policy matter better dealt with in the political process.

There is ample precedence for this. Fleming (1983) notes:

> For some situations the appropriate standard of conduct is prescribed by the legislature instead of being left to the evaluative process of judge and jury. The complexity of modern life has spawned a profuse progeny of governmental regulations, demanding observance of fixed and specific precautions for the safety of industrial operations, building construction, road traffic and so forth. (p.117)

This removes any debate regarding the principle of standard of care. The Government of Canada, through the CFIA, has examined and tested transgenic crops and deemed them to be substantially equivalent to the existing varieties and has allowed their registration for commercial purposes. Given that the seed development companies have complied with the government regulations and are legally entitled to sell transgenic seed anywhere in Canada, the courts may choose to recognize that any liability resulting from negligence would not be allowed in deference to policy.

Trespass and Nuisance

Some have argued crosspollination is a form of trespass or nuisance. Making an argument claiming trespass against the production of transgenic crops would seem to be difficult. In the decision in Philips v. California Standard Co. (1960), 31 W.W.R. 331 (Alta. S.C.) the judge identifies that in England and Canada trespass involves a physical entry on the property of another. While there is no physical entry in the sense of a human or an animal entering a property, there is physical entry of GM pollen. There have been some agriculture cases of trespass involving livestock but there are no known cases of legal action based on plants, portions of plants or weeds. Existing case law suggests that trespass only pertains to entries that can be physically prevented. To be successful in arguing that GM pollen should have been controlled would mean proving that the CFIA was negligent when approving GM canola. As a result, it would be doubtful that an argument based upon trespass could succeed[5].

Nuisance cases may be equally problematic. There are two variations of nuisance, private and public. Private nuisance can be defined as a substantial and reasonable interference with the use and enjoyment of land. In public nuisance there has to be a defined group or class of individuals that has perceived harm at the hands of another.

[5] Kershen, 2004, offers a different perspective on this argument by examining Canadian and American application of trespass case law to transgenic crops. Kershen argues that the law of stray animals provides valuable insight for producers that are faced with the inadvertent presence of transgenic crops.

While the discussions regarding nuisance are many, the decision of Lord Lloyd of Berwick in Hunter v. Canary Wharf Ltd. (1997) NLOR No. 324 NLC 197044701 provides a very concise definition of private nuisance:

> Private nuisances are of three kinds. They are (1) nuisance by encroachment on a neighbour's land; (2) nuisance by direct physical injury to a neighbour's land; and (3) nuisance by interference with a neighbour's quiet enjoyment of his land. In the case of encroachment the plaintiff may have a remedy by way of abatement. In other cases he may be entitled to an injunction. But where he claims damages, the measure of damage in cases (1) and (2) will be the diminution in the value of the land. This will usually (though not always) be equal to the cost of reinstatement. The loss resulting from diminution in the value of the land is a loss suffered by the owner or occupier with the exclusive right to possession (as the case may be) or both, since it is they alone who have a proprietary interest, or stake, in the land. (Notes 39 and 40)

An examination of the three kinds of nuisance is insightful. The first, encroachment, would only apply if it could be physically proven that GM pollen has encroached on the land of another producer. This argument would presumably follow the logic needed to prove trespass. Thus, it may be difficult to claim nuisance if there is no proof of encroachment.

The second form of nuisance, direct physical injury to a neighbour's land, may be a possible argument if the presence of GM pollen can be viewed as a direct injury. Pollen from any plant species is only viable for a few hours, thus making it challenging to demonstrate how the presence of GM canola pollen, for example, could be viewed as an injury to the land. The pollen from GM canola could be an indirect damage, as it may affect the plants growing on the land, but the pollen can not physically damage the land.

If an argument were made for physical injury, the damages awarded would be for the decrease in the value of the land or the cost or restoring the land to its original form. The latter option would only be possible with the complete ban of GM crops in Canada and the US. To show a decrease in land value would be extremely problematic, as there is no identifiable market for land that has not produced a GM crop. It would be very problematic in North America to try and determine what, if any, market premium exists for land that has not produced a GM crop.

The third kind of nuisance, interference with enjoyment of land, also seems a challenging argument, as pollen, in the conventional sense, is not an irritant about which individuals complain. Public nuisance is more difficult to prove than private nuisance, as proof of special damage must be made. Successful public nuisance cases have occurred where some form of toxic material is released by a company into a local body of water and poisons most or all of the local aquatic wildlife, thus being a public nuisance to local fishermen. A caveat to this is if 'interference with enjoyment of the land' can be interpreted to have a financial meaning. If a court decides that a farmer's financial enjoyment has been affected, the importance of nuisance may increase.

Furthermore, individual farmers are also often protected from nuisance suits. In Canada, for example, *The Agriculture Operations Act of Saskatchewan* states:

> The owner or operator of an agricultural operation is not liable to any person in nuisance with respect to the carrying on of the agricultural operation, and may not be prevented by injunction or other order of any court from carrying

> on the agricultural operation on the grounds of nuisance where the owner or operator uses normally accepted agricultural practices with respect to the agricultural operations. (p. 5)

A very important issue that develops from the above quote is how much time has to pass before a new technology is 'consistent with accepted customs and standards'. Two cases of aerial crop spraying may shed light on the issue. In the case of Mihalchuk v. Ratke (1966) 57 D.L.R. (2d) 269 a lawsuit arose from an aerial spray application made in 1965 and the judge noted that this was an unusual operation. The second case, Cruise v. Niessen (1977) 82 D.L.R. (3d) 190 is based on an aerial application made in 1975 and the judge noted that aerial spraying is no longer viewed as unusual. In the case of aerial spraying, ten years was enough to make this technology a common practice. Including the crop produced in 2004, genetically modified crops have now been grown for ten years. The transgenic canola acreage for 2003 was between 65% and 70% of all canola acres in the province. Two out of three canola growers use this crop technology and it has become a very popular option for weed management practices.

Strict Liability

The issue of strict liability is also relevant to transgenic crops. Typically, strict liabilities are found for one-time occurrences, such as is the case of Rylands v. Fletcher (1868), L.R. 3 H.L. 330, affg L.R. 1 Ex. 265. The ruling in Rylands v. Fletcher is based on the premise that an item or product not naturally occurring, but being stored on one's land may be inherently dangerous. In this case from Britain, Fletcher owned a mill and he constructed a reservoir to supply it with water. During the construction of the reservoir, the contractors discovered five long-abandoned vertical shafts. Not knowing they were abandoned mineshafts, the shafts were filled

with soil. The reservoir was partially filled with water and shortly afterwards one of the soil-filled shafts gave way, flooding the nearby coal mine owned by Rylands. Rylands sued Fletcher for the destruction of his mine. The ruling in Rylands v. Fletcher describes the item or product being stored on one's land as not naturally occurring and therefore, this product is inherently dangerous. In this case, creating a large inland body of water was viewed as a dangerous activity. This ruling has three important considerations for any GM cases: first, the drift of GM pollen is not a one-time occurrence, rather it happens annually for a period of 3-6 weeks; secondly, it would seem impossible to argue that GM pollen is stored in any form or fashion upon a farm; and finally, there are no scientific arguments that can be made in favour of the GM pollen being inherently dangerous, given that regulatory agencies have approved these varieties for all uses in both Canada and the US.

Pollution

Some have claimed that GM pollen is a form of pollution as defined under environmental protection legislation. Most existing pollution legislation refers to the discharge of a pollutant, defining the obligations of an owner of the pollutant and of those who control a pollutant that causes the damage or loss. It is important to note that legislation of this kind refers to the discharge of hazardous substances. The requirements for a product to be listed as a hazardous substance are that the product has the potential to harm the environment, human health and/or other living organisms. Such substances are usually listed in some form in a related environmental act.

Discharge as it relates to GM crops will vary, depending on whether it is applied to the GM seed or the GM pollen. There is no doubt that GM seeds have been deliberately discharged into the environment by seed development companies after receiving approval for unconditional release by federal regulators. In North America, the federal government approved the release (and thereby the discharge) of GM crops. Discharge as it relates to the pollen is a very complex issue to assess. Pollen from GM plants is released, dispersed or emitted into the environment just like the pollen of every other plant. The difficulty of this in a court of law would be how could a farmer who has been negatively affected identify which field was responsible for dispersing GM pollen.

Both 'owner of a pollutant' and the 'person having control of a pollutant' prior to first discharge include successor, assignee, executor or administrator of the owner or person. Executor and administrator are not applicable in this case by definition. One issue of importance is whether the use of a Technical Use Agreement (TUA) between the seed provider and the farmer identifies the farmer that signs the TUA as either a successor or assignee. Black's Law Dictionary (1979) defines assignment as, "… a transfer or making over to another of the whole of any property, real or personal, in possession or in action, or of any estate or rights therein. … the transfer by a party of all of its rights to some kind of property, usually intangible property such as rights in a lease, mortgage, agreement of sale or a partnership" (p.109). Based on this definition, a TUA would not be an assignment of property. Rather, it is an agreement that allows the farmer to use the technology in exchange for a fee,

and it remains the property of the technology owner. Arguably, the enforcement of intellectual property rights embedded in patents and Plant Breeders Rights would similarly vest ownership in the technology provider.

The definition of pollutant and pollution and their relation to GM pollen will be crucial to the success of any potential lawsuit. We do know that GM seed and pollen are not currently listed as hazardous substances in any country and there are no published data to suggest that consumption of these products is physically harmful. The organic industry argues the existence of GM pollen is harmful to its agricultural use of the environment. However, it must be made very clear that harm as it is applied in the organic sense is not harm in the physical sense of the word—the application of the word harm in this case is financial. The question courts will be asked to decide upon is whether harm as it is applied within the definition of pollution extends to financial harm.

Some opponents of agricultural biotechnology have tried to advance the argument that GM crops should have been subjected to more extensive environmental assessments by all levels of government, be they federal and state or provincial. The regulation and approval of plants Canada is exclusively a national responsibility—no sub-national government has yet developed legislation regarding the regulation of plants and many are constitutionally prevented from doing so.

3.3 The Problem of Socio-Economic Liability

For the purpose of this research, a socio-economic liability is defined as the decline in social trust for all innovations and the economic decline from commercialization delays when a company or government regulatory body fails to meet its publicly stated objectives, which are, ultimately, their social responsibility.

The differentiating feature between socio-economic liabilities and conventional legal applications of liability is that, with socio-economic liabilities, there is often no direct identifiable failure. Because there does not need to be an identifiable failure, there is no possibility of foreseeability and, therefore, no standard or duty of care exists between the social challenge and the owner of the innovation. This form of liability has no direct causation and firms that operate well outside the area of the innovation can be negatively affected by the actions of other firms in the industry.

When a regulatory failure occurs, the resulting media coverage has the ability to affect social perceptions of innovation. Negative media coverage will result in some consumers that were initially indifferent to a specific innovation becoming concerned about it or possibly even opposed to innovation in general. The bottom line is there is a loss of social trust in innovation, be it specific or general. This is not to say that the decline in trust will always be long term, or that it can not be reversed, but rather that there will be fewer consumers willing to express support for an innovation or the resulting commercial products.

Regulatory failure increases the likelihood that commercialization will be delayed, creating negative economic consequences. As we have seen, Heller (1995) has estimated that a one-year delay in commercializing an innovation reduces the rate of return on investment for a new product by 2.8%, while a two-year delay results in a reduction of 5.2%.

The absence of criminal or civil liabilities does not negate the fact that when a regulatory failure occurs, there are social externalities that are ultimately borne by other firms and by consumers. While these externalities may not generate a level of harm that is large or severe enough to trigger litigation for compensation, a socio-economic liability is created with regulatory failures.

Current Court Action on Liability

There is a clear delineation in the approach taken by North American governments opposed to that taken by the EU and in the government member states. The EU has adopted a precautionary, go-slow approach and has placed a de facto moratorium on the commercialization of transgenic crop varieties. The EU moratorium was lifted in April 2004 but it is yet to be seen how quickly GM comercializations will take place. North American governments have moved to legislate in favour of this technology and have approved numerous transgenic crop varieties.

Most court cases in Europe to date have dealt with the opponents of GM crops and their destruction of test plots. Meanwhile, European governments are examining their existing liability laws to determine if they adequately address potential lawsuits

involving co-mingling or the unintended presence of GM crops. For instance, the recent UK study on co-existence of GM crops recommends that compensation be made available to those that suffer financial loses due to the presence of GM crops through no fault of their own (AEBC, 2003).

Over the past few years there have been a variety of court cases in North America involving liability. Given that those negatively affected by the introduction of transgenic crops have little or no recourse of action with the regulatory agencies in North America, they have indicated that they may turn to the legal system in an attempt to seek remuneration. In Canada, for instance, the Saskatchewan Organic Directorate (SOD) representing a group of organic producers has filed a lawsuit against Monsanto and Aventis (now Bayer Crop Sciences) seeking compensation for alleged lost organic canola markets following the commercialization of transgenic canola. In addition to compensation for damages, the SOD is seeking an injunction against the commercialization of GM wheat. The justification for the injunction against GM wheat is that the SOD believes the presence of GM wheat will jeopardise their ability to export organic GM-free wheat to Europe.

One other Canadian court case is the counter-suit launched by farmer Percy Schmeiser against Monsanto for allegedly polluting his farmland. This case is separate from the patent infringement case that was just decided by the Supreme Court of Canada. The Supreme Court ruled that Schmeiser had illegally used Monsanto’s patented canola technology but was not required to compensate

Monsanto for the illegal use of this technology. Schmeiser's counter suit alleging pollution by Monsanto was put on hold until the decision was handed down by the Supreme Court in the patent infringement case. However, Schmeiser has publicly stated that his fight with Monsanto is over, so this action may not be pursued.

Liability lawsuits in agriculture related to potential market losses have the potential to severely limit future benefits of biotechnology. At the present, there is a growing unease in the agricultural biotechnology industry that legal injunctions may become increasingly common as opponents of GM crops attempt to use this strategy to prevent the commercialization of new GM varieties.

The remainder of this chapter focuses on the connection between the theory and structures from Chapter 2 and the above discussion regarding liability and demonstrates how these concepts can be combined into a single interdisciplinary concept for examining liabilities from innovation.

3.4 The Framework for Examining Socio-Economic Liability

The models and typologies discussed in the Chapter 2 offer, in their own unique way, a useful tool for analyzing innovations of transformative technologies. Components of these models and typologies provide the opportunity to build a comprehensive framework capable of assessing innovations in biotechnology.

The initial contribution to the comprehensive framework comes from the research of Picciotto (Figure 2.1). The three overlapping spheres representing the sectors of government, private goods and common pool goods provide one of the central key components for this research. Containing these three spheres within a triangle has also been adopted. While Picciotto does not clearly define the use of the triangle, this research has adopted the use of the triangle to define the borders of agricultural biotechnology. The key contribution of Picciotto's research is that he identifies who the actors are, the stakeholder relationships that develop, and that he focuses on the role of institutions and defines the governance issues that exist in the areas of overlap (defined as B, C and E in Figure 2.1). As was identified in Chapter 2, the major oversight of Picciotto's research is the lack of explanation at the center of the model where all three spheres overlap. A major focus of this research is to attempt to understand the actors and the relationships within this area.

The typology offered by Peters (Figure 2.2) identifies how public administration is influenced by culture, in this case, social, administrative and political cultures. The development of public policy needs to be conducted within the boundaries of a given society's cultural values. For the framework of this research, public administration is taken, at a broad level, to be the Canadian government and, more narrowly, the Canadian regulators of biotechnology. Peters' typology offers a good conceptualization of which formal and informal organizations influence public administration.

While Picciotto's research ignored what occurs at the center of his model where all three spheres overlap, Brooks provides some analysis of what actors and relationships exist within this area (Figure 2.3). Brooks suggests that this area is the focal point for the decision making process and researchers can learn a great deal by better understanding the dynamics of the actors and relationships. Brooks points out that none of the stakeholders act single-mindedly -- rather, he suggests that the actions of one affect the actions of the others. The following chapters examine this specific aspect of his typology. Brooks' typology is also important as his is one of the few that include special interest groups as key stakeholders in the decision making process.

In their typology, Etzkowitz and Leydesdorff (Figure 2.5) discuss the center of this diagram, where all three spheres overlap and they suggest that this area is characterized by trilateral networks and hybrid organizations. This provides an additional perspective on what takes place in the center of a diagram where three spheres overlap. Etzkowitz and Leydesdorff use the state, industry and academia as the actors for their typology and this research has modified their identification of major actors to include the suggestions presented in the research of both Baber and Mehta. These two researchers suggest that the Triple Helix concept is limited in its application due to the absence of a fourth helix, where the fourth helix is representative of society's views and concerns. This research considers these views and incorporates them into a unifying framework.

This section has identified the important components from the various discipline specific typologies that provide unique insights and useful approaches to analyzing innovations and resources. The following section explains how these various components can be incorporated into a new framework capable of analyzing transformative technologies.

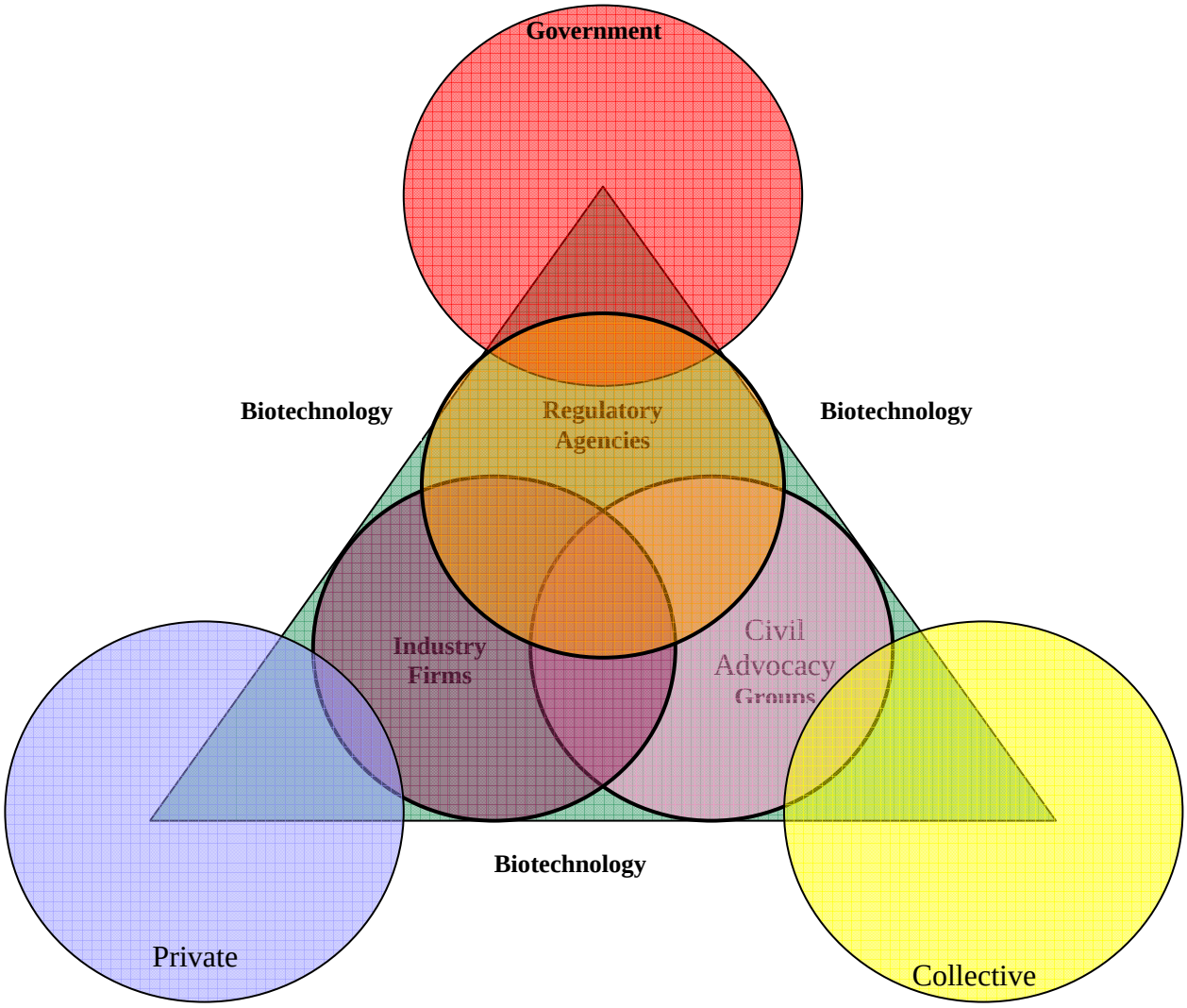
3.5 Defining the Framework

The following framework has been developed to examine the interactions among the stakeholders of government regulators, biotechnology industrial associations and civil advocacy groups as they attempt to manage socio-economic liabilities arising from transformative technologies such as agricultural biotechnology. Figure 3.1 offers a new framework for analyzing transformative technologies, such as agricultural biotechnology.

This framework is shown in a state of equilibrium where various academic disciplines are engaged in discussions and debates about the transformative technology, as defined by the three outer spheres. The triangle represents the transformative technology and the three key stakeholders within the triangle also are shown in a position of balanced power and authority. In reality, when the innovation or innovative product is commercialized, the triangle of the transformative technology would overlap the sphere of scientific research (the economy sphere) and the spheres of governance and society would be represented with less overlap, possibly to the point of being tangential to the triangle of the transformative

technology or completely outside of the triangle. This, of course, would change over time as the sphere of governance became increasingly engaged and this sphere would overlap to a greater degree as would the sphere of society (once the society began to show an increased awareness of the transformative technology).

Figure 3.1: Institutional Liability Framework



In addition to the three outer spheres being shown in equilibrium, so are the three inner spheres that are representative of the actors or key stakeholders within a transformative technology. At the early stage of the transformative technology the spheres within the triangle would not appear as balanced as they are in this framework. The sphere of industry firms would tend to be comprised of the small number of firms conducting research regarding the transformative technology. It would be too early in the development of the industry for an industry organization to have organized. The regulatory sphere would not be positioned entirely inside the triangle of the technology transformation as the regulations would be in development. The sphere of civil advocacy groups would likewise be moved to the edge of the triangle as the society in which the technology transformation was occurring would have limited awareness of the technology.

This framework provides a conceptualization that allows for the identification of institutional governance actors and their proximity to the technological transformation. Working towards the objective of including all of the actors in the decision making process, this framework provides a visualization of where the various actors would be positioned early in the debate about a technology transformation and solutions to the problem of how to more fully integrate the actors into the debate could be identified.

The three outer spheres represent the institutions of the marketplace or the economy, government and society. The private sphere contains scientists working in public

and private laboratories, industrial research and development and firms that produce products for the marketplace. The government sphere is comprised of government and the people that are employed by governmental institutions, international trade organizations, multilateral trade agreements, as well as elected officials and bureaucrats. The third sphere, collective, contains social groups and also represents all individuals within a defined geographical region, such as a country.

The triangle represents the parameters of the technological transformation, in this case agricultural biotechnology. This triangle has its points in the three outer spheres. The identification regarding these points is not meant to be a specific positioning of the actors, but rather an approximation of where each actor begins to interact with the transformative technology. The point in the private sphere is represented by private industry research and development and publicly funded researchers. The point in the government sphere is where the legislators of a nation debate and develop legislation pertaining to transformative technologies. The point in the collective sphere is defined as those within a society who are interested in a new innovation, such as, agricultural biotechnology. The closer an individual moves towards the sphere of the economy, the more they typify consumers and the closer they move towards the sphere of governance, the more they typify voters.

The inner sphere of industry firms is typified initially by private firms and by industry firms as the technology advances, taking actions or developing standards to ensure that risks are carefully managed to meet with the expectations of society. The

role of private firms is to take products that are approved following a risk analysis and to manage the successful commercialization of the product into the marketplace. An example of how exposure to risks is managed in agriculture can be the use of buffer zones for GM corn production. Buffer zones are used to manage the risk of the European Corn Borer developing resistance to Bt corn. A further example in the food processing industry is the use of hazard analysis critical control point (HACCP) standards to ensure that risks of food contamination are managed and minimized. This does not mean that the risks are reduced to zero, as the concept of zero risk as it applies to food safety does not exist. The reason tolerance levels exist is to ensure that the level of risk is within acceptable levels for safe human consumption.

The inner sphere of regulatory agencies is defined by government regulators who work conducting risk assessments. Materials and substances defined as hazardous have been identified by laboratory testing over time and substantial literature has been published on this subject. Government regulators provide lists of hazardous materials and substances and have developed procedures for handling and safe storage. In addition, levels of containment facilities have also been developed to ensure that there is no escape of hazardous products into the environment. This area of overlap is typified by government regulators and scientists working to further define hazards and thereby reduce the potential for the development of liabilities.

The inner sphere of civil advocacy groups is typified by the actions and demands of society regarding concerns that have developed from inefficient risk communication.

Risk communication frequently becomes the domain of the mass media and the media are well suited to provide the conditions for the onset of outrage when these concerns are not adequately addressed. Historically, new products and technologies have been introduced into the marketplace using enormous advertising campaigns in a time frame where societies had a high level of trust in government. Existing products and technologies that originated in the agriculture biotechnology industry were not marketed to the consuming public, which is a particular problem in a time when there is a decreasing level of society's trust in governments. Consumers have also gained power and authority of supply chains for food products at the expense of private firms when it comes to influencing the introduction of new products and technologies. The conditions for the development of outrage are strongest when the expectations of society fail to match the products and technologies emerging from industry in a time frame of low consumer trust in government.

The overlap between each of the three inner spheres can be defined by existing institutional actors. The overlap between industry firms and regulatory agencies is defined by the judicial institutions that exist. When regulatory agencies and industry firms in numerous sectors of the economy disagree on the interpretation of existing regulations or standards the method of resolution is frequently the court system. The legal institution in its role as a dispute settlement mechanism is called upon to render decisions that both parties will abide by. The challenge that arises from actions of this kind is that the Supreme Court of Canada does not have a mandate on social

policy, which is increasingly what it is being asked to decide upon. This overlap can also be represented by the actions of the Auditor General.

In Canada the interaction between the CFIA and the biotech industry is not structured to allow public involvement. Biotechnology firms provide data on new crop varieties following field testing and the data is assessed by scientists working at the CFIA, who may demand additional data be provided and will approve the variety when sufficient information is available. The CFIA will repeat some experiments to confirm that the data submitted is reliable and it is not uncommon for up to 50 different scientists to work on a particular varietal approval process. An additional process in Canada was the writing of the recent Royal Society of Canada report on GM foods. This report was written by a small group of experts after meeting and discussing GM food safety issues with government and industry officials.

The overlap between regulatory agencies and civil advocacy groups is defined by numerous government methods to share and gather information. Leading examples of this are royal commissions, specially structured government committees and government organized public forums. This form of public consultation allows individuals as citizens to address politicians directly to voice their support or concerns about the given topic of discussion. In Canada this area has been dominated by the Canadian Biotechnology Advisory Committee (CBAC). This committee was charged with the mandate of ‘engaging in a national conversation’ and as a result, held numerous public forums across Canada to gather input from

Canadian citizens and other interested societal groups and organizations. Designed to be an ongoing advisory body, the goal of the Canadian government is that CBAC will continually provide feedback and advice on biotechnology. Another process that is commonly used in this realm is the use of royal commissions, such as the recent New Zealand Royal Commission on Genetic Modification.

The overlap between industry firms and civil advocacy groups is defined by two factors. The first is private industry warranties or guarantees, where the industry has established standards that are designed to provide additional quality assurance as they exceed the defined mandatory regulation requirements. They allow individuals as consumers the ability to use the courts if they are not satisfied with a firm's policy. The second factor is the role of the media in today's instant information society. The media can be seen to have taken on the role of industry watchdog. The overlap between firms and civil advocacy groups can also defined by agencies or independent third parties that are involved in testing for food safety. These bodies are mandated to monitor processed and whole food products to ensure that tolerance levels for harmful contaminants have not been exceeded. The monitoring can be mandated by the regulatory agency or it can be a voluntary standard that is enforced by the industry. When a food safety concern is detected, these bodies inform the firm that produced the product and this firm then issues a product recall. In the Canadian food system, this process can instill consumer trust in the food safety system as consumers are reassured that the quality of their food is continually monitored and that the products on the store shelves are of the highest quality. An

example of this can be taken from the steady sales level of beef products following the announcement of ‘mad cow’ disease in Canada in 2003.

In developing a framework to examine the role of institutional governance in relation to liability management of agricultural biotechnology, attention was given to the contributions that focus on the relationships that exist, how they develop and who leads the process. A clear understanding of the actors, their roles and the relationships that exist within the areas of overlap provides an opportunity to apply this framework to socio-economic liability scenarios in the following chapters to assess if the framework contributed to the decision making process.

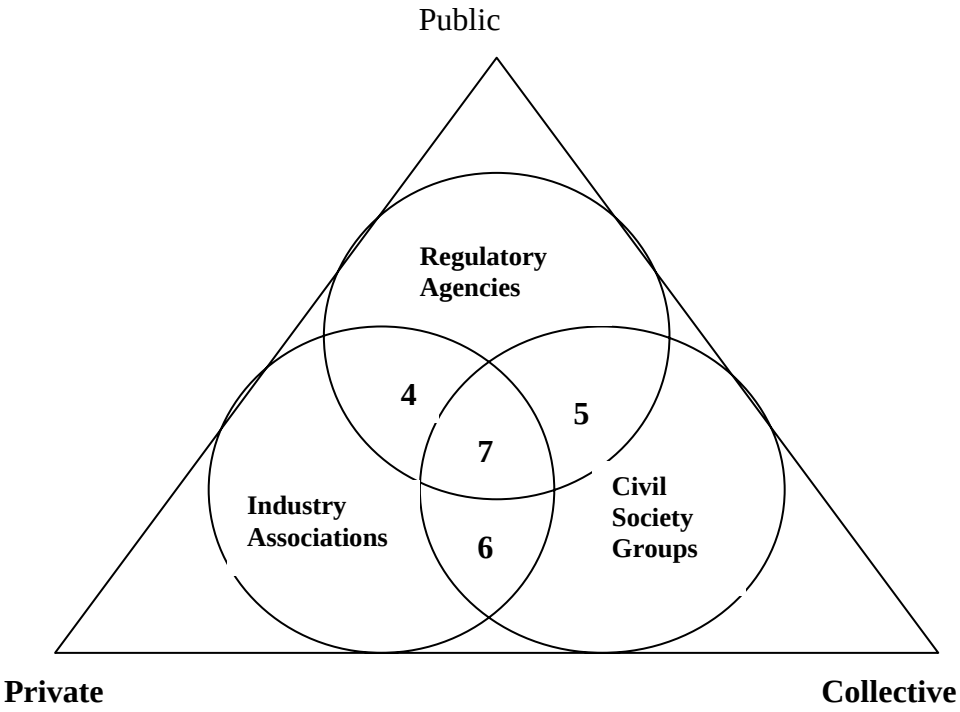
3.6 Applying the Framework

The above framework has been used in the course of the research for this thesis to better understand the regulation of agricultural biotechnology. The focus of the following research papers has been to examine what actors and relationships exist in the areas of overlap within the inner spheres. Figure 3.2 illustrates the central portion of the model and identifies where each research paper has focused. The framework has been largely applied to research related to genetically modified (GM) canola given that it is the leading transgenic crop in Canada. The following four chapters each examine one of the areas of overlap.

The overlap area identified by the number 4 represents Chapter 4. This chapter examines the regulatory gap that existed in the mid 1990s when the initial varieties

of GM canola were released. At this time, the Canadian government regulators approved GM canola and once this was done, the industry realized that its major export markets were not willing to accept GM canola. This chapter examines how industry and regulators worked together to develop an identity preservation system to ensure that all the GM canola was contained within the North American market.

Figure 3.2: Relationship of Research Papers with Framework



Source: Adopted by author from Picciotto, 1995.

The overlap area identified by the number 5 represents Chapter 5. This chapter reviews product differentiation literature and identifies the drivers that are unique to the various product differentiation systems. Using examples from Canadian agriculture, three product differentiation systems are outlined and additional costs

identified. This chapter examines the relationship between the federal regulators and society and what the role of the regulators can be regarding food safety.

The overlap area defined by the number 6 represents Chapter 6. This chapter examines the interaction between the industry associations and how they have managed GM crop production. The agricultural biotechnology industry's efforts to ensure the public that any liabilities from GM crops are being effectively identified and reliable information is communicated to the public is discussed in detail.

The area of overlap at the center of the diagram identified by the number 7 respresents Chapter 7. This chapter analyzes one of the newest technologies in agricultural biotechnology, that of plant-made pharmaceuticals. This agricultural innovation has been proceeding for the past 15 years, in many instances with minimal or a complete lack of regulation. This lack of regulation has resulted in several regulatory violations in the United States over the past year and this may be undermining consumer confidence in this techology. This chapter identifies where the regulatory gaps exist in the regulatory process and offers suggestions on how to improve the regulatory process to ensure that no further regulatory failures occur.

Positioning these research papers in this manner highlights the interdisciplinarity of the research for this thesis. Issues examined in these chapters include: consumer acceptance, gene flow, regulation, labeling, risk communication, supply chain management and liability. The result is a very thorough analysis of how to regulate the innovation of agricultural biotechnology.

Chapter 4

Marketplace Liabilities During Commercialization

4.1 Introduction

The global agri-food sector is in the initial stages of a rapid transformation. Historically, crop production has been pooled for transportation purposes. Today we are witnessing a move towards product differentiation. Identity preservation was initially used by the crop production industry to distinguish between grades of grains. The industry has now progressed to the point that it uses identity preservation for organic production, specialty contracts and buyer specific purchase requirements. Plant breeding technology over the years has created a large number of varieties with input and output traits that require identity preservation to maintain their value. Biotechnology has increased the number of varieties requiring identity preservation, which has led to the rise in use of identity preserved production and marketing (IPPM) systems. As end users continue to refine their purchase requirements, the number of IPPM systems will increase and the volume these systems are capable of handling will rise. Initial grade differentiation has been extrapolated to accommodate the increase in grain varieties requiring IPPM systems. As consumer demand grows in importance in terms of the entire food chain, IPPM systems are expected to become commonplace in Prairie agriculture.

This chapter applies the model to five IPPM systems used in the canola industry since 1995, concentrating on systems constructed to maintain regulatory conformity and market access. A number of regulatory systems have evolved to manage public expectations and concerns. In Canada and the US, once regulatory approval is complete, no further private industrial organization is required to maintain market access for GM canola. In Japan, private firms have chosen to adopt IPPM systems for GM canola to supplement and support the public regulatory system, in effect differentiating new products from old products in order to maintain market access and consumer acceptance. In the case of the EU, the regulatory system has not approved new varieties and the canola industry has decided it cannot operate profitably there and has abandoned that market for canola. Section 4.2 describes the background leading up to the development of the system. Section 4.3 presents the theoretical framework for examining the motivations and structure of IPPM systems. Section 4.4 uses the methodology to provide detail and analysis on the structure and costs of the systems adopted. Section 4.5 examines some of the implications of this analysis for other products and other markets.

4.2 Background

Biotechnology innovations entered global agri-food markets in 1995 with the introduction of recombinant Bovine Somatotrophin (rBST) and herbicide tolerant canola, corn, cotton and soybean varieties. Since then the rate of new product introductions has risen sharply, with more than 13 crops already transformed. James

(2003) estimates that in 2003, GM crops were being produced in 18 countries and that more than 40 new varieties involving input and output traits are in the R&D pipeline and likely will be ready for commercialization before 2007. Given the potential for stacking both input and output traits, the potential permutations and combinations leading to new products are enormous.

Irrespective of consumer attitudes, if new varieties introduced in Canada but pending approval in Japan or the EU were allowed to co-mingle with approved varieties, the resulting shipments to export markets would be jeopardized. Table 4.1 presents the distribution of Canadian production by consumer market. This table does not provide export data for all Canadian canola export markets, just the major markets prior to the commercialization of GM canola. Facing that market structure and the accelerating flow of new products, Canadian companies had three options. First, the companies could commercialize the new varieties, co-mingle production and lose access to the EU and Japanese markets, which in 1994-5 imported 42% of the Canadian output. Second, the companies could withhold their new varieties until they were approved in all key markets, even though Heller (1995) has estimated that a regulatory delay of even one year decreases the rate of return on a new product by 2.8%. Third, Canadian producers and exporters could accept responsibility to separate GM canola from traditional canola and develop a system to provide quality assurance of delivery to the key export markets, which would involve Canadian export companies developing new systems of identity preservation production and marketing.

Table 4.1: Canadian canola production and export destinations

Year	Canadian Production (000t)	% total production consumed domestically	% of production flowing to key export markets			
			Total	Japan	EU	US
1992-3	3,872	22%	78%	42%	8%	21%
1993-4	5,480	15%	85%	33%	19%	21%
1994-5	7,233	26%	74%	25%	17%	19%
1995-6	6,436	30%	70%	28%	6%	24%
1996-7	5,056	12%	88%	42%	4%	26%
1997-8	6,266	15%	85%	34%	1%	31%
1998-9	7,588	21%	79%	31%	0%	24%
1999-0	8,798	33%*	67%	31%	0%	23%
2000-1	7,088	4%**	96%	27%	0%	25%
2001-2	5,062	12%	88%	31%	0%	27%

* Due to record production in this crop year, domestic carry-over was 1.5-2 times normal.
** Domestic consumption still low due to record production in previous year.
Source: Exports are the sum of seed, oil and meal trade; retrieved from the World Wide Web at: http://www.canola-council.org/stats.

Developing product differentiation systems is usually precipitated by consumer demands, producer liability or regulatory requirements. So far IPPM systems have been adopted for seven input trait varieties of canola in order to maintain market access in Japan. All of the systems introduced in 1995-6 were explicitly designed to maintain technical regulatory access. Neither consumer attitudes nor product liability concerns played much of a role in these systems. Consumer attitudes toward GM food products in 1996 were significantly different to those of consumers today. At least partly due to lack of awareness of GM foods, consumers were not exerting significant pressure for segregation of GM from non-GM foods. North American consumers were voluntarily accepting Flavr Savr® tomatoes and rBST milk, Japanese consumers did not raise public concerns about GM foods and even EU consumers, who had just begun to express concerns, were willing to buy some

GM foods. In Britain, over 1.8 million cans of tomato paste labeled as being genetically modified were sold from 1996-98 (Agnet, 1999). Zeneca, the company that introduced the product, could not satisfy the demand of British retailers wanting to carry it. At least partly due to the generally neutral to positive consumer response and partly because of the nature of GM canola, food manufactures and retailers also faced few concerns about liability. Processed canola produces oils, which by their nature do not include any proteins and hence are free of GM elements, while the meal is not directly consumed by people. Rather, it is fed to animals as feed. The food manufacturers and retailers faced fewer risks of GM seeds entering the food chain and contaminating their supplies.

4.3 The Conceptual Framework

This section of the chapter uses the methodology from Figure 3.2 to examine the relationships and interactions that occurred between the Canadian canola industry and the federal government regulators to ensure that Canadian canola markets would not be jeopardized from the commercialization of GM canola. While the Canadian regulators have no mandate regarding new crop varieties post-commercialization, they closely observed the industry's process of ensuring market access and did work to facilitate discussions with specified export markets to provide quality reassurance. The focus of this section is to identify the important issues that existed in the area of overlap between industry associations and regulatory agencies. The following section then uses this framework to identify how these issues were addressed to the satisfaction of Canadian canola export markets.

Ultimately, identity preservation is about quality. Quality is a multifaceted aspect for any product. Neo-classical economic theory suggests that two key elements are vital to the creation of quality: consumer tastes and preferences; and producer efforts to develop consistent, safe, affordable, attractive fare that meets consumer demand. Economics supply chain theory suggests that most, if not all, of these elements can and should be produced within minimally regulated markets. Increasingly, however, the literature is pointing to variables of trust and confidence in the creation and operation of markets (Fukuyama, 1995 and Stiglitz, 1999). Markets for many products are often not able to create, by themselves, the conditions of trust that generate the socially optimal quantities of goods and services produced and consumed. Hence, there is a much more explicit role for public and private regulation in markets than neoclassical theory generally suggests. This is especially true for GM agri-food products, where perceived risks and public uncertainties abound. This section discusses the theoretical aspects of marketing GM products and will identify how this influenced the canola industry and its choice of marketing systems.

Tirole (1988) has explicitly identified a basis for integrating trust into conventional consumer theory. He posits that there are three types of goods: search goods, where consumers can visually identify attributes before consumption; experience goods, which require consumption to determine the attributes; and credence goods, where the unaided consumer cannot know the full attributes of consuming a good, at least

for some period after consumption. Trust usually is a key element in markets for experience and credence goods.

Applying this framework to genetically modified canola helps to illustrate how and why the industry has responded as it has to the different market circumstances. The search, experiential and credence attributes of canola have historically been assured through a combination of public and private regulatory systems (Table 4.2). In the production system, the public sector has tended to establish the general environment for private actors to effect transactions. The Canadian Food and Drugs Act sets rules for human consumption of low-erucic acid canola, the Feeds Act sets maximum tolerances for glucosinolate levels, the Canada Seeds Act specifies the performance standards for new germplasm, and the Canadian Grains Commissions sets and monitors the standards for the seeds trade. Although processors can grade canola on the basis of visual and physical attributes, such as seed weight, impurities, existence of cracked or green seed, percentage oil content, erucic acid and glucosinolate levels, and potentially the presence of transgenes (Canbra does some grading for GM elements), a consumer cannot distinguish any of the key quality differences valued by consumers through simple search procedures or for most attributes through consumption. At the retail level consumer labeling laws have operated to establish consistency of standards around labels. Meanwhile, the private sector has established common-property or private mechanisms to manage the transactional elements to the attributes. The Canola Council of Canada trademark on canola establishes the marketing standards for use of the name, processors have selected

canola seed to meet both government and industry standards, and the industry and private companies have used trademarks to manage their private interests.

Table 4.2: Product attributes and potential regulatory responses to GM plants

	Search attributes	Experiential attributes	Credence attributes
Public role in setting rules for the transaction	Consumer labeling laws to prevent fraud	Seeds Act regulations ensuring consistent quality	Health, safety and environmental regulations; product liability and tort laws
Private mechanisms for managing the transaction	Voluntary labeling	Trade marks backed up by IPPM systems	Private warranties and brands backed up by IPPM systems
Source: Smyth and Phillips, 2001.			

This type of public-private regulatory structure was more or less replicated in many other producing and consuming countries. As Kennett, *et al*., (1998) note, the existence of an effective grading system (which involves managing the experiential aspects and credence risks) reduces the need for vertical co-ordination between buyers and sellers of canola. As a product with little variation in consumer preferences in most countries, there was no incentive to establish any managed production or marketing systems. Nevertheless, as Jacquemin (1987), notes, "… hierarchies, federations of firms, and markets compete with each other to provide co-ordination, allocation and monitoring. It is only when one organizational form promises for specific activities a higher net return than alternative institutional arrangements that it will survive in the long run." (p.138)

Genetically modified canola has introduced some differences to the system. As noted above, consumers in different markets perceive significantly different risks

and have varying levels of uncertainty about the long-term benefits and costs of GM foods. All these credence factors require a much higher level of trust than the other product attributes. In Canada and the US, governments have addressed those concerns through their novel food, feed, seed and environmental regulatory systems. In addition, product liability and tort laws help to assure consumers that if dangerous products enter the food chain and cause harm, there are accessible means for consumer action to gain compensation. All of these mechanisms provide the base of 'trust' necessary for the marketplace to manage transactions, albeit moderated by extensive public and private regulatory measures.

The regulatory systems in Japan and EU have evolved somewhat differently, creating different market concerns. In Japan, the single largest export market for canola, the regulatory system has operated somewhat more slowly than in Canada, with the result that some varieties of GM canola have been approved for unconfined release in North America but approval has been delayed in Japan. To date, no products approved in North America have been rejected in Japan; all have been approved, if with a lag. As a result, the industry had three clear options about how to proceed: it could delay planting in Canada until approved in Japan; it could allow co-mingling of varieties that are both approved and pending in Japan, thereby jeopardizing the Japanese market; or it could operate a private IPPM system to separate and route sales of unapproved varieties to the North American market. As theory suggests, this ended up being a simple economic question, with the research companies assuming costs of $30-40/tonne for a purpose-built IPPM system in

exchange for accelerated adoption of their varieties, which improved the return on their investment.

The EU market represented a far different proposition because the choice of what to do was less clear. The EU regulatory system was held in such a low level of trust that it was unable to handle consumer concerns around GM canola (Gaskell, *et al.*, 1999). The Canadian export industry was faced with the choice of establishing a private regulatory mechanism to assure GM-free shipments, or to forego the market. A number of factors came into play in this case. The EU, while at times a large market for canola, has historically been a marginal, swing consumer. Furthermore, European consumers so far have not shown any willingness to pay a premium for GM free canola. In this case, the industry decided that the potentially large, permanent costs of an IPPM system to handle the risks in the EU market would not be compensated by either large sustained shipments or price increases. Hence, the industry declined to serve that market once the verifiable stocks of GM-free canola were run down.

4.4 Using the Framework

This section examines the specific actions taken by the canola industry to address the concerns regarding co-mingling of GM canola with conventional canola. The first part of this section outlines the structure and cost of the IPPM systems. It identifies all of the participating stakeholders and defines the collaborative efforts that were required to successfully reassure Canadian canola export markets that the

GM canola would and could be differentiated from conventional canola. The second part of this section discusses the governance structures that existed in the mid 1990s and explains why the industry needed to take the initiative on this issue. This section identifies the lead stakeholders and explains the role they played in the effort to reassure the Japanese importers that Canada would only export non-GM canola to Japan until the Japanese government approved the importing of GM canola. Japanese approval came in the winter of 1997.

The introduction in 1995 of two herbicide tolerant (HT) varieties of canola precipitated the first IPPM system for a GM crop in Canada, and the world. As the Government of Canada does not have the legal mandate to govern the exporting of GM canola, the industry chose to take the initiative and develop the export rules needed to assure continued access to foreign markets. The exporting of oilseeds in Canada has always been the responsibility of the private sector, although the Canadian Wheat Board would have played a small role in the transportation of oilseeds when it had the authority to allocate rail cars to Board and non-Board crops. The research/seed companies and grain companies shared this task. This group developed a series of strategic alliances vertically through proprietary supply chains and horizontally through the Canola Council of Canada to manage the flow of GM product in order to allay concerns in the Japanese market. This section focuses on the factors that brought these groups together to develop the Japanese market for GM food products and examines how they successfully accomplished the task of developing export regulations.

Monsanto and AgrEvo (now Bayer Crop Sciences) have been the two companies at the centre of the effort (Table 4.3). In the 1995 crop they each introduced HT varieties in Western Canada, initially through a seed multiplication program and then through commercial release. The 1995 harvest of approximately 30,000 acres and the 1996 harvest of approximately 240,000 acres were produced under IPPM conditions. Once market access to Japan was assured for the 1997 crop, the IPPM system was abandoned for *B. napus* varieties. Beginning in 1997 and continuing through the 1999 season, a number of Roundup Ready® *B. rapa* varieties were introduced under IPPM systems. In 1999 the four varieties accounted for 64,000 acres of production.

Table 4.3: Canola Acreage under IPPM systems, 1995-99

Year	**AgrEvo Liberty-Link™**	**Monsanto Roundup Ready® varieties**	
	B. napus varieties	*B. napus* varieties	*B. rapa* varieties
1995	25,000	5,000	0
1996	190,000	50,000	0
1997	0	0	Minimal
1998	0	0	50,000
1999	0	0	64,000
Sources: Evans, 1999; and Saskatchewan Wheat Pool, 1999.			

4.4.1 The Systems

By the spring of 1996, Monsanto and AgrEvo had developed a variety of IPPM systems to manage the differentiation of GM canola from the traditional canola stream (Table 4.4). Monsanto had two separate systems—one with the Saskatchewan Wheat Pool, Alberta Wheat Pool and Manitoba Pool Elevators and

the other with Limagrain and Cargill—while AgrEvo worked exclusively through the three Pool elevator companies. In 1997 Monsanto added two additional IPPM systems for Roundup Ready® *B. rapa* varieties. Each of these systems involved an agreement between the research company, a breeder, a grain merchant, farmers, truckers and an oilseed crusher. The objective of the IPPM system was to contain the herbicide tolerant canola separate and distinct from traditional canola marketing channels. This meant that the HT canola not touch any part of the export handling system, including elevators, rail cars and port terminals. The 1996 production was delivered to Canadian oilseed crushing plants that had markets for the oil and meal in Canada and the US where regulatory approval had been granted (Saskatchewan Wheat Pool, 1997). In each case, the grain merchant acted as the operating agent for the system, managing the supply chain from seed multiplication to processing.

As shown in Table 4.4, each of the supply chains began with a specific variety which included a proprietary herbicide tolerant gene which was backcrossed or inserted into a plant by either a contract breeder or by a partner company (e.g. Agriculture and Agri-Food Canada, Plant Genetics Systems, University of Alberta, Alberta Wheat Pool, Limagrain, AgrEvo, Pioneer Hi-Bred or Zeneca/Advanta). Once this variety was registered, Monsanto or AgrEvo contracted with one of the grain merchants (one of the three Prairie Pools elevator companies, United Grain Growers or Cargill) to manage the development and management of an IPPM system. That company then multiplied the seed, undertook production contracts with specific farmers, arranged delivery from farms to a processor with contract

truckers, and arranged for a custom crush, segregation and diversion of the resulting oil and meal into the North American market.

Table 4.4: Key elements in the canola IPPM systems, 1995-99

Links in the supply chain	**AgrEvo Liberty Link™ varieties**	**Monsanto Roundup Ready® varieties**			
Species	*B. napus*	*B. napus*	*B. napus*	*B. rapa*	*B. rapa*
Variety names (year approved)	Innovator (95)	Quantum (95); Quest (96)	LG3295 (96)	41P50 and 41P51 (96)	Hysyn 101 RR (97)
Seed developer(s)	Ag. Canada and Plant Genetics Systems in collaboration with AgrEvo	University of Alberta and Alberta Wheat Pool for 3 Pools	Limagrain	Pioneer Hi-Bred	Zeneca/ Advanta
Grain merchant(s)	Saskatchewan Wheat Pool, Alberta Wheat Pool, Manitoba Pool Elevators	Saskatchewan Wheat Pool, Alberta Wheat Pool, Manitoba Pool Elevators	Cargill	United Grain Growers (UGG)	Cargill
Farmers 1995 1996 1997 1998 1999	 310 2,375 0 0 0	 480 1,700 0 0 0	 0 incl 0 0 0	 0 0 minimal 625 800	 0 0 incl incl incl
Trucking arranged by:	Pools	Pools	Cargill	UGG	Cargill
Crushers	Canbra at Lethbridge, CanAmera at Altona and Harrowby	CanAmera at Nipawin and Lloydminster	Cargill at Clavet	Archer Daniels Midland at Lloydminster	Canbra at Lethbridge
Source: Smyth and Phillips, 2001a.					

The participating companies all agreed that the herbicide resistant technology brought real value to producers and all agreed that there was a need to bring this technology to the marketplace. Both AgrEvo and Monsanto acknowledged, however, that if these varieties were co-mingled in the export system, then Canadian canola would be shut out of export markets. In response, private Canadian firms agreed to release materials only if they were approved in the 'key canola markets',

defined as Canada, Japan, US and Mexico by the Expert Committee for Canola of the Pest Management Review Agency.

Cost estimates were found for two of the five IPPM systems (Table 4.5). While there is room for debate about the costs, the two estimates suggest that transaction costs for the IPPM system were very high. There are five main areas where additional costs were incurred: by the producer, during transportation, by the processor, in administration and through opportunity costs.

Table 4.5: Identified Costs of 1996 IPPM Systems ($C)

Cost Category	**AgrEvo & Manitoba Pool Elevators ($/mt)**	**Saskatchewan Wheat Pool ($/mt)**
Producer on-farm costs	$1	$1
Freight Inefficiency	$5-6	$7-10
Dead Freight	$1.50-2	$2-3
Processor	$3-4	$3-5
Administration	$4	$5
Opportunity cost	$20	$10
Collective subsidy		$5-7
Total IPPM Cost	**$34-37**	**$33-41**

mt = metric tonne
Sources: Manitoba Pool Elevators, 1996; and Saskatchewan Wheat Pool, 1997.

The added cost for producers was due to separate on-farm storage requirements of the IPPM system production contracts. Farmers were required to store these varieties in separate bins, which at times left some of the bin capacity unused. The cost of inefficient use of on-farm storage was estimated to be $1/mt.

The inefficiency in transporting the transgenic canola was more substantial as only selected crushers were used. AgrEvo used the CanAmera sites located at Harrowby, Manitoba, and Altona, Alberta, along with Canbra's site at Lethbridge, Alberta. Monsanto used a wider array of crushers, including CanAmera at Nipawin and Lloydminster, Cargill at Clavet and Archer Daniels Midland at Lloydminster. Nevertheless, each system used a specific set of crushers. With an average of 40-45% of the total Canadian canola production occurring in Saskatchewan, producers often faced lengthy trucking distances. These costs were shared among the producers, seed companies and the grain elevator companies.

Transportation costs were estimated to be higher due to freight inefficiencies and dead freight. Freight inefficiencies are defined as those costs of trucking that exceeded average costs of delivering to the nearest local elevator. A producer would normally deliver canola to their nearest local elevator, but the canola had to be trucked directly to the crushing facility because elevators were excluded in this system. The producers paid a portion of this cost. Dead freight costs relate to the volumes on-farm that had to be delivered as partial loads. The freight inefficiency cost of transporting the HT canola to processors resulted in costs of $7-10/mt. Dead freight costs were estimated to be $2-3/mt.

The canola processors faced cost increases due to the IPPM system. Manitoba Pool Elevator (1996, p. 1) documents note that "[t]he domestic crusher was obliged to segregate raw transgenic canola seed, transgenic canola oil and transgenic canola

meal from traditional stocks under the IPP [identity preserved production] system developed for transgenic canola introduction." This required the processors to physically clean the production equipment prior to crushing the HT canola (usually during a seasonal shutdown), as well as after the HT run was finished. This was done to ensure that the transgenic canola oil did not co-mingle with oils destined for export markets. The processors involved identified their incremental cost to be in the range of $3-5/mt.

Many non-recoverable costs occurred in administration. The Saskatchewan Wheat Pool, for example, actively managed all of the producer contracts it had to ensure that compliance with the terms were met and that co-mingling was avoided. In an effort to ensure the purity of the IPPM system, seed agents from AgrEvo, Monsanto and the Saskatchewan Wheat Pool (Pool) mapped all the fields in which HT canola was grown. Once harvest commenced AgrEvo, Monsanto and the Pool co-ordinated to ensure that an agent from one of the companies would be on farm during the harvest to inspect the harvested supplies, apply grain confetti and to seal the bin. The confetti had the company logo on one side and a unique grower identification number on the other. This placed a very real constraint on producers while at the same time providing the Pool marketing department with accurate information of where and how much HT canola was available. At this point, the Pool worked with the processors to arrange to have the HT canola trucked to be crushed at a designated oil crushing plant that was just about to have a scheduled shut down and cleaning. Once a crush date was determined, the Pool contracted with commercial

truckers to pick up the HT canola from farmers and deliver the HT canola to the designated processors. When the canola was to be trucked, an agent from the Pool was on farm to inspect to ensure that none of the bins had been opened or tampered with. This process was very difficult due to the simple logistics of trucking grain in the winter in Western Canada. Snowstorms, impassable roads and bad driving conditions all complicated the co-ordination of trucking process. These requirements were all labour intensive and were estimated to cost $4-5/mt.

The grain merchants also identified an opportunity cost of crops in IPPM systems. In effect, separating the seed, being constrained on when and where to bring it to the market and being forced to move it according to a predetermined plan, severely limited the marketer's ability to lock in high prices in what is traditionally a volatile market. The Saskatchewan Wheat Pool (1997, p.2) reported that "[f]rom a general market perspective, an IP program like this does not allow for access to all attractive alternative markets. This is a potential cost due to possible increased margin potentials, which cannot be achieved. The potential unrealized profit opportunity could well be in excess of $10/mt." It is not clear, but some of that opportunity cost could have been because North American buyers recognized that they had some market power in the circumstances and exploited it. Furthermore, the grain merchants estimated other unallocated expenses cost all parts of the supply chain an estimated $5-7/mt. The Saskatchewan Wheat Pool (1997, p.2) concluded that "[i]n order to develop and promote this technology, the producer of the technology, AgrEvo [and Monsanto], the producers of the seed, the [Saskatchewan Wheat Pool,

Alberta Wheat Pool and Manitoba Pool Elevators], and the beneficiary of the technology, the producer, all contributed to the subsidization of the IPP program."

In total, the two IPPM systems cost an estimated $33-41/mt. Based on acreage, it is estimated that the IPPM systems adopted in 1995-6 cost between $2.8-3.5 million for the AgrEvo based system and $750,000-930,000 for the Monsanto based systems. As noted, all the stakeholders in the IPPM process shared these costs. The producers assumed the identified on-farm costs and some of the increased transportation costs; they did not receive any price formal premium, and in some cases, were forced to take spot prices that were unattractive relative to other markets. The grain company assumed the dead freight costs, a portion of the freight inefficiency and part of the administration cost through their normal operating margins (Saskatchewan Wheat Pool, 1997). The crushers picked up most of the incremental crushing costs. The remaining costs (opportunity cost, administration and other subsidies) were divided and paid by Monsanto and AgrEvo, based on the acreage they had under cultivation. In Monsanto's case, they expensed this additional cost to research and development costs related to the development of the technology.

The total cost of the IPPM operated in conjunction with the Saskatchewan Wheat Pool in 1995-6 was estimated to exceed $4 million. The average five-year farm-gate price for canola, from 1991-96, was $280/tonne. Using the cost increase range of

$33-$41, the increased cost of these IPPM systems ranged from a low of 12% to a high of 15% of the average farm-gate price.

These cost increases, however, must be balanced against any expected or realized gains. Early figures suggested that farmers gained upwards of C$10/acre or C$5/tonne benefit from the new technologies (Mayer, 1997) and the Canola Council of Canada (2001) estimates that the net benefit to farmers between 1997 and 2000 was C$464 million, which for most farmers would have more than compensated for their added producer costs. The grain merchants may have gained margins on new volumes since then, which probably have compensated for their incremental system costs: by 2003 an estimated 89% of canola acreage involved HT varieties. Furthermore, in most cases the canola was crushed through subsidiary crushers, increasing their volumes and offsetting some of the incremental costs. Finally, although the research/seed companies may have lost some money due to the costs of the IPPM systems, they gained significantly in terms of market adoption (Table 4.6). It is very likely that if Monsanto and AgrEvo had introduced the seeds without IPPM systems, farmers would have shunned the new seeds. So the only real choice for early and aggressive adoption was to pay for IPPM systems. In this case one could argue that the two companies accelerated adoption by at least one year, which was estimated to have a net present value in 1995 of more than $100 million. Clearly, the IPPM system for HT canola directed to Japan was a win-win situation.

Table 4.6: Net present value of earlier adoption of new canola technologies in Canada

Year	% acres in GM canola		Revenue impacts of one year delay in introduction assuming $15/acre benefit ($M)			
	Actual	Delayed	Actual	Delayed	Absolute Difference	Net Present value in 1995 of difference
1995	1%		2.0	0.0	-2.0	-2.0
1996	4%	1%	5.3	1.3	-4.0	-3.6
1997	33%	4%	59.6	7.2	-52.4	-43.3
1998	44%	33%	89.3	67.0	-22.3	-16.8
1999	69%	44%	143.9	91.7	-52.1	-35.6
Total			300.1	167.2	-132.9	-101.3
Source: Smyth and Phillips, 2001b.						

The results are less clear for IPPM systems for either Europe or for *B. rapa*. Given the uncertainty about Europe, the canola industry made a deliberate decision to abandon the market in 1996. The European market was not a strong export market for Canadian canola—Europe is usually self-sufficient in terms of canola production and actually exports canola when price premiums are available. The canola industry's view was that future European canola exports had limited potential so, once Japan approved GM products in 1997, the IPPM system was discontinued, thereby removing all possibility of supplying European canola markets.

Monsanto's IPPM system since 1997 for four *B. rapa* varieties has posed more difficulties. Although the logic is the same as for the *B. napus* varieties, the economics are different. *B. rapa* has taken longer to get approval because of different environmental impacts (the seed can stay in soil for up to 15 years and still germinate). As a result of the longer approval time, and much smaller market (*B.*

rapa is estimated to account for less than 10% of canola acreage in Western Canada in 1999), Monsanto has decided to terminate its work on *B. rapa*.

4.4.2 Governance Mechanisms

This section utilizes the methodology to examine how transparency was incorporated into the process and how this facilitated foreign market reassurance regarding Canada's ability to differentiate the canola exports. Specifically, this section identifies the importance of the role played by the canola industry organization, the Canola Council of Canada (CCC). The Canola Council of Canada initiated and facilitated many of the discussions that were held with the Japanese importers. The CCC's role was crucial in providing trust and assurance that Canada would meet its commitment of exporting only non-GM canola to Japan. This section provides the details on the relationships that existed within the area of overlap in Figure 3.2 between the canola industry and Canadian regulators.

Although the Seeds Act requires that any new canola variety seeking registration in Canada be an improvement over existing varieties, decisions are made based on agronomic attributes and not potential market impacts. Given delays in approvals in Japan and the EU, the industry was challenged to develop a system that would provide assurances to import markets that the products shipped contained only approved varieties. This involved three discrete steps. First, the Canola Council of Canada worked with the industry participants to develop agreement that all shipments to Japan and the EU should contain only varieties approved for import by

those countries. Second, the individual industry actors developed their own IPPM systems to handle their proprietary products. Third, the CCC and the provincial growers' associations worked with the grain exporters and the key regulators and buyers in Japan and the EU to raise confidence in the Canadian solution.

The process began in February 1995 when the Pest Management Regulatory Agency submitted recommendations for approval for two varieties of HT canola to the Expert Committee for Canola (this followed three years of regulatory review for feed, food and environmental safety). The Department of Agriculture, which oversaw the Seeds Act (that responsibility has since devolved to the CFIA, approved the two varieties in March 1995. Once the new varieties were registered through the Seeds Act, the product was fully licensed to be grown and enter the grain handling system, which implicitly includes exports. The CFIA did not have any authority (nor do they at present) to require the owner of the variety or the canola industry to segregate the new varieties from traditional varieties. Once oilseed varieties are granted variety approval by the CFIA, all production and exporting issues belong to the various oilseed industries.

Early in 1995 the Canola Council of Canada asked the Expert Committee for Canola to delay making recommendations for future registrations of GM canola until such time as the developers could demonstrate that the product had regulatory approval in the defined market (i.e. Canada, US and Japan). Canada and the US had already approved the licensing and importing of GM products. Japan was in the process of

developing regulatory policies. Given the lack of a legal mandate, the regulators were not able to respond.

As a result, the canola industry came together in late 1995 to discuss the concern that the major canola importing countries had not yet developed guidelines for importing GM products. The result of this discussion process was a voluntary agreement between the seed, grain and processing companies to co-operate and to separate the 1996 production (the limited 1995 production was for seed purposes only and did not enter the handling system). This agreement respected the CCC's request that products from these fields not be allowed to reach international markets until the appropriate national regulators approved imports of GM products.

The second stage was to develop the IPPM systems. It was realized early in the process that the project could not be done without the full co-operation, support and involvement of a grain handler. The only way to develop an acceptable and efficient system was to have knowledge of the production process and the marketplace, which only existed in the grain companies. They analyzed grain flow patterns and designed systems, which fit with the market and the grain handling processes currently in place. The Saskatchewan Wheat Pool, Alberta Wheat Pool and Manitoba Pool Elevators, in particular, were instrumental in the early IPPM programs for both Monsanto and AgrEvo. Each company developed a set of procedures that each of the stakeholders (seed companies, producer, grain handler, transporter and processing companies) would apply to IPPM the grain. This involved a team of

experts in regulatory affairs, development and marketing departments in the grain and seed/research companies. The teams also kept the Canola Council of Canada and, through the Council, the Canadian regulators fully informed of the entire process, from design to planting and harvest to crushing. This transparent process helped build the trust within Canada that was necessary to convince foreign regulators and buyers of the sincerity of the effort.

While the IPPM systems were being developed, the CCC worked with grain exporters, regulators and importers in Japan to convince them that Canada was identity preserving GM varieties and that problems would not arise in export shipments. Both Monsanto and AgrEvo officials admit that the CCC played a vital role in providing the Japanese with the assurances that Canada could and would identity preserve, which allowed the Japanese to continue to import while the new varieties were under review. This mutually beneficial arrangement contributed to IPPM policy having greater legitimacy in the eyes of Canada's key canola export markets. One of the primary reasons that the Japanese had a large degree of *ex ante* trust in the Canadian IPPM system was that it was built upon a 20 year relationship. Beginning in 1977, the Canadian and Japanese industry began annual consultations on crop quality and quantity (Adolphe, 2000); these consultations became biannual in 1987. The CCC over the years convinced the Japanese that Canada has a credible variety registration system that prevents new varieties from being released without first being approved by industry and government. The lengthy working relationship and understanding of the variety registration system allowed the Japanese to trust

that the Canadian canola industry could identity preserve GM canola and did not demand any additional insurance clauses, right of inspection or testing.

It is extremely doubtful whether an outside group or agency could have developed an effective IPPM system. If the design of the system had been contracted to an outside agency that lacked a fundamental understanding of grain transfer, there is a high probability that the system would not have had the capability to successfully meet the defined objectives. Had the IPPM process been forced upon the industry by government, there is some doubt as to whether this would have produced superior results. AgrEvo and the Saskatchewan Wheat Pool believe that by taking the initiative on this issue and working with the CCC, they were able to develop a system that met the needs of Japanese regulators, Canadian farmers and the technology developers. A mandated program might have met the needs of regulators, but it would not likely have encouraged industry funding nor would it likely have been as effective in getting the seed in the hands of as many innovative farmers (a critical goal of the programs). Finally, it is worth noting that the system was effective—there were no documented reports of co-mingling.

4.5 Conclusions

The methodological framework would suggest that in the areas of overlap, one of the principal actors needs to be the initiator of a strategy to address the issues that are created from the commercialization of transformative technologies. Commonly, the initiator is the regulatory agency. In the case of ensuring that GM canola was

contained within the North American market, this was not an option--the initiative had to come from industry. Whether industry based initiatives to develop governance structures and to manage the marketplace liabilities would be met with the same level of foreign market assurance as existed in the mid 1990s is doubtful today. However, this study identifies how industry and regulators can and did work co-operatively to develop standards that provided confidence to concerned export markets. The market liabilities were identified, strategies were then developed and relationships were utilized to ensure that Canada could continue to export canola to concerned markets while these markets completed their own regulatory requirements.

Market transactions for goods with experience and credence attributes require a high degree of trust, which requires both effective public and private regulatory mechanisms. The canola industry's experience with genetically modified herbicide tolerant canola illustrates that, provided there is a public base for managing credence and experiential issues, the industry can effectively handle many of the market considerations through private identity preserved production and marketing systems. Provided the expected returns exceed the costs, private initiative will work. All industry participants assert that this will depend on tolerance levels for shipments (Kennedy, 1999). Regardless of whether an IPPM system is established to capture value for a GM trait, special crop trait or traditional variety, it can not deliver a 100% guarantee of purity. This lack of a purity guarantee has the potential to create outrage with consumers should co-mingling occur and products on grocery store

shelves be tested and found to contain GM ingredients. Realistic tolerance levels will need to be implemented prior to the increased use of IPPM systems.

Provided realistic tolerance levels can be established, IPPM systems may become a permanent method of capturing attribute value from food product markets. Kennett, *et al.,* (1998) observed that grading standards can reduce the need for vertical integration, which is likely true for search and experience goods. Credence goods, however, impose requirements that a grading system cannot handle. Industry participants in those IPPM systems studied observed that the design of every IPPM system will vary depending on the genetics and marketing of the variety involved. Grading, which homogenizes products, would not satisfy the commercial needs of the industry.

So far all of the IPPM systems developed have been custom built to meet the specifications of the technology owner and the market. The limited horizontal co-ordination between the systems has come through the research companies (e.g. Monsanto and AgrEvo) working with their agents (the grain companies) and through the CCC's efforts in export markets. For the most part the grain companies have viewed the IPPM systems as valuable proprietary services. Ultimately, however, these systems are designed to earn trust, which is a cumulative process. Past successful actions can contribute to achieving a higher level of trust but failures in one part of the market can spill-over to other market segments. If IPPM systems are here to stay, then it may not be enough to rely on independent systems.

One aspect of the operation of the IPPM system that, on the surface, is not readily identifiable as a benefit is the 'learning experience' that was gained by all stakeholders involved in this process. The operation of this IPPM system for genetically modified canola was the first incidence of a system designed to prevent the co-mingling of a transgenic product from conventional products. With the present day movement towards consumer-driven agriculture as opposed to producer-driven agriculture, the requirement for IPPM systems will only increase. The participants in this IPPM system have gained valuable knowledge in developing a functioning and internationally credibly system that insures the quality of export products.

This research is relevant to those in other grain and oilseed commodities that are considering product differentiation. The driver of this IPPM system was to ensure that access to foreign markets was maintained even after introduction of a new variety that was not yet approved in those markets. As the demands for product differentiation change, so to will the design specifications of the IPPM system. Striving to meet a 0.9% tolerance level (present EU level allowed for unintentional co-mingling) with a crop that is an open pollinator may be virtually impossible due to cross-pollination. The possibility of meeting 0.9% tolerance levels with self-pollinators is much greater. From this research it is clear that product differentiation systems require leaders or 'integrators'. The supply chain can be organized and regulated by an integrator at the start of the supply chain or at the demand end (as appears to be happening in the UK). Furthermore, this research suggests that

regardless of where the initiative starts, it is extremely important that that integrator have a financial stake in the outcome. Hence, demand side efforts will require a retailer or manufacturer who can see some benefit, such as a price premium or market share, from their activities. The costs are simply too large to do this as a *pro bono* effort.

There would appear to be two ways in which IPPM systems could be made more efficient. Ultimately, the goal should be to manage liability. One of the pan-industry participants—such as the Canola Council of Canada or the Canadian Seed Trade Association—could become the custom developer or integrator for the system, providing purpose-built but quality-assured systems to meet market needs. The difficulty is that neither entity has any equity at stake in the transactions which may lower the entity's commitment to the quality-assured system. This may reduce the quality-assured system's credibility in the eyes of producers and customers. Alternatively, the industry could adopt an external quality assurance system—such as the International Standards Organization (ISO) or Hazard Analysis Critical Control Point (HACCP) systems—to standardize the process of developing IPPM systems. This would differ from a traditional grading system in that the quality assurance system would assure integrity of process and not the standard itself, which would be a negotiated or contracted feature determined in the marketplace. The result of this is that the developer of the quality assurance system can not monitor the final product, just the overall system. Any time the standards are contracted to private firms, there is the chance for opportunistic behaviour. This would leave the

operation of the system in the hands of the firms with equity at stake but could help to build cumulative trust in the system.

Chapter 5

Product Differentiation and Consumer Labeling

5.1 Introduction

This chapter examines the relationship between the federal regulators and society and what the role of the regulators can be regarding food safety. This chapter specifically relates to the area of overlap identified by the number 5 in Figure 3.2. The focus of the research for this chapter is on how GM products can be differentiated during production and how that information is then communicated to the public. The intent is to examine the different product differentiation options and to assess how consumers relate to each of the options. The chapter identifies the driver for each of the product differentiation options and discusses how each of the different actors attempts to communicate the information to the consumer. The chapter concludes with a review of consumer labeling demands and attempts to identify what it is that consumers are searching for regarding label information.

Agricultural biotechnology has in less than a decade dramatically impacted the supply and demand of agricultural food products. While biotechnology has offered few new food products to the marketplace, it has revolutionized the method of producing and delivering conventional food products. An increasing number of cereals and oilseeds are being differentiated due to protein or health attributes, to

ensure their value or uniqueness is captured and maintained throughout the supply chain.

Over 28 countries plus the EU system have either developed or publicly declared their intent to introduce mandatory labeling legislation for GM products (Phillips and McNeill, 2002). If exporters in countries producing GM crops wish to retain those export markets requiring labeling as clients, then systems of product differentiation will have to be established to ensure the continuity of exports to these concerned markets.

Formal governance structures for these differentiation systems are frequently lacking. Product differentiation systems can be imposed at the time of variety registration if the novel trait is deemed to harm food safety. More often than not differentiation systems are not required by government edict. Rather, they are undertaken to realize private objectives. However, private firms must take great care to ensure that the product differentiation systems they choose correlates with their objectives.

If the Canadian agri-food industry does not adopt product differentiation systems, two alternatives are possible. First, the global agri-food market could continue to divide into two distinct markets with only limited interaction between the two. Some markets, such as the EU, and some food processors, have decided to forgo GM technology for now, and are devoting increasing effort to securing adequate volumes

of GM-free foodstuffs to satisfy their customers. Consumers in those markets for the most part do not have any opportunity to consume GM foods, as they simply are not available, even though a recent poll of British consumers found 40% were indifferent to consuming GM food (MORI, 2002). Other markets, such as in North America, have rapidly adopted the technology and for the most part do not offer a choice of GM-free food to their consumers. There are some small, but growing, niche markets for organic and GM-free products in North America that do label in a manner that allows the consumer to identify these products. Trade between these two blocks has slowed dramatically in all product markets where GM varieties are being used. As a result, Canada faces the possibility of losing export markets where GM traits have not been commercialized and the consumers in the export markets do not wish GM foods in any product lines. For example, US corn exports to the EU dropped from US$574 million in 1995 to US$175 million in 1999 and soybean exports dropped from US$2.1 billion to US$1.1 billion while Canada's canola exports to the EU dropped from C$204 million to C$8 million (Industry Canada, 2000). Kuntz (2001) has estimated that if GM wheat is introduced without a product differentiation system, Canada could lose as much as C$185 million per year or 70% of the annual premium it earns in the global wheat trade. Meanwhile, food processors in places like the EU have diverted their purchases to markets where GM varieties are not produced, such as northern Brazil for soybeans and Australia for canola.

A second alternative would be for companies to shelve their new technology. In Canada, GM seed potatoes were withdrawn from the market in 2001 in response to

food processor concerns while the developer of GM flax announced it had deregistered the variety because Europe, which imports approximately 60% of Canadian production, has not approved the variety for import. In the spring of 2004, Monsanto announced that it was withdrawing its application for approval of GM wheat in Canada due to the concern expressed by Canadian wheat import markets.

Neither of these alternatives is desirable. If Canada, for example, adopts the technology and loses key premium markets, much or all of the benefits of the new technologies will be offset by market losses, with producers facing the greatest losses. Similarly, if Canada forgoes productivity or quality enhancing opportunities, its producers will face even stiffer competition in the residual commodity markets (see Phillips and Khachatourians, 2001, for further discussion of this).

Lehnert, *et al*., (2000, p. 409) succinctly make the point about successful product introduction:

> Failures occurring during the establishment of a new product or a new process cause high correction costs. They may often lead to losses of market share and damage to the image of the supply chain. It is therefore reasonable to pay attention to potential failures in the early stages of establishment and process planning.

This lynch-pin concept regarding product commercialization, defines a new approach required for the introduction of new GM crops: do no harm! Caution, diligence and concern for others must be the leading motto for all participants in differentiation systems. In the past, the focus has been on getting new products into

the market, while adjustments to the supply chain were made as one went along. Clearly, this strategy is risky.

Industry needs to identify and learn from the difficulties, successes and failures that occurred when introducing GM canola, corn, cotton and soybeans to ensure the successful introduction of new GM crops.

Section 5.2 examines the literature on product differentiation and provides a definition for each system. A detailed examination of the features that are unique to each form of product differentiation and how they relate to the conceptual framework is offered in Section 5.3. Section 5.4 uses the framework to examine the labeling debate. Section 5.5 offers some conclusions.

5.2 Background

The definition of product differentiation can have several nuances, depending on the justification for the differentiation. Frequently the terms identity preserved production and marketing (IPPM), segregation and traceability are used interchangeably in the biotechnology and supply chain literature. This is creating misconceptions about the distinct role that each of these product differentiation systems has in the supply of agri-food products. The purpose of this section is to identify definitions that exist in the literature to date and to suggest definitions where the literature is absent.

Identity Preserved Production and Marketing

The first product differentiation system, identity preserved production and marketing, has evolved over time in the grain and oilseed industry. Purchasers of raw products became more demanding about the quality and purity of the product they were purchasing so the grain handling system gradually developed distinct channels to market the differing grades of grains and oilseeds. All grains and oilseeds are purchased by a grading system in today's marketplace and this grading system has premiums that rise as one moves from low to high grades. The relationship of premiums to differing grades for private market incentives is the definition of an IPPM system.

Identify preserved production and marketing systems are initiated by private firms in the grain and oilseed industry to extract premiums from a marketplace that has expressed a willingness to pay for an identifiable and marketable product trait or feature. An IPPM system is a 'closed loop' channel that facilitates the production and delivery of an assured quality by allowing identification of a commodity from the germplasm or breeding stock to the processed product on a retail shelf (Buckwell, *et al*., 1999; Lin, 2002). These IPPM systems are predominantly voluntary private firm based initiatives that range between systems that are loosely structured (i.e. malting barley) with high tolerance levels and those with rigid structures (i.e. non-GM European markets) with minimal tolerance levels. Firms operating in the minimal tolerance field achieve this by developing and adhering to strict protocols that specify production standards, provide for sampling and ensure appropriate documentation to audit the flow of product.

A survey of the literature on IPPM shows that while there is growing discussion about IPPM systems, there are very few working definitions. Lin (2002) suggests that an identity preservation system "… is a more stringent (and expensive) handling process and requires that strict separation, typically involving containerized shipping, is maintained at all times. IP lessens the need for additional testing as control of the commodity changes hands, and it lowers liability and risk of biotech and non-biotech commingling for growers and handlers." (p.263) This definition conflicts with the definition offered in this chapter as Lin sees IPPM as having a limited role in the movement of grains and oilseeds due to extremely low tolerance levels. Lin's definition of IPPM and segregation still deals with the same system, one that is initiated voluntarily by private firms in an attempt to capture premiums. It is shown below how IPPM systems differ from segregation systems.

The remainder of the literature on IPPM systems relates to theoretical and operational uses of IPPM systems. Bullock, *et al*., (2000) and Bullock and Desquilbet (2001) discuss differentiation between GM and non-GM products and Herrman, *et al*., (1999) examine the feasibility of wheat segregation. Bender, *et al*., (1999), Bender and Hill (2000) and Good, *et al*., (2000) have released a series of papers on handling specialty corn and soybean crops, with costs being the focus, not the defining of the system used to handle the specialty crop. Additionally, Miranowski, *et al*., (1999) offer some perspectives on the economics of IPPM, while Maltsbarger and Kalaitzandonakes (2000) provide a solid theoretical model for examining the cost of identity preservation.

Numerous IPPM systems are operating in Canada and around the world. Some extend only between the breeders and the wholesale market or processor, while others extend right up to the retailer. Their structure depends on the attribute they are trying to preserve. Some novel oils, such as low linolenic oils that are more stable in fryers, only have value at the processing level while others, such as high oleic oils, have health attributes that can be marketed to consumers. Identity preserved production and marketing systems are important for providing information to consumers about the provenance of a product, as those attributes are not visible or detectable in the product itself.

Segregation

The second product differentiation system, segregation, has frequently been incorrectly applied to the grading of different classes of grains and oilseeds in order to receive a higher price for the commodity than if it were allowed to be co-mingled. Segregation systems have a formal structure and in fact can act as regulatory standards. Segregation differs from IPPM in that the focus of the system is not on capturing premiums but rather on ensuring that potentially hazardous crops are prevented from entering supply chains that have products destined for human consumption.

Segregation can be defined as a regulatory tool that is required for variety approval and commercial release of grain and oilseed varieties that could enter the supply chain and create the potential for serious health hazards. The majority of these varieties would be crop varieties developed for industrial uses. Segregation systems

can be developed as part of a variety registration process, where government regulators use contract registration to ensure that certain novel varieties will not enter the handling system of like varieties. The private firm seeking registration of the novel variety has to demonstrate that there is a segregation system developed to ensure the containment of the variety.

Lin (2002) defines segregation as the requirement "… that crops be kept separate to avoid commingling during planting, harvesting, loading and unloading, storage and transport." (p. 263) Segregation systems will be used when potential food safety concerns exist over the co-mingling of the segregated product and all other like products. In short, IPPM are used to capture premiums and segregation is used to ensure food safety.

There are very few segregation system presently operation in Canada. There is a small amount of *Brassica juncea* being segregated for the first time in 2002. The best known segregation system in Canada is for high erucic acid rapeseed. This variety of rapeseed has been produced using a segregation system since 1982.

Traceability

The third product differentiation system, traceability, is commonly used in the food industry. Retail products found with unacceptable bacteria levels or intolerable levels of pesticide or chemical residues need to be quickly and completely removed from store-shelves. Traceability systems allow for retailers and the supply chain to

identify the source of contamination and thereby initiate procedures to remedy the situation.

The key focus of traceability is increasingly on food safety. For the purposes of this paper, traceability will refer to systems that focus on ensuring food safety. Recently, the focus for developing traceability systems for new sectors of the marketplace has shifted from food safety towards extracting premiums from the marketplace. Extracting market premiums could never be the driver for developing a traceability system. In and of itself traceability systems do not define quality, they simply trace it. If market premiums are the driver, then the developers need to use an IPPM system as these systems are properly structured to capture premiums.

The International Organization for Standardization has defined traceability as the "… ability to trace the history, application or location of an entity by means of recorded identifications …" and the Codex Alimentarius Commission has adopted this as its working definition for all Codex standards (Codex, 2001). The EU (2001) has defined traceability quite clearly in relation to GM products. Directive 2001/18/EC defines traceability as "… the ability to trace GMOs and products produced from GMOs at all stages of the placing on the market throughout the production and distribution chains facilitating quality control and also the possibility to withdraw products. Importantly, effective traceability provides a 'safety net' should any unforeseen adverse effects be established." (p. 2)

The economic literature from supply chain management defines traceability as the information system necessary to provide the history of a product or a process from origin to point of final sale (Wilson and Clarke, 1998; Jack *et al*., 1998; Timon and O'Reilly, 1998). While Dickinson and Bailey (2001) suggest that their results from a laboratory auction market regarding features of meat traceability show there is willingness by consumers to pay premiums for traceability, the key focus has to be on food safety. Prior to adopting traceability systems there has to a clear indication of specifically what aspects of food safety can be improved by the adoption. Marginal improvements in food safety would be a dubious reason for proceeding, rather there must be a clear and evident improvement in the level of food safety.

Traceability systems have been developed for beef products in Canada. Traceability was developed in conjunction with a quality assurance system to reassure export markets about the quality of Canadian beef products. However, it should be noted that this system has been met with great resistance at the farm level, as producers do not want to allow government regulators onto their farms or provide regulators with any sensitive farm information. In part, this is due to the lack of on-farm regulation to date in Canadian agriculture. In a similar quality assurance effort, the Canadian grain and oilseed industries are conducting a two-year pilot project in 2002 and 2003 to evaluate the costs and benefits of an on-farm HACCP based traceability system.

5.3 The Conceptual Framework

This section examines the area of overlap in Figure 3.2 identified by the number 5. This area of overlap between regulators and consumers is key to understanding how and why Canadian consumers express confidence in the quality and safety of the food products that are available to be purchased in Canada. Each product differentiation system provides the consumer with a different message and how elements of these systems can be incorporated to provide the most valued information to the consumer is an important issue. As will be shown, the way information is presented to consumers using labels is viewed in a variety of ways.

Each product differentiation system has features that are unique, while also possessing features that are common to one of, if not both of, the other systems. Table 5.1 compares numerous features of product differentiation. These features are classified into those that apply to the complete supply chain and those that apply to the three distinct stages of supply chains. The first stage are features that are most commonly related to the production stage of the supply chain. Included in this stage are seed development firms, producers and grain handlers. The second stage of the supply chain is the processing stage. This stage includes all firms involved in the supply chain from the point when a raw ingredient is received to the point that a final product is shipped to the retailer. The third stage is the retail stage of the supply chain. This stage includes those firms that provide products to consumers, such as grocery stores and restaurants.

Overall Supply Chain Management

The features in this stage are those that are important to the entire supply chain. Unlike the features in the following sections, these features span all sectors of the food industry and each participant in the supply chain must ensure that their commitment to these features is at least as strong as the other participants.

The objective of an IPPM system is revenue management. Premiums need to be available to attract participants and the efforts of participants will be directed towards receiving a share of the premium. Participation in these systems will be voluntary. The lead stakeholder in IPPM systems are private firms seeking to capture the increased value of special traits. The role of the regulatory body will be to ensure that industry standards are in place to prevent consumer fraud from occurring. The information may be asymmetric as only the product seller can know with certainty what level, if any, of cheating has occurred in the delivery of the product. Moral hazards may be present due to the presence of premiums. Effective IPPM systems that span entire supply chains must have accurate two-way information flows. This means that information about purity and quality of the product flows downstream and that information coming from consumer demand flows upstream. While the information flow in IPPM systems is two-way, the focus of these systems is downstream. Each participant in the system wants to ensure they extract a portion of the value of the special trait while they are involved with either the production, processing or retailing of the product. This means that each participant will focus on the needs of the next participant in the supply chain. Market failure can result in fraud charges for mis- or improper labeling and also create

awareness with consumers that certain brand names can not be trusted. Testing and auditing will be done by second parties acting on behalf of the brand owner or developer of the special trait.

Table 5.1: Comparing identity preservation, segregation and traceability

	IPPM	Segregation	Traceability
1. Overall management			
Objective	Revenue management	Liability management	Product safety
Status	Voluntary	Mandatory	Voluntary or mandatory
Lead stakeholder	Private company	Regulator	Commodity group, standards organization or regulator
Regulatory agency involvement	Consumer fraud	Regulatory oversight	Consumer fraud
Information	Asymmetric	Full	Asymmetric
Risk	Moral hazard	None	Moral hazard
Information flow	Two way	Two way	One way
Supply chain focus	Downstream	Downstream	Upstream
Penalties for failure in product market	Consumer fraud charges; lost brand value	Criminal prosecution; mandated product recalls	Consumer fraud charges; exclusion from product category
Testing/auditing	2nd party/brand owner	1st party/regulator	3rd party/standards organization
2. Production stage features			
Production arrangements	Formal production contracts	Regulation and contracts	Membership in quality standard
Production controls	In-season agronomic rules vary with product	Formal buffer zones; post production land use controls	Process standards adopted and record keeping
Premiums for producers	Short and long term	Short and long term	Short term
3. Processing stage features			
Enforcement	Private	Public	Collective
Quality criteria based on	Product standards	Regulations and or HACCP rules	Processes (e.g. ISO)
Tolerance levels	Variable	Set in law	Performance based
Testing/auditing	2nd party	1st party	3rd party
4. Retail stage features			
Provides access to	Branded product markets	Markets	Product categories
Information provided to	Consumer	Regulator	Regulator, retailer or processor
Final market price premiums	Yes	None	None
Labelling	Private brands	None	Quality standard
Source: Author			

The objective of a segregation system is to manage any and all liabilities that may arise through the production and processing of the commodity. Participation is not

optional, any producer or firm involved with segregated products will have to comply with standards established that have been approved by the regulatory agency. The private firm will have the responsibility of developing the actual system, but the regulatory agency will be the final arbiter on approving the system for field use. Information will be fully disclosed due to the importance of protecting food safety, which will result in the lowering of risks in the system. Segregation systems must have two-way information flow due to the concern about food safety should co-mingling occur. The focus of product delivery within a segregation supply chain will be downstream. Segregated commodities commonly have industrial value, so these products will be supplied to meet the criteria of the processor. The costs of market failure would most definitely see a complete recall of any and all products suspected of being affected. It may also result in criminal prosecution in the most severe instance. Testing and auditing will be vital features of segregation systems and will be conducted by agents of, or acting on behalf of, the regulator. This process will also reinforce the level of trust with foreign export markets.

The objective of traceability systems is ensuring that products available for consumption are as safe as possible. For example, the beef industry uses a traceability system to ensure that no animals are butchered with drug residues still in the meat, producers that sell livestock too soon after treatment can be prohibited from selling. Participation in a traceability system can be voluntary, this will depend on where in the supply chain the participant is located. The closer the participant is to the start of the supply chain, the more likely it will be that participation is

voluntary. The lead stakeholder may be a commodity group demanding greater clarity in or selection of food products, a standards council that is comprised of industry representatives from all sectors of the supply chain or the regulator to ensure consumer protection. Information may be asymmetric due to the voluntary nature at the start of traceability supply chains. A moral hazard may also exist due to the inability to fully test for some features of traceability. Traceability systems will only have information flows that are one-way as these systems are designed to react quickly to food safety concerns. If a product is discovered to exceed any defined tolerance level at any point in the supply chain, traceability will be used to identify the source of the problem and to locate any and all retail products that may be affected. This results in the focus of traceability systems being upstream. Market failures can also result in consumer fraud charges in addition to permanent exclusion from selling into that supply chain. Testing and auditing will be conducted according to the standards developed by third party organizations.

Production Stage Features

The production stage features are those at the front end of the supply chain and involve seed development firms, producers and grain and oilseed handlers. Historically, this has been the starting point for supply chains, as seed development firms would commercialize a new crop variety and marketing the benefits of the variety would result in producers adopting the variety. This push version of supply chains has had difficulty adapting to the demands of consumers for a pull supply chain.

Identity preserved production and marketing systems are voluntarily developed by private firms to ensure that all stakeholders in the supply chain for a specific product capture a share of the value from special trait varieties. Private firms may use technical use agreements to protect the intellectual property of the special trait or production contracts that have specific conditions that must be met in order to receive the premium. Grain companies typically organize and manage these contracts. These systems are typically developed for niche market products (i.e. organic products) and are typified by small acreage and low volumes. There is presently some debate as to whether long run premiums for producers are sustainable, as they may be bid away due to competition among producers. Producers may compete for contracts with premiums, causing the firm offering the contracts to lower the premiums and eventually removing the premium.

Segregation is focused on ensuring that the integrity of the special trait is not allowed to adventitiously co-mingle with other products destined for the human supply chain. Production contracts would be used by the private firms to ensure that all of the commodity being segregated is collected and that the producer retains no amount of seed. Buffer zones are required for segregation systems as a preventative measure for reducing cross-pollination. Producers may also have restrictions placed on what crop varieties would be allowed to be grown the following year on fields that produced segregated crops. Premiums would be available in both the short and long term to ensure that product supply is maintained.

Traceability is very fragmented at the producer stage. Production arrangement would largely be made through membership in the organization established to create and manage the industry. Production control would be through industry standards and stringent record keeping. The cost of initially becoming involved in a traceability system results in short term premiums being available to attract producers. This premium may be available to attract the necessary supply. Long term benefits are not evident as the premiums evaporate when the desired number of producers become involved.

Processing Stage Features

Processing stage features are those that relate to firms involved in the manufacturing of food products. Most of these features contain aspects of quality assurance and industry developed standards.

Quality standards will be enforced by private commitment to industry standards, as the value of the product will be greater given higher purity and/or protein levels. The enforcement of standards is crucial as products that do not conform to the desired quality level will not be accepted. Tolerance levels will vary from product to product and also will depend on the preferences of the final consumer. Testing and tolerance levels will be important to ensure that the purity and the high quality levels of the product are maintained. Frequently, these tests will be conducted by second parties.

Enforcement of standards will be very important in segregation systems. To ensure that products that could be a hazard to the human food supply chain are prevented

from entering that supply chain, functional operating standards must be agreed to by all participants. The enforcement of these standards will need to be rigorous. Quality will be defined in regulations or be created through the implementation of a HACCP system. Tolerance levels for co-mingling will be set by the regulator. Because of the importance of standards, the features of testing and tolerance levels will also be important. Testing will need to be conducted frequently to ensure that the commodity is being properly segregated and that none of the product is entering other supply chains accidentally. This will be done by agents of the regulator.

The processing stage is very important for traceability as this is the stage in the supply chain where traceability begins to be rigorously applied. Enforcement of standards is valued in traceability due to the nature of traceability to focus on increased food safety. The lack of high standards and careful enforcement of the standards may result in costly recalls of products therefore, the enforcement of standards will be done collectively in an attempt to ensure continued high quality. Quality will be focused on the production processes to ensure that the highest standards possible are maintained at all times. Tolerance levels exist for food safety reasons as no product can be entirely 100% free of potentially harmful effects, so tolerance levels are established at levels that ensure safe consumption. When tolerance levels are exceeded, the risk of harm to the public develops and these products must then be recalled from the marketplace. The costs of recall are substantial. Not only does the firm have the cost of gathering and disposing of the product in question, there may also be a loss of trust in that brand name by

consumers that will require aggressive marketing campaigns to overcome. Testing and auditing of traceability systems are done by third parties.

Retail Stage Features

The final stage of the supply chain is the retail stage. The features in this category apply to those firms that are involved with selling food products to consumers. This is the stage of the pull supply chain (as opposed to the traditional push supply chain) that is now seen as driving many modern supply chains.

Identity preserved production and marketing systems may play a large role in the introduction of new GM food products. New GM products may be introduced without complete international market acceptance and IPPM systems can be used to ensure continued access to these markets. An IPPM system will be able to provide information to the consumer about the uniqueness of the branded product that is being identity preserved. For an IPPM system to function properly, and ensure that all stakeholders remain committed to the process, final market price premiums must be available. If this premium is not available for the retailer, an incentive is created for the retailer to no longer carry the product. Products of IPPM systems will need to be labeled to justify the final market premium. If the consumer is not able to identify the value of the product, the consumer will not pay a premium to purchase the product.

Segregation systems will also be used to ensure that market access is continually guaranteed. A co-ordinated education and marketing effort by the regulatory agency

and the private firms involved can be effective in creating trust in foreign markets that production of potentially hazardous products can exist and not jeopardize export market streams. Most segregated products are differentiated until the product reaches the processing stage therefore, there are no final market premiums available, nor is labeling of the product a concern. Most segregated products will be for industrial uses only, that is why premiums and labeling are not determining factors.

Traceability is crucial for providing access to new categories of products. Many markets have demanded documentation regarding product composition prior to allowing market access. Consumer information is fundamental for traceability systems as they are designed to increase information regarding food safety to consumers. Information is also provided back up the supply chain to regulators and processors. Final market premiums are not available for traceability systems. Labeling is important to traceability to ensure high quality standards and allow consumers to identify with this feature.

The discussion above attempts to identify features common to product differentiation. These features are classified as to whether and how they pertain to identity preservation, segregation and traceability. As is evident, some features differ depending on the system in which they are applied. It will be important for those involved in product differentiation to examine what features are most commonly related to the product requiring differentiation and if and how those features overlap.

This model of comparison will assist with determining which system best relates to the identified needs of the product being differentiated.

5.4 Using the Framework

This section uses the framework to analyze the information that consumers are receiving from food labels. Mandatory and voluntary labeling of GM food products is a very contentious issue with North America preferring to voluntarily label and Europe following a mandatory labeling regime. The framework will be utilized to attempt to understand what message it is that consumers are looking for and what information they are receiving. Some recent studies of consumer purchase patterns seem to suggest that what consumers expect regarding label information does not reflect the reality of grocery store purchases. This analysis will show why label information needs to communicate clear information and that broad-based claims are being discounted by consumers.

Many individuals and social advocacy groups are calling on the Canadian government to force private firms involved in supplying food products to the marketplace containing GM ingredients to label for GM content. This segment of society advocates that the government should impose mandatory labeling on the food industry regardless of the cost. Meanwhile, the food industry has developed a voluntary labeling system for GM content. The key question that both groups seem to miss in this debate is whether labeling for GM content will provide consumers with product information that increases their knowledge about the product. Even if

labeling imparts some information, it is far from clear whether consumers will gain enough to justify the cost.

The lack of proper structures in supply chains to manage and communicate information to consumers has resulted in public distrust of GM food products. In some markets the level of mistrust is greater than in others. Many consumer acceptance studies of GM food products show the majority surveyed want labeling for GM content but in both experimental and real-market tests, the presence of GM-labeled food has not had a significant impact on actual purchase decisions. If 80% - 90% of consumers truly wanted products free of GM elements, then the demand for certified organic products and those few foods labeled as GM-free would be growing correspondingly. When consumers are faced with actual purchase choices, the presence or absence of GM labeling does not appear to be of great importance to the majority of the retail market. This begs the question that if consumers are not presently making conscious purchasing decisions to avoid GM foods, is there any incremental value that would be gained by labeling for GM content?

This creates a two-fold challenge. First, it is not clear that there are economic incentives for firms to provide GM labeling information. If there is no economic incentive, the market will not voluntarily provide this information. Alternatively, firms will simply provide what is most profitable and least risky, which could mean that only GM or only GM free products would be available, or that precautionary labeling claims (such as ‘may contain’) would be used. Alternatively, if GM labeling

is perceived to be of political value, the government has the option of requiring mandatory labeling. The cost of labeling for GM content would then be passed on to consumers. There is growing evidence, however, that consumers may not derive enough value from the added information to justify the cost. Second, even where economic incentives may exist, it is not clear how supply chains will provide greater information about GM food products to consumers. Research shows that labeling terminology such as GM, non-GM or GM-free is the least valued, in terms of providing product information, by consumers. This may be due to the limited amount of time that North American consumers devote to purchasing groceries.

The second challenge is how to manage and communicate information to consumers. As shown above, the three systems used to provide information to consumers are: segregation; identity preservation; and traceability. Each system communicates a different message to the consumer. Segregation and IPPM systems are initiated at the start of the supply chain and are used to manage the flow and/or quality of the food product, whereas traceability is initiated by downstream firms in the supply chain to provide the ability to detect origins of food safety problems and rectify the problem in the most efficacious and least costly way.

Relationship Between Willingness to Pay and Demands for Labeling

The challenge of determining how much consumers would be willing to pay to have increased product or labeling information is that, wherever possible, most people want that information at no cost. Frequently critics of biotechnology make the statement that ‘labeling for GM is costless, all that is required is to put a label on the

products'. Obviously nothing is costless, but the challenge is to determine what costs will be accepted by consumers. In short, consumer studies can go a long way to determining the aggregate value individuals place on this new information, making it possible to determine what would be the optimal amount of information that should be provided.

The recent literature in this field suggests that consumer willingness to pay for products labeled as GM can vary widely (Table 5.2). Rousu, *et al*., (2002) examine whether there is a consumer preference for products labeled with a 1% tolerance level versus a 5% tolerance level. This study found that consumption of products labeled as GM dropped between 7% - 13% regardless of whether the tolerance level was 1% or 5%. In fact, the authors suggest that there is no statistical support for American consumers having a preference for a 1% tolerance level over a 5% tolerance level. The conclusions reached from this research suggest that if the US were to adopt a tolerance level for the labeling of GM food products that a 5% would be the socially optimal level.

Moon and Balasubramanian (2002) examine willingness to pay in the US and UK by offering consumers the choice between two identically priced boxes of breakfast cereal: one box is labeled GM and the other is labeled non-GM. When asked which cereal they would choose if priced the same, 71% of UK respondents chose non-GM, while 2% chose the GM cereal and 23% were indifferent. Correspondingly in the US, 44% chose the non-GM product, 6% preferred the GM product and 22% had

no preference. However, willingness to consume non-GM cereal dropped considerably when a premium for non-GM was introduced. Support for non-GM dropped to 56% in the UK and to 37% in the US when a small premium for consuming non-GM cereal was required. The number of consumers not willing to pay a premium (22%) was identical in both countries.

New Zealand research on consumer willingness to pay by Kaye-Blake, *et al*., (2002) examines the strength for labeling by asking whether consumers would pay 2%, 5% or 10% more for groceries to learn about GM content. The authors found that 23% of the population would pay 10% more, 27% would pay 5% more and 24% would pay 2% more for product information on GM content. The aggregate value of the willingness to pay was estimated to be NZ$285 million annually, while the Australia New Zealand Food Authority has estimated the annual cost of labeling to be NZ$42 million. A previous analysis by Smyth and Phillips (2001b) suggests we should take this estimate of willingness to pay with some caution. In comparative Canada-US analyses, people tended to respond with higher amounts they were willing to pay if asked in percentage terms than in dollars and cents per week. Thus, the cost-benefit ratio may not be nearly as wide as the Kaye-Blake, *et al*., (2002) study suggests.

Table 5.2: Comparison of survey and research results

Author	Date	Countries	Methodology	Results
Rousu, *et al*.	2002	USA	Experimental auction	5% tolerance level for GM content is socially optimal
Moon and Balasubram -anian	2002	UK and USA	Consumer survey data	UK – 77% prefer non-GM US – 44% prefer non-GM
Kaye-Blake, *et al*.	2002	New Zealand	Consumer survey data	Value of willingness to pay is NZ$285M and cost of GM labeling is NZ$42M
Grimsrud, *et al*.	2002	Norway	Consumer survey data	Discount GM bread by 49% Discount GM salmon by 55%
McCluskey, *et al*.	2001	Japan	Consumer survey data	Discount GM noodles by 60% Discount GM tofu by 62%

A study of consumers in Norway by Grimsrud, *et al*., (2002) found that substantial discounts were required to get Norwegian consumers to purchase GM bread and GM salmon. The authors found that to entice consumers to purchase GM bread a price discount of 49.5% was required and a discount of 55.6% was required for GM salmon. One interesting result from this study found that 26.8% of consumers would purchase GM bread and 17.8% would purchase GM salmon with no discount. However, 61% said they would never purchase GM bread at any discount and 67% would never purchase GM salmon. A similar study done by McCluskey, *et al*., (2001) examined consumer responses to GM foods in Japan. This study examined willingness to purchase GM tofu and GM noodles and found that without a discount only 4% would purchase GM tofu and 3% would purchase GM noodles. The study determined that a discount of 60% was required to generate purchase of GM noodles and a discount of 62% for GM tofu.

This brief survey of willingness to pay literature highlights that every market has consumers who perceive and will purchase GM foods as an equivalent to conventional food purchases. On the other end of the spectrum are a group of consumers which will never purchase GM food products. The large group in the middle is the group of interest to researchers. Olubobokun, *et al*., (2002) conclude that "[i]f a consumer perceives a health benefit from the consumption of a particular product, this will be demonstrated by a willingness to pay a premium above the market price …." (p. 5) Willingness to pay does not appear to have a strong correlation to labeling for either GM or non-GM products.

The issue of labeling, whether it be mandatory or voluntary, spans the full spectrum of opinions. Critics of biotechnology and environmental groups constantly proclaim that over 95% of consumers are demanding labeling for GM content, while the biotech industry responds by saying that calls for GM labeling are only coming from 2% of consumers. Obviously both of these numbers are being used to promote specific agendas and the real number lies somewhere in the middle. The question is to which side of 50% does this number fall?

Consumer Perceptions About Food Labels Regarding GM Content

Huffman, *et al*., (2002) attempt to determine whether mandatory or voluntary labeling produces the most efficient economic outcome (Table 5.3). In an experimental bid auction involving products that had basic labels, voluntary labels and mandatory labels for cooking oil, chips and potatoes, the authors found that the participants discounted the GM labeled oil more than the other products. One

interesting result from this study was that in the mandatory labeling experiment the plain labeled products were perceived as the non-GM product, yet in the voluntary labeling experiment the plain labeled product was perceived as the GM product. This study demonstrates how consumers, when faced with a lack of clear information, make their own decisions based on the appearance of the product. These decisions may be correct or incorrect. This study concluded that for the US market, voluntary labeling would be a more efficient policy than mandatory labeling.

Table 5.3: Comparison of labeling surveys and research results

Author	Date	Countries	Method	Results
Wolf and Kari	2001	USA	Consumer survey data	80-92% of consumers wanted mandatory labeling
Wolf, *et al*.	2001	USA	Simulated market test	GM-free lowest rated information characteristic
Wolf and Pachico	2002	Colombia	Consumer survey data	Colombia: 13% aware of GM foods
Wolf, *et al*.	2002	Italy	Consumer survey data	Italy: 28% aware of GM foods
ABE	2002	Europe	Consumer survey data	52% of French consumers willing to purchase GM
IFIC	2002	USA	Consumer survey data	72% aware of biotechnology yet only 35% aware of GM foods
Council of Canadians	2000	Canada	Consumer survey data	When asked if GM foods should be labeled, 95% said yes
Greenpeace	2001	Canada	Consumer survey data	Asked if labeling should be mandatory, 87% said yes
Huffman, *et al*.	2002	USA	Experimental auction	Voluntary labeling more efficient than mandatory

A study by Wolf and Kari (2001) found that US attitudes to GM products over four time periods between 1999 and 2001 were relatively constant. The authors found that in each of the four surveys, 80% - 92% of respondents felt that the US

government should impose mandatory labeling for GM products. One interesting feature of this study regarding labels found that 80% of consumers read nutritional labels when purchasing a product for the first time and 60% read ingredient labels in the same situation. Einsiedel, *et al*., (2002) suggests that the percentage of consumers reading labels drops dramatically for subsequent purchases of the same product (to as low as 20% by some estimates).

Additional research by Wolf, *et al*., (2001) concluded that many consumers do not understand the term GM-free when included as product label information. Using simulated test markets for salty snack food and fresh packed vegetables, the authors found that of the eight characteristics available to inform the consumer about the product, the characteristic 'free of genetically modified ingredients' was the lowest rated in terms of providing information to the product purchaser. This experiment also revealed that consumers, who prior to the experiment indicated that GM free ingredients were extremely or very desirable when making a purchase decision, when faced with actual purchase choices did not express a higher interest in the food products labeled GM free.

Recent studies on consumer attitudes in Colombia and Italy (Wolf and Pachico, 2002 and Wolf, *et al*., 2002) show much lower levels of consumer awareness towards GM food products. Surveys in Colombia show only 13% had any familiarity with GM foods while 77% reported no awareness. This research points out that 40% of consumers routinely do not have enough food to feed their families

and that low prices were the most important factor when making a food purchase decision. This fact is important as almost 75% of consumers surveyed expressed food safety concerns about GM food products, yet nearly two-thirds of these consumers were willing to buy GM food products. Consumer surveys in Italy show that 28% of consumers are familiar with GM foods and only 43% would be willing to purchase GM food products. Interestingly, 40% of Italian consumers expect to increase their purchase of organic food products in the next 12-month period.

An Agricultural Biotechnology in Europe (2002) poll on purchasing GM food products found that 52% of French respondents would continue with usual food purchases if the products contained GM ingredients. Those that were opposed to purchasing GM products were then asked if they would purchase GM food products if there were environmental benefits and 47% of these respondents said they would be willing to purchase GM products. The remaining 25% were unwilling to purchase GM products for any reason.

As part of the ongoing polling of Americans regarding GM foods, the International Food Information Council (IFIC) released their eighth poll of consumers since 1997 (IFIC, 2003). This poll found that while 72% responded that they had either read or heard about biotechnology, only 36% were aware that GM food products are presently available for sale. Over six years of polling, IFIC has found that the number of consumers willing to purchase GM foods that had been engineered to taste better or be fresher ranged from a high of 62% in February 1999 to a low of

51% in October 1999. A new question for the polls done since 2001 asked for any additional information that consumers would prefer to see on product labels and in the four subsequent polls, only 1-2% responded that they would like labels to provide information on genetic modification

Critics of GM food products present numbers that represent the other end of spectrum. In early 2000, The Council of Canadians commissioned a national poll on attitudes to GM foods. Respondents were asked first a series of questions about their views on GM foods (such as 'I worry about the safety of GM foods'), to which 75% expressed concerns. Respondents were then asked if GM foods should always be labeled, and 95% agreed they should. In September 2001, Greenpeace released results from a Decima poll commissioned by Greenpeace and found that when asked if consumers had the right to know if GM ingredients were being used, 95% responded in the positive. When asked whether labeling systems should be mandatory or voluntary, 87% wanted mandatory labeling.

All of the calls for and information about labeling can be put in context when consumer shopping habits are examined. The Produce Marketing Association (PMA) has closely examined shopping trends and a recent study by PMA summarizing shopping habits for 2001 found that the primary factors for consumers when making produce purchases are: expected taste (87%); appearance (83%); cleanliness (74%); degree of ripeness (70%); and nutritional values (57%). Recent research from the UK supports these consumer purchase factors (Costello, *et al*.,

2002). This research highlights the fact that when consumers are in a retail store faced with a purchase decision, concern over whether the product is GM, non-GM or GM-free may be trivial for the vast majority of consumers, given North American purchasing habits. As a result, labeling systems alone would appear to be a poor way to communicate with consumers and would not substantially enhance post-market monitoring and surveillance.

5.5 Conclusions

Biotechnology innovations in agriculture present a clear challenge to the traditional marketing system. Transactions for new, proprietary, novel-trait crop varieties require a more extensive set of institutions than for traditional commodity varieties. Companies assisted by governments and industry associations have developed product differentiation systems that handle both the risks and assists with capturing the returns from the introduction of new products with commercially valuable input and output traits. Spot markets are increasingly competing with proprietary vertically integrated supply chains, which has the potential to lower the quality of the delivered product. The optimal structure and organization of these new supply chains has not evolved yet, but over time one would expect a more stable set of relationships to emerge.

The driver of each existing product differentiation system differs for important reasons from the drivers of the other systems. The use of IPPM systems is driven by private firm initiatives to capture the value associated with a special trait.

Segregation systems are driven by regulatory agencies, where the objective is to prevent a potentially hazardous commodity from entering the supply chain for human food products. Traceability systems are driven by informing consumers about increased food safety measures.

One observation is that the low level of consumer willingness to pay for labeling information regarding GM, non-GM or GM-free products means consumers do not perceive a benefit from the labels. Consumers willingly express desires to have these products labeled so that they can be differentiated, but when the purchase decisions are taking place within grocery stores the perceived value of this kind of labeling rapidly diminishes. Organic products are clearly labeled as such, yet consumption of these products is still small. The reality of this may be as simple as the large majority of consumers want to go into a grocery store and purchase their food products as quickly as possible. Produce and meats are purchased based on appearance and processed foods based on brand recognition. Within this context, labeling for GM content is largely ignored.

While mandatory GM labeling does not appear to be economically justifiable, some alternative is needed to provide consumers with the information they are demanding. It is also apparent that trying to develop traceability systems based on current definitions of GM foods would not be feasible, as there are simply too many contrasting market signals for this to work. Ideally, the best route would be for representatives of the biotechnology industry, the food processing industry and

government departments and agencies to come together with parts of civil society to develop a strategy for post-market monitoring and surveillance. In the first instance, the strategy should provide labeling information regarding GM content to consumers that is valid and meaningful, keeping in mind the way people actually shop and consume foods. To function and meet the needs of all consumers, it is likely that any resulting system will need to operate in such a way that enables all types of information to flow between the supply chain and consumers.

Ultimately, the success or failure of any resulting system should be judged based on whether it facilitates an increase in the amount of product information that flows down the supply chain, while at the same time enables commercialization and optimal production and use of safe food. Those international markets that prefer mandatory GM labeling to protect domestic markets may be demanding labeling for ideological or political reasons rather than ensuring the delivery of safe food. Overly complex and inflexible systems that simply impede commercial activity will not achieve the intent or goal of the program—delivery of healthy, nutritious and safe food to consumers. The argument about labeling for GM content is not focused on food safety, but rather on consumer choice.

Chapter 6

Institutional and Liability Challenges of Gene Flow From Genetically Modified Crops

6.1 Introduction

This chapter examines the area of overlap between industry and society in Figure 3.2. When a society is presented with the commercialization of a transformative technology, it is important to know whether the adopters of the innovation are also the consumers of the innovation. This is because the reason that the adopters will incorporate the innovation into their operations may not match what consumers demand. In the instance of genetically modified crops, the adopters are the farmers who plant the crops and the end user of the product is the largely urban consumer who is purchasing the final product from a grocery store. The focus of this chapter is to examine how the biotechnology industry has addressed some of the liability issues that have developed over the past decade.

The first generation products of biotechnology are poised to begin their tenth year of production in Canada, the US and several other nations. The large majority of these food products are derived from three leading biotech crops: canola, corn and soybeans. For the most part, these products entered the marketplace with minimal restricting regulations. The environment for the anticipated introduction of third

generation biotech crops (e.g. involving novel uses) is vastly different from the one that first generation biotech crops faced. Third generation crops, such as those producing proteins or antibodies for use in clinical drugs, will face restructured regulatory systems, radically altered marketplaces and new technology options (Phillips and Khachatourians, 2001).

Genetic engineering has the potential to create many new genetically modified (GM) crops that will create substantial value in the marketplace. There are two main challenges facing the industry. On the one hand, the investors and firms investing in these technologies are vitally interested in capturing a share of the returns on investment in order to pay for the large development and commercialization costs. On the other hand, firms and society are vitally interested in ensuring that the new traits and varieties created do not impose liabilities that offset the value being generated. At the farm level, in particular, there is significant risk of dilution of the rents and for co-mingling of the new traits with other crops, creating potential new liabilities.

There are methods available to restrict cross-pollination and volunteer seed, however, societal pressure would seem to have removed the option of seed sterility. Many development groups, environmental NGOs and third world governments expressed concern that the ‘terminator’ technology could threaten landrace varieties, increase corporate concentration, reduce biological diversity and ultimately destablize less developed countries agroeconomies (Visser, *et al*., 2001). In October

1999, Robert Shapiro, Monsanto CEO said: “We are making a public commitment not to commercialize sterile seed technologies, such as the one dubbed ‘terminator’” (Shapiro, 1999). Many expected that this would effectively close the door on further pursuit of this kind of gene research, as other seed development companies were expected to follow the lead of Monsanto. On March 26th, 2002, Syngenta received a patent for controlling plant fertility but since has publicly pledged not to commercialize this technology.

First generation, input-trait GM crops have been judged by regulators as substantially equivalent to existing varieties and allowed to be introduced into many of the existing commodity food systems without any separation. A number of liabilities exist. Many of these GM crops have the potential to cross-pollinate with other crops of the same species or weedy relatives, or to become volunteers in other crops, creating potential new environmental risks that may diminish the benefits of the technologies or create quality problems and new liabilities in other crops or the food system. Second generation crops, which involve output modifications, will likely only be viable if they can assure the purity of their quality, which is problematic with the potential for gene transfer. Third generation crops, with new industrial, nutraceutical or pharmaceutical properties, will clearly require significant gene control systems, or simply will not be allowed to be produced. In each case, the firms are also concerned that they face dilution of some of the benefits of their innovation because of the self-reproducibility of many of the GM crops.

Fundamentally, the allocation of the benefits and management of these risks will need to be brought about by a combination of institutions and biological controls. Institutionally, the public sector will continue to have a say on when, where and how GM crops are introduced and propagated, as well as in adjudicating property rights. Meanwhile, private firms will likely have a major role managing and enforcing contracts and systems to capture their benefits and to manage the risks and liabilities of these new crops. While regulation and markets may be able to control some gene transfers, many genes are likely to continue to travel. Regardless of how effective regulations or contracts are, some actors either deliberately or inadvertently will misappropriate these new technologies, diluting the benefits and creating potential new risks and liabilities. Furthermore, even if all 'cheating' could be controlled, many plant species are promiscuous sexually, creating natural gene flows. In short, we need to look for a combination of both organizational and biological control mechanisms to manage the benefits and risks.

This chapter lays out the argument and evidence supporting the position that both the public and private sector need to re-examine the role for biological control mechanisms in rent capture and risk and liability management. This is needed to increase the net private and social returns from GM crops, which are necessary for sustained innovation. Section 6.2 provides the background to this issue. Section 6.3 examines the scope and scale of the risks and liabilities for GM crops, as they relate to the conceptual framework. Section 6.4 applies the framework to develop an outline of the array of organizational and biological control mechanisms that exist.

Section 6.5 offers some concluding observations and a brief discussion of the implications for research and policy.

6.2. Background

There are two main streams of literature relevant to this issue. A large amount of legal and economic work exists on how patents and other intellectual property rights (IPRs) provide the conditions for private investment in agri-food research. Meanwhile, much of the economics literature related to GM crops focused on evaluating the 'gains to research' has acknowledged the potential for 'externalities' that could reduce the net gain from GM innovations.

Suffice it to say, there is a large body of literature related to the role of patents in creating the incentives for private investment (e.g. Santaniello, *et al*., 2000). The establishment of enforceable property rights for products of genetic crop research has significant implications for the amount of research that the private sector will provide. In the absence of enforceable property rights, many of the products of research can be copied or reproduced. While all firms that use the research output may benefit, without property rights there is no way for the market to fully remunerate any firm for doing research. This creates a 'public good' market failure resulting in under-investment in research activities. This is one of the main explanations given for the high internal rate of return for most agri-food research, estimated by Alston, *et al*., (2000) to be in the 70% range. Recently, governments, and to some extent the private sector, have addressed the 'public good' market

failure in research by establishing effective property rights over the products of research. As outlined by Gray, *et al*., (1999) the assignment of intellectual property rights provided some of the added ability to capture value from research. In Canada, for instance, the Seeds Act has always protected the name of registered varieties but it wasn't until the adoption of Plant Breeders' Rights in 1990 that breeders could forbid the sale of registered varieties without royalty payments. This assignment followed a number of milestones, including the US Patent and Trademark Office decision in 1985 to grant patents for whole plants.

The problem with the current package of IPRs is that they do not fully control the use of a new technology once it is expressed in seed. Most GM crops can be propagated in subsequent years with seed from previous years. While regulations and private contracts attempt to manage that activity, many in the industry note that they are far from effective. Industry sources estimate that in Saskatchewan alone, more than 300,000 acres of wheat in 2000 were planted to unregulated plant varieties and that up to 3% of exports by volume are composed of some varieties that have not been approved for release in Canada. This results in Canada exporting crops to other countries that contain small percentages of crop types not approved for use in Canada and possibly, not approved for import in the importing country. Furthermore, officials in Monsanto have estimated that without their TUAs, they would lose as much as 25% of the royalty payments for Roundup Ready® crops without hybrids; even with the TUAs, they estimate that 10% of the acreage planted to Roundup Ready® crops are not covered by agreements and do not involve royalty

payments (Phillips, 2001). Clearly, risks are greater and dilution is significant when the industry has to rely simply on the power of institutions.

The second literature, mostly from economics, offers estimates of the economic cost-benefit of GM crops. While the evidence is scarce, the early estimates (e.g. Moschini, *et al*., 1999 and Kalaitzandonakes, 2003) suggest that most of the new GM crops provide fairly significant net social benefits, with the innovators capturing a large share of the returns. While most of the works have simply looked at the productivity enhancement and its impact on markets, a few have examined the impact of new risks or liabilities on the demand or supply side of the analysis. On the demand side, the recent consumer backlash against GM foods highlights one possible risk of new GM crops. Following on Ackerlof's work (1970) on the market for lemons, Fulton and Giannakas (2001), for example, suggest that in some instances where consumer fears are high enough, the inability to segregate and label GM and non-GM crops and foods could result in global welfare losses. Kuntz (2001) examined the impact of GM wheat varieties on Canada's wheat exports, concluding that in a worst case, more than C$185 million or 70% of the quality premium earned in the market could be lost without effective separation. On the supply side, a number of researchers have looked at how unmanaged risks could diminish the benefits (e.g. Mayer and Furtan, 1997). In response, a number of researchers have looked at how either government or market institutions could manage that risk. Smyth and Phillips (2001a), Phillips and Smyth (2004) and Lin (2002), for instance, look at the how evolution of private identity preserved

production and marketing systems have evolved to manage the new GM crops. The overriding impression from the systems currently in place is that they are idiosyncratic, costly and do not manage all the concerns.

The key message from the literature is that both the distribution of benefits and the management of risks and liabilities can only partially be managed by institutions. The studies show that even with the best institutions in the world, some benefit dilution continues while risks and liabilities remain. Biological control mechanisms could provide a useful adjunct or alternative to often costly or inefficient institutional approaches.

6.3 The Conceptual Framework

This section of the chapter focuses on the area in Figure 3.2 identified by the number 6. This area of overlap, between industry and society, is very important for the successful commercialization and adoption of transformative technology products. If liabilities develop that are perceived by the public to be linked, either directly or indirectly, to the innovative product, consumers will be less likely to purchase the product. The interaction between industry and society can be very dynamic in some industries or sectors of the economy. This section will examine how the biotechnology industry has identified several liabilities that have developed relating to GM canola. The focus will be to identify how the biotechnology industry has communicated information relating to these liabilities to other stakeholders.

The liability cost of GM technologies escaping, co-mingling and adversely affecting the quality of other products is large and growing. A number of recent examples from canola and other sectors show the impact. Four key liability issues can be identified and at least partially quantified. Both volunteers and pollen flow create the conditions that could lead to co-mingling of GM and non-GM crops, which jeopardize the value of the crop in some markets and, if undetected until it is processed into foods, entire products or product lines. Finally, inability to control gene flow also has impeded transfer of genetic material between nations that developed the new varieties and those that want to adopt new technologies.

There are two ways that GM genes flow and create liabilities. First, through normal agriculture harvest practices, seed are left behind that germinate in the spring and depending on the crop planted may create a tolerance-level liability. The second is that pollen of the GM plant could fertilize a conventional plant and the resulting hybrid seed has the potential to possess the trait for that GM gene.

There is no harvesting system in place in the world that is capable of containing all the seeds that are produced on a plot of land. This is due to:

- lodging, where plants break in the wind and the seeds fall to the ground, germinating in the following spring;
- shelling, which occurs mainly in oilseed crops when the mature plant becomes brittle and the movement by harvesting equipment causes some of the pods to shatter prior to being harvested, falling to the ground and germinating the next spring;
- a wet harvest, which can cause some low-lying crop to be left to germinate the next season, or wind that can blow swaths apart leaving portions unharvested;

- animals or fowl feeding on crops in the fall and scattering heads of grain from a swath that are not harvested; and
- harvesting equipment for grain and oilseeds that, no matter how well set, puts over a small percentage of seed that germinates in spring.

Many of these factors can combine, with the result that a large number of seeds often remain in the field. Gulden, *et al.,* (2003) have estimated that as many as 3,000 canola seeds per square meter can lie in the soil following harvesting. When planting occurs the next spring, these seeds are present to germinate and create the problem of controlling volunteer grain. In canola for example, spraying with 2,4-D controls this problem. However this chemical application means an additional cost of C$1.50 - C$2.00/acre to the producer, while for organic producers this is not an option. The introduction of herbicide tolerant (HT) wheat is expected to make control of volunteers more difficult as 2,4-D does not control volunteer wheat, with the result that producers will have to use a more expensive chemical when controlling HT wheat volunteers. Officials with Monsanto have suggested that the most cost effective method to control volunteer GM wheat will be to tank-mix and apply Roundup® and Assure® at an estimated cost of C$6.19/acre. This method of volunteer GM wheat control is more than triple the cost of volunteer GM canola control. Officials with Aventis suggest that all corn chemicals, with the exception of Liberty™, can be used to control volunteer StarLink™ corn. The application rates of these chemicals vary.

A study prepared for the Canola Council of Canada surveyed 650 western Canadian canola growers on numerous issues, one of which was management of volunteer

canola (Canola Council of Canada, 2001). Half of the producers surveyed grew HT canola and half grew conventional canola. Of the producers planting HT canola in 2000, 61% said that management of volunteer HT canola was about the same as it was for managing volunteer conventional canola. Interestingly, 16% said that managing volunteer HT canola was easier than with conventional canola varieties. The remaining 23% said that it was more difficult to manage volunteer HT canola.

Cross-pollination is an issue that has great importance to commercial agriculture, yet in some crops minimal literature is available on this subject (Table 6.1). For example, the most recent research conducted on the drift of wheat pollen was done in Saskatchewan in the 1930s. This has resulted in a research gap of over 60 years and studies that have recently been completed are challenging the standards that are presently in place to prevent wheat cross-pollination (Hucl, 1996 and Hucl and Matus-Cadiz, 2001). In corn, Losey's (1999) study was the first to examine corn pollen drift in over 25 years. This study spawned numerous other studies that were conducted in 1999 and 2000, many of which concluded that 90% of corn pollen was deposited within 5 metres of the edge of the cornfield. Canola pollen however is dispersed over a much wider range. In one instance canola pollen has been traced to a distance of 25 kms (Kennedy, 1999).

Table 6.1: Impacts from GM Crops

Issue	Canola	Wheat	Corn
Potential to out-cross	Yes	Yes (limited)	Yes (limited)
Detected distance of pollen drift	25 kms	200 m for some varieties	50 m
Chemical control of volunteers	Yes $1.50-2.00/acre	Yes $6.19/acre	Yes Varying rates
Required isolation distance between plots for seed	100 m for like varieties, 800 m for other canola crops	3m for other crops, 1m for same variety	Ranges from 15 m to 200 m depending on plot size
Source: Canadian Seed Growers Association, 2001.			

Canola, for example, is frequently an open pollinating crop, which means that HT varieties can cross-pollinate with each other, with conventional varieties and with weedy relatives. This has resulted in cross-pollinated hybrids that are resistant to more than one chemical. In 1999, the first triple-resistant canola was discovered in Alberta (Western Producer, 2000). These plants were subjected to chemical and DNA testing and were found to be resistant to Roundup®, Liberty™ and Pursuit™. While many in the canola industry were predicting that this would eventually occur, this triple-resistant hybrid was created in just two years. While resistant to new stronger chemicals, the hybrid variety is still susceptible to 2,4-D and can be controlled. The concern among many producers is that other crops, such as wheat, may already have developed resistance to some chemicals, making it more difficult to control cross-pollinated weeds or volunteers, with the result that efforts may be extremely expensive or all but impossible.

Because canola is open pollinating, particularly the *Brassica rapa* variety, this also creates concerns about canola gene escape into wild relative species. Technically, *Brassica napus* is capable of self-replicating but frequently up to as much as 50% of the pollen is dispersed. Mayer and Furtan (1997) estimate that any infestation of herbicide resistant wild mustard above four plants per square metre would reduce the benefits of HT canola to below zero. There is already significant evidence that some weeds are developing resistance to one or more of the herbicides involved in the canola industry.

Recent research from France has examined the potential for genes from rapeseed to flow into wild mustard (known as out-crossing), hoary mustard and wild radish (Chèvre, *et al*., 2000). This study found that on average, the rate of out-crossing was 0.18% for wild mustard, 1.9% for hoary mustard and 23.8% for wild radish. Collaborative research between Canada and France (Lefol, *et al*., 1996a) has shown that cross-pollination between canola and wild mustard is virtually non-existent. This study examined 2.9 million wild mustard seeds and concluded that no hybrid was found and that the actual cross-fertilization rate would appear to be very low, below one per million (*ibid*.). A study on the possible hybridization between canola and hoary mustard (Lefol, *et al.*, 1996b) found that while it was technically possible, the hoary mustard seed had to be imported from France to enable the study to take place in Canada, as hoary mustard is unable to survive the winter season on the Canadian prairies. While wild radish is a weed in the Maritimes of Canada (with

only one sighting in Alberta), given limited canola production in the Maritimes, the potential for gene escape into wild radish was judged to be remote at best.

Given this level of biological uncertainty, volunteers and cross-pollinated varieties or weeds are inevitably going to be co-mingled in the commodity food system. Consumer demand is constantly increasing in regard to whether consumer products should contain GM materials. Regardless of the market, consumer surveys continue to show rising preferences for organic and non-GM products. However, presently these markets are small, niche markets that frequently operate with a price premium exceeding 100%, thereby prohibiting many segments of society from being able to purchase these products. At a minimum, consumers simply want to know what they are eating, be it organic, GM-free or GM foods. To foster consumer trust in products labeled non-GM and organic, control of GM cross-pollination and volunteer GM seed will be essential.

There are a number of examples where co-mingling has imposed significant costs on an industry. Perhaps the best known case relates to Aventis' StarLink™ corn. That variety was approved for use in the US as an animal feed and was required to be produced in segregated areas, surrounded by a buffer crop, which also was supposed to be marketed as feed. To make a long story short, the GM trait in the feed corn was found in the food chain, contaminating an estimated 10% of all foods containing corn meal. The costs of containing and removing the offending variety have been huge. Aventis has settled at a cost of US$110 million to compensate producers and

pay for the logistics of withdrawing the variety while many food manufacturers, such as Taco Bell, had to recall whole product lines that were produced using this unapproved corn event.

While the StarLink™ contamination was an extreme case, it does not seem to have destroyed public confidence in the entire product line. There are, however, examples where contaminations have jeopardized entire product lines. The introduction of HT canola in western Canada destroyed the growing, albeit limited, market for organic canola. Because of the likelihood of out-crossing and pollen flow, buyers have shown increased reluctance to buy organically produced Western Canadian canola because it might contain transgenes, which would violate the voluntary organic standard in Canada. There is little authoritative data on the volumes or prices for Western Canadian organic canola, but some ballpark estimates are possible using industry sources (Grier, 2001). A conservative estimate would put the size of the market at less than 2% of the total canola market, equal to about 20,000 tonnes of organic canola traded annually, at a 100% price premium to conventional oil. This lost market amounted to between C$100,000 and C$200,000 annually, but probably underestimates the opportunity cost of a market that many viewed had significant potential for growth over this period.

It is important to note that this market loss can not be solely attributed to the biotechnology industry. The organic industry's decision to adopt a zero tolerance regarding the presence of transgenic seeds or ingredients has, to a large degree, forced it out of the marketplace. It is possible to provide a counter-argument that the

organic industry's inability to produce and export organic canola is the direct result of its own standards that reflect impractical production logistics. The production and sale of certified seed has tolerance levels for co-mingling of other seed, so if the professional seed industry has internationally accepted tolerance levels, the organic standards of zero percent tolerance, essentially acts as a barrier for the whole industry. Additionally, as discussed by Kershen (2002), the inadvertent presence of transgenic material in organic products does not result in the loss of organic certification for that crop. Kershen shows that organic producers only lose their certification if it can be proven that they intentionally used a prohibitive substance, such as transgenic seeds, or do not take adequate product differentiation strategies. Organic canola producers may have been able to serve foreign markets for their products had they been able to demonstrate that any detected transgenic material was inadvertently there and that they could document the procedures they had taken to prevent co-mingling.

It is not clear yet who bears ultimate liability for cross contaminations or co-mingling. The StarLink™ incident spawned numerous lawsuits by producers, producer organizations and the state of Missouri against Aventis in an attempt to seek compensation for depressed corn prices that they claim resulted from lost foreign sales. Similarly, the pending counter-suit in Canada by Mr. Percy Schmeiser against Monsanto argues that because Monsanto owns the intellectual property, it also should be liable for any lost sales due to contamination.

While co-mingling and adverse market responses are important, the problems of managing gene flow also have significant potential to lower the diffusion and adoption of new technologies, and hence lower the commercial and social benefits of the investments. There are a number of ways that poor gene controls have impeded technology transfer.

An incident in Europe highlights the challenges facing governments and industry. In the spring of 2000 it was announced that the EU found a breeders lot of canola seed imported by Advanta that contained 0.4% unapproved GM traits. Advanta quickly determined that the unexpected presence of GM canola was caused by gene flow from GM foundation seeds that had been planted in a neighbouring field. Canadian seed growers had followed isolation rules but the genes still moved into the conventional foundation seed. While the total acreage in most countries was insignificant (Sweden and Germany had 300ha and France had 600ha) the outrage expressed by environmental groups, the media and some government officials surprised many in the Canadian canola industry. While many in the Canadian canola industry termed the EU response an ‘over-reaction’ and felt that they were acting with ‘hysteria’, this incident highlights the need for a technology that can prevent reoccurrence of similar incidents. The European countries faced a cost in dealing with this problem: France ordered all 600 ha to be ploughed down and Sweden allowed the canola to be harvested but prohibited the canola from entering the domestic or European market.

Containment regulations can also make adoption of new crops prohibitive. Many producers only adopt new crop varieties after watching a neighbour have success with that variety. A common practice for producers in Western Canada is to seed 80 acres of a new variety as a test before fully adopting the variety. When Monsanto and AgrEvo introduced their GM canola varieties, they did so with 80 acre production contracts as they believed this was the most economical method for producers to evaluate the new technology. The increased use of buffer zones to control cross-pollination has the potential to drastically reduce the adoption rate of new technology crops. If the StarLink™ buffer zone of 660 feet is used as a base, this entirely removes the option of 80 acre production contracts as the buffer zone consumes the entire 80 acres. Moving to 160 acre production contracts is still very restrictive, as 76% of the land would be consumed in the buffer zone. Producers would be required to plant 40 acres in the center of a quarter-section, a sub-optimal evaluation size, and plant 120 acres to a crop that provides sub-optimal rent.

Finally, ineffective IPRs in many countries reduce their attractiveness as markets for new technologies, causing them to lag in the adoption of new traits and varieties. In the canola sector, few companies would chose to export new cultivars to major growing regions in China or India because of the lack of effective IPR protections. As a result, about half of the producers of rapeseed/canola in the world are unable to access the latest technologies, which is one of the contributing factors to lower yields in those areas. India, for instance, posts average canola crop yields almost 40% below Canada's while China, in spite of significant subsidies for irrigation and

fertilizer use, still post yields about 3% below Canada's. Finding a more effective IPR mechanism that is not dependent on institutions that are often very weak in many of these countries might improve diffusion of new cultivars and technologies. If Third World yields were to rise even 5% due to new varieties, total canola production there would rise by about one million tonnes, worth approximately US$225 million to those producers and their markets.

In brief, plants and people cannot be trusted to do what markets require. As a result, genes move, creating co-mingled traits in the food system and liabilities in the transfer of technologies between markets.

6.4 Using the Framework

While the previous section outlined some of the liabilities that have arisen from GM crops, this section of the chapter focuses on what kinds of controls, both organizational and biological, are available to control and manage these liabilities. The application of Figure 3.2 to the challenge of managing marketplace liabilities provides the opportunity to assess how seed sterility technologies may be part of the solution to the problem of cross-pollination and co-mingling. In reality, the outcomes of the application of seed sterility are well known to all consumers in the form of seedless grapes and watermelon.

Fundamentally, risks can be managed by either institutions or biological controls or a combination of the two. Institutionally, the public sector evaluates new GM crops

for safety considerations, examining the new products against known products to determine whether they involve any new risks related to human consumption, the environment and livestock (if used as feed ingredient). If the new variety is determined to be substantially equivalent, then it will usually be approved for release. Most regulators also have some ability to examine risks once the products enter the market and may intervene if an unexpected risk is detected. While some of these products might be only conditionally released (e.g. for production in a specified area or under conditions of isolation from food crops), most will be released without condition. In both cases, the private sector is generally responsible for managing the risks of new GM products once they enter the market. They use a combination of contracts, testing and auditing to ensure conformity. While these mechanisms are very important, they cannot manage all the risks—genes are likely to travel. Regardless of how effective regulations or contracts are, some actors will either deliberately or inadvertently misuse new technologies, creating potential new liabilities. More importantly, however, many plant species are promiscuous sexually, creating natural gene flows. In short, we need to look for biological control mechanisms to manage many of the risks and liabilities of these new crops.

Pollens are produced in large numbers and are transferred to the carpels by vehicles such as wind, animals and insects. Pollination as a process allows for a limited fertilization of plant ova across the species spectrum. In order for pollination to be successful, physical attributes of pollen must be genetically competent to endure the

physical carriers and fulfil their intended function. Interference with these attributes could become the choice of scientific options for control of the GM gene flow.

Smyth, *et al*., (2002) provide a thorough summary of the options available for genetic manipulation and the interference of pollen development. Recent Canadian research conducted by Agriculture and Agri-Food Canada has developed a seed containment strategy for plants. Schernthaner, *et al*., (2003) describe a two-part system where a seed lethality gene prevents the second generation seed from germinating, but allows the plant to grow in conjunction with a second component that represses the lethality gene, thus controlling it from spreading to other plants. This system of preventing unwanted spread of novel traits within sexually compatible plants was successfully tested in tobacco.

Given that pollination is simply the means for distributing genetic material, pollens with an incomplete set of genetic material would potentially impede pollination. The 1990s brought new efforts to ensure sterility, not for processing or gustatory value, but for commercial IPRs protection. Efforts are underway to limit the diffusion of transgenes through genetic use restriction technologies (GURTS) to turn off reproduction for either transgenic varieties or traits. Some dubbed this approach the 'terminator gene.' Smyth, *et al*. (2002), provide a summary of recent patents that restrict genetic expression, thus resulting in sterile seed. The GURTs technology has the ability to address an identifiable concern in agriculture, the unwanted spread of transgenic seeds possessing specific traits. This concern may become elevated with

the expected increased production of plants with identified industrial and pharmaceutical applications.

The use of sterile seeds *per se* is widely practiced and has not been objectionable while the GURTS technology is being criticized because it could deny poor farmers from saving seeds for future use. However, the crudest form of this technology was known and is documented long before notions of inheritance and genetics were known. From ancient writings of the Mediterranean, seedless grapes were known to have existed. Since the 1930s seedless edible crop varieties produced by traditional plant breeding methods have been produced (e.g. seedless grapes in 1936 and watermelons in 1951) and posses certain advantages (Table 6.2).

Table 6.2: Advantages of Seedless Fruit and Vegetable Crops

	Advantages					
Crop	**Fruit quality**	**Shelf life**	**Taste**	**Processing**	**Production**	**IPRs**
Citrus	More tissue	NA	Better	Juice	NA	Yes
Cucumber	Crunchier	NA	Better	Pickles	NA	Yes
Grapes	More tissue for raisins	NA	Better	Juice	NA	Yes
Tomato	More tissue	NA	Better	Juice and ketchup	NA	Yes
Watermelon	More tissue	NA	Better	Juice	NA	Yes
NA = no advantage over seed variety Source: Smyth, *et al*., 2002.						

The ultimate question may well be that of choice—that is, whether the 'terminator' technology is the only option. There is the possibility that many of the concerns about genetically modified crops could be overcome by the further advancements in science (Daniell, 1999). A number of biological options exist, depending on the crop

and its attributes. Both traditional and molecular genetic methods already provide mechanisms to create hybrids while working at a more refined molecular level offers the potential to control GM traits. Recently there has been an effort to reduce the risk of biotechnology crops by engineering foreign genes via the chloroplast instead of the nuclear genome. Such recombinants would only express the new traits in selected parts of the plant, rather than in the whole plant. Hence, any pollen drift would not include the transgenes. These and other options offer some promise.

'Terminator' technology, which has come to symbolize all the possible scientific options, is the end result of an evolved 'normal science' process. It could be argued that because Monsanto has ceased efforts to purchase this technology from Delta & Pine Land, that efforts to develop the concept and other technologies will cease. This may, however, be a classic case of paradigm shift and start of another wave of 'normal science' that targets the new tools of genetics and biotechnology towards management and control of GM gene flow to non-GM plants in the first instance and to bolster IPRs in the second.

Biological control of liabilities, either through contemporary technologies described above or those yet to be devised, are the science side of the story. The human, institutional element is the complementary side. Ultimately these two parts fit together in a discussion of the relative costs (risks) and benefits of alternative options. As noted in section 3, the costs of not managing the risks are potentially very high, ranging from a net present value of C$1-2 million lost sales in the organic

canola market to the US$110 million cost of the StarLink™ failure. Similarly, control mechanisms are not cheap. Often incomplete institutional approaches can cost in the millions for those technologies that are widely dispersed, with both high fixed and variable costs. One potential advantage of the GURTs biological control mechanism is that while it is costly to develop, the marginal cost may be as low as US$250,000 per new variety released (Visser, *et al*., 2001), which would add only about 10% to the cost of a new commercial variety. Given that many firms report they lose at least 10% of their returns due to incomplete property rights, this option may be significantly more effective than other approaches.

While biological control mechanisms offer a cost effective and practical means to control the spread of transgenic crops, the firms engaged in this area of research are fully aware of the potential social backlash that may result if the application of this technology is not communicated appropriately to the public. While biotechnology companies employ scientists who continually explore new horizons in molecular genetics and push back the barriers of knowledge, all of this is done within a society that exhibits less and less confidence in large multi-national corporations. There are multiple reasons for this lack of confidence, but one looming and potentially crippling impact upon agricultural biotechnology is that consumers will reject innovative new products and this will lead to a collapse of the industry. Enterprises that are undertaking basic scientific research and those that are commercializing the new transformative technologies, need to adopt innovative strategies for educating

and informing societies about the benefits and the risks of new transgenic crop developments.

6.5 Conclusions

The area of overlap from Figure 3.2 that is addressed in this chapter, identifies how society and industry have real challenges in communicating in an informative manner. The two-way lack of trust is painfully evident. Consumers do not trust what industry tells them and industry hears what consumers want, but are not convinced that this represents the majority of consumers. When there is a gap in the level of trust between industry and society, the framework would suggest that the only remaining stakeholder that can provide some basic level of reassurance in this situation is the regulatory agency.

As long as a new product is safe, Canadian regulators are virtually powerless to remove products from the marketplace. Possibly what is needed regarding post market surveillance and monitoring of transgenic crops is a multifaceted organization of industry, regulators and societal representation to provide a basic and solid level of confidence for these products, in an increasingly sceptical society. Clearly, when private, for profit capitalism collides with a society that has a growing consciousness regarding the production and composition of food products, there is an absence of a body, organization or stakeholder that can act as a trusted intermediary. Identifying and promoting this trusted intermediary is crucial to the

continued successful commercialization of new transformative technology products in modern societies. Increasingly, it appears that the logical intermediary to provide this basic level of trust is the regulatory agency.

Regulators will be faced with two options regarding third generation GM crops: they can outright reject them or they can impose detailed production and market segregation regulations. The outright rejection of new biotech crop varieties may be excessive given the level of risk and potential benefits. Numerous benefits have already been suggested for third generation GM crops such as tobacco that fights cancer, tomatoes that reduce heart disease and cholesterol-reducing grains. If new risk management measures are excessive, they could certainly jeopardize future research and development (R&D) investments in those areas. Capital is one of the most liquid commodities in today's marketplace and, by banning GM products, countries (and the global industry) risk losing not only investment capital but R&D firms as well.

In this chapter it is argued that GURTs types of technology could provide some advantages. First, they could act as built-in safety mechanisms to prevent the escape of potentially harmful traits (e.g. HT) from new GM crops. Second, they could prevent pirate growers from exploiting GM seeds. Third, they could reduce product liabilities assigned to the seed growers by preventing contamination with non-transgenic crops.

There would appear to be a three pronged approach that could realize the benefits of new crops while at the same time minimizing risks. On the institutional side, governments can and should improve the regulatory oversight of second and third generation GM crops, possibly aggressively using refugia, contract registration, regional regulation and mandatory crop rotations and audits. Meanwhile, industry must take its responsibilities more seriously. The introduction of first generation GM products was directed at getting producers to adopt the technology, and many of them do not appear to have a strong appreciation for the importance of managing the technology and containing it. Moreover, the launch of these products went largely unnoticed by consumers and much of the industry. This approach cannot and will not work for second and third generation products. Many of the risks and potential liabilities of GM crops are only partially manageable by public and private institutions. Institutional costs to manage risks are high, while the cost of failure is even higher. Ultimately, inability to manage the risks and control the liabilities may sink the technology.

As has been demonstrated, the lack of control mechanisms of GM pollen and seed are presently affecting producers and exporters of not only crops and oilseeds, but other products as well. To continue in this direction where no control mechanisms exist will only result in higher costs for seed development companies and producers. With domestic subsidies on the decline, affected producers may turn to litigation as a means of recouping lost revenues. Regulators and industry officials need to examine what the market impacts would be from commercially releasing a control

mechanism for GM crops versus leaving the situation as it is, with an expected rise in litigation costs. While the initial cost of introducing a control mechanism may be high, the long-term benefits of such a technology may justify commercialization.

In short, even with the best institutions, some risks will remain. Hence, biological control mechanisms need to be considered. While control mechanisms address many of the problems occurring in agriculture, they are also seen as a major concern by many even within the industry. The problem of GM cross-pollination and volunteer GM growth are both resolved when the use of a biological control is considered. However, the technology still has to resolve many questions regarding its stability and the method of expression prior to allowing it to be seriously considered as a viable technology.

Ultimately, what is now needed is a full and open discussion by proponents and opponents of the technology, in an attempt to determine how to address the existing problems. Delay will only compound these problems.

Chapter 7

Regulatory Challenges and Liabilities from Plant-Made Pharmaceuticals

7.1 Introduction

This chapter focuses on the final area of overlap from Figure 3.2, the very center where all three spheres overlap. This particular section of the framework can be defined as an area where there is a regulatory vacuum. At this point, the science is far ahead of the regulatory ability to keep pace and in many instances, the regulations are only preliminary and more detailed regulations are in the process of being developed, but have not yet been legislated. The intent of this chapter is to examine one such area, molecular production of novel proteins in plants, to gain a more thorough understanding of the stakeholder relationship dynamics that occur within a regulatory vacuum.

The introduction and rapid adoption of GM crops at the close of the 20th century was arguably one of the defining moments in the history of agriculture within the century. This rapid global adoption of GM varieties of canola, corn, cotton and soybeans was not without controversy. At the opening of the 21st century the contentious debate shows no signs of abating. The array of issues is wide and varied, ranging from social issues such as consumer acceptance to scientific issues like gene

flow. One hot, new issue is whether and how we should produce pharmaceutical proteins in food plants.

The application of this technology has great potential to increase availability of pharmaceutical products to consumers. Some estimates by the pharmaceutical industry suggest that as little as one-and-a-half acres of pharmaceutical crop could satisfy the therapeutic needs of 10,000 patients. As the population ages, the need for therapeutics will rise, raising the importance of researching new protein and antibody delivery systems. However, the use of food plants as the host organism for the expression of pharmaceutical proteins and antibodies is fraught with peril if the pharmaceutical plants are allowed to co-mingle with other food plants and enter the supply chain for human consumption. The detected presence of co-mingled pharmaceutical plants in processed food products has the potential to greatly disrupt (and destabilize) markets.

This chapter examines the science and economics of pharmaceutical gene flow, discusses the development of regulations targeted at controlling gene flow and reviews the results of commercialization of these crop varieties.

7.2 Background

Debate about gene flow has grown in importance over the past several years, especially with the commencement of crop trials involving plants expressing pharmaceutical proteins. The cost of producing drugs is incredibly expensive, with

the average drug costing over US$260 million to develop and commercialize; some drug companies report spending in the range of US$700-800 million for specific new drugs. In an attempt to lower the cost of producing base components (proteins and antibodies) for new drugs, research involving the use of plants as vectors of expression is occurring (Table 7.1). Numerous countries have experimented with pharmaceutical crop trials, but only Canada and the US have any long-term history regarding the development of regulations targeted at pharmaceutical field trials and sustained experience with field trials.

As Table 7.1 shows, the potential economic benefit from using transgenic plants as the basis for expression of pharmaceuticals is high compared to other production vectors. The cost of using plants to produce pharmaceutical proteins is relatively low and some plants may be able to produce pharmaceutical proteins for an extended period of time. The quality of the product is expected to be high relative to some other production systems. The risk of contamination from other sources of contaminants is low and importantly, the cost of storing PMP products is expected to be relatively inexpensive.

Gene flow between transgenic plants and conventional plants and weedy relatives has been a hotly contested issue in recent years. New research is continually appearing regarding a variety of transgenic plant types that challenges conventional thinking about gene flow, but as of yet there is no point of consensus in the scientific community regarding gene flow. Debates have mainly focused on the ability of

transgenic food crop varieties to cross-pollinate conventional varieties and whether the resulting progeny are viable. A parallel debate is focusing on gene flow and progeny viability with weedy relatives of transgenic crops. While literature is emerging regarding transgenic gene flow, there is a noticeable absence of literature regarding cross-pollination and gene flow involving pharmaceutical plants.

Table 7.1: Comparison of production systems for recombinant human pharmaceutical proteins

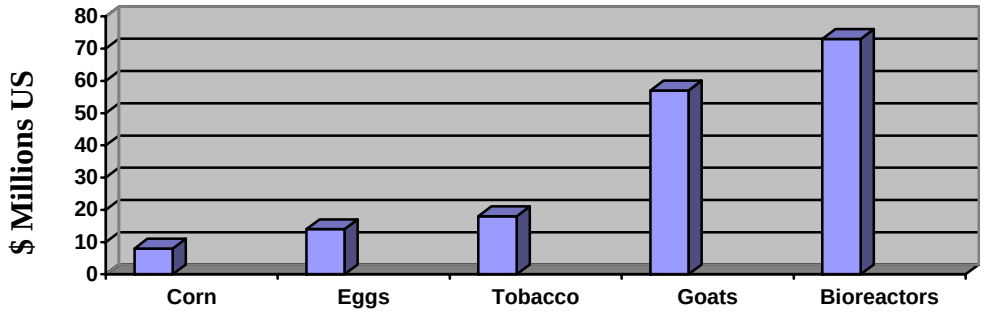
System	Overall Cost	Production timescale	Scale-up capacity	Product quality	Glyco-sylation	Contamination risks	Storage cost
Bacteria	Low	Short	High	Low	None	Endotoxins	Moderate
Yeast	Medium	Medium	High	Medium	Incorrect	Low risk	Moderate
Mammalian cell culture	High	Long	Very low	Very high	Correct	Viruses, prions and oncogenic DNA	Expensive
Transgenic animals	High	Very long	Low	Very high	Correct	Viruses, prions and oncogenic DNA	Expensive
Plant cell cultures	Medium	Medium	Medium	High	Minor differences	Low risk	Moderate
Transgenic plants	Very low	Long	Very high	High	Minor differences	Low risk	Inexpensive
Source: Ma, *et al*., 2003.							

Scientists and industry offer two justifications for pursuing plant made pharmaceuticals (PMPs). First, production of high-quality biological material is presently done using mammalian cells inside a bioreactor, which is very expensive and results in high drug costs that could potentially limit the number of people that benefit from new drugs. Second, even at the present time, there is an insufficient level of bioreactor capacity available to meet the current demand, let alone the expected increase in demand over the next decade.

At root, the issue comes down to cost. Figure 7.1 compares the costs of the various antibody production systems that are used in treatment. The production of these antibodies are valuable for the treatment of several diseases in two categories, those which affect the general population, like arthritis, viral infections and cancer and those which affect smaller cohorts of people with particular inherited disease or metabolic disorders.

The prevailing technology of using mammalian cells to produce human antibodies costs in the range of US$105-175 per gram. It has been estimated (McCloskey, 2002) that PMPs might be able to produce the same amount of antibodies at a cost of US$15-190 per gram. The range of variation in anticipated PMP costs arises from the prospect that the use of PMPs will lower production costs to a level that is economically feasible for potential new proteins that are presently prohibitively expensive to produce. Mammalian cell bioreactors take an average of five to seven years to build and cost US$600 million. Given the lumpiness of this investment, there is a real chance that there could soon be inadequate supply. McCloskey estimates that at present 20 to 50 products could be delayed due to the unavailability of bioreactor capacity. Currently the production of four pharmaceutical products requiring biologics occupies 75% of mammalian cell fermentation capacity. By the end of this decade, there could be more than 80 competing antibody dependent products with an estimated value exceeding US$20 billion, provided adequate production systems can be developed. The potential size of the market underlies the importance of exploring the potential of developing PMPs.

Figure 7.1: Cost of various antibody production systems ($M US to produce 300 kg)



Source: Pew Initiative on Food and Biotechnology, 2002.

As the technical possibilities of and demand for human antibodies grow, there will be increasing pressure to use PMPs in the production system, forcing industry and government to consider the appropriate regulation of those plants. Of paramount importance will be assurances that the production of pharmaceutical proteins in food plants will not co-mingle with conventional crop production destined for human consumption. The detection of drug proteins in processed food products could destroy the social trust in pharmaceutical crop technology and ultimately destroy the ability to take advantage of this technology.

Pharmaceuticals field trials first began in 1992 in the United States (Table 7.2). In North America, the use of pharmaceutical trials was limited through the early to mid 1990s. In the US, trials became more common in 1998 and appeared to have declined following 2001. Trials accelerated earlier in Canada (beginning in 1996), but peaked earlier at a lower level and declined following 2000. A host of other

countries recorded a small number of pharmaceutical field trials between 1995 and 2002.

Table 7.2: History of pharmaceutical field trials

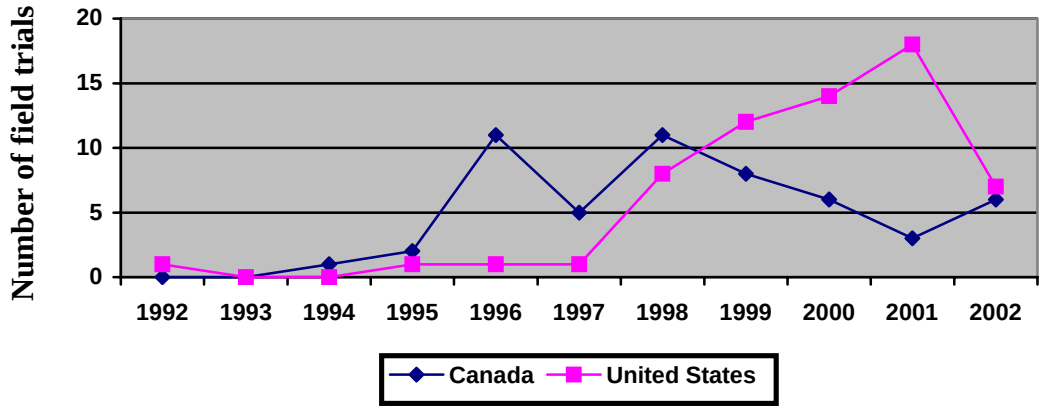
Country	History of Pharmaceutical Crops Trials											
	'92	**'93**	**'94**	**'95**	**'96**	**'97**	**'98**	**'99**	**'00**	**'01**	**'02**	**Total**
US	1	-	-	-	1	1	8	12	14	18	7	62
Canada	-	-	1	2	11	5	11	8	6	3	6	53
Japan	-	-	-	-	-	-	-	-	7	-	-	7
France	-	-	-	1	-	1	-	3	-	1	-	6
Argentina	-	-	-	-	-	-	3	-	-	-	-	3
Australia	-	-	-	-	-	-	-	-	-	-	1	1
Italy	-	-	-	-	-	-	-	-	-	1	-	1
Spain	-	-	-	-	-	1	-	-	-	-	-	1
Total	**1**	**0**	**1**	**3**	**12**	**8**	**22**	**23**	**27**	**23**	**14**	**134**
Source: Smyth, *et al*., 2004.												

There are several reasons for variations in the number of field trials during the past decade. First, the issuance of approvals differed amongst nations and regions. Second, the pace of discovery can be serendipitous or planned. The crop pharmaceutical industry itself is in the early stages of development so that there is great uncertainty and lumpiness in its need for trials. Field trials, as well as conventional pharmaceuticals clinical trials, are unlikely to have a predictable trend. Third, variations in field trials can occur because of seasonal and/or environmental conditions can dictate postponement of trials, this adds to the fluctuations in the numbers. Fourth, as judged by the analysis of the crop kinds, we should expect fluctuations in the numbers of pharmaceuticals that could be derived from any one crop. The genetic and physiological constraints in plants place limits to their use for

transgenic plant construction, both in food and pharmaceutical contexts (Khachatourians, *et al*., 2002).

There was no identifiable advantage for either country in the early stages of PMP crop research (Figure 7.2). Canada enjoyed a research advantage from 1996-1998, while the US enjoyed the advantage from 1999-2001. Both countries converged again in 2002. Canada's early advantage was derived from the research conducted with canola, which proved in the late 1990s to present too many safety concerns to proceed. The US lead was based upon research using corn as the plant of choice between 1999 and 2001. By 2002, corn may be falling out of favour in the US for crop trials, while trials are climbing in Canada again based on testing with safflower.

Figure 7.2: Competitive Advantage Comparison in Pharmaceutical Trials



The evolution of PMPs has mirrored the research trends in agricultural biotechnology: transformation research started with tobacco, moved to dicotyledons like canola and finally to monocotyledons, where the first research was with rice

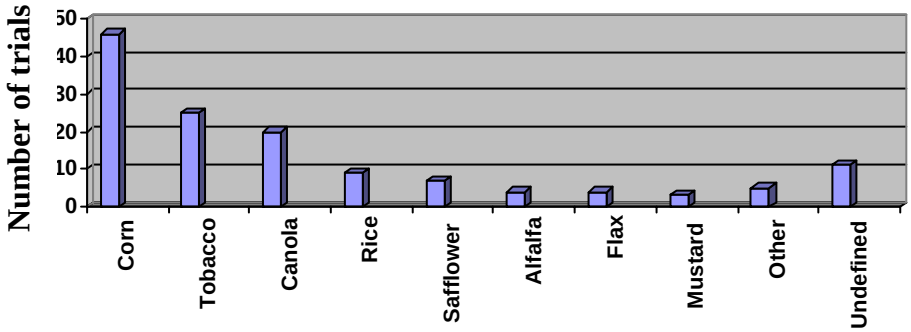
(Smyth, *et al*., 2004). The different crop varieties used for pharmaceutical trials are shown in Table 7.3. Canola was the early favourite due to the canola transformation research that had already taken place and its attractive oil properties. After several years of pharmaceutical crop experimentation in Canada, it became obvious that canola was not a suitable host plant due to the high incidence of pollen flow and the threat posed to the large farm production of canola in Western Canada. At the time that pharmaceutical canola trials were ending, trials started with corn, rice and tobacco. The use of corn and tobacco for pharmaceutical trials grew between 1997 and 2001, while experiments with rice have been minimal. Experiments with the use of flax occurred briefly in Canada in the late 1990s, but concerns about seed dispersal during harvest removed the potential of further trials. Safflower trials have commenced in the past three years as this research has replaced the previous canola research. A variety of other crops such as forages, vegetables and flowers have been experimented with, but it would seem that little in the way of useful pharmaceutical potential is available in these plant varieties. The one exception to this may be the use of poppies in Australia for improved production of opium. Field trials of transgenic pharmaceutical poppies started in 2002 and it would appear that there is some long-term potential with the use of poppies. Figure 7.3 provides a summary of global pharmaceutical variety trials by crop.

Table 7.3: Historical perspective of pharmaceutical crop kinds

Crop	'92	'93	'94	'95	'96	'97	'98	'99	'00	'01	'02
Alfalfa	1	-	-	-	-	-	3	-	-	-	-
Barley	-	-	-	-	-	-	-	-	-	1	-
Canola	-	-	1	2	2	8	4	-	-	-	-
Clover	-	-	-	-	-	-	-	-	-	1	-
Corn	-	-	-	-	-	1	5	11	11	14	4
Flax		-	-	-	-	-	1	1	2	-	-
Mustard	-	-	-	-	1	-	2	-	-	-	-
Poppy	-	-	-	-	-	-	-	-	-	-	1
Rice	-	-	-	-	-	1	2	2	2	2	-
Safflower	-	-	-	-	-	-	-	-	1	2	4
Sugar Cane	-	-	-	-	-	-	-	-	-	1	-
Tobacco	-	-	-	1	-	1	-	5	5	9	4
Tomato	-	-	-	-	-	-	1	-	-	-	-
Source: Smyth, *et al*., 2004.											

There was a noticeable decline in pharmaceutical crop trials in 2002. There may be three reasons for this. First, crop trials are cyclical by their very nature and this may be nothing more than a natural dip in the number of trials. Second, drug companies have been conducting trials for 5-6 years with some crop kinds and have now completed Phase 3 clinical trials and are waiting to see what the financial outcome will be prior to commencing new research. Third, the smaller drug companies conducting the trials may be seeking strategic partnerships with the large pharmaceutical firms before proceeding.

Figure 7.3: Breakdown of Pharmaceutical Trials into Crop Kinds



Source: Smyth, *et al*., 2004.

The three leading crop species used for pharmaceutical trials by design (availability of vectors and transformation systems) and/or choice (agronomy and growers) have been corn, tobacco and canola. The problem is that corn and canola are intended for human consumption and, as outcrossers, the potential for co-mingling or cross-pollination exists, raising concerns about using these species for pharmaceutical trials. Table 7.4 presents the major transgenic crop kinds, identifies whether they are used in pharmaceutical trials and examines their modality of consumption.

Table 7.4: Transgenic crops and human consumption

Crop category	**Specific transgenic crops (either approved or in trials)**	**Use in pharma-ceutical trials**	**Cross-pollination potential**	**Modality of consumption**	
				Plant tissue(s) and organs*	**Extracell-ular plant metabolic ingredients**
Cereals	Corn, barley, rice, wheat	Yes	Low-Medium	Direct	No
Oilseeds	Canola, flax, mustard, cotton, safflower	Yes	High	Mainly indirect	Yes
Pulses	Soybean	Yes	Low	Direct and indirect	No
Forages	Alfalfa, clover, tobacco, sugar cane, sugar beets	Yes	Medium	Very minimal indirect	No
Fruits and Vegetables (including juices)	Poppy, cantaloupe, melon, radish, potato, squash, tomato, strawberry, lettuce and papaya	Yes	Low-High	Direct	Yes
Note: Includes plant cells, tissues and organs that include rDNA and/or primary or secondary metabolites (i.e. excluding DNA such as oils, starches, proteins, amino acids and processed materials and tissues, including juice). Source: Smyth, *et al*., 2004.					

Transgenic crop is the leading cereal corn. It is grown in ten countries and accounts for 11% of global corn acres (James, 2003). The leading transgenic oilseed is

canola—grown in Canada and the US—with about 16% of world acreage planted to transgenic varieties. Soybean, the sole transformed pulse crop, is grown in eight countries and GM soybeans account for 55% of the global soybean acres. The leading transgenic forage crop is tobacco, while a wide variety of transgenic fruits and vegetables are in field trials and are expected to enter commercial production shortly. Transgenic cereals, fruits and vegetables are for the most part, consumed directly or in lightly processed forms. Cereals such as table corn and rice, are consumed both directly (without industrial processing) and in various processed snacks and meals. Transgenic fruits and vegetables are also consumed directly, while some processing occurs in the juice-making process. Transgenic oilseeds are largely used to produce processed oils, which are used as minor ingredients in processed foods or to fry foods. While most pulses are consumed directly, soybeans, the only transgenic pulse, is mostly used for animal feed or as a feed stock in food processing—only a small portion of soy proteins are used in the production of directly consumed products, such as tofu. Forage products are rarely consumed directly by humans, except for a small amount of alfalfa sprouts.

As the technology of PMPs rapidly moves from laboratory to field, the regulations developed to control these new crop varieties have been severely tested. While regulators in the US have argued that the detection of ProdiGene's experimental pharmaceutical corn in a silo of soybeans late in 2002 is proof that the regulations are working, the simple fact that a pharmaceutical crop that was supposed to be contained on-farm actually reached a grain terminal without being detected, shows

that the regulations are likely not stringent enough. The containment of living plants is proving to be increasingly challenging given the scientific inability to completely control nature.

The issue of gene flow in canola was documented by Smyth, *et al*., (2002) and that situation remains unchanged. Scientists and regulators are still in a conundrum at best or conflict at worst about the impacts and regulations of gene flow. The issue of unintended gene flow first became a global news issue in the fall of 2001 with the discovery that some varieties of Mexican maize contained transgenic material that should not have been there (Quist and Chapela, 2001). While this research was contested within the scientific community and is presently the subject of a North American Free Trade Agreement (NAFTA) Commission for Environmental Co-operation (CEC) Chapter 13 panel review, the concern continued into the summer of 2002 as a research team led by Allison Snow of Ohio State University reported preliminary evidence suggesting that the trait from transgene insertions in sunflowers may be able to move to other plants, thus creating the conditions for 'superweeds' (Snow, *et al*., 2003).

As we have seen, the first, and most widely publicized regulatory violation, was the debacle of StarLink™ corn introduced by Aventis (Table 7.5). Aventis received split-run approval for this variety of corn, meaning that it could be produced within an identity preservation system for use as animal feed, but had not received approval for human consumption. Although Aventis paid a premium of US$0.25/bushel to

contain the corn and suggested rules to ensure it was used only for animal feed, the evidence suggests that Aventis and the US Environmental Protection Agency (EPA) did not do enough to ensure that producers were aware of the split-run approval. As a result, the StarLink™ corn co-mingled with corn destined for human consumption. Close to 300 food products containing StarLink™ corn were detected and recalled, at an estimated cost of US$100 million. Aventis recently settle a lawsuit with affected corn producers for US$110 million.

The extent of the problem was more clearly defined in the fall of 2002 and the spring of 2003 with a few high profile regulatory actions. In November 2002, ProdiGene Inc. was fined US$250,000 for allowing experimental pharmaceutical corn grown in 2001 to volunteer and grow to maturity within a soybean crop grown in the same field in 2002. The regulatory infringement was discovered by inspectors with the United States Department of Agriculture Animal and Plant Health Inspection Services (APHIS). The affected soybean crop was harvested and pooled in a commercial grain silo, thus contaminating an estimated 500,000 bushels of soybeans. The cost to ProdiGene for buying the contaminated soybeans and having them transported to be destroyed was estimated to be US$3.5 million.

Table 7.5: Transgenic crop regulatory violations, 1998-03

Company and crop year of violation	Crop	Location	Violation	Impact
Aventis CropScience, 1998-2000	Corn	Numerous states	Failed to prevent corn approved for animal feed from entering corn destined for human consumption	Paid US$0.25/bushel premium to contain corn, recall of nearly 300 corn food products at an estimated cost of US$100 million and settled lawsuit for US$110 million
ProdiGene, 2001-02	Corn	Nebraska	Volunteer corn growing in soybean field	Fined US$250,000 and forced to pay clean-up costs of US$3.5 million.
Dow AgroSciences, 2002	Corn	Hawaii	No tree windbreak and bordering rows	Fined US$8,800
Pioneer Hi-Bred, 2002	Corn	Hawaii	Plot planted in unapproved location	Fined US$ 9,900
Dow AgroSciences, 2003	Corn	Hawaii	Plants detected with unapproved gene and failure to promptly notify the EPA	Fined US$72,000
Source: http://131.104.232.9/agnet-archives.htm.				

Finally in April 2003, Dow was again fined for violating an EPA permit in Kauai. This time the fine was US$72,000 and resulted from the detection of 12 transgenic corn plants that contained an unapproved gene that is suspected of coming from the pollen from another experimental plot located nearby. Although Dow officials discovered this unplanned gene flow, Dow failed to notify the EPA promptly and EPA officials expressed disappointment over the delayed response by Dow. When this incident was reported in the Washington Post (April 24, 2003), the article stated that this incident was "… the latest setback for a biotechnology industry struggling to comply with government rules. … some advocates say the problems cast doubt on

a fundamental premise of government policy: that experimental varieties of corn or other crops can be planted in fields but kept out of food crops."

Four separate, but related, regulatory violations within a six-month period may be nothing more than a freak occurrence and may never happen again. What is troubling however, and likely more representative of the real issue, is that these regulatory violations may be simply the tip of the iceberg and that evidence of regulatory violations may continue to surface over the coming years. So far there appears to be a lack of commitment and understanding of the importance of a transparent, accountable and effective regime for new trait crops.

7.3 The Conceptual Framework

This section of the chapter examines the institutional actors that have the potential to play a role when a regulatory vacuum exists. The absence of clear, concise regulations results in a myriad of potential stakeholders attempting to position themselves as the leader. This can result in power struggles within bureaucratic departments and can also lead to marketplace liabilities due the lack of regulations. The focus of this section of the chapter is to understand how liability is managed by institutions and regulations.

The challenge of regulating pharmaceutical crops is with the overlap of medicine and agriculture. Drug companies are beginning to use plants as expression vectors for proteins and antibodies that are used in the production of new drugs. The

regulation of pharmaceutical crops is not clearly organized in the US, as it involves the United States Department of Agriculture (USDA), the EPA, the Food and Drug Administration (FDA) and, at times the National Institutes of Health (NIH). In Canada, the regulation of PMPs involves Health Canada, the CFIA, Environment Canada and the Canadian Institute of Health Research (CIHR). A clearer model of regulation is required to adequately address the emerging liabilities from pharmaceutical crop regulatory violations.

Ultimately, regulatory systems are designed to assess risks of new products or processes, using a scientific risk assessment framework. When a firm violates the regulations or the regulations fail to properly assess and manage the risks, a liability is triggered. Legally, a liability results when an obligation is not fulfilled. From this perspective, there are only two recognized kinds of liability, criminal and civil. Criminal liability occurs when there has been a criminal act committed, such that the liable party broke the obligation of the law of the land. Civil liability occurs when an obligation has not been met by a party, which can then result in civil litigation to seek compensation on behalf of those affected. Lawsuits from those affected by thalidomide and silicone breast implants are examples of civil liability. While many will say that putting any other adjective in front of liability is meaningless, this chapter argues that transgenic innovations can potentially foster the establishment of socio-economic liability. For the purposes of this research, a socio-economic liability has been defined as the decline in social trust for all innovations and the economic decline from commercialization delays when a company or government

regulatory body fails to meet their publicly stated objectives, otherwise viewed as their social responsibility.

One key concept of liability that is particularly relevant to PMPs is the concept of strict liability. Strict liabilities are found for one-time, unnatural occurrences. With strict liability, the prosecution has to prove there was unnatural use of a product and that the plaintiff suffered harm, but the prosecution does not have to prove how the harm arose. The case of *Rylands v Fletcher* (1868) is frequently cited in legal literature as a reference for strict liability, and is explained in Chapter 2. This ruling has three important considerations for the gene flow of pharmaceutical crops. First, the drift of transgenic pollen is not a one-time occurrence, rather it happens annually, for a period of up to three to six weeks in many crop varieties. Second, it would seem impossible to argue that transgenic pollen is stored in any form or fashion upon a farm or a field test plot. The third consideration important to this issue is that the presence of pharmaceutical genes in crops destined for human consumption could be inherently dangerous. The key argument from *Rylands v Fletcher* was that the danger was not naturally occurring. There is a strong argument to be made that PMPs are not naturally occurring and that the unintended gene flow from these crops may be inherently dangerous.

The different forms of liability can be classified according to the following governance mechanisms. Criminal liability is strictly a legal issue and dealt with by the courts. In these cases, individuals have broken the law and are either punished

financially or by serving time in a penal institution. Civil liability is an economic issue and, while it can be handled by the court system, it is more common for these cases to be settled out of court. Many American civil litigation lawsuits are class action suits against large firms and courts often awards financial compensation to those negatively affected regardless of the ability to pay. Executives of the offending firms are not normally prosecuted through criminal proceedings or even held liable for any court findings, unless there is demonstrated breech of their fiduciary trust. Socio-economic liability, in contrast, is not dealt with by the court system, but rather, is reflected in the attitudes of the consumers within a given society. Whereas the other two forms of liability have handling mechanisms, this form of liability incurs public costs reflected in the loss of trust in a product line or producing region, rather than simply directed at a specific company or a branded product.

The relationship between the stakeholders can be analyzed using an inter-disciplinary framework (Figure 3.2). Each sector has control over a central domain, which can be described as their portion of the sphere that does not overlap with any other sphere. In the areas of overlap however, the jurisdiction and incentives can be difficult to discern. In the US, regulations for biotechnology are the shared responsibility of the USDA, the EPA and the FDA. The combined regulations of these government agencies have, for the most part, been effective at preventing regulatory oversights. The private firms in the agriculture biotechnology industry have developed their own operating procedures, which enact and manage the regulatory decisions and in some instances have greater stringency than the

regulations established by the federal regulatory bodies. Industry associations in the US, such as the Biotechnology Industry Organization (BIO), have worked progressively with the private firms to develop industry standards (a collective activity that requires voice) that are designed to support the federal regulations, but also to demonstrate to the public that the industry is conscious of potential concerns and have taken action to try and ensure that no oversights exist.

The response of regulatory agencies has differed between Canada and the US. Canada has adopted a three channeled product differentiation system that distinguishes products for different economic reasons. Smyth and Phillips (2003) have demonstrated how identity preserved production and marketing systems are used by private firms to capture premiums for niche market products, how the CFIA has implemented segregation of industrial crops (such as high erucic acid rapeseed) that could endanger food safety through co-mingling and how retailers and others in the supply chain are implementing traceability systems to meet consumers demands for more timely product recalls and tracing. This array of product differentiation systems has worked well in Canada, while in the US, the difference is that the federal regulatory agencies involved in the regulation of transgenic crops are less specific about the purposes of their systems—for example they have never demanded the same level of segregation of crops as in Canada.

Recently, the federal regulatory bodies in the US have relaxed some of the regulations relating to crop production and a process is in place for applications to

deregulate some transgenic crop varieties. The federal regulatory agencies in the model have moved out of the portion of the spheres where overlap occurs but this regulatory withdrawal has not been followed-up by actions initiated by the private firms or the industry associations. The lack of progressive actions from private firms and the industry associations has resulted in the creation of a regulatory gap for the field testing of PMPs. The result of this was regulatory violations between 2001 and 2003, which prompted the federal regulatory agencies in the US to respond by strengthening the regulation of PMP crop trials.

7.4 Using the Framework

This section of the chapter uses the framework to provide an understanding of how important it is to have strong institutions associated with transformative technologies. This section highlights that even industrialized countries have struggled with this at times. As will be shown, the absence of strong institutions, can result in numerous marketplace liabilities associated with the products of the transformative technology.

Strong governance institutions are especially important for the production of PMPs, which have the possibility of entering and endangering the human food supply chain. These governance institutions currently range from national regulatory agencies, to private industry organizations, to judicial systems. An international comparison of the three leading forms of governing institutions (Table 7.6) illustrates which institutions lead in different markets. The commercialization of

PMPs varies greatly from country to country, depending upon how far the actual governance system diverges from a comprehensive regulatory regime—what can be posited as the optimum.

Table 7.6: Relationship of governance institutions

Country	Type of Governance Institution		
	Federal Regulatory Body	**Industry Association**	**Judicial System**
Canada	Strong	Medium	Strong
United States	Medium	Strong	Strong
France	Strong	Weak	Medium-Strong
Australia	Strong	Medium	Strong
Argentina	Weak	Weak	Weak
Japan	Strong	Weak	Strong
Italy	Weak	Weak	Not available
Spain	Medium	Weak	Not available
Source: Author.			

The terminologies used in the above table are made using the Canadian institutions as baselines. The regulatory system in Canada is science based, requires firms to submit raw data and delivers consistent decisions. Comparisons of foreign regulatory bodies are made against this basis. The evaluation of the industry association is derived from the size of the biotechnology industry and the fact that there is a lack of a single national organization to speak on behalf of the sector, rather there are several regional-based organizations competing for a voice with the national organization. Industry organizations in other countries are compared against this structure. The Canadian judicial system is evaluated by the courts (both provincial and federal) ability to protect the intellectual property of the firms. Granted, there are a limited number of cases on which to base this evaluation,

however, the protection of intellectual property rights is an important component of future R&D investments. Assessments of judicial systems in other countries have been made using this baseline.

The optimum would include three strong institutional pillars that are able to anticipate and manage risks. This would require a strong regulatory body that anticipates issues of concern to society and begins to develop regulations prior to the commercialization of products. Strong industry associations are also needed to operate as progressive lobby groups with a wide network of industry representation that can develop industry standards that either can become the base for regulations or can exceed the regulations provided by government. Finally, strong judicial systems are needed to mediate issues relating to the commercialization of transgenic crops and the ownership of the corresponding intellectual property (in effect, they keep industry operating and accountable).

A closer examination of the regulatory systems in Canada and the US reveal some surprising differences. Some would argue that the Canadian regulatory agencies have been more vigilant regarding transgenic crops that their American counterparts. Beginning in the early 1990s Canadian regulators stated that all transgenic crops (as well as all mutagenic crops) would be treated as plants with novel traits (PNTs) and therefore, subject to additional regulation than conventional crops varieties. Every new PNT requires mandatory trial oversight, efficacy and impact on safety of food, feed and the environment. Government agencies demand to see both the raw data

and summaries of all tests performed and have the final say on every introduction. The Canadian system also has a formal system of contract registration for risky industrial crops and imposes criminal penalties for infractions. While the Canadian regulators have not completed their development of special rules for PMPs, they have been very influential in directing companies away from areas deemed to be of higher risk (e.g. canola) by simply reminding the developers that such products will not be approved. Meanwhile, BIOTECanada is a smaller association than in the US and has not developed the synergy that its counterpart, BIO, enjoys in the US. While the Canadian judicial systems is viewed highly in terms of its independence and professionalism, it is inherently weaker than in the US because of the limited use of class action suits and the very narrow parameters applied for punitive damages.

The initial regulations in the early 1990s in the US were viewed by the industry as being too lax and therefore insufficient to establish trust with consumers. In response, the industry asked the regulators to strengthen the regulations for transgenic crops. Nevertheless, the American regulatory system has consistently been less rigorous in the approach to dealing with transgenic crops that regulators in Canada—e.g. most reviews are voluntary, non-transgenic novel traits are not reviewed and the regulatory agencies only see study summaries rather than raw data. As in Canada, the US regulators have not sorted out how to handle PMPs. The extra challenge they face is that they do not have the same powers and legal authority that Canadian regulators have to direct developers away from crops. While the regulatory mechanism may be weaker, the other two domains are stronger. The

industry association is considerably larger than in Canada, has better access to key decision makers within the US government and a stronger voice in the US than in Canada. BIO is viewed by many as a very authoritative voice when speaking on issues affecting the industry. The courts, similarly, are more engaged, partly because they are more open to class actions and because they award much higher punitive damages than in Canada. For instance, Aventis was pursued by a class action suit in the US claiming that the impacts of StarLink™ had depressed corn prices in the US and resulted in economic losses for corn producers. Faced with a potentially larger judgement, both parties settled very early into the trial, agreeing on US$110 million in compensation.

On 6 March 2003, APHIS announced that they would strengthen permit conditions for field testing transgenic crops, including field trials for PMPs. The number of site inspections will increase to five during the trial and two the following season. The permits for pharmaceutical trials will state that no corn can be grown within one mile of the trial site and that no food or feed crop can be grown on the site the following season. The size of the buffer zone was doubled from 25 to 50 feet. This strengthening of regulatory requirements, in part, can be seen as a method to address the concerns that arose following the regulatory violations between 2001and 2003.

With the exception of Canada and the US, there have been very few PMP crop trials and this creates a challenge when trying to evaluate the relative strength of the related governance institutions. Three European nations have varying levels of

government regulatory bodies. France has been strongly opposed to transgenic crops and developed strict regulations for transgenic field trials, Italy has changed positions over the past five years and transgenic crops are presently forbidden, while Spain has averaged between 45,000 and 55,000 acres of *Bt* corn for the past five years (Brookes, 2002). While this is a relatively small amount of production, it does indicate that the Spanish regulators have developed a functioning regulatory system for the co-existence of transgenic and conventional cropping. The main industry association in Europe, EuropaBio, is a loose coalition of biotechnology firms operating in Europe, but due to the high level of organized opposition, diverse nature of the EU and widely dispersed power and authorities in the EU, its voice is not heard loudly. The French judicial system has, albeit with a limited number of cases, protected the integrity of research and field trials of transgenic crops (ensuring the isolation of trials, even from protestors, is a foundational requirement for any effective regulatory regime), while the court systems in Italy and Spain have not been tested.

It is important to remember that in the context of European PMP field trials, the role of well organized and well funded opposition groups should not be overlooked. Environmental organizations and anti-technology groups are experts at using the European media to present biased and uninformed views of biotechnology. These organizations hold considerable power, especially in countries where the environmental political parties participate in coalition governments.

The countries of Australia, Argentina and Japan have allowed PMP trials to take place, but on a very limited basis. Australia's regulatory agency is modeled on those of North America and therefore, has adopted policies consistent with North America for transgenic crops. The recent collapse of Argentina's economy has resulted in, at best, chaotic regulations. Japan has a very strong regulatory agency whose decisions are consistent with North American decisions, but lag by a period of several years. Australia has a developing industry association, but it is limited as Australia has only commercialized transgenic cotton. Argentina and Japan have virtual no effective industry associations. Australia has a judicial system similar to North America but the federal constitution empowers each Australian state individually to approve or ban transgenic crops, which may possibly create a legal jurisdictional battle, with a number of expected lawsuits against the states enacting moratoriums. Again, the disruption of Argentina's economy has reduced the ability of its judicial system to provide consistent decisions, especially in relationship to protecting intellectual property. Japan's judicial system has historically been a strong supporter of biotechnology, but there is growing social concern about biotechnology and this may be reflected in future court decisions.

Based on an analysis of the Canadian and American governance institutions relating to biotechnology, it can be argued that to have a functioning regulatory system there is a requirement to have strong institutions in all three pillars. Australia is developing a functioning regulatory structure, but only after careful observation of events in North America. All the other countries, France, Argentina, Japan, Italy and

Spain, are lacking a strong institution in at least one of the three governance pillars. This lack of institutional leadership results in an imbalance of authority, which may indicate that either the government agencies have too much regulatory power and are unrealistic in their expectations of biotechnology companies, or that there is no structured bureaucracy capable of making consistent policy decision.

7.5 Conclusions

The challenge of PMPs is going to be to structure a fully integrated regulatory system that effectively evaluates, manages and communicates about the liabilities of a system, and ultimately one that both enforces and is seen to enforce failures. In spite of the US regulatory changes, there is an apparent inability of regulators to enforce the regulations. In the ProdiGene case, the cost of the fine, clean-up and destroying the contaminated soybeans was estimated to be US$3.75 million. The problem with imposing such a large fine on a small biotechnology company is that there is seldom enough cash-flow within the company to pay a fine of this magnitude. For example, the American government had to loan ProdiGene the money to pay the fine. This is symptomatic of the biotechnology industry as a whole, as small biotechnology companies do not have sufficient financial resources to pay large regulatory violation fines. The problem is that if firms know that governments will provide loans or loan guarantees in the event of fines from regulatory violation, what incentives exist for the firms to adopt standards that improve the control of pharmaceutical crops? If existing enforcement mechanisms are found wanting or are lacking, can trust be sustained?

While the framework used in this research shows the equilibrium, quite clearly, these frameworks are not in equilibrium in many of the countries undertaking PMP crop trials. In the US, it can be argued that none of the spheres are overlapping with each other. This creates regulatory gaps that, little by little, erode society's faith in the ability of government and industry to manage these new crop technologies. The intention of the crop trial process is to build integrity for the crop variety engaged in the trial process. When regulatory violations occur within this process, not only is the integrity of the process diminished but people begin to question the merit of, in this case, PMPs being grown in food crops.

The challenge would seem to be that in countries where the regulators are unwilling or unable to step forward and be the leading and dominant institution, private industry is shirking the responsibility as proper guardians of new innovations. Similarly, where industry organizations are unable to generate consensus on or adherence to proper standards and procedures, governments have often been unwilling or unable to fill these gaps. One option might be to let the legal system step in and establish standards and regulations based on decisions from multiple lawsuits. This may well occur if these stakeholders do not begin to take more seriously their responsibility to society regarding the production of PMPs.

Chapter Eight

Conclusions

8.1 Introduction

Innovation is perhaps one of the most interesting phenomena in society. It has the ability to amaze us with the advancement and/or the capability of the commercialized product. Conversely, it has the potential to frighten us when we consider the possible applications of the technology.

The purpose of the research for this thesis has been to examine how innovation has affected agriculture, specifically through the commercialization of products from the innovation of agricultural biotechnology. The commercialization of the products from this innovation in Canada had dramatic impacts within the industry, the federal regulatory agencies and the end consumers. The agricultural biotechnology industry was ill-prepared for the social backlash against this technology and scrambled wildly to implement measures of control. Regulator faced conflicting pressures from proponents and advocates of the technology. Many consumers expressed concerns about the application of this technology and demanded better methods of identification of these products in the marketplace. The commercialization of products from agricultural biotechnology affected the whole of society.

Each of the three academic disciplines relevant to the research for this thesis has grappled with how to understand innovations from transformative technological change. Economics has started to develop literature on how intellectual property rights play a role in protecting innovations, but do not examine the actual challenge of regulating the innovation. Political science theories and typologies have been developed to analyze the process of policy development, but have not proceeded to develop models that assess how innovations force dramatic changes on the policy development process. Sociology frameworks focus on the risk analysis process and how information about these risks are managed and communicated, but there has been little research into how innovations create flux in the risk analysis process.

The economic literature relating to intellectual property is focused on developing models that take the number of patents issued and attempt to quantify how this knowledge is captured in the marketplace and what level of economic benefit is generated. While this is new and exciting research, it does not focus on the root of the issue, which is, the process of innovation. Economists are beginning to identify that the knowledge-based economy impacts their discipline, but to date, there has been minimal research that examines the economic cost of the regulatory process for innovative products resulting from transformative technologies. Developing a greater level of understanding about the how regulations can, and do, affect the innovation process will grow in importance over the next decade as societies witness a rapid growth in the commercialization of innovative products.

Political science has developed an extensive area of research regarding policy development and the analysis of these developments. The challenge of applying these typologies and theories to innovation is that technology transformations can create such a paradigm shift that multiple factors are changed in the policy analysis process, thus reducing the reliability and/or the predictive value of the analysis. When a transformative technology shift happens in a society, so many factors are changing at one time, that it is difficult to hold everything constant and to measure the effects of changing one variable. Technology transformations have a dynamic all their own and a better understanding of the impact on institutions and authority structures would be highly valued.

There is a growing amount of research on risk management and risk communication and how to broaden the entire risk analysis process to make it more socially encompassing and, thereby, more socially acceptable. The challenge of understanding risk management and risk communication within technology transformation is that in some societies, the institutions required to facilitate these processes are incapable of rapidly responding to innovative products. While the institutions in some societies may be capable of this rapid adjustment, the means to inform wide cross-sections of the society are not. The result of this is that only a very small percentage of a society's citizenry is aware of the technology transformation at the crucial period of regulatory policy development. Innovations from technology transformations have a dramatic impact on the way that the entire

risk analysis process is undertaken and additional research that focuses on these impacts would be very timely.

The challenge of regulating innovation is a precarious balance – on one hand the regulator can under-regulate and face the risk of an onslaught of consumer concerns, while on the other they can over-regulate and risk having R&D investments either cease or move to other jurisdictions with less stringent regulations. The sensitivity of too much or not enough regulation is crucial to the continuing success of the biotechnology industry.

8.2 Findings

The results of this research relate to the commercialization of products from agricultural biotechnology in Canada between 1995 and 2004. While this innovative technology has been regulated for a decade now, the science is advancing rapidly, requiring ongoing regulatory efforts. The products are moving from input based, producer benefit varieties to output based, consumer benefit varieties. The regulation of GM crops and foods is new and there are still gaps in the regulatory structure for this innovation.

In the process of examining the four different areas of overlap within the framework outlined in Chapter 3, several key findings were identified. As innovative products from transformative technologies increasingly make their way through the

regulatory approval process and gain entry to the marketplace, it will be important to understand the role of institutions and the influence that they may be able to exert on the commercialization process. While there is great reluctance within Canada to move away from a science-based regulatory system, it is becoming increasingly evident that some form of societal harmonization between industry, government and consumers needs to be developed.

Most of the regulatory framework relating to the approval of new agricultural crop varieties, applies to pre-commercialization issues and concerns. Historically, the use of a sciences-based risk analysis system was utilized to determine if the proposed variety was at least as good as existing varieties. Once approval was granted, regulators no longer possessed a mandate to regulate for commercialization or market acceptance issues. The advent of agricultural biotechnology brought market acceptance to the forefront, as outlined in Chapter 4, and ultimately forced industry competitors to join forces to protect export markets from the products which had just received regulatory approval. Chapter 4 highlights the importance of industry-government communications facing innovative products.

Market transactions for goods with experience and credence attributes require a high degree of trust, which requires both effective public and private regulatory mechanisms. The canola industry's experience with GM canola illustrates that where there is a public base for managing credence and experiential issues, the industry can effectively handle many of the market considerations through private identity

preserved production and marketing systems. Ultimately, these systems are designed to earn trust, which is a cumulative process and past successful actions can contribute to achieving a higher level of trust. Failures in one part of the market can spillover to other market segments. Provided the expected returns exceed (or are at least aligned with) the scale and distribution costs, private initiative to minimize and manage liabilities will work.

Biotechnology innovations in agriculture present a clear challenge to the traditional marketing system. Transactions for new, proprietary, novel-trait crop varieties require a more extensive set of institutions than for traditional commodity varieties. The optimal structure and organization of these new supply chains has not evolved yet due to the lack of clear market signals. Over time one would expect a more stable set of relationships to emerge. In the case of business, the low level of consumer willingness to pay for labeling information regarding GM, non-GM or GM-free products would appear to indicate that consumers do not perceive a benefit from the labels. While mandatory GM labeling does not appear to be economically justifiable (as there are simply too many contrasting market signals for this to work), some alternative is needed to provide consumers with the information and choice they are demanding. To function and meet the needs of all consumers, it is likely that any resulting system will need to operate in a way that enables the appropriate information to flow between the supply chain and consumers. Ultimately, the success or failure of any resulting system should be judged based on whether it facilitates an increase in the amount of product information that flows along the

supply chain, while at the same time enables commercialization and optimal production and use of safe food.

The relationships between product differentiation and consumer demands for product labeling are examined in Chapter 5. This chapter discusses how innovation has affected the supply chain for agricultural biotechnology products and identifies the dynamics of the relationship between consumers and regulators. The majority of consumers are calling for mandatory labeling of genetically modified food products, something that the government, at this point, is clearly not prepared to undertake. The opposing government/social perspectives, shows that when innovation affects consumer confidence in the commercialized product, society expects government to interject in the process as a means of re-establishing trust in the product. Government may not have the mandate or the political desire to implement what society requests, but the innovation of agricultural biotechnology shows that society has expectations of government, especially government regulators, to take action.

Regulators will possibly be faced with three options regarding the commercialization of future GM crops: they can outright reject them as may be dictated by the use of the Precautionary Principle; they can impose detailed production and market separation regulations that provide informed choice with low to reasonable levels of risk; or they can forego regulations altogether. The outright rejection of new biotech crop varieties may be excessive given that capital is one of the most liquid commodities in today's global marketplace and by banning GM

products countries (and the global industry) risk losing not only investment capital but R&D firms as well. Institutionally, governments can and should improve the regulatory oversight of future generations of GM crops, while industry must take its responsibilities more seriously. The whole concept of consumer empowerment has been badly dealt with by government and industry. These stakeholders have, for the most part, adopted the strategy of ignoring the consumer and hoping their concerns will go away. This strategy has not worked and it has been the recent willingness of the judiciary to hear lawsuits against multi-national seed development firms that has forced a reconsideration of this strategy. However, the challenge in trying to accommodate consumer empowerment is that the fragmentation of the voice of consumers makes it difficult to legitimize the concerns of society. Consumer groups need to be more willing to participate in joint regulatory decision making processes (e.g. the recent voluntary labeling report from the Canadian General Standards Board), thus providing the process with a degree of social credibility. Completely unregulated production and processing is what worries many, as firms may move to these jurisdictions and export products where no information needs to be provided.

Chapter 6 presents an analysis of the interactions between the agricultural biotechnology industry and the larger society. This chapter identifies the importance of the global marketplace regarding commercialization of innovative products. While the direct user of GM crops in Canada has largely been producers in the three Prairie provinces, the ultimate end user of the final product is consumers the world over. Marketplace failures caused by firms rushing to gain the all important market

share with a new innovative product, has the potential to not only jeopardize the local marketplace, but the global marketplace as well when faced with market failure. The increased degree of connectivity between innovative firms and global consumers has resulted in situation where local liabilities become global concerns in a rapid manner. The marketing phrase ‘think globally, act locally’ may have no greater application than in the agricultural biotechnology industry.

The challenge of future innovations from agriculture biotechnology is going to be to structure a fully integrated regulatory system that effectively evaluates, manages and communicates about the liabilities, and ultimately one that both enforces rules and is seen to remedy failures. Regulatory gaps erode society’s faith in the ability of government and industry to manage innovations and ineffective enforcement mechanisms undermine the integrity of the entire liability management process. A major concern regarding agricultural biotechnology is that regulators are unwilling or unable to step forward and be the leading and dominant institution, while private industry is shirking the responsibility as proprietors of new innovations. Similarly, where industry organizations are unable to generate consensus on or adherence to effective standards and procedures, governments have often been unwilling or unable to fill these gaps. Consensus on how to identify regulatory gaps needs to be rapidly addressed by all participating stakeholders. Further erosion of public confidence in agricultural biotechnology innovations may be a distinct possibility if action is not soon taken.

The importance of removing or at least addressing regulatory gaps is identified in Chapter 7. This chapter highlights how one of the newest innovations within agricultural biotechnology is creating numerous regulatory challenges as the products of this innovation move closer to commercialization. The idea of producing drug proteins within plants has presented regulators with some challenging questions. The attempts of regulators within Canada and the US to develop effective and meaningful regulations have demonstrated the importance of finding the correct regulatory balance. To date, Canadian regulators have adopted a case-by-case approach to the regulation of PMPs, in part, to ensure that no aspect regulatory oversight is neglected, which could have the potential to ultimately cause economic hardship on this sector of agricultural biotechnology.

Many of the risks and potential liabilities of GM crops are only partially manageable by public and private institutions. Although institutional costs to manage risks are high, the cost of failure is even higher. Ultimately, an inability to manage the risks and control the liabilities may reduce net returns on investment so much that GM technology may become unfeasible for application in agriculture. As Canada moves closer toward the litigious society of the US, the ability to manage marketplace liabilities will become of paramount concern to the commercializers of new innovative products.

There is no stakeholder consensus on how to address the issue of socio-economic liability management surrounding transgenic crop varieties. Science-based

assessments are not designed to reduce risks to zero. However, societies are expecting this unrealistic level of liability management due to the lack of comfort zones with this new innovation. Risks in so many other segments of modern industrialized societies have been lowered dramatically in the past century (i.e. childbirth death rate, water pollution, workplace injuries) that consumers are expecting that the risks regarding food consumption be lowered to similar levels. In actuality, the food we consume today is markedly safer that it was in the past due to greater investments in food safety. We have quality programs in place that work. What may be needed is greater awareness of the measures already implemented as opposed to entirely new measures.

The key to the successful innovation (or lack thereof) and use of transgenic plant and animal products will be regulation. Regulators are becoming increasingly aware of the importance of the role they have to play in reassuring society about new innovations. But what is also needed to ensure the success of transgenics and future innovations is for industry to step up and become a more responsible stakeholder. Trust would be created by having industry admit to failures, work more closely with concerned groups and by allowing academics to have better access to confidential data, given that one of the claims from biotechnology critics is the lack of peer-reviewed data. Inviting social actors to the table will legitimize concerns and provide an avenue for discerning between groups with actual concerns and groups that are more interested in press coverage than real liability management. The key to socio-economic liability management is to ensure that the appropriate set of stakeholders

work together. Even though each stakeholder may have separate agendas, the goal needs to be consensus on the process objectives.

This research has identified how the initial products of biotechnology entered the marketplace with minimal consumer awareness, which meant that co-ordinated regulatory approaches did not occur. Has this lack of co-ordination affected the acceptance of transgenic products in today's marketplace? Possibly. But it can be said, with certainty, that a co-ordinated approach to the regulation of innovative products in the future will be essential for the successful marketplace integration. Strong institutions can use this framework to identify the proper stakeholders that are needed to develop acceptable regulations and to promote these regulations within the larger society. The inability to achieve this will only delay and frustrate those involved in the regulatory process of transformative technologies.

8.3 Strengths and Weaknesses of the Framework

Over the course of this research period, several publications have resulted. From these publications, the following contributions or strengths have been identified. Discussion and feedback from these publications have resulted in the identification of several challenges regarding the framework.

First, the concept of socio-economic liability has been developed and offered as a new category of liability. This concept of liability describes how failures within a marketplace can carry over and affect other sectors of the marketplace. The key

difference between socio-economic liability and conventional liability is that it is not always possible to seek remuneration for damages with socio-economic liability, given that the damages may be a loss of trust in a private firm, a federal regulatory body or an entire industrial sector. Additionally, liability does not mean that an individual experienced pain and/or suffering -- rather the liability can be a reduction in confidence of the ability of institutional governance to adequately address a societal concern. The value from this new category of liability is that it can be used in conjunction with the identification of hypothetical risks to determine the marketplace effect that may develop should a risk occur.

Second, clear and concise definitions were provided for the various terminologies that existed within product differentiation alternatives. Much of the existing literature relating to the topic of product differentiation uses the terms segregation and identity preservation interchangeably, which was creating confusion. This research offered definitions for three distinct product differentiation options and discussed how the governance structures for each system, while similar, have features that are unique. The various governance structures were outlined in relation to the way the marketplace affects the supply chain for each of these various systems. Each product differentiation system has its own driver and economic justifications, while at the same time, serving as a liability management tool for the different institutional stakeholders. This contribution has been highly valued by industry and international regulators as it provides a basis upon which to discuss the issues of co-mingling and co-existence between conventional and transgenic crops.

Third, this research outlines the importance of strong institutions (public, private and collective) and the vital role that they play in relation to innovation. As transformative technologies, such as nanotechnology and stem cells, continue to enter modern day society, the importance of strong institutions will remain and possibly increase. Strong institutions need to be in place in relation to regulation, industry and judiciary to allow the necessary parameters for trust to develop and be sustained in relation to the transformative technology. If a society is lacking in strong institutions, this will have an effect on the successful commercialization of the technology and the confidence that consumers have in the marketplace product. There is a large information gap in all industrial societies between scientific research and development and social awareness. Strong institutions will be required to ensure that this information gap does not reduce or negate potential benefits arising from future technology advances.

Finally, the focus of this research is a narrow application to a specific period of regulatory development in Canada. The result of adopting this approach has been an assessment of an actual commercialization scheme for a genetically modified product. This kind of assessment is only possible in two countries, Canada and the United States and the focus has been largely Canadian. An assessment of an operational commercialization scheme would not be possible in Europe, as no successful commercialization of a genetically modified product has taken place. By demonstrating how successful commercialization can occur, the case study offered

in this research will provide valuable insights into how other jurisdictions will deal with this issue when faced with commercialization decisions.

The above strengths of the research are related to the identified weaknesses of the research. First, the concept of socio-economic liability will be questioned by the legal community. For many in the legal community, putting any adjective in front of the word liability is meaningless. Classical definitions of liability will always be either civil or criminal. Any new classifications of liability will be able to categorized into one of these two forms. While some lawyers understand the concept of a socio-economic liability, they do not accept that it is a new category; rather, many see it as an extension of civil liability.

Second, if regulations can help limit the liabilities from a transformative technology, it is not known if this will translate into a greater level of societal trust in innovative products. If the regulations do not foster the development of consumer trust in innovative products, then the regulations are a cost that will have to be borne by the industry, that has little or certainly reduced means to recover this regulatory cost. If the cost is high enough and no option for recovery can be identified, it is possible that R&D investments would change.

Third, the framework has been developed from an inter-disciplinary standpoint to be flexible and fluid. These same conditions may not exist if the framework is applied within a narrow, specialized area of innovative research. The framework has been

developed to be broadly applied to larger social issues and concerns and its application to narrower, more specific issues and concerns has been beyond the scope of this research. However, it is important to highlight that the framework has not been applied in such a manner and it is possible that the value of its application would change.

Finally, it can be argued that by focusing on such a narrow application and time frame, the overall quality of the final study is jeopardized. This argument is well formulated, but the challenge of actually incorporating it into this research was the fact that the innovation of biotechnology is so new, that there are an extremely limited number of potential applications at this point in time.

8.4 Limitations of Present Research

Undertaking research in an area where the data are not quantifiable as they can be in scientific or mathematical disciplines creates some challenges regarding what is, or is not, acceptable levels of risk and liability. Individually, we all have varying levels of risk that we are comfortable with. For example, some people invest in highly speculative penny stocks on junior stock exchanges while others prefer bonds or even guaranteed saving accounts. The result of this is that we all have different comfort levels and different perceptions of liability. Certainly this varies among individual, but it can be manifested considerably when measured across cultures.

One important factor can be included in relation to societal unease, change. Frequently, change is one of the most feared aspects of life and work that people are forced to deal with. Regardless of its application, it forces us out of our existing comfort zone. Change is generally accompanied by a lack of clear and factual information, which further compounds the challenge of attempting to understand the specific perceptions that societies have regarding innovations. Change creates uncertainty and this is not an easy parameter to measure with a high confidence level.

Change can also apply to new methods of examining issues, which is the underlying rational for this research. Conducting inter-disciplinary research within an institution that is based on distinct academic pillars creates its own unique set of challenges. Institutions are notoriously slow to respond to change and it requires a strong mindset to follow through with a detailed research agenda. A research combination of innovation, which by its own characteristics is rapid and fast paced, with that of institutional reaction, which tends to be the opposite of innovation, provides for an interesting observation of opposing dichotomies. A limitation to this research and this process is that the pace of institutions impedes innovation in all its applications and this has to be reversed in order to foster and support all innovation applications.

The focus of the research (and thereby the findings), could also be viewed as a limitation. The focus of this thesis has been considerably narrow, meaning that it is focused specifically on canola and agri-food products within a North American

context. The research essentially provides a past, present and future snapshot of one innovative product. As a result, the findings are thereby narrowly focused and could be viewed as less relevant than a large, more encompassing study.

The focus has also been very narrow in terms of the institutional approach. The focus has been on domestic institutions from Canada and partially from the US. The result of this limited application is that it only illuminates one aspect of the application of this technology. A broader institutional perspective would be valuable.

8.5 Extensions of Present Research

The major challenge is that innovation does not have a deterministic relationship that can be modeled by a single academic discipline to provide consistent reliable outcomes. While institutions are the key to successful technological transformations, institutions by their very design have always been limited in the ability to react rapidly to an innovation.

Integrated academic research offers a new option to assess transformative technologies and the impact they have on society. In drawing upon the research strengths of various academic disciplines, future researchers may be able to develop frameworks that are capable of providing reliable and consistent outcomes of innovation. Research extensions from this thesis could be either case studies or theoretical modeling of innovations. The more research undertaken through an

interdisciplinary approach, the greater the pool of literature available for future students and researchers to draw from and utilize in new and novel approaches.

The development of a more technical model or framework would provide for greater in-depth analysis of the specific impacts that would occur from the commercialization of products from transformative technologies. The refinement of the model may allow for the opportunity to test a specific market impact while holding the rest of the model constant. This ability to focus on one specific parameter would provide valued understanding of how wide-reaching the impact from an innovation can be.

Examining this issue from an international institutional perspective would provide an interesting comparison. Comparing the perspectives under the World Trade Organization and the BioSafety Protocol would provide for a comprehensive evaluation of the issue. Another possible option would be to assess this issue under the existing regulatory regime in the European Union to provide a contrast to what has occurred in Canada.

Of course, the major benefit would be to have more cases to apply the model to and observe the results. One of the challenges in trying to gain a greater understanding of transformative technologies is that they are not an everyday occurrence. If they were, they would not be classified as transformative. It would be beneficial to apply this methodology to some of the other technology innovations of the past few

decades, such as the introduction of computers or the Internet. Each application of the model will generate greater levels of knowledge about this emerging issue and that will be a benefit to all interested in the study of innovation.

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