The Innovation and Diffusion of Policy: Novelty in the Canadian Regulatory System for Plants with Novel Traits

A Thesis Submitted to the College of Graduate Studies and Research in Partial Fulfillment of the Requirements for the Degree of Master of Public Policy at the Johnson-Shoyama Graduate School of Public Policy at the University of Saskatchewan in Saskatoon, Saskatchewan

Jaime Leonard

PERMISSION TO USE

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

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

Graduate Chair, Johnson-Shoyama Graduate School of Public Policy
University of Saskatchewan
Saskatoon, Saskatchewan
S7N 5B8

ABSTRACT

In 1993, the Canadian federal government made a decision with respect to the direction that the country would take in regulating agricultural products of biotechnology, commonly referred to as GMOs or GM crops. Following the lead of the United States, Canada adopted the innovative "product-based" approach to regulation, making it necessary for all GM crops to go through the regulatory system in order to gain approval for commercialization. However, the iteration that Canada's adoption of the policy took differed from the form that the product-based approach took in the United States. Canada created a category of "plants with novel traits", which is based on the concept of novelty and reflects the idea that products of newer technologies such as recombinant DNA are not fundamentally different than those developed through more conventional means. The United States does not require regulation on novel plants created through conventional means via a regulatory trigger which seeks out plant pathogens, present only in newer, recombinant technologies. As a result, many crops developed through more conventional modification techniques such as mutagenesis are not subjected to the American regulatory system, but are in Canada.

The objective of this paper is to determine how Canada and the United States came to adopt the product-based approach to regulation, where the Canadian system began to differ from the American system, and why the Canadian system has not diffused internationally, despite being the most directly implemented representative of the product-based approach.

This is accomplished via the application of the policy change, policy diffusion, and policy innovation literatures. Theories of policy change and diffusion are introduced. I trace the history and diffusion of novelty using the historical method, and test the applicability of other diffusion models to the case study in order to determine their predictive power in an international diffusion scenario. The innovation literature is also applied in order to explain how and why the product-based approach to regulation has been incorporated differently at multiple levels of regulatory policy. I conclude with an argument that Canada has lost a "standards war" with the United States for regulatory superiority, in light of lost marketability and a less permissible regulatory landscape, which must prompt us to re-evaluate our regulatory approach.

ACKNOWLEDGMENTS

The completion of this Master's thesis is due in no small part to the efforts of a number of individuals and organizations that supported me and my research. I would like to thank the University of Saskatchewan and the Johnson-Shoyama Graduate School of Public Policy for the academic and financial assistance that enabled me to complete this work. The Canadian Agricultural Innovation and Regulation Network (CAIRN) also provided funding to support this thesis and for that I am grateful.

I wish also to acknowledge Genome Prairie and the Value Additional through Genomics and GE^{3}LS (VALGEN) project for providing the exciting and inspiring organizational backdrop against which this work was completed. In addition, VALGEN allowed me to meet and work with a number of individuals who contributed in many ways to this thesis, all of whom deserve thanks. In particular, I would like to acknowledge Dr. Lisa Clark for all of the invaluable wisdom and advice that helped to show me the way through.

Special thanks and deepest gratitude goes to my supervisor, Dr. Peter Phillips, for the many, many hours of guidance, and his unending patience and understanding. Thank you for sticking with me through all the drafts and always pointing me in the right direction. I would also like to extend my thanks to my committee members: Jeremy Rayner, Amy Zarzeczny, David Castle, and Neil Bradford for their vital assistance and advice throughout this process.

Finally, I must offer my sincere gratitude to my family and friends for walking this path with me in any number of small ways: to my parents for absolutely everything; to my brother Jeffrey for always keeping me on my toes; to my friends for all of their words of encouragement; and to Kev for regulating and ensuring my sanity throughout all of this. This could not have been done without the contributions all of those mentioned and I am eternally grateful.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

INTRODUCTION

Policies exist because of problems. Like the problems that they attempt to address, policies and the theories which underpin them can be quite varied in their nature. The policy literature has effectively been split into a series of branches, each of which attempts to explain various parts of the policy process. For example, academics have covered the initial issues, how they come to appear on the radar of decision-makers, the development of policies meant to address these issues, the evaluation of policies, and the spread of policies, among other aspects. However, when it comes to the origin of policies - that first idea, its institutional and operational prompt – the literature is lacking. Somewhere along the line, a policy existed for the first time. It was invented, with or without intention. Existing policies are now under perpetual revision by academics and decision-makers alike, who are now searching for new ways to solve both new and old problems. In order to be effective in addressing a policy's challenges and limitations, we must first understand how and why it was created, and its theoretical and practical foundations. If we can identify the original form or source idea of a specific policy, we will be better able to recognize the traces of that source idea in later iterations of that policy. That recognition not only allows us to better understand the specific impetus to a policy's invention, but also provides the opportunity to identify and explore the potential impact of any contextual elements (for example, the social norms of the time period, any relevant political factors, et cetera). This concept of policy invention and diffusion is what I delve into in this thesis, via an examination of the innovation of the product-based approach to regulation of agricultural products of biotechnology, and its subsequent diffusion into the Canadian regulatory system for plants with novel traits (PNTs).

Issues with Canada's current regulatory landscape for agricultural biotechnology trace back to the late 1960s and early 1970s, when research into deoxyribonucleic acid by a barrage of scientists reached a climax, leading to the development of recombinant DNA (rDNA) technology. This technology was applied to the world of agriculture in the 1970s, largely as a response to a perceived crisis in food shortages (Crisp 1974). The 'novelty' of the technology and its products, defined both in the context of new phenotypical traits that were introduced and the degree of familiarity in the global agri-food system, forced potential adopter countries to form regulations to address the potential for any associated risk factors in terms of food and environmental safety. However, these regulations and the policies that underscored them were not uniform across the countries involved. Countries generally followed one of two approaches, regulating based on either the product or the process. The product-based approach holds the characteristics of novel products to be most important, while the process-based approach considers the methods used to create them to be paramount. There are variations within each approach; Canada's unique approach to product-based regulatory policy is one of them.

In Canada, agricultural products of biotechnology fall under a category termed "plants with novel traits". Essentially, all novel crops, regardless of the method used to produce them, must go through a lengthy scientific risk assessment process, as mandated in the Canadian Food Inspection Agency's Directive 94-08, "Assessment Criteria For Evaluating the Environmental Safety of Plants with Novel Traits" (Plant Biosafety Office 1994) and Health Canada's "Guidelines for the Safety Assessment of Novel Foods" (Health Canada 1994). This is not the case in other parts of the world. Even Australia and the United States, nations with which Canada shares a unique colonial heritage and comparable socioeconomic conditions, differ in their interpretations of agricultural biotechnology regulatory policy.

The economic consequences of Canada's unique approach to regulating agricultural products of biotechnology are difficult to quantify. Requiring a series of expensive and time-consuming risk assessment procedures for the release of a crop into Canada, when a similar process is not triggered in other countries such as the United States, places Canada at a competitive disadvantage in terms of investment and trade (Ag West Bio 2007). The trade-related consequences of Canada's position and the product-versus-process regulatory debate are acknowledged but not discussed at length in this paper.

To determine the implications of Canada's regulatory position, especially vis-à-vis major trading partners like the USA and Europe, it is necessary to first understand how Canada developed its policy. This will be examined in the context of policy diffusion. First, I review the policy diffusion, policy innovation, and innovation literature. Then, I use the historical method to trace in reverse the diffusion of Canada's policy and determine its source. After this, I apply innovation diffusion theory and policy diffusion models to my diffusion pathway in order to reach further conclusions and offer guidance with respect to agricultural biotechnology regulation and associated policies. The theories and methods used for the analysis of policy and innovation diffusion will also be tested in this thesis in order to examine their usefulness and applicability to an ex-post diffusion study for which information constraints are an issue.

The basic policy process itself is fairly straightforward. Generally, it begins with an unmet need in a certain area. Next, policymakers develop a policy in an attempt to address that issue, and implement it. Finally, assessments are made, evaluations performed, and policies are either kept or replaced. What this simplification leaves out however, is a space to ask the real questions: how are these policies initially developed? Where do they come from? Importantly, who are the policymakers, *really*?

According to Bradford (1998), policies begin with the introduction of ideas or propagating events. Ideas frame the issues that get set onto the policy agenda. They are broad tools with which to engage policy reform. They guide the process, and in doing so influence the underlying assumptions of a policy area undergoing change (Beland 2009). However, ideas alone are not the sole drivers of change. Ideas are abstract concepts, but they come from very concrete sources: individuals, organizations, and governments.

It is possible at any given time to recognize the traces of one source idea in the policies in several different jurisdictions. The interpretations of a single idea in multiple states or institutions may be as varied as the polities themselves. Scholars of policy diffusion and policy learning have spent decades attempting to codify and predict how one idea becomes involved in many different places.

The spread of ideas can be understood through the lens of policy learning. It is unusual for there to be problems which are dissimilar entirely from those in other countries or states; as a result, the simplest way to develop new policies is to look outside the jurisdiction to see what others have done in similar situations. Simply put, governments learn from one another's policies. This is referred to as lesson-drawing (Rose 1991). If one government has a problem and develops an effective policy, another government may adapt that policy to the specifics of their jurisdiction. If a state has had a policy which has failed, other actors learn what to avoid. Rose (1991) argues that policymakers seek experienced or lived policies because they reflect feasibility. This is important; according to Meltsner (1972), a proponent of political feasibility analysis, it can at times be quite difficult to integrate political considerations into the analysis of policy options. Policy learning and lesson drawing can be integral parts of gaining an understanding of how realistic a policy may be if adopted elsewhere. However, what happens

when a situation arises for which there is no precedent? With all of the policy transfer and lessons being drawn, how does the initial policy innovation itself develop?

Such were the questions around how to manage the introduction of new genetic modification techniques into food in the latter half of the twentieth century. If we can understand the genesis of the policies in Canada governing GM products, it provides an opportunity to ask a follow-up question: are they still relevant?

I. LITERATURE REVIEW

The literature surrounding diffusion dates back centuries to epidemiological studies regarding large outbreaks of disease, like the 1854 London cholera outbreak, which English physician John Snow famously traced back to an infected water pump (Cameron and Jones 1983). Over the years it has evolved to a discussion of innovation and of inventions, to which the theories of diffusion have been effectively applied. Innovation theory and diffusion theory have evolved to complement each other well, inspiring further academic work in the area of innovation diffusion (Rogers 2003, for example). Since the 1960s, there has also been a branch of the literature which is dedicated to the diffusion of government policies and programs. It is in this application that the innovation diffusion literature is lagging.

While the bulk of the case studies in the policy diffusion literature are related specifically to the United States, there are subsections which attempt to address diffusion and change more broadly. A prime example is the development of sometimes nebulous classifications of policy change in an effort to establish the degree, order or magnitude of change. This literature theorizes about the extent of change, and where the policy change sits in terms of its potential to alter world situations and generate new paradigms. Both Hall (1993) and Rose (1993) have created typologies to assess the impact of change and to distinguish between policies based on how much they vary in form as they diffuse. For example, Hall's 'first-order change' is one in which the settings of a policy may be altered because of new information or experiences, but all of the goals remain as they were, like in a budget. 'Second-order change' is where both policy settings and strategies to achieve policy goals are retooled, but the goals themselves are not reprioritized. By contrast, 'third-order change' involves an overhaul of the system, with policy settings, strategies and goals all being changed. Third-order change can be viewed as a total paradigm shift. The example commonly cited for third order change is the replacement of the

Keynesian macroeconomic policy with a monetarist and supply-side microeconomic approach beginning in the late 1970s (Hall 1993).

Richard Rose (1993) assessed the extent to which a policy is altered when diffusion occurs. He defined four degrees of transfer: copying, which is effectively replicating the policy; emulation, where the basic ideas underpinning the policy are diffused; combinations, or mixing two or more policies; and inspiration, whereupon a policy in one polity may prompt a policy change in another, without transferring any of the aspects of the original policy. This typology has been applied throughout the literature and has been adopted into similar frameworks (i.e., Shipan and Volden 2008).

Some have created typologies of research approaches themselves. Haas categorized policy change as being understood through one of four main lenses: with regard to epistemic communities, neorealism, dependency theory, or post-structuralism (Haas 1992). For each lens, his typology offers a corresponding level of analysis, area of study, and set of factors that are catalytic to policy change. The mechanisms and results of change, as well as the primary actors for each approach, are also detailed as seen in Table 1 below.

Table 1: Haas's Typology of Policy Change Approaches

Approach	Level of analysis; area of study	Factors that influence policy change	Mechanisms of change; effects	Primary actors
Epistemic communities	Transnational; state administrators and international institutions	Knowledge; causal and principled beliefs	Diffusion of information and learning; shifts in the patterns of decision making	Epistemic communities; individual states
Neorealist	International; states in political and economic systems	Distribution of capabilities; distribution of costs and benefits from actions	Technological change and war; shifts in the available power resources of states and in the nature of the game	States
Dependency theorist	International; global systems	Comparative advantage of states in the global division of labour; control over economic resources	Changes in production; shifts in the location of the states in the global division of labour	States in the core, periphery, and semi-periphery; multinational corporations
Poststructuralist	International; discourse and language	Usage and meanings of words	Discourse; the opening of new political spaces and opportunities	Unclear

Taken from Haas (1992), pg. 22.

Those who consider the role of epistemic communities in widespread policy change pinpoint groups of experts, as well as states, as being the primary actors in the change process. Taking the perspective of neorealists, states act to change policy as a result of the changing distribution of capabilities, using technological change and war. Dependency theorists likewise see states as the primary actors; however, states are identified as being part of the core, the periphery, or the semi-periphery. Policy change occurs because of the status of some states vis-à-vis others, where these states utilize changes in production as a mechanism to project their interests. The post-structuralist approach to understanding policy change is also focused on an international level, with major actors not clearly identified. Post-structuralism sees policy change as occurring via discourse and the freeing of political spaces, considering it the result of the changing use of words and their meanings. Knowledge, principles and information drive change, which occurs via information-sharing and the diffusion of knowledge through epistemic networks (Haas 1992).

There has also been work done on the ability of actors to affect change in policies that are meant to address complex issues. For example, Bernstein and Cashore (2012) created a typology of four pathways that international actors could follow in order to influence domestic policies, using the specific example of forest governance and other complex environmental problems. The first pathway is via international rules, such as the influence of treaties or international organizations (such as the World Trade Organization). Domestic policies are likely to be affected because nations are bound (in some cases) by organizations' charters or by their treaty obligations. The second pathway is through international norms and discourse, which usually find their roots in international organizations and fora. Norms and discourse can affect what type of domestic behaviour may be considered appropriate, and responsiveness to the external

pressure that the international community may enforce can be reputationally significant. The third pathway involves controlling markets (to the extent possible) in order to drive domestic changes. Economic sanctions and like mechanisms can be used to push policies in a particular direction. The fourth pathway of influence is for actors to have direct access to domestic policymaking, which may include provision of assistance (whether financial or otherwise) to existing domestic groups that are working toward a specific policy outcome (Bernstein & Cashore 2012). Each of these provides an opportunity for actors who are not traditionally part of a nation's domestic policy structure to be able to assert their influence and assist in policy change, whether it be through diffusion of innovative ideas or the transfer of existing policies from one area to another.

Since the 1990s, there have been further contributions to the transfer literature which have attempted to qualify transfer and offer typologies to better understand it. Shipan and Volden (2008) offer four instruments of policy diffusion that have been partly derived from Rose's (1993) degrees of transfer: learning, which they say has positive results when based on effective policies; imitating, which could be unsuitable for the adopting polity; competition, which produces negative externalities and generally bad results; and coercion, leading to policies which are generally ineffective in the receptor system. The authors constructed seven models to test several hypotheses that they proposed about the behaviour of large and small cities in American states with respect to each of these mechanisms. Their results showed that while large and small cities had equal capacity to be influenced via coercion by the state government, large cities were less likely to engage in strict imitation of one another's policies, less likely to have an aversion to economic competition, and more likely to learn from the innovative policy experiences of their peers.

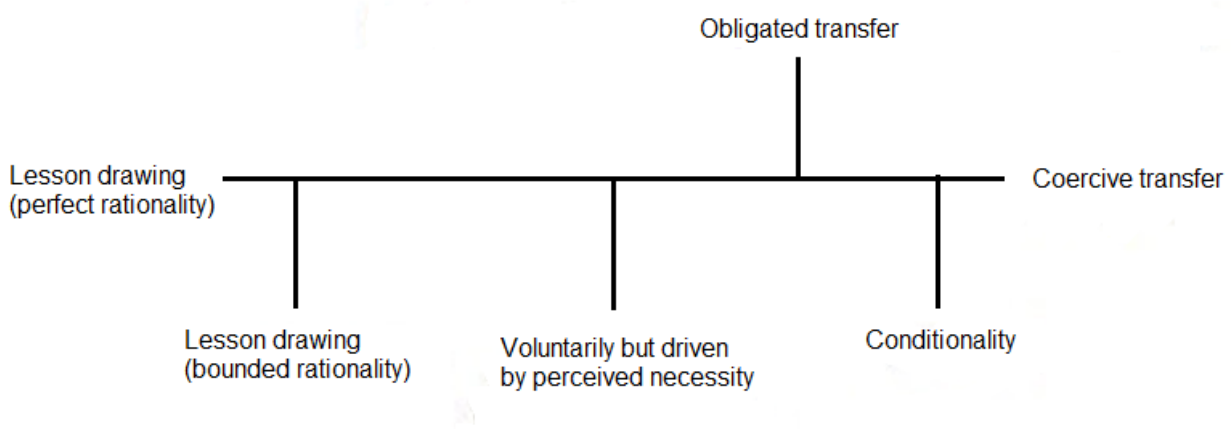
Scholars of diffusion and transfer have also undertaken studies which aim to test specific determinants of diffusion. For example, Grossback et al (2004) utilized the data from three prior studies of diffusion, including Berry and Berry's (1990) study of state lottery adoptions, and added in a variable to represent ideology in an effort to ascertain whether it played a role. They found that ideology was the only measure which was significant in all of the three cases. Similarly, Ka and Teske (2002) ran a regression model to test for ideology in the regulation and deregulation of electricity in American states, showing that in more liberal states, electricity rate structures tend to favour residential consumers.

In the context of this, it is relevant to acknowledge the existence of a body of literature which explains policy change via behavioural economic theory. It begins with Simon's (1955) articulation of rational choice, whereby a rational actor will (after setting goals and identifying alternatives) choose an option which allows him to receive the largest payoff. The literature continues with the concept of incrementalism, best attributed to Lindblom (1959), wherein change occurs as the result of a series of smaller decisions – what he calls "muddling through" – rather than in a large step. Following this, Baumgartner and Jones (1993) introduced the idea of punctuated equilibrium into social science theory as an alternative to incrementalism and associated theories that followed, such as garbage can theory (Cohen et al 1972). Punctuated equilibrium suggests that the status quo is generally maintained in a society, except for sudden, radical shifts where change occurs quickly. This literature has also been challenged by Stone, who contends that rational models of economic choice are limited in the real world (2002). Stone also contends that the causal story of a policy issue, or the way that a problem is viewed, impacts upon the process of policy change and decision making (1989). Further discussion of the behavioural decision-making literature is out of the scope of this thesis, but must be

acknowledged as it contributes to the broader understanding of policy change across jurisdictions.

Other attempts to classify the process of policy diffusion involve cataloguing the types of transfer in an attempt to identify the degree of volunteerism involved. Dolowitz and Marsh (2000), for example, constructed a continuum with lesson drawing based on the assumption of perfect rationality at one end and coercive transfer via direct imposition at the other. In between are varying conditions, such as lesson drawing under bounded rationality, voluntary transfer with perceived necessity, obligated transfer, and conditionality, as seen in Figure 1.

Figure 1: Dolowitz and Marsh's Transfer Continuum



The state to the furthest left on the continuum involves voluntary lesson drawing under the assumption of perfect rationality. As this is unrealistic in a real-world scenario where actors are susceptible to their own cognitive limitations and to the influence of external stimuli, lesson drawing under the assumption of bounded rationality is more likely. This theoretically could include all voluntary lesson drawing which is independent of outside pressure. The more that external influence exists in a policy transfer decision, the further right on the continuum that situation would be. For example, if a country adopts a policy with the main motive being to

make a favourable impression on the rest of the global community, then it would fall best under the transfer state responding "voluntarily but driven by perceived necessity". This is different from obligated transfer, which occurs because of some type of deal or treaty among nations. Conditionality is another state which lies further still along the continuum, just to the left of a directly imposed transfer via coercion. Conditionality is often seen in the transfer of ideologies via political parties but also includes policies transferred as a result of loan programs such as the International Monetary Fund's structural adjustment programs, where money is lent to poor nations with the provision that certain economic and democratic criteria be met.

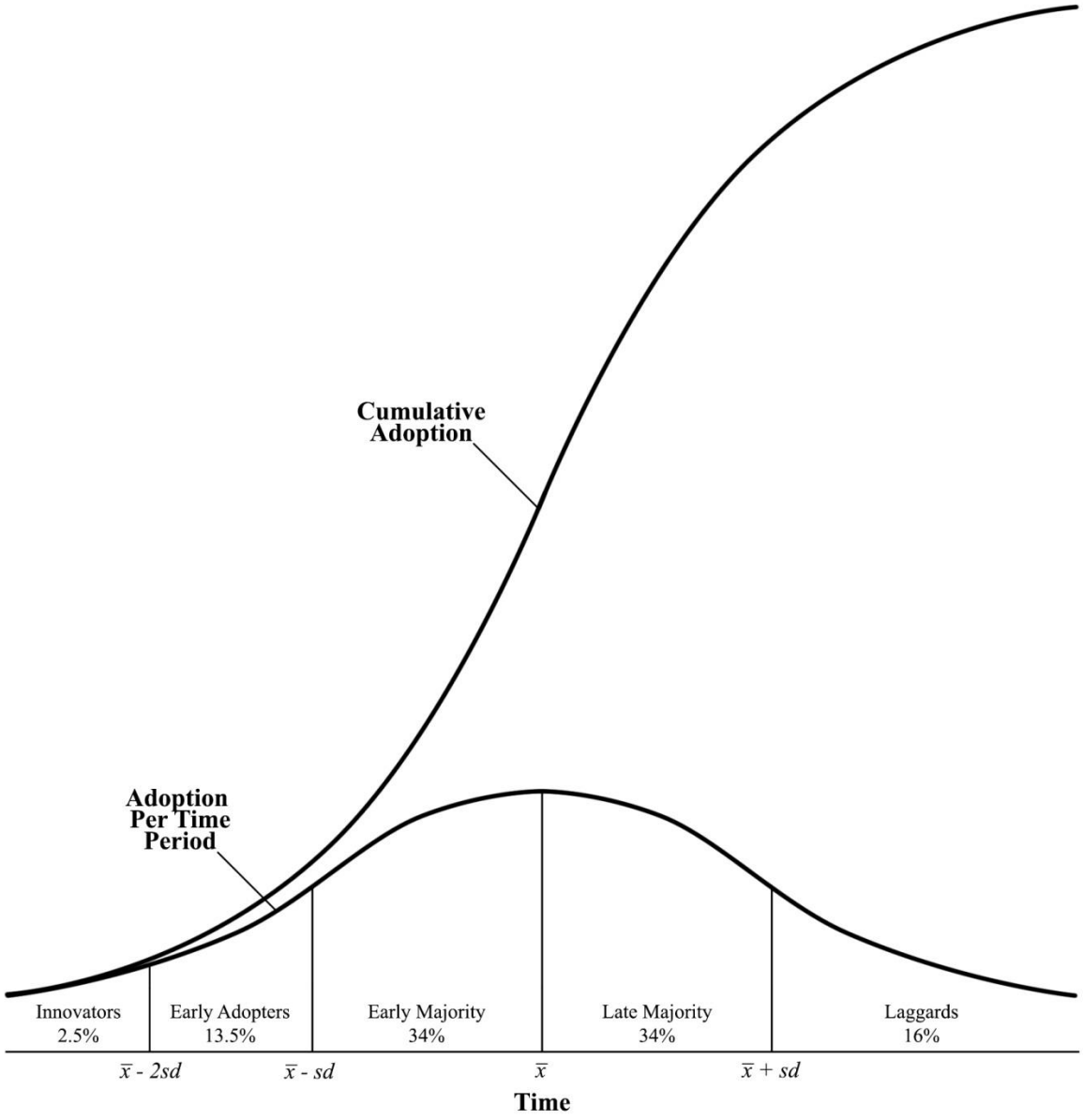
Scholars of policy diffusion have also recently begun to involve cognition and heuristics in their analyses, seeking to identify the role that the decision-making tools and practices play in permitting policy change. Weyland (2005) employed heuristics in his study of pension reform in Latin America, using (among others) the availability heuristic to contribute to an understanding of the initial regional diffusion of a reform first undertaken by Chile. The availability heuristic, whereby the examples that can be immediately called to mind are assigned greater importance simply by the virtue of their mental availability, explains why Chile's pension reform spread more easily to neighbouring Latin American countries than did other potential alternatives which were not implemented within geographic proximity to adopter nations. Weyland also considered heuristics as part of his exploration of institutional change in political regimes in developmental and welfare states (2008). He again utilized the availability heuristic and representativeness heuristic, the latter of which refers to actors interpreting the similarity, or representativeness, of an event to mean that the probability of occurrence or success in other jurisdictions is high, to explain the cognitive biases inherent in diffusion processes. Heuristics are useful with respect to

the decision-making aspects of policy change and transfer, but do not improve the predictive power of diffusion models.

There have also been strong contributions made to the innovation literature with regard to diffusion that can be borrowed and applied generally to policy. Rogers (2003) defined diffusion of innovations by breaking it down into what he has identified as four main elements: the innovation itself, the means of communication, time, and the network or system through which the innovation seeks to diffuse. The innovation itself may be a physical object like a DVD player, a non-physical entity like the Internet, or in this case, a policy. The means of communication includes word of mouth, and in a policy case may involve actors such as professional associations or other networks of experts.

Scholars of the diffusion process are best able to represent the role of time via the creation of diffusion curves. The cumulative number of adopters can be represented by an S curve. A normal S curve begins slowly, with a few early adopters; it then steadily grows until a midpoint at which half of the potential adopters have done so. The curve rises more slowly after that, as the number of actors who could adopt decreases (see Figure 2).

Figure 2: The Innovation Diffusion S-Curve and Adopter Categories (Rogers 2003, adapted)



The S-curve is useful in explaining the effect of networks in the diffusion process. In the beginning, early adopters spread the word of the innovation throughout the system. As more actors adopt, more interpersonal networks are engaged, and eventually a point is reached where more actors have adopted than have not (Rogers 2003).

Similar to the S-curve, the bell curve plots adoption over a time variable. Unlike the S curve, the bell curve is not cumulative, which allows for a researcher to impose a set of adopter categories. These are groupings of actors put together based on the relative proximity of the time that they adopted the innovation. Categories are set up by determining the mean ($\bar{x}$) and the standard deviation (*sd*) of the independent variable, time (*t*). Rogers (2003) has produced a useful and seminal set of general categories, as seen in Figure 2.

The first group of adopters can be found to the left of $\bar{x}$ - *2sd* and, as the first 2.5 per cent of adopters, are called "the innovators". The next 13.5 per cent of adopters, between $\bar{x}$ - *2sd* and $\bar{x}$ - *sd*, are "early adopters". Those who fall in the area between $\bar{x}$ - *sd* and $\bar{x}$ are part of the "early majority" of 34 per cent. The analogous area to the right of $\bar{x}$ is made up of the "late majority". To their right, at $\bar{x}$ + *sd* and onward, are a final group known as "the laggards", equal to 16 per cent of actors.

There are limitations to diffusion curves. Both the S curve and the bell curve are not as useful for studying innovations whose diffusions were incomplete, failed or inexhaustive. Those who did not adopt would fit neither on a bell curve nor an S curve for diffusion and thus would not be captured by this methodology.

Still, adopter categories like those illustrated by Rogers (2003) can offer a profile of actors who should have ideally adopted next. From that, it may be sometimes possible to extrapolate information regarding why an innovation did not diffuse. For example, in consumer theory, early adopters are more likely to be literate and have more years of education than those who adopt later. They are also likely to be socioeconomically better off, more flexible with their belief systems, more rational, and more capable of managing risk and uncertainty (Rogers 2003). Analogies can be found among states and governments for these categories.

There are five aspects of innovations which can largely explain varying rates of adoption: relative advantage, compatibility, complexity, trialability, and observability (Rogers 2003). Relative advantage is simply the idea that an innovation is superior to whatever it is replacing. Success in adoption also depends on how compatible the innovation is with those who may adopt, their values and needs. A possible hindrance to successful diffusion of innovations is if a new product or idea is too complex to understand. Those innovations which are simpler are more likely to be adopted. The fourth characteristic is trialability, or the possibility to test out a new innovation without needing full adoption. The concept of trialability can be seen in the implementation of pilot programs for new policies. According to Sanderson (2002), evaluations for pilot programs attempt to address two questions: whether the innovation worked, and how it can be improved. The final characteristic is observability, which is the ability of potential adopters to observe the experiences of an earlier adopter. If an actor or state is able to engage in trial use of an innovation or watch a peer utilize the innovation, they are more likely to adopt it (Rogers 2003).

Where the literature is lacking is in the area of policy innovation and invention. Theories and typologies abound as to how a policy finds its way into different jurisdictions, and acknowledgement is given that third-order-type change (Hall 1993) exists, but not much attention has been paid to the actual processes of invention and innovation specifically for the policy realm. Of course, most policy change is incremental, but at some point in any policy's history, a pioneering polity adapted and adopted it from its inventors. Effort must be made to clarify that there is a difference between policy innovation and policy invention – policy innovation may be considered new to any state that adopts it, while policy invention is new everywhere (Berry & Berry 1999). The problem with defining policy innovation as anything new

to a state, as Mintrom (1997) does, is that the initial action is subsequently ignored and is thus left under-theorized. Bradford (1998), when discussing the innovation process in policy, claims that literature should explain where and how policy is developed in new areas, but makes little effort to do so. While there is little in this area, it is important to view this identification as an opportunity and not a constraint.

II. METHODS

Within the policy diffusion literature, approaches to testing hypotheses are limited to a few major methodologies. Among the first published studies of diffusion to involve statistics was Walker (1969). The study sought answers to two questions: first, why some American states more quickly implemented new programs than did others, and second, how these programs or policies dispersed across the country from their initial pioneering states. After conducting some limited statistical analysis, he concluded that as more states adopted a policy, the quicker remaining states would be to also adopt, particularly if one of the states in question was perceived to be like-minded, or "a point of legitimate comparison" (Walker 1969, p. 897). Initially, most quantitative diffusion methods involved common statistics, including cross-sectional analyses with regression (i.e. Gray 1973). Even as authors utilized this method in their studies, they acknowledged its limitations. While it has been incorporated largely into another method known as event history analysis, statistical regression models are still sometimes used (Ka & Teske 2002, first analysis).

Event history analysis is the method which is most popular with studies of policy diffusion among the American states, which dominate in the diffusion literature. Event history analysis lends itself well to the study of American states because of their identical structure, the large number of units of analysis, and the relative availability of data. It seeks to analyze a policy change, which is called "the event", as it transpired in an actor at a given time. The data involved, known as the "event history", is built into either a discrete time model or a continuous time model. A discrete time model involves a set of units for a prescribed time frame, while a continuous time model assumes the event occurs at one point in time. The models include the risk set, which is comprised of the states at risk of adopting a certain policy. It may decrease over

time if the event is unrepeatable. The 'hazard' rate ($P_{i,t}$) is the variable that must be explained: it is the likelihood (P) that a state (*i*) will adopt the policy in a given time parameter (*t*). As a probability, the hazard rate is an unobserved variable and thus a dummy variable must be used for statistical analysis.

There are several strengths to the event history analysis method. The likelihood of claiming a spurious relationship to be causal is reduced, since theoretically other causal effects can be controlled for. Event history analysis incorporates longitudinal data with variation, so slight differences from year to year will be included in the assessment of the hazard rate. Importantly, unlike in statistical models using cross-sectional data, event history analysis accounts for time frames. As a result, when socioeconomic characteristics change, they are related appropriately to the time-dependent variable. Berry and Berry (1990) championed this method in an early study of state lottery adoptions, and since then it has become the preeminent method of diffusion analysis for scholars working with the American states (Balla 2001; Berry & Berry 1992, 1999; Ka & Teske 2002; Mintrom 1997; Shipan & Volden 2008).

There is a small subsection of the literature that involves diffusion within a polity. In such cases, diffusion is usually tested with a non-quantified model, such as in Mintrom & Vergari's (1996) comparison of policy entrepreneurship and advocacy coalition models with regard to education reform in Michigan. The advocacy coalition framework has a longer time frame best suited to incremental policy learning. It involves tracing groups of cross-institutional policy actors with similar perspectives, known as policy coalitions (Sabatier 1988). The policy entrepreneurship model, by contrast, operates within a short period of time and involves altering the status quo in a major way. The model focuses on the involvement of policy entrepreneurs, actors within the policy system who have managed to gain influence with or without elected

authority. The two models are not mutually exclusive and may rather be viewed, according to Mintrom & Vergari, like two different types of maps.

The vast majority of case studies are those which involve state-to-state diffusion of policies or programs. Of these, event history analysis is the predominant methodology used. It and its predecessor, cross-sectional statistical regression models, are the major quantitative research methods within the policy diffusion literature. The policy entrepreneurship model, the advocacy coalition framework, and the historical method lead the qualitative research methods in the literature. The dominance of quantitative methodologies – and the large focus on American states in diffusion studies – leaves open an opportunity for further research and method formulation in the qualitative realm.

The diffusion literature also utilizes a qualitative technique called the historical method. Common throughout the social sciences, scholars who pursue the historical method use primary sources and historical record to trace an event. Carpenter (2001) used the historical method to analyze patterns of policy innovation in the USA, particularly with regard to the bureaucratic autonomy of the U.S. Postal Service, USDA, and the Department of the Interior. In the policy realm, the historical method means that building a narrative relies on news, government documents, and published academic articles as primary sources. Kraemer et al (1992) tracked the diffusion of computing technology through Asia-Pacific nations and were unable to attain the type of data that could prove causality, although their historical narrative shows a clear relationship between levels of development and investment in computing vis-à-vis government policies of intervention or non-intervention.

In the context of the theories and methods discussed here, I will be employing the historical method to identify the root of the PNT category within Canada's regulatory system for

agricultural products of biotechnology. Given that the PNT category is unique, it both warrants further study and helps to narrow and focus the analysis. Testing drivers of diffusion theory, like in methods such as event history analysis, is difficult in a situation with international scope because of insufficient data. In practice, innovation and diffusion theory are applied most often to innovations that are widely diffused and adopted. This puts a bias on understanding successful diffusion. In this case, we are looking at the creation of a new policy, the PNT trigger, which was promoted by Canada and some international scientific partners as a good policy for global use, but has not diffused beyond Canada. Where diffusion theory helps, in this case, is in identifying first the sources and flows of some of the underlying concepts and second in understanding why it failed to be taken up more broadly. The historical method provides an unquantified alternative. My narrative begins with the roots of Canada's regulations in the initial movements with rDNA technology in the 1970s. It then follows the history of the technology's regulation, from recommendations in the international sphere to the development and implementation of Canada's domestic regulations. The case that follows is bounded by a few choices: the focus on PNT as the regulatory trigger generally defines the forums where there were discussions, the actors who were engaged and the period under review. The next chapters chronicle the events, outline the key events and documents that drove the policy effort, signalled the key actors and organizations and their activities. As already noted, this analysis focuses on the explicit choice in Canada of the PNT trigger and not on the process that delivered the dichotomy of product versus process regulatory approaches that characterizes the global regulatory system for GM foods.

III. CASE STUDY: Development of Agricultural Biotechnology Regulation in Canada

Tracing the Steps of Novelty

Traditional plant breeding has gone on since the advent of agriculture millennia ago. Technological development in agriculture has moved in discrete step adjustments. The emergence of planned seed selection and forced crossing techniques in the last half of the 1800s generated significant innovation of seeds—the opening of Western Canada, for instance, was at least partly due to the development of faster maturing wheat varieties (Fedak 2013). In the 1930s the development of hybridization radically altered the agroeconomy, with corn becoming the anchor to a major part of the global food and feed industry (Griliches 1957). In the 1960s the development of dwarf varieties of wheat and rice precipitated the Green Revolution (Evanson & Gollin 2003). All of these techniques simply worked to reorder the genetic materials in the target crops. With the discovery of rDNA in the 1970s, that limitation was removed and now the only constraint was imagination.

Recombinant DNA technology facilitates the creation of DNA molecules that would not be naturally found in organisms, via the combination of genes extracted from the DNA of two or more different organisms (Griffiths et al. 2000). Since its discovery, rDNA technology has been applied in many areas, notably medicine and agriculture. Scientists have used rDNA technology to make old drugs in new ways, such as recombinant insulin, new drugs, such as various gene therapies, and a wide range of crops with special traits, such as herbicide-resistant canola, insect resistant corn and viral resistant papaya . Before rDNA, the isolation of single genes or groups of genes was virtually impossible. The idea of being able to combine genes to create unique DNA sequences (and subsequently organisms) offered great promise. As Dr. Paul Berg, one of the pioneers of rDNA technology, described:

> "The overwhelming body of scientists view the recombinant DNA methodology as an extraordinary opportunity to solve important biological problems; the knowledge gained will illuminate our biologic nature and heritage; and very likely, help to alleviate the tragedies of human disease, starvation, and the pollution of our environment" (Testimony by Paul Berg, 1977, p.2).

Recombinant DNA technology began to be applied to agriculture largely because of the global food crisis in the 1970s, during which food insecurity had reached a crucial point. Because of a rapidly expanding population (Crisp 1974), the conventional Malthusian wisdom was that the ability of agriculturally-viable areas of the world to meet food needs was or would soon be outpaced by population growth. This combined with what Dyer calls a "crisis of mass consumption" (1998, p.105), caused by the global recession and 1970s Russian Wheat Deal.[1] It led to a push for finding innovative solutions for pressing issues, including stress on animal food sources. Plant protein was sought as an alternative, and experimentation with agricultural technology and biotechnology began.

The development of biotechnology centered, as does much novel technology, on an epistemic community. An epistemic community can be defined as a "network of professionals with recognized expertise and competence in a particular domain" (Haas 1992, p.3). In 1972, the United Nations University's Protein Advisory Group released laboratory safety guidelines to be followed when utilizing the new technology (Jonas 2000).[2] Their interpretation of 'novel sources' was the first to incorporate specific connotations of unfamiliarity in this context; from this point on, "novel" would no longer simply mean newness, but would indicate something unknown, thereby necessitating the application of a risk management structure.

[1] The Russian Wheat Deal is sometimes also referred to as the "Great grain robbery". It refers to the Soviet purchase of American wheat at prices that had been subsidized, which had the effect of increasing domestic prices for wheat in the US (Luttrell 1973).

[2] The guidelines were titled "Preclinical Testing of Novel Sources of Protein" and would later be updated and rereleased as PAG/UNU 1983.

It was around this time that the Risk Analysis Framework was developed. First iterated in 1983 in the National Academy of Science's "Redbook," the RAF is a methodological approach to managing technological innovation and is now embedded within policy systems of most OECD states. The RAF has three main functions: risk assessment, risk management, and risk communication. It is logical and science-based: the risk assessment portion involves looking at the relative short-term safety effects and long-term health effects of a product, ignoring socioeconomic factors. Some scholars have claimed that there are substantive problems with relying on this method of risk analysis for assessing the safety of products derived from agricultural biotechnology: accountability and transparency in the regulatory process are threatened by technical jargon; in addition, the concept of 'sound science' is problematic (Isaac 2006). Furthermore, the RAF's end-stage of risk communication may now often be considered a first step for the scope definition of a risk assessment process (Phillips 2009). Nevertheless, its blend of rationality and caution aims to ensure that no product is overregulated or under-regulated.

The Convention on Biological Diversity (CBD) presents an interesting parallel to the RAF. Signed in 1992 and operationalized in 1993, the CBD is a multilateral treaty that introduces and enshrines (among other things) the precautionary principle. While the RAF sets out a logical pathway for risk assessment undertaken by a potential adopter, the precautionary principle shifts the uncertainty surrounding risk onto the proponent of a new technology. Originally part of the Rio Declaration at the Earth Summit in Rio de Janeiro in 1992 (incorporated into the Preamble of the CBD), the precautionary principle states that "where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat"

(CBD 1992, preamble). Since then, the scope of the precautionary principle has broadened past simple biological diversity to include other environmental concerns and beyond. It has been embedded within the domestic policies of European Union countries and others, used in part to restrict products derived from controversial or novel processes and technologies such as recombinant DNA.

In 1973, researchers held the Gordon Research Conference on Nucleic Acids to discuss recent research and movements with respect to DNA technology, as well as safety concerns. Afterward, the attendees published a letter in *Science* calling for a committee to assess potential risks and hazards associated with the technology (Singer & Soll 1973). Such a committee was convened, comprised of ten scientists: Paul Berg of Stanford University, the chairman of the committee; David Baltimore of the Massachusetts Institute of Technology; Richard Roblin of Harvard Medical School; Stanley N. Cohen of Stanford University; Ronald W. Davis of Stanford University; David S. Hogness of Stanford University; Daniel Nathans of Johns Hopkins University; James Watson of Cold Spring Harbor Laboratory; Sherman Weissman of Yale University; and Norton D. Zinder of the Rockefeller University. They released the 'Berg letter' in 1974, which called for a moratorium on rDNA experiments until safety assessments could be conducted (Berg et al. 1974). In an unprecedented move, the scientific community agreed. On November 2, 1977, Dr. Paul Berg testified to the U.S. Senate's Subcommittee on Science, Technology and Space; he revealed that years of hazard testing and risk assessment had led him and colleagues to withdraw their earlier concerns about potential harms of rDNA technology, stating that overregulation of the technology "could stultify the creativity and initiative that has characterized the recombinant DNA technique" (Testimony by Paul Berg, 1977, p.6).

The following year, the 1975 Conference on Recombinant DNA Molecules was held in Asilomar, CA. Perhaps more famously known simply as the Asilomar Conference, it resulted in a set of guidelines for laboratory practices involving rDNA experiments. It was attended by over a hundred scientists, government representatives and journalists from around the world, including all of the ten signatories to the Berg letter. Its summary statement (Berg et al. 1975) includes references to products of rDNA technology, forthcoming biotypes, and associated risk. This focus on the new processes of biotechnology would be the dominant pattern for the next decade, with most of the concentration on laboratory work without any kind of commercial release.

By the early 1980s, it was obvious that the new biotechnologies were not going to be limited to the laboratory permanently and that regulatory systems for commercial release would need to be developed. International organizations like the Food and Agriculture Organization (FAO) and the Organization for Economic Cooperation and Development (OECD) took the lead, gathering panels of experts from the epistemic community surrounding agricultural biotechnology to make assessments on potential structuring elements for regulatory systems. The OECD initially released a report (Bull et al. 1982) with regard to the new technology, claiming agreement with a Dutch report from the year prior (van Apeldoorn 1981) in which the authors recommended a process-based regulatory approach.

Meanwhile, first-mover countries began to get organized as well. In 1983, the United States Environmental Protection Agency began regulating microbial GMOs under the *Toxic Substances Control Act*. Its focus on novel effects and the like complimented the existing pressure at the time to make regulatory decisions with the influence of scientific evidence alone (Levidow & Carr 2000). The White House's Office of Science and Technology Policy

subsequently released its proposal for a Coordinated Framework for Regulation of Biotechnology, which included the concept of product-based regulation, or evaluating products based on their characteristics as opposed to their method of production. Two years later, they released the completed Framework. It emphasized the need for inter-agency cooperation in US regulation because of the broad characteristics of biotechnology. It also specifically outlined that "the manufacture of new technologies … will be reviewed by FDA, USDA and EPA in essentially the same manner and efficacy as products obtained by other techniques" (Office of Science and Technology Policy 1986, p.7), but also left open the opportunity for those agencies to monitor the technological landscape for potential future implications.

One of the pivotal moments for the product-based approach came in 1986. The OECD released its completed 1986 document, *Recombinant DNA Safety Considerations*. In it they backtrack[3] on their earlier (Bull et al. 1982) assertions of the process approach, indicating that "risks associated with applications of rDNA organisms may be assessed in generally the same way as those associated with non-rDNA organisms" (OECD 1986, p. 30). Also at this time, the FAO and World Health Organization began joint consultations on assessments specifically related to foods produced via biotechnology, the reports from which give no indication that there is justification for separate regulatory systems based on process (World Health Organization 1991). International organizations, drawing expert advice from the global agricultural biotechnology epistemic community, including university professors and researchers, public

[3] The Group of Government Experts responsible for the compilation of the report acknowledge the Bull et al. (1982) report as one of many "useful reviews" (OECD 1986, p. 16) that have been conducted, but do not give very specific reasons as to why the OECD's position changed. However, it is the nature of consensus in documents produced from a collective such as the 1986 report that experts from national bodies will consult with colleagues with expertise in the field, particularly in a knowledge-intensive and quickly-changing area such as biotechnology, which may have led to the re-evaluation of the technology.

scientists and regulators and industry scientists, reached a theoretical consensus on the debate between a regulatory system based on the process of alteration and one based on product.

Although there were many European scientists that took part in the OECD working group who produced *Recombinant DNA Safety Considerations*, European governments at this point made a conscious choice to pursue a process-based regulatory system for transgenic crops so that they could control their adoption. This is where disconnect between the two main broad approaches to regulation finds its roots. The European Economic Community released Directive 90/220/EEC in 1990. It regulates the release of genetically modified organisms which are defined by techniques (elaborated in an annex). Recombinant DNA and cell fusion or hybridization "by means of methods that do not occur naturally" are considered to be genetically modified, while in vitro fertilization, polyploidy introduction, mutagenesis and "any other natural process" like conjugation or transformation are not considered to be genetically modified (EEC 1990, Annexes 1A, 1B).

This directive is reflective of the precautionary principle (CBD 1992), the preventive guideline which has come to govern much of European policy with regard to biological organisms and the environment. The precautionary principle is just as it sounds: it involves restricting activities to which the consequences or effects are unknown in order to protect the general populace, with the assumption that the negative results would outweigh any potential benefits either to society or the academy (Miller and Conko 2004). Advocates of the precautionary approach are not willing to endure risk in order to pursue a post-normal science like biotechnology, which calls for stakeholder participation beyond simply those with specialized knowledge (Funtowicz and Ravetz 1994). By institutionalizing the precautionary principle, Europe has taken a "look before you leap" attitude. From the early 1990s forward,

Europe formally adopted a process-based stance on agricultural biotechnology regulation, believing that GMOs that result from rDNA technology are more dangerous than organisms derived from more conventional methods.

The European perspective, novelty of process rather than product, would later be reiterated in 1997 with the European Commission's Novel Food Regulation 258/97. It regulated the release and approval of novel food in the European Union in accordance with the definition of GMOs provided earlier by the EEC directive on genetic modification (European Commission 1997).[4] Meanwhile, the 1991 document from the joint Food and Agriculture Organization of the United Nations and World Health Organization task force on biotechnology, titled "Strategies for assessing the safety of foods produced by biotechnology," created a definition of biotechnology that refers to both GM and conventional breeding practices, meaning to express that there is "no fundamental difference between traditional products and contemporary ones obtained by means of biotechnology" (WHO 1991, p.3). This infers that the principles of safety and methods of assessment should also be the same. The risks regarding safety considerations may exist in traditional breeding and not solely in the application of rDNA technology, argues the task force. With regard to the FAO/WHO position, the most compelling idea is not the novelty of the process, or even of the traits; indeed, it is the concept that there would be no novel risks associated with new technologies. Basically, as it applies to risks with rDNA versus conventional techniques, novelty does not exist – the risks are the same. These ideas lend more credence to the bases of the Canadian regulatory system.

[4] The European perspective, novelty of process rather than product, would later be reiterated in 1997 with the European Commission's Novel Food Regulation, numbered 258/97. It regulated the release and approval of novel food in the European Union in accordance with the definition of GMOs provided earlier by the EEC directive on genetic modification (European Commission 1997).

The concept of product over process was originally enshrined in regulations with respect to trade. Article III of the General Agreement on Tariffs and Trade (GATT), which came into effect in 1948, introduces the principle of non-discrimination with regard to the treatment of imported products vis-à-vis "like products of national origin" (GATT, Article III (4)). The interpretation of Article III has been the subject of much debate and litigation, with one version being that any approaches to regulating imported goods which are based on anything other than the physical attributes of the product should be considered violations of GATT (exceptions in Article XX, such as the use of slave labour, notwithstanding). On the other hand, the movement for the inclusion of process production methods (PPMs) into GATT holds to an Article III interpretation whereby process-based measures are not covered, and are thus not GATT violations (Howse & Regan 2000). The PPM movement has been disputed, with one argument against it being that this could lead to a "slippery slope" of process-based regulation (Jackson 2000).

Complicating things are the TRIPs, SPS and TBT Agreements which came into effect alongside the establishment of the World Trade Organization on January 1, 1995, which superseded GATT: The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) provides minimum standards for the administration of intellectual property rights, which under TRIPS, extend to GMOs. This has been the subject of much debate and controversy, notably with respect to the ability of large GM seed giants like Monsanto to seek legal action against farmers who use their seed without the proper permissions (Strauss 2009).

Another agreement also introduced, the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), acknowledges that countries have a right to set protections for health with regard to food safety, animal, and plant standards, provided those measures do not

create unnecessary restrictions to trade. In order to ban a group of bioproducts such as GM food, the SPS Agreement requires that a scientific risk assessment be undertaken; however, paragraph 7 of Article V provides an exception to that requirement, providing that "in cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members" (WTO 1995b, Article V (7)). This has permitted many European countries to go ahead with what is effectively a ban on GM products. The third agreement introduced, the Agreement on Technical Barriers to Trade (TBT), has a similar function to the SPS Agreement with regard to testing, certifications, and other technical regulations or standards, and has experienced many of the same issues surrounding interpretation with respect to GMOs and labelling requirements. The application of novelty in intellectual property is an additional stream of the concept but its development had little material effect on novelty in regulation. Much of the controversy involving trade-related aspects of the product vs. process debate is out of the scope of this case study, but provides important context for the rest of the paper.

Two years after the OECD and the United States championed a product-based approach, Canada began movements toward its own regulatory policy for agricultural biotechnology. The Canadian Agri-Food Research Council (CARC) held a workshop entitled "Workshop on the Regulation of Agricultural Products of Biotechnology" in 1988, bringing together Canadian academics, government and industry representatives, as well as officials from the United States. This workshop was the culmination of a decade of Canadian agricultural biotechnology policy orientating around promotion and the importance of embracing innovation (Abergel & Barrett 2002). It was tasked with improving Canadian agricultural biotechnology policy via an

examination of the landscape, a comparison with the United States and Europe, and the recommendation of regulations for risk assessment. The idea of plants with novel traits, conceptually but not by name, was borne at this conference.

A small number of key actors can be identified via their presence at three events which were integral to the development of the product-based regulatory approach. These people may have unwillingly or willingly played the role of an agent of change. The 1975 meeting of scientists in Asilomar, California, discussed the potential for risks and hazards of biotechnology, including concerns about the stability of the new genetic constructs, their potential to be invaisive and the possibility that new hazards might be introduced into otherewise safe biological activities. The main result of the event was a call for a temporary mostly voluntary halt to some research activities and to commercialization in order to figure out what might be needed in terms of potential regulation. This event had two attendees who also participated in the *ad hoc* Group of Government Experts (GGE) on Safety and Regulations in Biotechnology. OECD GGEs, now referred to as "expert advisory groups", consist of individuals with relevant knowledge and expertise who have been nominated for service by their and other member governments (OECD 2014). The GGE conducted a substantial review of the techniques and products of recombinant DNA technology in order to identify criteria that may be used to establish safety in the use of recombinant DNA and its products, and were contributors to the 1986 OECD report, *Recombinant DNA Safety Considerations* (see Table 2). Two of the members of the GGE were also present at the CARC workshop in Ottawa in 1988. While there are no actors who were present for all three events, the summary reports of each of these workshops or working groups, as well as subsequent publications and the spread of proceedings via word of mouth through the epistemic community are all factors which contributed to the diffusion of policy ideas.

After the 1988 CARC workshop, the Government of Canada turned to Dr. Wally Beversdorf, (a 1988 CARC workshop attendee, one of the fathers of canola and then the Chair of the Department of Crop Science at the University of Guelph, for assistance in developing risk assessment and safety guidelines for the wide release of agricultural products of biotechnology. Dr. Beversdorf held a series of workshops to develop draft regulations, including a workshop in November of 1993, entitled Regulating Agricultural Products of Biotechnology. Its objectives were consensus on PNT approaches, regulatory consistency with previously used criteria, sharing of information and the development of strong working relationships. There was a stress placed on safety over economics, a focus on scientifically-founded risk, and preference toward coordination in development of regulations (Smyth 2009).

The presence of these individuals at multiple events suggests engagement, whether or not the spread of information and ideas throughout networks and academic disciplines was intentional is undetermined. Table 2 serves to illustrate a potential diffusion pathway for the ideas surrounding the regulation of recombinant DNA technology which underlay the novelty approach. This pathway is also a representation of the interactivity of the agricultural biotechnology epistemic community; the individuals presented are not intended to be specifically identified as carriers of policy information, but rather represent institutions and governments. Institutions are made of people; people carry ideas, utilizing them in debates and discussions and aiding in their diffusion.

Table 2: Conference Attendees

Actor	Asilomar 1975[5]	OECD 1986[6]	CARC 1988[7]	Ag Canada 1993 workshops
	158 attendees; 16 members of the press; resulted in laboratory guidelines	88 attendees; resulted in first rec. of product-based regulation	107 attendees; produced novelty rec., series of workshops to develop regulations	Various attendees; resulted in Directive 94-08, regulating plants with novel traits
G. Bernardi (France) Institute de Biologie Moleculaire, Faculte des Sciences	*X*	*X*		
W. Gartland (USA) National Institutes of Health	*X*	*X*		
F. Young (USA) Department of Microbiology, University of Rochester	*X*	*X*		
V. Sgaramella (Italy) Instituto di Genetica	*X*	*X*		
T. McIntyre (Canada) Commercial Chemicals Branch, Environment Canada		*X*	*X*	
D. B. Shindler (Canada) Canadian High Commission		*X*	*X*	
W. Beversdorf (Canada) Department of Crop Science, University of Guelph			*X*	*X*

[5] Taken from Appendix A of NAS (1975).
[6] Taken from OECD (1986) appendices.
[7] Taken from CARC (1988) appendices.

Following the advice and the work that came out of these workshops, Agriculture Canada's Plant Biosafety Office[8] released Directive 94-08 in December of 1994. Directive 94-08 is officially titled "Assessment Criteria For Evaluating the Environmental Safety of Plants with Novel Traits" and has been updated three times since 1994, most recently in 2012 (Plant Biosafety Office 1994). It was the first regulatory rulemaking document to accompany the Government of Canada's 1993 Federal Regulatory Framework for Biotechnology in Canada (CFIA 1993), a policy outlining government positions. Directive 94-08 is the document that first explicitly outlined the all-encompassing nature of the regulatory trigger for new agricultural bio-products in Canada: novelty, regardless of the process of gene alteration.

Canada's regulatory system represents the institutionalization of the product approach which had been championed by the OECD in the 1980s. Table 3 provides a rough visualization of its diffusion through relevant documents and events, from the 1970s to the 2000s. It began with discussions at an international level, with major scholarly events occurring in the 1970s. This was followed in the 1980s and early 1990s with reports on regulatory approaches from international bodies. Legislation at the national level began in the 1990s in the United States and Canada, when both countries cemented their domestic institutionalization of the approach. In the 2000s, concerns around efficacy and efficiency within the context of the Canadian agricultural sector were raised. The visualization itself is interesting, as it provides the opportunity to see how the product approach has diffused from international scholarship, to international organizations, through to the national government level and then to non-governmental fora where academic and industry stakeholders are engaged.

[8] The Plant Biosafety Office after 1997 was housed within the Canadian Food Inspection Agency, an independent agency reporting for 1997-2013 to the Minister of Agriculture and since then to the Minister of Health.

Table 3: Diffusion Visualization, 1970s-2000s (Canadian events in bold)

TYPE	1970s	1980s	1990s	2000s
Decisions			**Approved field trials & release**	Approved field trials & release
Directives			**-1990: 90/220/EEC** **-1994: Dir94-08** **-1996: Dir96-13** **-1997: EC 258/97 Novel Food Regulation**	-2000: Dir94-08 reissue -2004: Dir94-08 reissue -2009: Dir2009-09
Regulation		-1986 USA Coordinated Framework	**- 1993 Federal Regulatory Framework for Biotechnology (Canada)** **-1997 creation of CFIA**	**-2004 Auditor General Report (Canada)**
Legislation	-1972 PAG/UNU Guidelines	-1983 PAG/UNU reissue -1985 Seeds Act (Canada)	-1992 USA Policy Statement 22984 (FDA 1992) -1992 CBD **-1997 Seeds Regulations (Canada), esp. *Part V*** **-1997 NAFTA**	
International Discussion	-1973 Gordon Conference on Nucleic Acids -1974 Berg letter -1975 Asilomar Conference on rDNA	-1982 Bull OECD: Biotech Trends -1986 rDNA Safety Considerations OECD	-1991 FAO/WHO -1992 Earth Summit -1993 OECD *Safety Evaluation of Foods Derived by Biotech* -1993 OECD *Scale-Up of Crop Plants*	
Canadian Discussion		**-1988 CARC Workshop**	**-1993 CFIA workshops**	**-2004 CFIA Conferences** **-2004 Seed Sector Review** **-2004 National Forum on Seed conference** **-2007 U of S/AgWestBio conference**

The United States also followed the product-based method of regulation, although it was not interpreted in American regulations in the same way as in Canada. In the United States, the regulatory trigger for transgenic plants is plant pest potential and pathogenic presence (Monpetit 2005).

The other key element is the difference in the way the two countries utilize the concepts of familiarity and substantial equivalence. Familiarity, which was first used in the chemical industry (Barrett & Abergel 2000), is the "knowledge and experience" which can be applied to a new product for the purposes of risk analysis and management (OECD 1993a, p.28). This knowledge and experience is based upon a history of the seed, including specific cultivation practices and traits of similar non-modified crops. Similarly, substantial equivalence is decided based upon the "reasonable certainty of no harm [of a new product] as compared with its conventional or traditional counterpart" (OECD 1993b, p. 14). The Animal and Plant Health Inspection Service (APHIS) of the USDA utilizes familiarity, while the Food and Drug Agency uses substantial equivalence, both at the inception of decision-making. On the other hand, Canada's utilization of these concepts is limited to within the risk assessment process itself, and not beforehand as a filter (see Table 4). It is this employment, as well as the ambiguity surrounding the pathogen regulatory trigger, which makes the United States' regulatory policy more lenient for conventional breeders than that of Canada (Monpetit 2005). What results is the opportunity for a novel mutagenic plant to be able to escape the expensive and time consuming regulatory process in the United States, depending on its traits.

Table 4: Familiarity and Substantial Equivalence in Canada and the United States

Term	First used	Who; how Canada uses	Who; how USA uses
Familiarity	Chemical industry	CFIA, Health Canada; within decision making process	APHIS; beginning of decision making
Substantial equivalence	OECD 1993b		FDA; beginning of decision making

For example, in 2010 Dow AgroSciences developed a genetically modified corn variety using a new zinc-finger nuclease (ZFN) technique. It was not subjected to regulation by the USDA because it did not represent a plant pest or pathogenic threat (Waltz 2012). The same crop triggered the novelty requirement in Canada and needed to go through the Canadian regulatory system before commercialization or wide release. Additionally, crops created through older methods such as mutagenesis are generally considered novel in Canada but escape regulation in the United States (Ag West Bio 2007). A recent study conducted by CropLife International estimated the cost of getting a genetically modified crop through regulation to market to be approximately US$31.5 million, so this is not an insignificant difference (Phillips McDougall 2011).[9] Table 5 illustrates the Canadian, American, and European regulatory triggers as well as their stance toward GMOs.

Table 5: Triggering mechanism for regulation: Canada, USA, and Europe[10]

Country	Stance on GMOs, as defined by Monpetit (2005)	Trigger
Canada	Favourable	Novelty of traits
United States	Favourable	Plant pest potential; pathogen presence
Europe	Not favourable	Method of production

[9] Commercialization is defined as a GMO which was approved in two producing countries and five importing countries.
[10] Adopted from Monpetit 2005, pp.344-346.

The disparity in regulation between Canada and the United States is an issue on both sides of the border. Some argue that the United States at risk for allowing genetically modified products into the system untested, which may cause trade issues if this material is then triggered as a GMO import elsewhere (Lusser 2012). By contrast, Canada's system may truly be 'catch-all', but it runs the risk of being seen as having a less permissible regulatory landscape for both conventional breeders and biotechnologists involved with both traditional and very new techniques (such as synthetic biology).

Diffusion

How is it possible that Canada, typically a policy-borrower country (Dolowitz & Marsh 2000) with an established history of adopting American and American-led policy innovations (Hoberg 1991), ended up with a regulatory system unlike that of any other nation? In order to understand, it is prudent to examine the Canadian situation with the tools of policy learning, diffusion and innovation theory.

Biotechnology largely came to the attention of academics and policymakers in the 1970s, during a period of social and economic upheaval. The problems of the world had come to a head in a way they hadn't before, due in part to increasing globalization and interconnectivity. The associated uncertainty found its way into academia, with the introduction of concepts like wicked or inherently unsolvable problems (Rittel & Webber 1973). However, the sudden ambiguity about the world left opportunities for scholars of both innovation policy and theory, including the not-often mentioned regulations that are sometimes associated with innovation. The disciplines evolved alongside one another and were significantly influenced by this period of dramatic change.

It was at this point that actors outside the normal realm of policymaking began seeking what Mytelka and Smith (2002) call a "new innovation paradigm" (p. 1469), via collaboration with international organizations like the OECD and FAO. It was in these locales that consensus was primarily sought and built. Finding agreement and creating rules to keep up with the hastening pace of change in technology and the globalized economy became the primary role of these organizations and their members and partners.

However, to echo Beland (2009), while international actors such as IGOs are certainly important, sovereignty in lawmaking and enforcement lies ultimately with national governments. In interpreting advice from the OECD, FAO and other international organizations, policymakers within nations sometimes end up with policies and programs that look quite different from one another despite having nearly the same roots. In the case of novelty in Canada, policymakers took their cues from the country's own specialists. Canada implemented a system that directly embodies the product-based approach, triggering regulation for any 'new' product regardless of technology or process used. Recommendations from the OECD stated that safety assessments should be the same for GM products as they are with conventional products, and this policy idea diffused directly.

It is here that the innovation literature may be able to assist in interpreting the limited diffusion of the novelty approach. After the development of an innovation, there is a period where a potential adopter undergoes what is known as the innovation-decision process. It is this process which is particularly interesting when applied in reference to the diffusion of the product-based approach. The process has five stages: knowledge, persuasion, decision, implementation, and confirmation (Rogers 2003).

In the knowledge stage, an actor first becomes aware of an innovation. This is called awareness knowledge. Information on the uses of an innovation (how-to knowledge) as well as any theories underpinning the innovation (know-why/principles knowledge) also is brought forward in this stage. In the case of the product approach, this would include the period before and after the approach first was touted by the OECD.

In the next stage, the actor will develop either a positive or negative view of the innovation. This is done by seeking out "innovative evaluation information" (Rogers 2003, p. 175). By acquiring qualifying information about the innovation, the actor is attempting to manage their uncertainty about adopting. This information is usually sought from peers instead of scientific journal sources because of peers' perceived subjectivity. Interestingly, this idea is rendered moot in the case of the novelty approach, as the highly technical nature of the policy innovation limited the potential adopters' peer group to the other members of a mostly academic community of educated experts. It was unavoidable to consult scientific sources because the content was such that the potential adopters either were themselves academics or had to consult with academic experts in order to ascertain an understanding of the innovation.

After coming to either a positive or negative conclusion about the innovation, the actor makes a decision. They may adopt it, either fully or partially, or reject it. Rejection can be passive, where the consideration that occurs is not very serious if at all, or active, where the decision not to adopt would be a more intentional, purposeful act. If adopting, an actor has two possible options: adopt the innovation as is, or adopt it after adapting it to the specific needs of the adopter. Occurring in the implementation stage, this adaptation is also known as reinvention (Rogers 2003). Innovations may not always fit neatly within an organization. Reinventing may be useful or, at times, necessary. The likelihood that an actor will reinvent an innovation upon

adoption is directly related to their adopter status vis-à-vis other actors. Early adopters are more likely to adapt an innovation, while those who adopt later are more likely to implement the innovation, unaltered (Westphal et al, 1997). Objectively, this is both true and false in the case of novelty. While the US did adopt first (with a degree of reinvention), if its adoption and that of Canada are placed in historical context, Canada would also be considered an early adopter. Canada's early engagement with canola, a Canadian invention and arguably the first large area GM crop to be commercialized, made Canada an early-adopter with not only the specific product-based innovation, but with novel plants more broadly.

The final stage of the innovation-decision process is confirmation. In this stage, actors may reinvent based on experiences, seek more information, or cease using the innovation. Since the adoption of the novelty approach in Canada, there been further attempts made to clarify, understand and improve regulations. Most of these efforts have been undertaken by plant breeders' associations on behalf of producers. For example, a workshop on the role of novelty in regulations of plants with novel traits was held by Ag West Bio and the University of Saskatchewan in 2007, where attendees discussed the existing issues and proposed a tiered approach to risk assessment of PNTs in an effort to address concerns. Questions continue to be asked and improvements continue to be sought, indicating that while those with authority (in this case, the government of Canada) may have completed the innovation-decision process, at least some affected actors have not.

This may potentially be explained when considering the type of decision that was undertaken in the novelty case. There are three types of innovation decisions to consider with regard to the adoption of an innovation: an optional innovation-decision, where the choice to adopt is made by an individual; a collective innovation-decision, where group consensus decides

whether adoption will take place; and an authority innovation-decision, where the a small number of people decide whether or not to adopt on behalf of everyone in the system (Rogers 2003). The latter type, authority innovation-decisions, may include those which are made by elected representatives of a group. The decision of the Canadian government to adopt the novelty-based approach to regulation is an authority innovation-decision. Although the policy development process in this case, which included the consultation of experts and stakeholders via the CARC meeting and succeeding workshops, suggests initial consensus, the subsequent re-evaluation of novelty by individuals and groups is evidence that differences did emerge later.

One intriguing aspect of this diffusion pattern is not so much the stakeholder consultation, nor the mirroring from international organizations and the epistemic community, but the fact that Canada and the United States did not harmonize on a common set of rules. When Rose's (1993) degrees of transfer are applied to the experience of the US and Canada with the product approach, it is clear that Canada's implementation is the closest to that which was proposed by the OECD, suggesting it should be categorized between replication and emulation. The trigger adopted by the US would place it between emulation and combination, as the viruses that are being detected by that trigger are not things that could be applied to conventional counterparts; this has been attributed to the influence in part by existing regulations about toxic substances utilized to regulate microbial GMOs (Levidow & Carr 2000).

Shared values play an important role in lesson-drawing and policy diffusion (Rose 1991). Canada and the United States have a strong history of mutually embraced values making their regulatory disparity in this case particularly interesting. One perspective with respect to this lack of convergence comes from Hoberg, who discusses the history of what he calls Canada's "constrained emulation" (1991, p. 126) of US environmental policy, with the notable exception

of institutional processes to avoid Americanization. The discrepancy in regulatory interpretation of biotechnology seems on the surface to be symptomatic of this. However, there is a contrasting perspective which argues that Canadian and American environmental policies are moving neither toward nor away from one another, but mutually toward a third path (Howlett 2000).

Attempts have been made to move Canada and the U.S. toward that third path, at least with respect to regulatory policies. In 1998, representatives from the CFIA and Health Canada met in Ottawa to talk about regulatory cooperation with their counterparts with the USDA and APHIS. They discussed the harmonization of molecular genetic characterization and agreed upon methods of analyzing the genetic material that is submitted for regulatory approval, with a view that if the compliance requirements were the same or similar in both countries, proponents of transgenic crops would be more likely to make submissions for regulation in both the U.S. and Canada (CFIA et al., 1998).[11] This work has continued with the standardization of laboratory methods under the auspices of the NAFTA Harmonization Council (CBSA 1998).

Further to this, Canada has fallen behind on its internal commitments to the development of new regulations for novel animals and novel fish. In 1999, a date of February 2000 had been identified as the target release date for the publication of Health Canada's *Guidelines for the Safety Assessment of Novel Foods, Vol. III: Genetically Modified Livestock Animals and Fish* (CBAC 2003). As of 2003, development of regulations for novel and cloned animals were stalled at the request of a proponent and dates for novel fish guidelines had been reset to June 2004 (CBAC 2003). As of 2014, no such guidelines have been released and there are no target dates for any release.

[11] These requirements were updated in 2000 (CFIA et al 2000).

The way that plants with novel traits are currently regulated in Canada allows the system and regulators to evolve in tandem with technology. Rather, the dominant issue with the system is that there are no other polities currently regulating agricultural products of biotechnology with the same comprehensive approach as in Canada. The United States, which is discussed in further detail elsewhere in this paper, utilizes plant pest potential and pathogenic presence to trigger regulatory oversight. Australia, which only recently allowed genetically modified crops, but has had a regulatory system in place for quite a few years, regulates GMOs based on the process used rather than the traits involved (OGTR 2000). Brazil, second in the world in terms of acreage of GM crops grown (Kaphengst et al. 2011), defines 'genetically modified' as being altered by DNA and RNA engineering techniques and regulates based on that (CTNBio 2005). Australia and Brazil, as well as other GM adopter countries like Argentina, India, Paraguay, South Africa and China, developed their regulations after Canada and none took its approach.

This may be explained by borrowing from the business and technology literature. Shapiro and Varian (1999) have a useful typology of advantages for proponents of a technology or innovation to hold in order to win a standards war. Their research is specifically related to technological battles such as Microsoft vs. Apple and Betamax vs. VCR technology, but can be broadly translated to policy innovation. One product may win a standards war over another, regardless of the whether the 'winning' product is actually objectively superior, for a variety of reasons. For example, in the 1930s, electric refrigerators won a standards war over gas refrigerators, despite the advantages that gas refrigerators offered. These included being less prone to breaking down due to its lack of moving parts, and running without the humming noise that accompanies electric-motor refrigerators. However, the large corporations who were investing in the research and development for these products determined that electric

refrigerators would result in a greater profit margin (Rogers 2003). Subsequently, more investment was made into electric refrigerators and they eventually became ubiquitous.

Sharpiro and Varian (1999) propose seven criteria for winning a standards war, two of which are relevant for application to the issue of novelty and Canadian policy innovation. The first advantage is that of being the first-mover, or the first to adopt or introduce an innovation. While Canada and the US both integrated policy advice from IGOs and the epistemic community into their regulatory systems, the United States system was established prior to Canada's. The second advantage, and perhaps the most important, is that of brand name and reputation. The United States is the world's superpower, a dominant force in nearly every aspect of the globalized world and the world's lead developer and adopter of GM crops. In comparison, Canada is not. While Canada was an inventor initially, its efforts have collapsed recently. Canada is now an adopter, not a leader.

What Canada has is not so much a policy problem as it is a promotion problem. Policies are overwhelmingly drawn and emulated from nations or states similar in a variety of ways to potential adopter polities. If Canadian policy is similar in characteristic to that of the United States, differing mainly in institutionalization and implementation, as Hoberg (1991) claims, and GMO adopter countries are more closely following the American approach to regulation of novel bioproducts than they are the Canadian approach, then it can be concluded that Canada has lost the standards war with the United States to be the representative polity of those ideals. Like the Betamax experience illustrates, superior technology does not always guarantee a win. Potential adopters of GM regulatory policy look to the United States to draw lessons and emulate policy, ignoring Canada because of its lower international profile, even though, as discussed above, the

policy has the potential to be more responsive to changes in the technology that could change risks.

CONCLUSIONS

The product-based approach to regulation, which was built on advice sourced from international organizations and experts in the field, successfully managed to diffuse from consensus-building institutions like the OECD and into authoritative regulation in countries like the United States and Canada. This occurred largely because of the relatively small size of biotechnology's epistemic community and its members' interconnectivity during regulatory construction. The Canadian system has the most technically accurate institutionalization of this idea; however, interestingly, other countries have not elected to emulate its widely-encompassing regulatory oversight trigger. The presence of both success and failure makes it a particularly useful case study with which to evaluate the interrelated policy diffusion, policy learning, and policy innovation literature. These characteristics also allow for the evaluation of the research methodologies of policy diffusion, and to test for their applicability to a case study such as the one outlined in this paper.

There are three main parts to the problem presented in this thesis. The first aspect to be considered is the product-based approach to regulation itself and its status as a policy innovation. The second is the differing adaptations of that policy by two countries, Canada and the United States, and the problems presented by their dissimilarity. The third and final part of the issue is the diffusion – or lack thereof – of the Canadian institutionalization of their product-based approach versus others. The theories that were reviewed and employed here each explained parts of the issue, but none on its own would fully amplify my case.

The historical method is the only diffusion methodology that is easily applied to an *ex-post* study of agricultural biotechnology regulatory diffusion, but it is not without its weaknesses. It is particularly susceptible to what is referred to as the respondent recall problem. The

respondent recall problem is the difficulty involved in attempting to study the diffusion of a particular innovation or policy after the fact. Personal interviews and individual responses are not always reliable, and become less so as the amount of time that has passed since adoption increases (Rogers 2003). Additionally, retrospective studies of innovations, because of their reliance on documents available, generally have a greater focus on the research and development of an innovation and significantly less on its diffusion, which results partly in issues surrounding ascertainment of causality.

This is certainly true in the case of the diffusion of the product-based approach. Even considering the difficulty of ascertaining primary source material from before personal computers were widespread (compared to the relative ease of doing so after, when documents are more readily available and searchable), there is more documentation available from the product approach's early years in international organizations and less so from after it became established within government, including how it got to be there in the first place. However, it is difficult to tell whether this is more a commentary on the public availability of information from international organizations and academic institutions versus the behaviour of domestic governments with the same material, or an observation on the innovation diffusion process itself.

While quantifiable diffusion methods such as event history analysis are fairly accurate when it comes to studies involving intra-country state-to-state diffusion, they do not work well in an international case with data availability constraints such as this. The advantage that event history analysis has in intra-country state-to-state diffusion cases is that there is an automatic risk set, or group of states that are susceptible for policy adoption, and that all of these states are identical in institutional construct. The trouble arises when an attempt is made to apply the statistical methods of event history analysis to inter-country diffusion. Barriers include the

inconsistency of data, with both collection method and availability issues; differences in government structures; conflict with differing jurisdictional authority within nations; dissimilarity in organizational cultures, and variance in the way that things like regulations are administered. There are too many variables that are dissimilar to compare adequately among countries, and thus this type of analysis does not lend any predictability or explanatory power to diffusion cases like Canadian agricultural biotechnology regulation.

Furthermore, statistical models say nothing about the initial policy innovation itself, only what can happen to that policy afterward. While diffusion is important to understand, there are significant advantages to being an innovation pioneer, particularly in policy. Better understanding how policy innovation and invention occurs may perhaps lend another dimension to the idea of diffusion and predictability of specific outcomes. As it stands, the limited literature around policy innovation does not have many generally useful quantitative methods. The existing qualitative research is either anecdotal in nature or will require extensive work before predictive models can be developed.

The innovation diffusion literature has elements which can be applied to policy innovation, albeit qualitatively. Everett Rogers (2003) warns against the biases existing in innovation diffusion literature, specifically its positive stance toward innovations themselves. Scholars of diffusion tend overwhelmingly to favour the permeation of an innovation throughout a network, and that it should do so in its current state, without reinvention. This is partly due to the statistical analysis possible in tracing and measuring rates of adoption and other benchmarks. Innovations which do not work and do not diffuse, while potentially very informative, are not as easily lent to quantitative methods of diffusion such as event history analysis.

Additionally, while the innovation diffusion literature can tell us much about why good innovations diffuse and the processes that they go through as they become more widespread and popular, it is less helpful when addressing why good innovations do *not* diffuse. Rogers (2003) touches on this briefly when he discusses research and development investment in standard wars between variations on innovations, such as electric versus gas refrigerators, but apart from first-mover advantage and brand status criteria from Shapiro and Varian (1999), much of the innovation, business and technology literature is not easily translatable to the policy realm.

Neither the existing research methods in the policy diffusion literature nor in the innovation diffusion literature are very useful when seeking to understand how innovative policies and regulations are constructed, particularly with regard to transformative technologies like biotechnology. In cases where there is a high level of technical knowledge required for decision making, such as with biotechnology or nanotechnology, it is necessary to consult with individuals who have recognized expertise in those areas. International organizations with foci on research for consensus building like the OECD, WHO and FAO thus can play vital roles as the institutional home of networks of experts.

When it comes to the diffusion and adoption of policy for these types of innovations, however, the onus is on governments of sovereign nations and associated departments to interpret recommendations in the most appropriate way, given contextual and national characteristics. In Canada's case, this may have meant a fully science-based, novelty-trigger regulatory system. However, a comprehensive analysis of potential consequences of the lack of regulatory harmony with important trading partners, specifically the United States, may have helped avoid some of the issues that it is currently facing. Even if Canada's system could be objectively proven to the best, the presence of a strong policy paradigm leaves a government less

vulnerable to outside pressure (Hall 1993). The United States' strong presence in international policy arenas contributes to that kind of a paradigm, and thus it will probably be Canada that will have to make regulatory amendments if harmony is to be attained.

There are many theories and bodies of literature that I did not examine in the process of this thesis, including behavioural economics, agenda-setting, neorealism, complexity, and institutional analysis. Any number of these may offer insights and may serve to support the further study of innovative policies and their diffusion pathways throughout a relevant system.

APPENDIX A: CONFERENCE ATTENDEES LIST

0. National Academy of Sciences – International Conference on Recombinant DNA Molecules
February 24-27, 1975 (Asilomar, California) (Taken from NAS 1975)

Attendee	**Affiliation**
Organizing Committee	
Paul Berg, Chairman	Department of Biochemistry, Stanford University Medical Centre, Stanford, California
David Baltimore	Center for Cancer Research, Massachusetts Institute of Technology, Cambridge, Massachusetts
Sydney Brenner	Medical Research Council Laboratory for Molecular Biology, Cambridge, England
Niels K. Jerne	Basel Institute for Immunology, Basel, Switzerland
Richard O. Roblin III	Harvard Medical School and Massachusetts General Hospital, Boston, Massachusetts
Maxine F. Singer	Laboratory of Biochemistry and Metabolism, National Institute of Arthritis and Metabolic Disease, National Institutes of Health, Bethesda, Maryland
NAS-NRC Staff	
Artemis. P. Simopoulos	Division of Medical Sciences, National Research Council, National Academy of Sciences, Washington, D.C.
Elena O. Nightingale	Division of Medical Sciences, National Research Council, National Academy of Sciences, Washington, D.C.
Howard Lewis	Press Office, National Academy of Sciences, Washington, D.C.
Foreign Participants (non-U.S.)	
Ephraim S. Anderson	Enteric Reference Laboratory, Public Health Laboratory Service, London, England
Toshiko Arai	Department of Microbiology, Keio University Shinjuku, Tokyo, Japan
Werner Arber	Department of Microbiology, University of Basel, Basel, Switzerland
A.A. Bayov	Institute of Molecular Biology, Moscow, USSR
Douglas Berg	Departement de Biologie Moleculaire, University de Geneve, Geneva, Switzerland

Yuriy A. Berlin	M.M. Shemyakin Institute of Biorganic Chemistry, Academy of Sciences of the USSR, Moscow, USSR
G. Bernardi	Institute de Biologie Moleculaire, Faculte des Sciences, Paris, France
Max Birnstiel	Institute of Molecular Biology, University of Zurich, Zurich, Switzerland
Walter F. Bodmer	Genetics Laboratory, Department of Biochemistry, Oxford, England
N.H. Carey	G.D. Scarle and Company, Ltd., Research Division, Bucks, England
Y.A. Chabbert	Bacteriology Department, Institut Pasteur, Paris, France
Ray Dixon	ARC Unit of Nitrogen Fixation, University of Sussex, Brighton, England
W.A. Englehardt	Institute of Molecular Biology, Academy of Sciences of the USSR, Moscow, USSR
Walter Fiers	Laboratorium voor Moleculaire Biologie, Ghent, Belgium
Murray J. Fraser	Department of Biochemistry, McGill University, Montreal, Quebec, Canada
W. Gayewski	Department of Genetics, Warsaw University, Ujazdowskie, Poland
Stuart W. Glover	Department of Genetics, University of Newcastle-upon-Tyne, England
Walter Goubel	Gesellschait fur Molekularbiologische Forschung, Braunschweig, West Germany
Carlton Gyles	Department of Veterinary Microbiology and Immunology, University of Guelph, Guelph, Ontario, Canada
Gerd Hobom	Institut fur Biologie II der Universitat Freiburg, Freiburg, West Germany
Peter H. Hofschneider	Max-Planck-Institut fur Biochemie, Munchen, West Germany
Bruce W. Hollaway	Department of Genetics, Monash University, Victoria, Australia
H.S. Jansz	Netherlands Biochemical Society, c/o Vendellan 24[A], Netherlands
Mikhail N. Kolosov	M.M. Shemyakin Institute of Biorganic Chemistry, Academy of Sciences of the USSR, Moscow, USSR
Philippe Kourilsky	Institut Pasteur, Paris, France
Ole Maaloe	Department of Microbiology, University of Copenhagen, Copenhagen, Denmark
Alastair T. Matheson	Division of Biological Sciences, National Research Council, Ottawa, Ontario, Canada

Kenichi Matsubara	Department of Biochemistry, Kyushu University, Fukuoka, Japan
Andrey D. Mirzabekov	Institute of Molecular Biology, Academy of Sciences of the USSR, Moscow, USSR
Kenneth Murray	Department of Molecular Biology, University of Edinburgh, Edinburgh, Scotland
Ramon Naranjo	Guadalajara University, Guadalajara, Mexico
James Peacock	Division of Plant Industries, CSIRO, Canberra City, Australia
Lennart Philipson	Department of Microbiology, the Wallenberg Laboratory, Uppsala University, Uppsala, Sweden
James Pitard	Department of Microbiology, University of Melbourne, Parkville, Victoria, Australia
Mark H. Richmond	Department of Bacteriology, University of Bristol, Bristol, England
A. Rorsch	Department of Biochemistry, Leiden State University, Leiden, Netherlands
Vittorio Sgaramella	Instituto di Genetica, Pavia, Italy
Luigi G. Silvestri	Gruppo Lepetit, Milano, Italy
Lou Simonovitch	Department of Medical Genetics, University of Toronto, Ontario, Canada
H. Williams Smith	Houghton Poultry Research Station, Huntingdon, England
Peter Starlinger	Institut fur Genetik der Universitat Koln, Koln, West Germany
Pierre Tiollais	Institut Pasteur, Paris, France
Alfred Tissieres	Department de Biologie Moleculaire Sciences, Universite de Geneve, Geneve, Switzerland
John Tooze	EMBO, Heidelberg, West Germany
Alex J. Van der Eb	Laboratory of Physiological Chemistry, Leiden, The Netherlands
Charles Weissmann	Institut für Molekularbiologie, Universität Zurich, Switzerland
Robert Williamson	Beatson Hospital, Glasgow, Scotland
Ernest Winocour	Department of Genetics, Weizmann Institute of Science, Rehovot, Israel
E.L. Wollman	Institut Pasteur, Paris, France
Hans. G. Zachau	Institut für Physiologische Chemie und Physikalische Biochemie, Universität München, West Germany
Domestic (US) Participants	

Edward A. Adelberg	Department of Microbiology, Yale University W. Emmett Barkeley, Head, Environmental Control Section, National Cancer Institute
Louis S. Baron	Department of Bacterial Immunology, Walter Reed Army Institute of Research
Michael Beer	Department of Biophysics, The Johns Hopkins University
Jerome Birnbaum	Basic Microbiology, Merck Institute
J. Michael Bishop	University of California Medical Center, San Francisco
David Botstein	Cold Spring Harbor Laboratory
Herbert Boyer	Department of Microbiology, University of California Medical Center, San Francisco
Donald D. Brown	Department of Embryology, Carnegie Institution of Washington
Robert H. Burris	University of Wisconsin, Madison
Allan M. Campbell	Department of Biology, Stanford University
Alexander Capron	University of Pennsylvania School of Law
John A. CarboN	Department of Biological Science, University of California, Santa Barbara
Dana Carroll	Department of Embryology, Carnegie Institution of Washington
A. M. Chakrabarty	Physical Chemistry Laboratory, General Electric Company
Ernest Chu	Department of Human Genetics, University of Michigan Medical School
Alfred J. Clark	Department of Molecular Biology, University of California, Berkeley
Eloise E. Clark	Division of Biological and Medical Sciences, National Science Foundation
Royston C. Clowes	Institute for Molecular Biology, The University of Texas at Dallas
Stanley Cohen	Department of Medicine, Stanford University Medical School
Roy Curtiss III	Department of Microbiology, University of Alabama Medical Center
Eric H. Davidson	Department of Developmental Biology, California Institute of Technology
Ronald W. Davis	Department of Biochemistry, Stanford University Medical Center
Peter Day	Connecticut Agricultural Experiment Station, New Haven

Vittorio Defendi	Department of Pathology, New York University Medical Center
Roger Dworkin	Department of Biomedical History, University of Washington Medical School
Marshall Edgell	Department of Bacteriology, University of North Carolina, Chapel Hill
Stanley Falkow	Department of Microbiology, University of Washington School of Medicine, Seattle
W. Edmund Farrar, Jr.	Department of Medicine, South Carolina Medical University
Maurice S. Fox	Department of Biology, Massachusetts Institute of Technology
Theodore Friedman	Department of Medicine, University of California, San Diego
William Gartland	National Institute of General Medical Sciences
Harold Green	Fried, Frank, Harris, Schriver, and Kampelman, Washington, D.C.
Irwin C. Gunsalus	University of Illinois, Urbana
Donald R. Helinski	Department of Biology, University of California, San Diego
Robert B. Helling	Department of Botany, University of Michigan
Alfred Hellman	Biohazards and Environmental Control, National Cancer Institute
David S. Hogness	Department of Biochemistry, Stanford University Medical Center
David A. Jackson	Department of Microbiology, University of Michigan Medical School
Leon Jacobs	Collaborative Research, National Institutes of Health
Henry Kaplan	Department of Radiology, Stanford University Medical Center
Joshua Lederberg	Department of Genetics, Stanford University Medical Center
Arthur S. Levine	Section on Infectious Diseases, National Cancer Institute
Andrew M. Lewis	Laboratory of Viral Diseases, National Institute of Allergy and Infectious Diseases
Herman Lewis	Cellular Biology Section, Division of Biological and Medical Sciences, National Science Foundation
Paul Lovett	Department of Biological Sciences, University of Maryland, Baltimore

Morton Mandel	Department of Biochemistry and Biophysics, University of Hawaii School of Medicine
Paul Marks	Medical Affairs, College of Physicians and Surgeons, Columbia University
Malcolm A. Martin	Physical Biochemistry Section, National Institute of Allergy and Infectious Diseases
Robert G. Martin	National Institute of Arthritis, Metabolism, and Digestive Diseases
Carl R. Merril	Laboratory of General and Comparative Biochemistry, National Institute of Mental Health
John Morrow	Department of Embryology, Carnegie Institution of Washington
Daniel Nathans	Department of Microbiology, Johns Hopkins University School of Medicine
Richard P. Novick	Department of Microbiology, Public Health Research Institute, New York
Ronald Olsen	Department of Microbiology, University of Michigan
Richard J. Roberts	Cold Spring Harbor Laboratory
William Robinson	Department of Infectious Diseases, Stanford University Medical Center
Stanfield Rogers	Department of Biochemistry, University of Tennessee Medical Units
Bernard Roizman	Professor of Microbiology and Biophysics, University of Chicago
Joe Sambrook	Cold Spring Harbor Laboratory
Jane Setlow	Brookhaven National Laboratory
Philip Sharp	Center for Cancer Research, Massachusetts Institute of Technology
Aaron J. Shatkin	Roche Institute of Molecular Biology
George R. Shepherd	Los Alamos Scientific Laboratory
Daniel Singer	Hastings Institute of Society, Ethics, and Life Sciences
Robert L. Sinsheimer	Division of Biology, California Institute of Technolog
Anna Marie Skalka	Department of Cell Biology, Roche Institute of Molecular Biology
Mortimer P. Starr	Department of Bacteriology, University of California, Davis
Dewitt Stetten, Jr.	National Institutes of Health

Waclaw Szybalski	McArdle Laboratory, University of Wisconsin, Madison, Wisconsin
Charles A. Thomas, Jr.	Department of Biological Chemistry, Harvard Medical School
Gordon M. Tompkins	Department of Biochemistry and Biophysics, University of California, San Francisco
Jonathan W. Uhr	Department of Microbiology, University of Texas Southwestern Medical School
Raymond C. Valentine	Department of Chemistry, University of California, San Diego
Jerome Vinograd	Departments of Chemistry and Biology, California Institute of Technology
Duard Walker	Department of Medical Microbiology, University of Wisconsin, Madison
Rudolf G. Wanner	Division of Research Services, National Institutes of Health
James Watson	Department of Biology, Harvard University
Peter Weglinski	Department of Biology, Massachusetts Institute of Technology
Bernard Weisblum	Department of Pharmacology, University of Wisconsin Medical School, Madison
Sherman Weissman	Department of Medicine, Biology, and Molecular Biophysics, Yale University
Pieter Wensink	Brandeis University
Frank Young	Department of Microbiology, University of Rochester
Norton D. Zinder	The Rockefeller University
Press Participants	
George Alexander	Los Angeles Times
Stuart Auerbach	Washington Post
Jerry Bishop	Wall Street Journal
Graham Chedd	New Scientist and Nova
Robert Cooke	Boston Globe
Rainer Flohl	Frankfurter Allgemeine
Gail McBride	JAMA
Victor McElheny	New York Times
Colin Norman	Nature

Dave Perlman	San Francisco Chronicle
Judy Randal	Washington Star-News
Michael Rogers	Rolling Stone
Cristine Russell	Bioscience
Nicholas Wade	Science
Janet Weinberg	Science News
Dermot A. O'Sullivan	Chemical and Engineering News

1. OECD Recombinant DNA Safety Considerations Group of National Experts (Taken from OECD 1986).

Participant	**Affiliation**
B.P. Ager	Advisory Committee on Genetic Manipulation, Health and Safety Executive, London, UK
A. Albagli	NRC, Ottawa, ON, Canada
A. Albert	Direccion General de Politica Cientifica, Madrid, Spain
P.H. Andersen	National Food Institute, Institute of Toxicology, Soborg, Denmark
L. Archer	Universidade Nova de Lisboa, Instituto Gulbenkian de Ciencia, Oeiras, Portugal
M. Bara	Faculty of Sciences, Instabul University, Istanbul, Turkey
R.E. Benedick	Environment, Health and Natural Resources, Department of State, Washington, D.C., USA
G. Bernardi	Laboratoire de Genetique Moleculaire, Universite Paris VII, Paris, France
G. Del Bino	Environment, Consumer Protection & NUclear Safety Directorate, Brussels, Commission of the European Communities (CEC)
G. Brunius	Swedish Recombinant DNA Advisory Committee, National Board of Occupational Safety and Health, Solna, Sweden
A.W.J.J. Buijs	Ministry of Housing, Physical Planning and Environment, Leidschendam, Neitherlands
P. Cazala	Minsitre du Redeploiement Industriel et du Commerce Exterieur, Paris, France
M.F. Cantley	Directorate-General for Science, Research and Development, Brussels, CEC

D. Clay	Office of Toxic Substances, Environmental Protection Agency, Washington, D.C., USA
J. Cohrssen	Office of Science and Technology Policy, Washington, D.C., USA
H. Cousy	Katholieke Universiteit Leuven, Leuven, Belgium
J. De Ley	Microbiology Laboratory, Rijksuniversiteit, Ghent, Belgium
S. Doonan	University College, Cork, Ireland
D.L. Dull	Office of Toxic Substances, Environmental Protection Agency, Washington, D.C., USA
Van EE	Gist Brocades N.V., Delft, Netherlands
P. Flaherty	Department of Industry, Technology & Commerce, Canberra, Australia
J.R. Fowle III	Environmental Protection Agency, Washington, D.C., USA
W. Frommer	Bayer AG, Wuppertal, Germany
C. Frontali	Istituto Superoire di Sanita, Laboratorio di Biologia Cellulare
T. Fukumizu	Bioindustry Office, Ministry of International Trade and Industry, Tokyo, Japan
I. Fuller	Industrial Competitive Assessment, Office of the US Trade Representative, Washington, D.C., USA
J. Furesz	Bureau of Biologics, Department of Health and Welfare, Ottawa, ON, Canada
W.J. Gartland	Office of Recombinant DNA Activities, National Institutes of Health, Bethsda, MD, USA
T. Garvey	Internal Market and Industrial Affairs, Brussels, CEC
Vladimir Glisin	Institute for Biological Research, University of Belgrade, Belgrade, Yugoslavia
W. Gundersen	Institute of General Genetics, University of Oslo, Oslo, Norway
H. G. Gyllenberg	Department of Microbiology, University of Helsinki, Helsinki, Finland
D.G. de Haan	Laboratory for Microbiology, Rijksuniversiteit te Utrecht, Utrecht, Netherlands
S. Hagen	State Pollution Control Authority, Oslo, Norway
H. Harada	Institute of Biological Sciences, University of Tsukuba, Sakura-mura, Niihari-gun, Japan
B. Hareide	National Institute of Public Health, Oslo, Norway

B. Harvald	National Research Councils' Registration Committee for Genetic Engineering, Copenhagen, Denmark (until June 1984)
R. Higashiuchi	Ministry of Health and Welfare, Tokyo, Japan
H. Hiramatsu	Bioindustry Office, Ministry of International Trade and Industry, Tokyo, Japan
N. Inoue	Ministry of International Trade and Industry, Tokyo, Japan
T. Ito	Biology and Antibiotics Division, Ministry of Health and Welfare, Tokyo, Japan
W.E.O. Jones	Health and Safety Executive, Medical Division, London
E.L. Kendrick	USDA, Washington, D.C., USA
M.A. Koch	Bundesgesundheitsarnt, Berlin, Germany
M. Koenzi	Ciba-Ceigy AG, Basel, Switzerland
M.C. Kroon	Ministry of Housing, Physical Planning and Environment, Leidschendam, Netherlands
R. Lafferty	Institut fur Biotechnologie, Mikrobiologie und Abfalltechnologie, Graz Uniersity, Graz, Austria
Peter Lange	Bundesministerium fur Forschung und Technologie, Bonn, Germany
M.A. Levin	Office of Research and Development, Environmental Protection Agency, Washington, D.C., USA
E. Lund	Royal Veterinary and Agricultural University of Copenhagen, Copenhagen, Denmark (June 1984 onward)
C. Mantegazzini	Consumer Protection and Nuclear Safety, Brussels, CEC
C. Mazza	Office of Toxic Substances, Environmental Protection Agency, Washington, D.C., USA
T. McIntyre	Environmental Protection Service, Department of the Environment, Ottawa, ON, Canada
E. Milewski	Office of Recombinant DNA Activities, National Institutes of Health, Bethesda, MD, USA
Henry I. Miller	Medical Officer, Food and Drug Administration, Rockville, MD, USA
N. Nelong	Ministere du Redeploiement Industriel et du Commerce Exterieur, Paris, France
N. Nolard	Institut d'Hygiene et d'Epidemiologie, Brussels, Belgium

K.S. Norbraathen	State Pollution Control Authority, Oslo, Norway
R. Nourish	Technology and Air Pollution Division, Health and Safety Executive, Merseyside, UK
A. Oya	Department of Virology and Rickettsiology, National Institute of Health, Tokyo, Japan
H. Pedersen	DVM, National Agency of Environmental Protection, Copenhagen, Denmark
M. Pratt	Ministry of Agriculture, Fisheries and Food, Harpenden, Herts, UK
A.M. Prieels	Services de Programmation de la Politique Scientifique, Brussels, Belgium
P. Printz	Ministere de la Recherce et de la Technologie, Paris, France
R. Revenilla Peoreira	Ministerio de Industria y Energia, Madrid, Spain
W. Roskam (*consultant*)	ELF Bio Recherce, Castanct, Tolosan., France
Ken Sargeant	Directorate-General for Science, Research and Development, CUBE, Brussels, CEC
M. Sarvas	National Public Health Institute, Helsinki, Finland
F. Sauer	Internal Market and Industrial Affairs Directorate, Pharmaceutical Division, Brussels, CEC
H. Schwab	Institut fur Biotechnologie, Mikrobiologie und Abfalltechnologie, Graz Uniersity, Graz, Austria
V. Sgaramella	Dipartimento di Genetica e Microbiologia, University of Pavia, Pavia, Italy
D.B. Shindler	Ministry of State for Science and Technology, Ottawa, ON, Canada
M.L. Smith	Biotechnology Group, Office of Policy Development, Washington, D.C., USA
R.J. Smith	Bureau of Oceans and International Environmental and Scientific Affairs, Washington, D.C., USA
T. Takahashi	Life Sciences Division, Science and Technology Agency, Tokyo, Japan
K. Tanaka	Japan Association for Advanced Research of Pharmaceuticals, Tokyo, Japan
M. Tanaka	Bioindustry Office, Ministry of International Trade and Industry, Tokyo, Japan
Bruna Teso (*OECD Secretariat*)	Directorate for Science, Technology and Industry
J.F.A. Thomas	Department of Environment, London, UK

J.F. Thorley	DISTA Products, Ltd., Liverpool, UK
S. Tolin	USDA, Washington, D.C., USA
S. Tsuru	Council of Agriculture, Forestry and Fisheries, Tokyo, Japan
G. Tzotzos	Ministry of Research and Technology, Department of Science Policy, Athens, Greece
H. Uchida	University of Tokyo, Tokyo
William J. Walsh, III	Biomedical Research and Health Affairs, Department of State, Washington, D.C., USA
I. Watanbe	Faculty of Hygiene, Kitazato University, Sagarnihala-City, Japan
C. Whitehead	Consumer Protection and Nuclear Safety Directorate, Brussels, CEC
F.E. Young	Food and Drug Administration, Rockville, MD, USA

2. Canadian Agri-Food Research Council - Workshop on the Regulation of Agricultural Products of Biotechnology
December 4-7, 1988 (Ottawa, Ontario) (Taken from CARC 1988).

Attendee	**Affiliation**
S.D. Acres	VIDO, Saskatoon, SK
D.C. Alexander	Veterinary Biologics, Health of Animals Directorate, Agriculture Canada, Ottawa, ON
W.D. Beversdorf	Department of Crop Science, University of Guelph, Guelph, ON
R. Blair	Department of Animal Science, University of British Columbia, Vancouver, BC
R. Blewett	Feed and Fertilizer Division, Plant Health Directorate, FP&I Branch, Agriculture Canada
Martin Boddington	Commercial Chemicals Branch, Environment Canada, Hull, QC
W.T. Bradnock	Seed Division, FP&I Branch, Agriculture Canada, Ottawa, ON
Al Brown	Norden Laboratories, Inc., Lincoln, NE
Allan Brown	DuPont Canada Ltd., Mississauga, ON
W. Bulmer	Animal Health Division, Health of Animals Directorate, FP&I Branch, Agriculture Canada, Ottawa, ON
V.D. Burrows	Plant Research Centre, Research Branch, Agriculture Canada, Ottawa, ON

C.D. Caldwell	Plant Science Department, Nova Scotia Agricultural College, Truro, NS
K.W. Campbell	Funk Seeds, Plattsville, ON
J.R. Castagno	Allelix, Inc., Mississauga, ON
A. Cepica	Atlantic Veterinary College, University of Prince Edward Island, Charlottetown, PEI
R.G. Christian	Research Division, Alberta Agriculture, Edmonton, AB
Orrin Clayton	Canadian Seed Growers' Association, Ottawa, ON
W.P. Cochrane	Laboratory Services Division, Food Inspection Directorate, FP&I Branch
Brian Cox	Guelph-Waterloo Biotech, Office of Research, University of Guelph, Guelph, ON
John V. Cross	Philom Bios Inc., Saskatoon, SK
L. de March	Freshwater Institute, Fisheries and Oceans Canada, Winnipeg, MB
E. Dickson	Biotechnology and Health Care Products, ISCT Canada, Ottawa, ON
L.H. Duke	Plant Health Directorate, FP&I Branch, Agriculture Canada, Ottawa, ON
J.I. Elliot	Animal Research Centre, Research Branch, Agriculture Canada, Ottawa, ON
G. Fedak	Plant Research Centre, Research Branch, Agriculture Canada, Ottawa, ON
G. Flores	Pesticide Directorate, FP&I Branch, Agriculture Canada, Ottawa, ON
Sheila Forsyth	Pesticide Directorate, FP&I Branch, Agriculture Canada, Ottawa, ON
D.J. Gannon	R&D Biotechnology, CIL Research Centre, Mississauga, ON
Ann Gibbins	Department of Animal and Poultry Science, Ontario Agricultural College, Guelph, ON
D. Gordon	Feeds and Fertilizer Division, Plant Health Directorate, FP&I Branch, Agriculture Canada, Ottawa, ON
Wayne Gosselin	Saskatchewan Agriculture, Regina, SK
R.D. Gray	Plant Health Directorate, FP&I Branch, Agriculture Canada, Ottawa, ON
S. Haber	Winnipeg Research Station, Research Branch, Agriculture Canada, Ottawa, ON
J. Peter Hall	Canadian Forestry Service, Hull, QC

W.C.D. Hare	Animal Diseases Research Institute, FP&I Branch, Agriculture Canada, Ottawa, ON
Bryan L. Harvey	Department of Crop Science, University of Saskatchewan, Saskatoon, SK
M.W. Henry	Allelix Inc., Mississauga, ON
S.K. Ho	Animal Research Centre, Research Branch, Agriculture Canada, Ottawa, ON
Jean E. Hollebone	Issues, Planning and Priorities Division, Pesticide Directorate, FP&I Branch, Agriculture Canada, Ottawa, ON
F.J. Ingratta	Horticulture Research Institute of Ontario, Vineland Station, ON
M. Kalous	Seed Division, Plant Health Directorate, FP&I Branch, Agriculture Canada, Ottawa, ON
M. Kenny	Feed and Fertilizer Division, Plant Health Directorate, FP&I Branch, Agriculture Canada, Ottawa, ON
K.J. Kirkland	Scott Experimental Farm, Research Branch, Agriculture Canada, Scott, SK
D.R. Knott	College of Agriculture, University of Saskatchewan, Saskatoon, SK
T.C. Kuchnicki	Commercial Chemicals Branch, Environment Canada, Hull, QC
Andrew Lam	Plant Health Directorate, FP&I Branch, Agriculture Canada, Ottawa, ON
W. Leask	Canadian Seed Trade Association, Ottawa, ON
H. Lerer	Commercial Chemicals Branch, Environment Canada, Hull, QC
K.A. MacMillan	Legal and Regulatory Affairs, Monsanto Canada Inc., Mississauga, ON
A. MacDonald	Pesticides Directorate, FP&I Branch, Agriculture Canada, Ottawa, ON
D. Mahon	Toxicological Evaluation Division, Health and Welfare Canada, Ottawa, ON
E.K. Makowski	Hoechst Canada Inc., Regina, SK
Margaret Maxwell	Langford, Inc., Guelph, ON
Sally McCammon	BBEP, APHIS, USDA, Hyattsville, MD
A.G. McHughen	Department of Crop Science, University of Saskatchewan, Saskatoon, SK
T. McIntyre	Commercial Chemicals Branch, Environment Canada, Hull, QC
Terry L. Medley	APHIS, USDA, Hyattsville, MD

J.R. Messier	Bureau Veterinary Drugs, Health and Welfare Canada, Ottawa, ON
G.W. Miller	Plant Health Directorate, FP&I Branch, Agriculture Canada, Ottawa, ON
J.D. Miller	Plant Research Centre, Research Branch, Agriculture Canada, Ottawa, ON
R. Morgan	Saskatchewan Wheat Pool, Saskatoon, SK
E.D. Murray	Food Science Department, University of Manitoba, Winnipeg, MB
W. Murray	Agricultural Chemicals Section, Food Directorate, Health and Welfare Canada, Ottawa, ON
A.J. Myers	Plant Health Directorate, FP&I Branch, Agriculture Canada, Ottawa, ON
G.A. Neish	Research Branch, Agriculture Canada, Ottawa, ON
E.R. Nestmann	CanTox Inc., Oakville, ON
A.O. Olson	Research Branch, Agriculture Canada, Ottawa, ON
J.F. Pantekoek	Animal Health Division, FP&I Branch, Agriculture Canada, Ottawa, ON
N.J. Poole	Plant Protection Division, Imperial Chemical Industries, Bracknell, Berks. UK
V. Poysa	Research Branch, Agriculture Canada, Harrow, ON
Patricia A. Rae	Sim, Hughes, Dimock, Toronto, ON
Kathy R. Rasmussen	Conti-Seeds Ltd., Winnipeg, MB
R.D. Reichert	NRC, Calgary, AB
I.R. Reid	FP&I Branch, Agriculture Canada, Ottawa, ON
L. Ritter	Pesticide Division, Bureau of Chemical Hazards, Environmental Health Center, Ottawa, ON
Real Roy	Plant Health Directorate, FP&I Branch, Agriculture Canada, Ottawa, ON
S. Sabijanski	Department of Biochemistry, University of Ottawa, Ottawa, ON
Ron Scharfe	Laboratory Services Division, Food Inspection Directorate, FP&I Branch, Agriculture Canada, Ottawa, ON
B. Samagh	Animal Diseases Research Institute, Health of Animals Directorate, Nepean, ON
Frank Scott-Pearse	King Agro Inc., Chatham, ON

W.R. Scowcroft	Research and Development, BioTechnica Canada, Calgary, AB
F. Sedun	Safer Ltd., Victoria, BC
K.A. Seifert	Forintek Canada Corp., Ottawa, ON
Wendy A. Sexsmith	New Brunswick Department of Municipal Affairs and Environment, Fredericton, NB
David B. Shindler	Canadian High Commission, London, UK
J. Smith	Environmental Health Directorate, Health and Welfare Canada, Ottawa, ON
W.F. Steck	Plant Biotechnology Institute, NRC, Saskatoon, SK
I.L. Stevenson	Plant Research Centre, Research Branch, Agriculture Canada, Ottawa, ON
W. Stewart	Priorities, Strategies Directorate, Grains and Oilseeds Branch, Agriculture Canada, Ottawa, ON
L.A. Stobbs	ELANCO, Eli Lilly Canada Ltd., London, ON
C.M. Switzer	Ministry of Agriculture and Food, Toronto, ON
Aladar Szalay	Department of Plant Science, University of Alberta, Edmonton, AB
R.G. Taylor	Pesticide Directorate, FP&I Branch, Agriculture Canada, Ottawa, ON
F.C. Thomas	Animal Diseases Research Institute, Health of Animals Directorate, Nepean, ON
S. Thompson	Agricultural Inspection Directorate, FP&I Branch, Agriculture Canada, Ottawa, ON
Peggy Tsang	Pesticide Division, Bureau of Chemical Hazards, Health and Welfare Canada, Ottawa, ON
Brian Ure	ELANCO, Eli Lilly Canada Ltd., Scarborough, ON
Richard Veinot	Production Services Branch, PEI Department of Agriculture, Charlottetown, PEI
Ivan Veliky	Division of Biological Sciences, NRC, Ottawa, ON
H. Versteeg	Pesticide Management Advisory Board, Ottawa, ON
Claude Vezina	Institut Rosell Inc., Montreal, QC
R. Walter	ISTC Canada, Ottawa, ON
Alan Watson	Department of Crop Science, Macdonald College, Ste-Anne-de-Bellevue, QC

Martin Weintraub	Agriculture Canada, Vancouver, BC
Jessie Weldon	Biotechnology Office, ISTC Canada, Ottawa, ON
R.F. Welton	Masterfeeds, Feed Division, Maple Leaf Mills, London, ON
Bruce N. Wilkie	Ontario Veterinary College, University of Guelph, Guelph, ON

References

(1977). Testimony by Paul Berg. US Senate Subcommittee on Science, Technology and Space. Washington, DC, Legislative Record.**:** 1-8.

Abergel, E. and K. Barrett (2002). "Putting the cart before the horse: a review of biotechnology policy in Canada." Journal of Canadian Studies 37(7).

Adler, E. and P. M. Haas (1992). "Conclusion: epistemic communities, world order, and the creation of a reflective research program." International Organization 46(1): 24.

Ag West Bio (2007). Final Workshop Report. Canada's Regulations for Novelty in Plants, Feed and Food, Saskatoon.

van Apeldoorn, J. H. F., Ed. (1981). Biotechnology: A Dutch Perspective. Report by the Netherlands Study Centre for Technology Trends. Amsterdam, Delft University Press.

Auditor General (2004). Report of the Auditor General of Canada to the House of Commons. Chapter 4: Canadian Food Inspection Agency - Regulation of Plants with Novel Traits. Ottawa, ON. 1-32.

Balla, Steven J. (2001). "Interstate Professional Associations and the Diffusion of Policy Innovations." American Politics Research 29(3): 221-245.

Barrett, K., and E. Abergel (2000). "Breeding unfamiliarity: environmental risk assessment for genetically engineered crops in Canada." Science and Public Policy 27(1): 2-12.

Baumgartner, Frank and Bryan D. Jones (1993). Agendas and Instability in American Politics. Chicago: University of Chicago Press.

Beland, Daniel (2009). "Ideas, institutions and policy change." Journal of European Public Policy 16(5): 701-718.

Berg, P., D. Baltimore, et al. (1974). "Potential Biohazards of Recombinant DNA Molecules." Science **185**(4148): 303.

Berg, P., D. Baltimore, et al. (1975). "Summary Statement of the Asilomar Conference on Recombinant DNA Molecules." Proceedings of the Academy of Sciences of the United States of America 72(6): 4.

Bernstein, S., and B. Cashore (2012). "Complex global governance and domestic policies: four pathways of influence." International Affairs 88 (3): 585-604.

Berry, Frances Stokes and William D. Berry (1990). "State Lottery Adoptions as Policy Innovations: An Event History Analysis." American Political Science Review 84(2): 395-415.

Berry, Frances Stokes and William D. Berry (1992). "Tax Innovation in the States: Capitalizing on Political Opportunity." American Journal of Political Science 36(3): 715-742.

Berry, Frances Stokes and William D. Berry (1999). "Innovation and Diffusion Models in Policy Research." In Theories of the Policy Process, ed. Paul A. Sabatier. Theoretical Lenses on Public Policy. Boulder, CO: Westview Press, 169-200.

Bradford, N. (1998). Commissioning ideas : Canadian national policy innovation in comparative perspective. Toronto: Oxford University Press Canada.

Bull, A. T., G. Holt, et al. (1982). Biotechnology: International Trends and Perspectives. Paris, OECD: 1-78.

Cameron, Donald and Ian G. Jones (1983). "John Snow, the Broad Street Pump, and Modern Epidemiology." International Journal of Epidemiology 12(4): 393-396.

CARC (1988). Proceedings. Workshop on Regulation of Agricultural Products of Biotechnology, Ottawa, ON, Canadian Agricultural Research Council.

Carpenter, D. (2001). The forging of bureaucratic autonomy : reputations, networks, and policy innovation in executive agencies, 1862-1928. Princeton, NJ: Princeton University Press.

CBD (1992). Convention on Biological Diversity. Rio de Janeiro. Available from: http://www.cbd.int/convention/text/

CBSA 1998. NAFTA Harmonized Laboratory Methods. Memorandum D 11-12-1. Canadian Border Services Agency.

CBAC (2003). "Biotechnology Regulatory Framework Advisory Memorandum". Canadian Biotechnology Advisory Committee.

CFIA (1993). "Federal Government Agrees on New Regulatory Framework for Biotechnology." Canadian Food Inspection Agency. Retrieved June 3, 2010, from http://www.inspection.gc.ca/english/sci/biotech/reg/fracade.shtml.

CFIA, et al. (1998). Summary Report: Canada - US Bilateral Discussions on Agricultural Biotechnology. Canadian Food Inspection Agency. Ottawa, Canada.

CFIA, et al. (2000). Summary Report: Canada - US Bilateral Discussions on Agricultural Biotechnology - Amendments. Canadian Food Inspection Agency. Ottawa, Canada.

Cohen, Michael, et al (1972). "A Garbage Can Model of Organizational Choice." Administrative Science Quarterly 17 (1), 1-25.

Crisp, D. E. (1974). "Proteins for the New Generation." Nutrition and Food Science 74(3): 4.

CTNBio (2005). Law 11.105: Biosafety Law. Comissão Técnica Nacional de Biossegurança. Brasilia.

Dolowitz, David P. and David Marsh (2000). "Learning From Abroad: The Role of Policy Transfer in Contemporary Decision Making." Governance 13(1): 5-24.

Dyer, S. (1998). "Flexibility Models - A Critical Analysis." International Journal of Manpower **19**(4): 11.

EEC (1990). Council Directive 90/220/EEC: On the deliberate release into the environment of genetically modified organisms.

European Commission (1997). Novel Food Regulation (EC) 258/97. Council of the European Union. Brussels.

Evanson, R.E. and D. Gollin (2003). "Assessing the Impact of the Green Revolution: 1960 to 2000." Science 300(5620): 758-762.

Fedak, George (2013). Marquis Wheat. In The Canadian Encyclopedia. http://www.thecanadianencyclopedia.ca/en/article/marquis-wheat/

Food and Drug Administration (1992). Food for human consumption and animal drugs, feeds and related products: Foods derived from new plant varieties; policy statement, 22984. Department of Health and Human Services. Washington, D.C. 57.

Funtowicz, S., and J. Ravetz (1994). "Emergent Complex Systems." Futures 26(6): 568-582.

GATT (1986). The General Agreement on Tariffs and Trade. Geneva.

Gray, Virginia (1973). "Innovation in the States: A Diffusion Study." American Political Science Review 67(4): 1174-1185.

Griffiths, A.J.F., et al. (2000). "Making recombinant DNA." An Introduction to Genetic Analysis. 7th edition. New York: W. H. Freeman. Available from: http://www.ncbi.nlm.nih.gov/books/NBK21881.

Griliches, Zvi (1957). "Hybrid Corn: An Exploration in the Economics of Technological Change." Econometrica 25(4): 501-522.

Grossback, L.K., et al. (2004). "Ideology and Learning in Policy Diffusion." American Politics Research 32(5): 521-545.

Haas, P. M. (1992). "Introduction: Epistemic communities and international policy coordination." International Organization **46**: 1-35.

Hale, Kathleen (2011). How information matters: networks and public policy innovation. Washington DC: Georgetown University Press.

Hall, Peter A (1993). “Policy paradigms, Social learning and the State: the case of economic policymaking in Britain.” Comparative Politics 25(3): 275-292.

Health Canada (1994). Guidelines for the Safety Assessment of Novel Foods. Health Canada. Ottawa: ON. 1-32.

Hoberg, George (1991). “Sleeping With An Elephant: The American Influence on Canadian Environmental Regulation.” Journal of Public Policy 11(1): 107-131.

Howlett, Michael (2000). "Beyond Legalism? Policy Ideas, Implementation Styles and Emulation-Based Convergence in Canadian and U.S. Environmental Policy." Journal of Public Policy 20(3): 305-329.

Isaac, G. E. (2006). Biotechnology Policy and the Risk Analysis Framework. Governing Risk in the 21st Century: Lessons from the World of Biotechnology. P. Phillips, S. Smyth and W. Kerr, Nova Science Publishers**:** 15.

Jonas, D. (2000). "Safety Evaluation Of Novel Foods: A European and International Perspective." EUFIC Review: Reference Paper of the European Food Information Council: 3.

Ka, Sangjoon and Paul Teske (2002). “Ideology and Professionalism: Electricity Regulation Over Time in the American States.” American Politics Research 30(3): 323-343.

Kaphengst, Timo, et al. (2011). Assessment of the economic performance of GM crops worldwide. Report to the European Commission. Council of the European Union. Brussels.

Kraemer, et al. (1992). “Economic Development, Government Policy, and the Diffusion of Computing in Asia-Pacific Countries.” Public Administration Review 52(2): 146-156.

Levidow, L. and S. Carr (2000). "Normalizing Novelty: Regulating Biotechnological Risk at the US EPA." Risk: Health, Safety and Environment 11(9): 9-34.

Lindblom, Charles E (1959. "The Science of Muddling Through". Public Administration Review 19 (2), 79-88.

Lusser, Maria et al (2012). “Deployment of New Biotechnologies in Plant Breeding.” Nature Biotechnology 30(3): 231-239.

Luttrell, C.B. (1973). "The Russian Wheat Deal - Hindsight vs. Foresight". Federal Reserve Bank of St. Louis.

Meltsner, A. (1972). "Political Feasibility and Policy Analysis". Public Administration Review 32(6): 859-867.

Miller, H. I. and G. Conko (2004). The Frankenfood Myth: How Protest and Politics Threaten the Biotech Revolution. The Frankenfood Myth: How Protest and Politics Threaten the Biotech Revolution. H. I. Miller and G. Conko. Westport, Praeger Publishers.

Mintrom, M. (1997). "Policy Entrepreneurs and the Diffusion of Innovation." American Journal of Political Science 41(3): 738-770.

Mintrom, M. and S. Vergari (1996). "Advocacy Coalitions, Policy Entrepreneurs and Policy Change." Policy Studies Journal 24(3): 420-434.

Monpetit, E. (2005). "A Policy Network Explanation of Biotechnology Policy Differences Between the USA and Canada." Journal of Public Policy 25(3): 28.

Mytelka, Lynn K., and K. Smith (2002). "Policy learning and innovation theory: an interactive and co-evolving process." Research Policy 31: 1467-1479.

NAS (1975). Appendix A: Participants. International Conference on Recombinant DNA Molecules. National Academy of Sciences. Asilomar, California.

National Forum on Seed (2006). Plants with Novel Traits: Working Group I Summary. Ottawa, ON, National Forum on Seed: 8.

OECD (1986). Recombinant DNA Safety Considerations. Geneva, Organisation for Economic Co-operation and Development: 74.

OECD (1993a). Safety Considerations for Biotechnology Scale-Up of Crop Plants. Paris, Organisation for Economic Co-operation and Development: 43.

OECD (1993b). Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles. Paris: 77.

OECD (2014). "Expert advisory group". Retrieved July 5, 2014, from http://www.oecd.org/site/innovationstrategy/expertadvisorygroup.htm.

Office of Science and Technology Policy (1986). Coordinated Framework for Regulation of Biotechnology. Washington, D.C., Executive Office of the President: 123.

OGTR (2000). Gene Technology Act. Office of the Gene Technology Regulator. Canberra.

PAG/UNU (1983). Revised PAG Guidelines. Food and Nutrition Bulletin. U.N.U. Protein Advisory Group. 5.

Phillips McDougall. (2011). "The cost and time involved in the discovery, development and authorisation of a new plant biotechnology derived trait." Crop Life International. 1-24.

Phillips, P. 2009. The kaleidoscope of risk analysis: The state of the art 25 years after the Red Book. Commentary on the proceedings of the 1st International Conference on Risk Assessment, Brussels, November 18-19.

Plant Biosafety Office (1994). Regulatory Directive 94-08: Assessment Criteria for Determining Environmental Safety of Plants With Novel Traits. Canadian Food Inspection Agency. Ottawa, ON.

Plant Biosafety Office (1996). Regulatory Directive 96-13: Import Permit Requirements for Plants with Novel Traits (incuding Transgenic plants) and their products. Canadian Food Inspection Agency. Ottawa, ON.

Plant Biosafety Office (2000). Regulatory Directive 2000-07: Guidelines for the Environmental Release of Plants with Novel Traits Within Confined Research Field Trials in Canada. Canadian Food Inspection Agency. Ottawa, ON.

Plant Biosafety Office (2009). Regulatory Directive 2009-09: Plants with novel traits regulated under Part V of the Seeds Regulations: Guidelines for determining when to notify the CFIA. Canadian Food Inspection Agency. Ottawa, ON.

Rittel, H.W.J. and M.M. Webber (1973). "Dilemmas in a General Theory of Planning." Policy Sciences 4: 155-169.

Rogers, E. (2003). Diffusion of Innovations. Fifth Edition. New York: Free Press.

Rose, R. (1991). "What Is Lesson-Drawing?" Journal of Public Policy 11(1): 29.

Rose, R. (1993). Lesson Drawing in Public Policy: A Guide to Learning Across Time and Space. Chatham: Chatham House.

Rose, R. (2005). Learning from Comparative Public Policy: A Practical Guide. New York City, Routledge.

Sanderson, I (2002). "Evaluation, Policy learning and Evidence-Based Policy Making." Public Administration 80(1): 1-22.

Seed Sector Review (2004). Report of the Seed Sector Advisory Committee. Ottawa, Agriculture and Agri-Food Canada: 82.

Shapiro, C., and H.R. Varian (1999). Information Rules: A Strategic Guide to the Network Economy. Boston: Harvard Business School Press.

Shipan, Charles R. and Craig Volden (2008). “The Mechanisms of Policy Diffusion.” American Journal of Political Science 52(4): 840-857.

Simon, Herbert A (1955). "A Behavioral Model of Rational Choice." The Quarterly Journal of Economics 69 (1), 99-118.

Singer, M. and D. Soll (1973). "Guidelines for DNA Hybrid Molecules " Science **181**(4105): 1114.

Smyth, S. (2009). Forestalling Liabilities? Stakeholder Participation and Regulatory Development. Emerging Technologies: From Hindsight to Foresight. E. F. Einsiedel. Vancouver, UBC Press: 20.

Stone, Deborah (1989). "Causal Stories and the Formation of Policy Agendas". Political Science Quarterly 104(2), pp. 281-300.

Stone, Deborah (2002). Policy Paradox: The Art of Political Decision Making. New York, NY: Norton, 1-448.

Strauss, D (2009). "The Application of TRIPS to GMOs: International Intellectual Property Rights and Biotechnology." Stanford Journal of International Law 45: 287-320.

Walker, Jack L. (1969). "The Diffusion of Innovations among the American States." The American Political Science Review 63(3): 880-899.

Weyland, Kurt (2005). "Theories of Policy Diffusion: Lessons from Latin American Pension Reform." World Politics 57(2): 262-295.

Weyland, Kurt (2008). "Toward A New Theory of Institutional Change." World Politics 60(2): 281-314.

Sabatier, Paul A. (1988). "An advocacy coalition framework of policy change and the role of policy-oriented learning therein." Policy Sciences 21 (2-3): 129-168.

Waltz, Emily (2012). "Tiptoeing Around Transgenics." Nature Biotechnology 30(3): 215-217.

Westphal, J.D. et.al. (1997). "Customization or conformity? An institutional and network perspective on the content and consequences of TQM adoption." Administrative Science Quarterly 42(2): 366-394.

WHO (1991). Strategies for assessing the safety of foods produced by biotechnology: Report of a joint Food and Agriculture Organization/World Health Organization consultation. World Health Organization. Geneva: 1-28.

WTO (1995a). "Agreement on Technical Barriers to Trade." World Trade Organization. Geneva. Available from: http://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

WTO (1995b). "Agreement on the Application of Sanitary and Phytosanitary Measures." World Trade Organization. Geneva. Available from: http://www.wto.org/english/docs_e/legal_e/15sps_01_e.htm

WTO (1995c). "Marrakesh Agreement Establishing the World Trade Organization." World Trade Organization. Geneva. Available from: http://www.wto.org/english/docs_e/legal_e/04-wto_e.htm