SCIENCE, INTERNATIONALIZATION, AND POLICY NETWORKS: REGULATING GENETICALLY-ENGINEERED FOOD CROPS IN CANADA AND THE UNITED STATES, 1973-1998

by

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ABSTRACT

The early history of the commercialization of genetically-engineered food crops in Canada and the United States is a cautionary tale that underlines the importance of adequate policy capacity. As of the late 1990s, precedent-setting regulatory responses had established far more systematic evaluations of environmental and food safety risks of new plant varieties but were failing to secure consumer acceptance at home and abroad. This case study compares the two countries' responses, as global pioneers in the use of these crops, to the three issues of environmental release, food safety, and food labelling.

The comparison reveals that despite expected pressures for Canadian policy choices to converge with American models, Canadian regulators have been given greater discretion and capacity to respond to the issues of environmental release and food safety. Domestic variables explain much of the substance of policy choices in both countries including these differences. Variation in the scope of regulation across issues and countries correlates with differing domestic policy networks. Further, the role of science as an idea and resource within domestic policy networks varies consistently with the degree of discretion and thus capacity given to regulators across issues. The effects of internationalization are largely in shaping preferences and contributing to resources exploited within domestic policy networks. This result suggests that it is difficult to gauge fully the impact of internationalization on domestic policy making without exploring its interaction with domestic institutions.

Guided by historical institutionalism, the case study includes an assessment of the inertia of policy legacies and the constraints on policy making imposed by policy boundaries. Policy legacies provide starting points for policy making, including levels of state capacity and autonomy. Policy boundaries (created by key moments of the intersection of ideas, interests, and institutions)

shift advantage within policy networks.

Lessons from the case study include the conclusion that policy capacity may rest substantially on three interrelated factors: first, *state capacity and autonomy*; second, *scientific legitimacy* (the way in which science is used during policy making); and third, *democratic legitimacy* (conducting policy making in a manner that will be widely perceived as legitimate in a democratic sense).

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INTRODUCTION

The first quarter-century of the prophesized modern biotechnology revolution came to a close in 1998.[1] Its constant companion was hyberbole about both the great promise and the irreversible risks of applying genetic engineering. The first successful transfer of genetic material from one organism to another in 1973 through recombinant DNA techniques ushered in the era of genetic engineering. During the 1980s and 1990s, the technology and its applications advanced rapidly. Medical, agricultural, food processing, and environmental applications of genetic engineering became commonplace.[2] The potential socioeconomic impact of genetic engineering has resulted in comparisons to previous technological revolutions that have disrupted and restructured economic and social relationships, including the Industrial Revolution and the informatics / computer revolution. Like the technologies of these earlier revolutions, genetic engineering was not subjected to a democratic screening process prior to its pursuit. There was no weighing of its benefits and costs to humanity for the purpose of seeking a consensus on whether to proceed. Its application raises scientific, socioeconomic, and ethical questions that are difficult or impossible to answer with certainty or through consensus.

For policy makers, genetic engineering has raised some challenging issues such as: Should there be a coordinated policy response to a technology that spans such discrete and disparate policy sectors as health, mining, fisheries, and agriculture? And how should policy making assess and respond to competing claims about benefits and risks with only limited data on which to base policy choices? Theoretically, there are no limits to the tasks to which genetic engineering can be applied. From altering a single trait in a crop plant to cloning humans, the virtually immeasurable scope of the utility of this technology suggests that products commercialized and in the developmental pipeline as of the late 1990s are truly only the tip of the iceberg. It is this immense scope and the vast range of potential applications that fuel controversy over genetic engineering and

[1] It is the development of *genetic engineering*, often used as a synonym for recombinant DNA (rDNA) techniques, that has provoked the regulatory policy responses examined in this dissertation. However, the less precise and older term *biotechnology* , or sometimes *modern biotechnology*, is favoured by state and industry officials in Canada and the United States. Here, the term *biotechnology* is used to refer to the industry and issue generally, and the term *genetic engineering* when referring specifically to the use of rDNA techniques. See the Appendix for a brief primer on genetic engineering.

[2] For general discussions of genetic engineering, its likely applications, and potential impacts, see Yoxen (1983), Wheale and McNally (1988), Wheale and McNally (1990), Krimsky (1991), Davis (1991), Fox (1992), Tudge (1993), Grace (1997), and Rifkin (1998).

subsequent demands from some quarters for policy makers to establish limits on its use.

Few new technologies in recent times have generated such dramatic speculation. Visions crafted of the biotechnological future range from a new Garden of Eden to apocalyptic nightmares.[3] Current agricultural applications, if one believes everything one reads, will result in any or all of the following: keep food prices low or increase them, solve world hunger or threaten food security, increase or reduce the sustainability of agricultural practices, result in environmental havoc by disrupting ecosystems, and create new food safety threats or provide better quality food.[4] Against the backdrop of these contradictory claims, policy makers have made choices about whether and how to regulate the development and products of this technology.

This dissertation compares regulatory responses to the commercialization of genetically-engineered crop plant varieties in Canada and the United States. It examines how science and internationalization work, and sometimes intersect, within policy communities and networks, and consequently shape policy making. The study results in findings that can be applied elsewhere. Regulation of biotechnology is one of a growing number of policy areas characterized both by contestation of its scientific underpinnings and internationalization. These other policy areas include climate change, fisheries management, food safety, and pesticide regulation. These policy areas often pit perceptions of economic rewards and costs against those of environmental and/or health risks. They confront policy makers with the "postindustrial quandary" of issues that are complex and often scientific in an era when citizens are demanding greater participation in policy making.[5] Higher levels of education, growing accessibility to information, and the unpleasant surprises that have accompanied the introduction of the products of other recent innovative technologies, such as nuclear energy, encourage citizens to be scientific skeptics. In an era of continuous innovation, when new scientific theories are constantly relegating older ones to the

[3] Biotechnology skeptics often argue that the predicted benefits of using genetic engineering in agriculture have received far less scrutiny than arguments about potential risks. For example, Krimsky and Wrubel (1996): 231 warn that optimism surrounding the potential of genetic engineering has resulted in a "myth of genetic power" that can be used to blunt criticism.

[4] This list of predictions does not include the effects of other products under development in the late 1990s, such as plants that produce industrial chemicals, pharmaceutical drugs and vaccines, and help to clean up toxic waste.

[5] See Pierce et al (1992) for a discussion of this "postindustrial quandary" which they describe as the intersection of value change at the level of individuals (which results in changing policy demands, including the amount of influence on policy choices) and the increasing scientific content of both old and new issues (the by-product of the continuous scientific discovery that characterizes postindustrial society).

dustbin, citizens are more aware that scientific knowledge is rarely final or absolute. They are less hesitant to express apprehensions about the possible risks accompanying new technologies.[6] In the postindustrial era, public perception that regulatory measures are adequate to protect environmental and human health is critical to acceptance of a new technology. Policy makers turn to risk analysis in the hope that it will provide an authoritative basis for regulatory policy choices that in turn will bolster public confidence in regulation. The reliance on risk analysis to regulate agricultural biotechnology places science at the centre of policy making in the form of scientific expertise and authority. The location of expertise becomes a key determinant of the nature of policy communities and networks. At the same time, the use of risk analysis to respond to issues characterized by high levels of scientific uncertainty about long-term risks erodes the neutral image of science on which scientific authority is based.

THE CASE OF REGULATING PLANT BIOTECHNOLOGY

This dissertation focuses on one aspect of the pursuit of commercial applications of genetic engineering: its use in plant agriculture.[7] Plant biotechnology, which uses the techniques of genetic engineering to add new traits to conventional plant varieties, is one of the earliest commercial applications of genetic engineering. The first genetically-engineered plant varieties were developed in the early 1980s, although widespread cultivation began only in the mid-1990s.[8] In Canada and the US producers rapidly switched to genetically-engineered plants in the late 1990s

[6] This study does not examine the role of public opinion, if any, in shaping regulatory responses. In the late 1990s, public awareness in North America of the use of genetic engineering in agriculture was growing quickly as the first generation of products reached the marketplace and as a spillover from the adverse consumer reaction in Europe. However, for much of the period examined in this dissertation, agricultural biotechnology was not highly visible as a policy issue among the public. There have been several efforts to measure public opinion toward biotechnology generally, as well as toward the products of agricultural biotechnology. Most of these efforts have been funded by proponents of biotechnology as part of strategies to educate the public about genetic engineering. See the Appendix for a brief summary of some survey results.

[7] Restricting a case study to one discipline within agricultural sciences facilitates comparison across countries and reflects the reality of the separation between disciplines. There has been movement toward more interdisciplinary research in agricultural science in the 1980s and 1990s, increasing informal interaction among scientists across disciplines. However, the more formal institutions that bring together agricultural scientists for regular interaction, especially the scientific societies, still tend to segregate the disciplines. This study further focuses only on major food crops, excluding cotton and tobacco for example, although the use of these crops is regulated by some of the same measures.

[8] The American company Monsanto has been a pioneer in the development of genetically-engineered plants. It genetically engineered a plant cell in 1982 and was growing whole genetically-engineered plants by February 1983. For a brief in-house history of Monsanto's efforts in agricultural biotechnology, see Rogers (1996, 1997).

(see Table I-1).[9] In 1998, seventy million acres worldwide were planted with genetically-engineered varieties, up from thirty-one million acres in 1997, and seven million in 1996. Biotechnology proponents predict this rapid growth will continue as more seed and more varieties become available, including genetically-engineered wheat which is expected early in the first decade of the new century. Almost all of the seventy million acres sown in 1998 were with varieties genetically-engineered to include the trait of herbicide tolerance or that of insect resistance. Of those seventy million acres, the US grew fifty-one million and Canada grew seven million.[10] Most of the acres were sown in corn, canola, or soybeans. In 1998, 50 per cent of the Canadian canola crop, 32 per cent of the American soybean crop, and 25 per cent of the American corn crop came from genetically-engineered varieties.[11]

For many observers, genetic engineering of plants poses fewer ethical issues than applying the same techniques to humans or animals. The potentially huge-scale adoption of genetically-engineered plants, however, has provoked questions about their environmental, human health, and socioeconomic impacts. These questions have encouraged some citizens to oppose the application of genetic engineering to agriculture outright. Others have called for a more cautious approach to the use and commercialization of its products. Resistance to new technologies is not new, but genetic engineering's position in the procession, on the heels of the rosy promises of the now-blemished agri-chemical and nuclear energy industries, ensures it a rougher ride. Genetic engineering is being developed in an era when concepts like ecosystems and the precautionary principle have become familiar, although not yet widely institutionalized. Further, the use of risk analysis techniques presents the possibility of precautionary regulation. As Krimsky notes, unlike much regulation which is a response to evidence of undesirable outcomes, the biotechnology industry initially had the distinction of being regulated on the basis of speculation. Early regulatory policy choices were made with little or no evidence of any hazards arising from the actual use of these products.[12]

[9] James (1997) and Union of Concerned Scientists (1998). See the web site of the International Service for the Acquisition of Agri-Biotech Applications at http://www.isaaa.cornell.edu/ for the latest statistics.

[10] Other countries growing significant acreages of genetically-engineered crops in the late 1990s were Argentina and China.

[11] See Union of Concerned Scientists (1998) for the American statistics. Statistics on the Canadian canola crop come from the Canola Council of Canada. Further, in 1998, 45 per cent of the American cotton crop was planted in genetically-engineered varieties.

[12] Krimsky (1991): 182.

Beyond the health and environmental questions explored in this dissertation, questions have also been raised about the socioeconomic impact of agricultural biotechnology.[13] How will genetic engineering transform agriculture over the longer-term, and who stands to benefit and lose? What will be its impact on the viability of the farm community and family farm? How will it restructure economic relationships within the agri-food industry? What will be the long-term impact on agricultural competitiveness, including its impact on the ability and incentives to move toward more sustainable agricultural practices? The first wave of products has already changed relationships among agricultural input suppliers, producers, and food processors. Contractual agreements between input suppliers and producers, and between producers and food processors, appear to be more common, through technology-use agreements and identity-preserved cultivation and handling systems. There are concerns among producers that the move to genetically-engineered crop varieties will allow a few multinational firms to control much of the seed industry. In the late 1990s, the technology of a few large firms dominated crop plant biotechnology. Monsanto alone accounted for almost half of the environmental safety approvals and food safety assessment consultations regarding genetically-engineered crop plants as of 1998 in both Canada and the US .[14]

These socioeconomic questions and the ethical quandaries that genetic engineering raises for some observers, particularly those who equate it with "playing God", provides additional complexity to plant biotechnology regulation. The prospect of seeking a strong public consensus on how to respond to the technology and its possible impacts must appear daunting to policy makers. Between 1973 and 1998, Canadian and American policy makers chose not to tackle such a difficult task. They avoided launching an extensive public debate, particularly on the

[13] Answering these questions is beyond the scope and timeframe of this study. However, predictions elsewhere range from making conventional agriculture more efficient, more reliable, more environmentally-friendly, and more profitable to bypassing traditional techniques altogether through the production of agricultural commodities in laboratories. Some have predicted that biotechnology would intensify the industrial character of agriculture, including through its restructuring of traditional relationships among agricultural suppliers, farmers, and the food processing industry through the creation of science-based and vertically-integrated agricultural companies. See Busch et al. (1991): 1-4, Organisation for Economic Co-operation and Development (1992a), and Davis (1991).

[14] See Chapter Three, Tables 3-2, 3-4, 3-6, and 3-8.

socioeconomic and ethical issues.[15] This strategy left leadership on these complex issues squarely on their shoulders. Policy makers have sidestepped these issues and instead concentrated on providing a conducive environment for development of biotechnology, including establishing a regulatory regime to assess potential risks to human and animal health and the environment. Somewhat ironically, the lack of a public forum for the wide-ranging issues emerging from the applications of agricultural biotechnology and the general avoidance of most of these issues by policy makers have situated the regulatory regime as the primary battleground for competing views about the use of the technology. Biotechnology regulation is a high-stakes endeavour in that it can determine the future of the technology through the limits it sets on its use. Citizens, by dint of degree of acceptance, have the potential to make or break entire sub-sectors of biotechnology. In theory, regulation performs a balancing act between the requirements of the regulated, who may see a regulatory regime as reducing or improving competitive advantage, and the demands of citizens or, more abstractly, the public interest. Jasanoff suggests that regulation is "a kind of social contract that specifies the terms under which state and society agree to accept the costs, risks, and benefits of a given technological enterprise."[16] If regulation of plant biotechnology between 1973 and 1998 was indeed a social contract, a very small circle of individuals drew up the contract and signed it on behalf of the Canadian and American publics.

RESEARCH DESIGN

Comparative and diachronic choices

This dissertation compares the Canadian and American regulatory responses at the federal level to three common issues arising from the commercialization of genetically-engineered crop plants: environmental release, food safety, and whether to establish additional labelling requirements for foods produced from these plants. In each country, these three issues have created domestic policy networks out of the same domestic plant biotechnology regulation policy

[15] However, Canadian and American state officials would probably point out that, in comparative terms, there has been more public consultation on biotechnology policy, including on regulatory issues, than in many other policy areas. The varied means by which the interested public has been consulted are summarized in Chapters Three and Four. However, even these consultations have exempted the vast majority of Canadian and American citizens, who still have little awareness or understanding of how genetic engineering works, the ways in which it is being or could be applied, and the potential impacts of these applications.

[16] Jasanoff (1995a): 311.

community. Although the issues are rooted in the same broader context, they differ in their policy legacies, the nature of the role of science, the degree and nature of internationalization, and in the nature of the policy networks that emerge around them.

In comparing Canada and the US, the perennial question remains whether to emphasize similarities or differences,[17] although differences may be more remarkable given all the forces that can be marshalled for expectations of similarity. The intent here is to identify the key factors contributing to both similarities and differences in policy choices across the two countries. The research design provides a "most similar" comparative case study over a time frame that appears to provide fertile conditions for policy convergence.[18] As major producers and exporters of agricultural commodities, Canada and the US share broad agricultural policy issues, such as sustainability, producer income stabilization, and access to export markets.[19] Canadian and American policy makers, given their countries' common status as major agricultural traders and active participants in international institutions, are equally likely to be exposed to international economic trends, international norms and standard-setting efforts, and the activities of transnational actors. The use of science as a basis for policy making on the technical issues of regulation provides further potential for similar choices. Beyond similar domestic factors, growing economic integration between Canada and the US following the 1988 free trade agreement and the international character of the plant biotechnology industry would appear to provide powerful pressures for policy convergence. In particular, Canadian policy choices might be expected to converge toward American choices over time, given the importance of the American market for Canadian agri-food products and the country's status as home base for some of the large multinational firms active in plant biotechnology, including the pioneer Monsanto.

At the same time, key differences exist between the two countries at the sectoral level in the composition of the two domestic policy communities. Variations in the resources of policy community members and in the location of scientific capacity result in differing policy networks. At the macro level, governing institutions and the norms they incorporate differ. Further, the US maintains its longtime position as a hegemonic power internationally and is less vulnerable to economic globalization than Canada, even though economic interdependence may somewhat

[17] Banting et al. (1997).

[18] See Przeworski and Teune (1970): 32-34 for a discussion of a "most similar systems" design.

[19] See Chapter Six for more details on the two countries' agricultural economies, particularly Table 6-1.

constrain its power and political influence. In contrast, Canada ranks as a "middle power" at most and its economic dependence on exports may limit its potential to exercise international leadership. Finally, although there may be powerful forces encouraging similar policy choices in Canada and the US, the contribution of policy legacies to distinctive policy styles and choices should not be overlooked. Policy legacies may maintain notable differences between Canada and the US when they "embody the traditions of earlier decades when the underlying societies formed sharper contrasts than they do today".[20] There may be a time lag between the presence of pressures for convergence and evidence of convergence due to the mediating effects of policy legacies, especially when major investments have been made in previous policy choices and powerful interests are dependent upon them.

To assess the potential importance of "path dependency", this dissertation includes a survey of relevant policy legacies. Although the policy issues studied in this dissertation appear unprecedented given their origin in the use of a new technology and its novel products, policy making in response did not begin with a blank slate. Regulation of agricultural biotechnology has intertwined longstanding agricultural research and regulation policy communities more closely into a new blended policy community. Carried from older policy communities into new ones, policy legacies are a source of inertia, with the potential to perpetuate patterns of interaction and protect ideas with the force of institutionalization. A historical approach that examines policy legacies provides more insight into whether policy making is travelling in a consistent direction and whether there may be distinctive national policy styles.

The focus of the dissertation on the period from 1973 to 1998 captures regulatory policy making from its roots in the response to laboratory work on recombinant DNA organisms until the first few years of wide-scale commercial cultivation of genetically-engineered crops in both countries. While the three issues examined in-depth here have captured policy makers' attention since the early to mid-1980s, earlier decisions on regulating genetic engineering may have acted as important templates. The time frame also permits an assessment of evidence of policy convergence and examination of change over time in policy communities and policy networks, the degree and nature of internationalization, and the characterization of science and location of scientific capacity. Change in these independent and intervening variables may correlate with shifts in policy choices,

[20] Banting et al. (1997): 14.

possibly locating a critical juncture in policy making. Beyond seeking conclusions about the contributions of patterns of relationships to policy making, this comparative study, with its historical perspective, is guided by Ashford's description of policy studies as:

> simultaneously a historical narrative, a portrayal of particular motives and intentions at work in a particular setting, an account of prevailing ethical and moral standards at work in political and social life at some moment in history, and an exercise in defining political and social reality for policy makers and the public.[21]

Policy convergence

Convergence is a flexible concept that simply implies that whatever is being measured across countries is becoming more alike over time.[22] Early work on convergence in the 1950s and 1960s argued that technological change adopted across countries would cause convergence in economic structures.[23] However, evidence of persistent national differences in macroeconomic policy, such as varying levels of state intervention, dispelled the idea that technological determinism would obliterate divergence. In recent decades, the phenomenon of globalization has given the concept of convergence a renewed lease on life with more sensitivity paid to assessing external influences on domestic policy making. Scholars have searched for evidence of convergence at both the macro and sectoral levels. Macro-level studies continue to examine the hypothesis that similar paths of economic development will produce similar economic and social structures and, when they don't, pinpoint the distortions caused by differences between political institutions.[24] Sectoral-level studies of policy convergence seek to reveal the important differences that macro-level studies tend to obscure. Assessing policy convergence at the sectoral level increases precision; policy making can be disaggregated to allow for a methodical comparison. Disaggregation, however, may lead to findings of convergence on some aspects of policy making coexisting with distinctive national policy styles.[25] This result highlights one of the pitfalls of applying the concept of convergence--the difficulty of assessing whether the findings of convergence or divergence are more notable.

[21] Ashford (1992): 4-5.
[22] Bennett (1991).
[23] See Berger (1996) and Kerr (1983) for a discussion of this earlier work. Kerr's 1983 book is a more recent example of convergence studies focusing on broad societal and state indicators across many countries. Works that examine variations in capitalism across countries include Kitschelt et al. (1999) and Hollingsworth and Boyer (1997).
[24] Bennett (1991) and Berger (1996).
[25] Coleman (1994), Bennett (1992), and Brickman et al. (1985).

The degree of convergence observed in a case study is perhaps most interesting for the light it sheds on state capacity in the presence of internationalization, when we assess the relative importance of the domestic and external variables in which its explanation lies. Internationalization is assumed to place similar external pressures on states and, in the absence of resilient domestic filters, implies that we should be seeing a great deal of policy convergence. In policy sectors where the degree of internationalization is high, divergence across countries in policy making becomes that much more interesting because it suggests that the state is both willing and able to assume its higher costs.[26]

When macro- and sectoral-level variables such as policy networks are similar, divergence would draw our attention to the remaining differences between countries which may be critical components of state capacity and autonomy in internationalized contexts. For example, at the sectoral level, differences in the composition of policy communities, in prevailing ideas within a policy community, or in patterns of exchange within a policy network may provide resilience to external pressures when desired. Such findings may encourage further exploration of how distinctive policy styles and domestic institutional arrangements contribute to state capacity within a context of internationalization.[27] At the same time, evidence of convergence does not automatically imply that internationalization is its cause. Parallel domestic factors may also contribute to convergence and should be excluded as possible explanations before turning to internationalization.[28] Further, before we assume that state capacity and autonomy are constrained by internationalization, we should demonstrate that such external constraints exist and clearly restrict the state's freedom to choose.[29]

[26] Simeon et al. (1997).
[27] Weiss (1998) argues that globalization will encourage such distinctiveness as states build on their ability to adapt successfully--an effort which is largely determined by differing versions of institutional linkages between the state and industry.
[28] Bennett (1991).
[29] Simeon et al. (1997).

Theoretical framework

The dissertation blends the insights of the policy community / policy network literature and historical institutionalism for use as a theoretical guide. For its guiding hypotheses, it builds on findings from investigations of the role of ideas, the use of science, and the impact of internationalization on policy making. The dissertation explores hypotheses elaborated around the argument that science and internationalization can play a significant role in determining the relative power of policy community members within policy networks, in turn shaping policy making and policy choices. These two variables have the potential to reinforce the existing structure of policy networks, challenge them from outside, or disrupt them from the inside. They also appear to be central to policy making in plant biotechnology regulation, given the frequent description of the regulatory regimes as "science-based", the international nature of the plant biotechnology industry, and the increasing interest in biotechnology regulation shown by an array of international institutions. There is a growing literature on the role of ideas in policy making and an emerging literature on internationalization and policy making. However, few works examine the role of ideas or internationalization in the context of policy communities and networks as this dissertation does.[30] Finally, attention to the role of science in policy making has been consistent but meagre, and few political scientists have explored it in detail.[31] The examination of the two independent variables, science and internationalization, is conducted separately in an effort to assess their relative importance in contributing to policy choices. This decision is consistent with the argument made earlier that policy convergence is not necessarily a result of internationalization in the form of external constraints, but may also be a product of domestic factors.

The level of analysis is primarily sectoral, examining the structure and dynamics of policy communities and networks. Studies of policy making have demonstrated that macro-level generalizations, such as those about the capacity and autonomy of state actors, often do not hold true across all sectors within a country. This finding suggests that there are important variables operating at the sectoral level and that efforts toward explanation may be rewarded by disaggregating the state.[32] Studies of policy networks attempt to compensate for the weaknesses of

[30] Exceptions include Lertzman et al. (1996), Zahariadis and Allen (1995), Coleman et al. (1997), and Dunn and Perl (1994).
[31] Studies include Jasanoff (1990), Jasanoff (1995b), Renn (1995), Ozawa (1991), and Salter (1988).
[32] Coleman and Skogstad (1990b).

pluralist and corporatist analyses.[33] Advocates also argue that it is difficult to understand much of modern policy making through a focus solely on more formal institutional structures such as legislatures, the executive, or the organization of bureaucracy.[34] Consistent with conclusions from other studies within the broader approach of institutionalism, there is agreement that policy communities and networks do not solely determine policy choices, but may have a significant influence.[35] The research design of the dissertation does not allocate a central role to macro-level independent variables such as the division of authority among branches and levels of governments, and the norms embedded within these institutional structures. The nature of federalism in the two countries, for example, appears to be of minor importance since in both countries the federal government has taken a leadership role in the issues examined, with both provinces and states acquiescing. The contribution of variables such as political culture and public philosophies is expected to be evident within policy communities and policy networks, if it is notable. The question of the importance of macro-level variables is revisited in the concluding chapter.

Other theoretical frameworks, including traditional pluralist, neo-Marxist, political culture, and state-centered approaches, have been set aside largely because they tend to rely exclusively on either societal or state factors for explanation. These theories do not consider how interaction between state and societal actors over time contributes to structured relationships that may significantly shape policy making. They ignore evidence of the blurring of the boundary between state and society in recent decades, as seen in the emergence of new hybrid governing structures. This development is reinforced by newfound enthusiasm for introducing and expanding formal public-private partnerships in many policy areas, but more fundamentally by the older trend of an increasing scope of state intervention and the growing complexity of policy making, particularly in

[33] Marsh and Rhodes (1992) find that neither pluralism nor corporatism provided "a very realistic picture of the relationships between government and interest groups, largely because they purported to offer a general mode of these relationships" and did not adequately recognize variations among policy areas. pp. 3-4. Smith (1993) also discusses the limitations of pluralism, corporatism, and Marxism at greater length, in favour of the policy network approach. See Chapter Two.

[34] Kenis and Schneider (1991): 35-36 argue that the utility of the concept of policy network reflects the transformation of political reality, including sectoralization and differentiation within the state, leading to a set of "relatively discrete institutional apparatuses". He states that societal differentiation, sectoralization, and policy growth have resulted in political overload, making governments dependent on the cooperation of policy actors outside their control. Policy networks examine the emergence of "webs of relatively stable and ongoing relationships which mobilize dispersed resources so that collective action can be orchestrated toward the solution of a common policy problem".

[35] Marsh and Rhodes (1992): 2.

"high technology" sectors.

Historical institutionalism, policy communities, and policy networks

Historical institutionalism focuses on how institutions mediate political conflict over time, through their effects on the interaction among actors.[36] As Thelen and Steinmo describe it, historical institutionalism "explicitly focuses on intermediate variables in order to integrate an understanding of general patterns of political history with an explanation of the contingent nature of political and economic development".[37] An institutional approach identifies "formal or informal procedures, routines, norms, and conventions embedded in the organizational structure of a polity".[38] It may also examine the "beliefs, paradigms, codes, cultures and knowledge that surround, support, elaborate, and contradict" such institutional rules.[39] These characteristics of institutions are assessed for their effects on, for example, state capacity, the strategies of actors, the distribution of power among actors, and how actors define their interests and thus policy preferences.[40] There is a consensus in the literature that institutions do not "cause" political outcomes or policy choices, but can shape policy making. For March and Olsen, the distinctiveness of an institutional approach includes a recognition that the actions of actors are "often based more on identifying the normatively appropriate behaviour than on calculating the return expected from alternative choices" and that what is appropriate behaviour is defined by institutions and communicated through socialization.[41]

Historical institutionalism has been critiqued for overemphasizing continuity, failing to recognize or account for the role of change, and not specifying causal mechanisms through which institutions are affecting behaviour.[42] However, some work within this approach specifies causal sequences in which other variables combine with institutions at critical junctures of change. For example, Weir's concept of "bounded innovation" suggests that both institutional and contingent

[36] See Hall and Taylor (1996) and Thelen and Steinmo (1992) for concise summaries of historical institutionalism.
[37] Thelen and Steinmo (1992): 28.
[38] Hall and Taylor (1996): 938.
[39] March and Olsen (1989).
[40] Pontusson (1995).
[41] March and Olsen (1989): 22-23.
[42] Hall and Taylor (1996) and Thelen and Steinmo (1992). Pontusson (1995) also takes historical institutionalism to task for obscuring the fundamental importance of economic structures, such as the nature of capitalism.

factors set boundaries on policy making.[43] Identifying causal sequences through a careful tracing of policy making over time pinpoints key moments of intersection among institutions, interests, and ideas, when their impact on each other contributes to the bounding of policy choices. Both internal and external dynamics can disrupt institutions such as established policy communities and networks. The concept of bounded innovation further recognizes that while policy legacies and boundaries may place powerful constraints on policy makers, there is sometimes still room to manoeuvre.

An institutional approach is compatible with the concepts of policy community and policy network because they share a focus on identifying how institutional structures shape policy making, sometimes resulting in asymmetries of power. The policy community / policy network literature draws attention to the impact on policy making of the sectoral organization of state and societal actors, and the relationships among them.[44] The literature provides a set of concepts and hypotheses that helps to correct the tendency in historical institutionalism to be imprecise when it comes to identifying causal mechanisms. These concepts assist in the identification of policy communities and policy networks and in the assessment of their influence on policy choices. The growing body of research on policy communities and networks suggests that a focus on the structure of relationships at the sectoral level is a fruitful approach for understanding and explaining policy making. At the same time, the ongoing refinement within the literature results in some differences in definitions of terms and choice of indicators.[45]

This dissertation uses the definitions of policy community and policy network provided by Coleman and Skogstad. A policy community is:

> all actors or potential actors with a direct or indirect interest in a policy area or function who share a common 'policy focus' and who, with varying degrees of influence, shape policy outcomes over the long run.[46]

Identifying the members of a policy community is the first step in examining the policy networks that form among these members on the specific issues that arise within a more general policy area.

[43] Weir (1992a, 1992b).

[44] There is a growing literature in political science and sociology that uses the concept of policy network, albeit often in somewhat different ways. See, for example, Coleman (1990), Atkinson and Coleman (1989), Coleman (1991), Coleman et al. (1997), Dohler (1991), Dunn and Perl (1994), Knoke et al. (1996), Lertzman et al. (1996), Kenis and Schneider (1991), Marsh and Rhodes (1992), Smith (1993) and Zahariadis and Allen (1995).

[45] Atkinson and Coleman (1996) and Marsh and Rhodes (1992).

[46] Coleman and Skogstad (1990b): 25-26.

Policy network is defined by Coleman and Skogstad as "the properties that characterize the relationships among the particular set of actors that forms around an issue of importance to the policy community".[47] Broadly, the nature of the policy network is determined by the combination of the internal resources of members which underpins the nature of exchange among these members and the type of activity of each member which is a function of issue importance and resources.

Within a policy network, the persistence and evolution of relationships create an informal organizational structure that can be treated like an institution from a theoretical standpoint. Consequently, the structure of state-societal relationships can be hypothesized to have causal impacts similar to those attributed to other institutions. For example, as an institution, a policy network can shape the development of policy by narrowing the range of ideas likely to receive a hearing, establishing modes of discourse, determining whose voices are authoritative, limiting options, and reinforcing certain values and beliefs, while excluding others.[48]

The policy network literature has been critiqued for a tendency to encompass all actors and variables without a compelling theoretical edge, resulting in description without clear explanation.[49] To draw the causal link between the nature of policy communities / networks and policy choices more clearly, the dissertation builds on the insights the literature provides on sources of power within these sectoral institutions. Broad indicators used in the literature, such as state capacity and state autonomy, the level of organizational development of societal actors, and patterns of exchange of resources, capture how power in the form of material and intangible resources (such as authority and legitimacy) may be exercised in policy making within policy networks. Thinking of a policy network as a relational concept of power assists in identifying causal mechanisms by drawing attention to how the mutual dependency of policy community members translates into patterns of interaction that in turn allocate power.[50]

[47] Coleman and Skogstad (1990b): 26.

[48] Weir (1992a): 163-167 describes the types of effects institutions may have on policy making. Knoke et al. (1996): 218 focuses on how relationships among actors within a policy network forge a "power structure" that provides opportunities and constraints for collective outcomes and expresses norms about appropriate political strategies. Dohler (1991): 238 notes that interactions inside a network are fused into a set of standard operating procedures, which points to a type of structural inertia.

[49] Lindquist (1996) argues that the proliferation of concepts in the policy community / policy network literature, and the lack of attempts to relate them to each other promises to yield little in the way of additional explanatory power of conceptual integration.

[50] Coleman and Skogstad (1990a): 6, Smith (1993): 228-230, 234; and Knoke et al. (1996): 17-18.

This dissertation contributes to the refinement of the concepts of policy community and policy network through its examination of two independent variables, science and internationalization, that are likely to contribute directly to the character of the indicators underlying the typology of policy networks set out by Coleman and Skogstad.[51] A recent evaluation of the literature employing the concepts of policy community and policy network suggests that fruitful further directions would include expanding the breadth and depth of analysis.[52] One recommendation is to incorporate an international level of analysis in order to reflect the growing international character of many policy areas. Another recommendation is to conduct such studies over a timeframe adequate to allow the identification of the ideas that provide a foundation for policy making and an assessment of the durability of types of policy networks, including their openness to outside influences. This dissertation responds to these suggestions, although they add to the complexity of the research task.

SCIENCE, POLICY COMMUNITIES, AND POLICY NETWORKS

Political scientists have long noted the potential of expertise as a political resource. The increasingly technical and professional character of the bureaucracy in developed nations in the twentieth century has provided fuel to the argument that expertise can be a powerful influence on policy making. Innovation in science and technology, including in the techniques of risk assessment, has brought a sophisticated technical aspect to regulation in the late twentieth century. Most recently, science has become a prominent instrument at international levels of policy making.[53] Literature on the role of science in policy making often focuses on the use of science as a resource by actors, the way in which institutions reshape science for their purposes, and the gap between the ideal image of value-free science and the way it is is often closely intertwined with

[51] Coleman and Skogstad (1990b).
[52] Atkinson and Coleman (1996).
[53] For example, the Sanitary and Phytosanitary (SPS) Agreement that came into force with the new World Trade Organization in 1995 places the burden of resolving trade disputes over food safety, animal or plant health regulations on science. The SPS Agreement requires countries whose regulations are alleged to be trade barriers to justify them on scientific grounds if such standards are found to be higher than those endorsed by the international organizations referenced by the Agreement, such as Codex Alimentarius.

other values or ideas when used in policy making.[54]

Salter has coined the term "mandated science" to describe the type of science produced when policy makers place pressure on scientists for conclusions imbued with certainty and authority that can be used as a credible basis for policy making, particularly when setting scientific standards. Mandated science does not conform to the ideal image of science as an objective and thus authoritative source of knowledge, but relies on this image for its influence. Instead, mandated science is the product of the intersection of science, 'values' (the term Salter uses to encompass ideas and interests), and policy making. In a similar vein, Ozawa, in discussing how science is used by actors as a political tool or resource, argues that decision-making procedures that fail to acknowledge the political aspects of what appears to be a science-based policy debate exclude many actors by setting limits on which issues are examined and on who may participate.[55]

The literature on the role of science in policy making is relatively small; its findings can be supplemented by those from works on topics relevant to this dissertation, including research on "epistemic communities" and studies of risk.[56] The literature on epistemic communities includes an examination of how scientific knowledge can translate into policy influence.[57] Epistemic communities are defined as networks of "professionals with recognized expertise and competence in a particular domain and an authoritative claim to policy-relevant knowledge within that domain or issue-area".[58] For a network to qualify as an epistemic community, its members must share normative and causal beliefs and agree on appropriate criteria for the validation of knowledge in their domain. Further, they must have a "common policy enterprise" which involves using similar

[54] See, for example, Salter (1988), Doern (1981), Hellström (1996), Ozawa (1991), Renn (1995), and Kasanmoentalib (1996). Jasanoff has studied the role of scientific advisory committees in regulatory politics and the intersection of science and the legal system in the US. See Jasanoff (1990), (1995b).

[55] Ozawa (1991).

[56] There are several recent works on the concept and implementation of risk analysis, reflecting the growing popularity of this concept as a policy tool. See, for example, Brunk et al. (1991), Kadvany (1996), Linder (1995), Franklin (1998), Leiss and Chociolko (1994), and Powell and Leiss (1997). Harrison and Hoberg (1994) compares regulatory policy making involving risk analysis in Canada and the US.

[57] The concept of "advocacy coalition" is similar to that of epistemic community. An advocacy coalition is a group of individuals from various locations "who share a particular belief system--that is, a set of basic values, causal assumptions, and problem perceptions--and who show a nontrivial degree of coordinated activity over time". See Sabatier and Jenkins-Smith (1993): 25-26. This literature focuses on how advocacy coalitions, defined and distinguished by their "belief systems", contribute to policy change. However, the literature does not focus as much on the role of expertise and scientific knowledge as does that on epistemic communities, although it does incorporate it as an aspect of a belief-system.

[58] Hass (1992) and Adler and Haas (1992). Definition is from Haas (1992): 3.

methods to deal with the same set of problems. The activities of epistemic communities are presented as a possible explanation for policy convergence across countries and international policy cooperation and coordination. Their influence is primarily a function of their knowledge, but is dependent on various conditions such as uncertainty among policy makers about appropriate policy choices.

With the notable exceptions of the epistemic community literature and Harrison and Hoberg's comparative study of regulatory science, much of the work on science and risk analysis in policy making lies outside of the discipline of political science and lacks a coherent theoretical framework. Examining the role of science through the concepts of policy communities and policy networks provides such a framework. Further, findings from the literature on the role of ideas in policy making assist in investigating the more abstract role of science within policy communities.[59] The classification of ideas can be helpful to empirical analysis by indicating, for example, in what ways they may be expected to influence policy making. Authors who have classified ideas tend to divide them into first, public philosophies or world views often based on deeply-held values; and second, causal or programmatic beliefs that provide solutions by suggesting cause-and-effect relationships and proper means to achieve policy goals. This dissertation distinguishes between guiding ideas which set out policy goals, and programmatic ideas, which prescribe the means to achieve those goals. Sectoral ideas may be incompatible or aligned with society-wide public philosophies. The literature also identifies factors that may contribute to the salience of an idea including its ability to preempt, exclude, or limit the credibility of other ideas; how strongly embedded it is within an institution; its fit with preexisting ideas, such as previous policies and deeply-held normative beliefs; its ambiguity (which can cloak interests); and the respect and authority enjoyed by its proponents.

As a variable within policy communities and policy networks, science operates at two levels. First, science works in a more abstract sense as a programmatic idea with a great deal of potential to exclude or marginalize other ideas. As an idea institutionalized within a policy community, the image of ideal science confers authority on actors with scientific capacity and may reduce the legitimacy of those with little or no scientific capacity. Second, depending on the institutionalized characterization of science within the policy community, scientific capacity as a

[59] Weir (1992a), Hall (1989), Goldstein and Keohane (1993), Sabatier and Jenkins-Smith (1993), and Yee (1996).

tangible asset may be an important internal resource that shapes patterns of exchange and thus situates its holder within the policy network.

INTERNATIONALIZATION AND POLICY NETWORKS

The study of internationalization in policy making responds to evidence that growing economic interdependence, the creation and strengthening of international regimes, and the activities of transnational actors are influencing domestic policy making processes and choices. The apparent arrival of the much-studied phenomenon of "globalization" has provided further impetus to examine external sources of domestic policy making. As a concept, globalization describes the current period of unprecedented levels of international flows in goods, services, capital, and technology that are expected to diminish the ability of states to maintain distinctive national policies and politics. However, as Weiss points out, by its name and meaning globalization implies that states are anachronistic when in fact the evidence suggests otherwise.[60] Further, globalization is such a sweeping and nebulous concept as to be not very useful when examining its impact on domestic policy making. Scholte draws useful distinctions among variations in the conceptualization of globalization.[61] First, the phenomenon of cross-border flows and influences, which deepens international interdependence, should be termed internationalization. Second, the opening of borders to flows of goods, services, and capital is simply liberalization. Finally, the term globalization is most aptly reserved for the *transcendence* of borders when organizations and patterns of financial and cultural interaction evolve in a context in which borders are irrelevant. For analytic purposes, it is useful to distinguish between globalization and internationalization, since the latter focuses on the cross-border phenomena sometimes subsumed under the wider umbrella of globalization. Internationalization can be defined as the "process by which various aspects of policy or policy making are influenced by factors outside national territorial boundaries".[62]

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[60] See Weiss (1998): 167-187 for an assessment of the evidence of globalization. Weiss concludes that, with the exception of capital mobility, we are not seeing globalization entailing the disappearance of national differences and the diminished status of the state, but rather a more internationalized world where national differences not only exist, but can be a competitive advantage.

[61] Scholte (1997). Like Weiss, Scholte concludes that globalization's main threat is not necessarily to the state. He argues that democracy is most under threat.

[62] Doern et al. (1996): 3.

Studies of the process of internationalization share the broad goal of investigating how developments outside a country interact with domestic institutional structures and political patterns, but they differ in their emphasis on certain elements of internationalization. Some case studies highlight the economic drivers of internationalization, such as how changes in trade and investment patterns alter political coalitions, and thus concentrate more on the impact of internationalization on societal actors.[63] Others focus more directly on the policy making process and choices, centring on the reaction of domestic policy making institutions.[64] What most have in common is their acknowledgement that domestic institutions, including the policy communities and networks which link state and society, can impede or facilitate the influence of internationalization.[65]

The literature sets out hypotheses as to what conditions facilitate or impede internationalization during policy making, including economic factors, the contribution of international institutions and transnational activities, and the role of domestic institutions.[66] Within policy sectors, internationalization is expected to be facilitated by export dependence and the presence of multinational firms. For example, mobile firms might be able to exit a country should their policy preferences be ignored. Internationalization also may occur through the introduction into domestic policy communities of societal actors that are active internationally or transnationally.[67] Well-established international institutions can enhance the legitimacy of transnational activities and thus may reduce the barriers to access to domestic policy making for transnational actors. The existence of international institutions may create a "political space" that allows and encourages state officials to act independently of their countries of origin if they adopt policy goals and programmatic ideas embedded within these international institutions which differ

[63] See Keohane and Milner (1996a, 1996b). This collection of case studies takes as a starting point responses in society to changing transaction costs that trigger change in patterns of trade and investment flows and thus provoke political and policy change.

[64] See Doern et al. (1996). This collection includes a focus on how sectoral state actors respond to a changing mix of external pressures and the degree to which they adapt or resist these pressures.

[65] In particular, Thomas Risse-Kappen's edited collection incorporates an explicit focus on how the nature of state-society linkages contributes to the impact of transnational actors and activities. See Risse-Kappen (1995a, 1995b).

[66] See Garrett and Lange (1996), (Keohane and Milner 1996a and 1996b), and Doern et al. (1996).

[67] Some case studies have concluded that internationalization tends to result in broader policy coalitions by requiring broader policy tradeoffs. See Doern (1996): 9.

from existing dominant domestic policy ideas.[68] The activities of international institutions may also promote regular transnational relations among societal actors who form cross-national links in their efforts to participate at the international level. Domestic actors who are active internationally or transnationally can import the ideas of international institutions or foreign policy networks into their own domestic policy networks which may lead ultimately to their incorporation in policy choices. Some of these ideas may even encourage greater sensitivity to economic and political developments at the international level during domestic policy making.[69] Evidence of the import of these ideas may be found in the discourse surrounding specific policy issues and in problem definitions.

Across policy areas and over time, we may find varying levels of internationalization, but in all cases domestic institutions can determine the extent to which internationalization affects policy making and policy choices. Differences in domestic institutions are expected to translate into differing responses ranging from accommodation and adaptation to resistance. In examining how policy networks filter internationalization as domestic institutions at the sectoral level, it is useful to identify which actors are active and influential within the network, and what ideas are embedded within the network. The discourse and problem definitions that accompany policy making, along with patterns of consultation and information gathering, shed light on how policy networks may be facilitating or impeding internationalization. As Keohane and Milner suggest, domestic institutions can delay the transmission of "price signals" from the international economy, thus slowing the rate of adaption of societal and state actors to changing economic conditions. They may also make the costs of political change very high. Further, a more open or pluralist policy network is likely to be easier to access for transnational actors than a closed policy

[68] Risse-Kappen (1995a, 1995b). Risse-Kappen defines "transnational relations" as "regular interactions across national boundaries when at least one actor is a non-state agent or does not operate on behalf of a national government or an intergovernmental organization". See Risse-Kappen (1995a): 3-4. Risse-Kappen also uses the concept of "transgovernmental networks" which are interactions among state officials active in international institutions that pursue an agenda independent of that of their national governments and which serve to broadcast ideas. He distinguishes between transgovernmental and intergovernmental by including only networks in which at least one actor is pursuing an agenda that differs from national goals.

[69] Toner and Conway (1996), for example, argues that the concept of sustainable development encourages internationalization, given its emphasis on interdependence.

network.[70] Such differences in domestic institutions also establish differing requirements for transnational actors hoping to form a "winning coalition" with domestic policy community members that succeeds in its policy goals. Beyond its impact as filtered through domestic institutions such as policy networks, internationalization may also have a direct impact on options for policy choices. International regimes, such as trade agreements, may render some policy instruments ineffective or even unusable. Such regimes may also allow transnational actors, such as nongovernmental organizations, to achieve policy change.[71]

The literature on internationalization does provide a wealth of hypotheses about how it may affect domestic policy making. It is sometimes less explicit on how to assess the degree of internationalization and rarely distinguishes consciously among the types of conditions that contribute to internationalization, such as between economic and political factors and how they may have different effects on the direction of policy making.[72] The literature also tends to focus on globalization / internationalization as a threat to state capacity and autonomy, although there is some awareness that states can capitalize on internationalization to bolster their capacity and autonomy.[73] This dissertation builds on the literature on internationalization through greater specification as to how different types of internationalization may have different effects, as outlined below in the discussion of guiding hypotheses.

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[70] Risse-Kappen provides a typology of domestic institutions based on three dichotomized variables: strong versus weak societies, consensual versus polarized policy networks, and centralized versus fragmented political institutions. This typology provides hypotheses about how differing domestic institutions will filter the influence of transnational actors and activities. See Risse-Kappen (1995a): 23-28.

[71] Trade liberalization and trade agreements can, for example, provide non-governmental organizations with the opportunity to secure higher regulatory standards in the countries that trade with their home country. See Vogel (1995).

[72] Some studies recognize that there can be stronger and weaker forms of internationalization, and different modes of internationalization, but remain somewhat vague in how to distinguish among them. See Doern et al. (1996).

[73] See, for example, Coleman and Porter (1996) argue that by participating in international institutions and adopting their discourses, the Canadian state became stronger and more autonomous in banking and securities policy in comparison to societal actors and the population generally. Keohane and Milner (1996a) also note that internationalization may create political space for leaders to undertake major domestic reform, particularly when it is provoked by economic crisis.

GUIDING HYPOTHESES

This dissertation is guided by a set of hypotheses about the role of science and internationalization in shaping policy choices, through their influence on policy preferences and their contribution to the relative power of members of domestic policy communities. These hypotheses build on and expand the findings of the literature discussed earlier.

1A) First, the dissertation hypothesizes that, for policy issues that have a technical or scientific aspect, **the institutionalized characterization of science within a policy community will alter the relative importance of various resources in contributing to the influence of policy community members on policy making.** For example, when science is viewed as neutral within a policy community, the allocation of scientific capacity within a policy community would be expected to be the most important factor in determining whose policy preferences are reflected in policy choices. Science will likely be perceived as neutral when policy legacies have institutionalized an ideal or value-free characterization of science. The idea of neutral science is also likely to prevail when there is a strong scientific consensus within the policy community that translates into agreement on the appropriate goals, methods, and scope of regulation. Further, the combination of a neutral science policy community with an uneven and concentrated allocation of scientific capacity is expected to result in relatively closed policy networks in which the possession of scientific capacity acts as a dividing line between core and peripheral members. Conversely, when science is contested within a policy community, resources other than scientific capacity should be equally or more important in determining whose policy preferences are incorporated into policy choices. Science is likely to be contested when policy legacies, scientific uncertainty, and/or the existence of competing scientific paradigms contribute to the overt politicization of science. Further, when science is contested within a policy community, policy networks are more likely to be open because scientific capacity as a resource is relatively less important. Such openness is contingent on the distribution of other resources not being highly skewed among members of the policy community.

1B) As a supporting argument, the dissertation also hypothesizes that **the degree to which policy community members possess relevant scientific capacity is linked to their relative support or opposition to the concept of "neutral science".** Accordingly, policy community members with scientific capacity are more likely to promote the

institutionalization and reinforcement of "neutral science", particularly within the context of a closed neutral science policy network. They may be socialized by policy legacies that entrench neutral science. They will attempt to use science as a resource to marginalize or exclude competing ideas that clash with their own preferences, even if those preferences are not clearly science-based. They are likely to promote narrow, science-based problem definitions that enhance their influence and call for policy choices restricted to responding to these definitions. They are also expected to make claims about possessing relevant scientific resources to defend or improve their position within the policy network.

In contrast, policy community members lacking in scientific capacity are expected to be more likely to contest the idea of "neutral science" if they seek to influence or change policy choices. Their success will be contingent on three related factors in particular: the perceived degree of scientific uncertainty, the existence of legitimate competing scientific paradigms relevant to the issue at hand, and the ability to portray risk analysis as a political process. Their efforts will focus on recasting the characterization of science within the policy network from neutral to contested. Success may include triggering problem redefinition or multiplication through the inclusion of competing ideas. Such success may ultimately disrupt closed policy networks fortified by scientific expertise by transforming them into more open or pluralist networks in which science no longer operates as a gatekeeper.

1C) Science-based policy making would appear to be a likely candidate for policy convergence, given the expected harmonizing effect of objective scientific evidence. However, the political and institutional trappings in which the production of scientific evidence occurs, including the process of priority-setting for research, the location of scientific expertise, and the level of public funding for research on which to base policy making, provide the basis for variation across countries in the use of science in policy making.[74] Such diverse processes may or may not permit similar regulatory policy choices. Thus, the dissertation hypothesizes that **in the absence of internationalization, science will encourage regulatory policy convergence only when there is a high level of scientific certainty about the nature of the risks posed by the use of a technology or product and how to control the level of risk.**

2) Second, in assessing the impact of internationalization, the dissertation hypothesizes

[74] Brickman et al. (1985), especially Chapters Six, Seven, and Twelve.

broadly that **the degree and nature of internationalization is expected to shape the policy preferences of members of domestic policy communities and possibly alter the resources they employ within domestic policy communities and networks, thus influencing policy choices.** Overall, a high degree of internationalization suggests a greater likelihood of policy convergence. Further, **the nature of internationalization is expected to indicate the likely direction in which any observed convergence would travel.** Two central types of internationalization (economic and political) may coexist, but can be layers which trump or reinforce each other. Political internationalization, such as the presence of international institutions, has the potential to mediate or reinforce the effects of economic internationalization.

A) Specifically, the dissertation hypothesizes that **increased economic integration and trade liberalization, when it contributes to relatively high levels of external economic dependence, will result in policy convergence.** In the face of economic internationalization, domestic actors will adapt their policy preferences accordingly and increase pressure for policies that enhance their economic position.[75] For example, export dependence will encourage policy convergence toward major trading partners, while the presence of dominant multinational firms within a sector will encourage policy convergence toward the most competitive and/or pioneering domestic regulatory regime.

B) Further, **if a policy area is characterized by a high degree of international institutionalization, then we would expect policy choices to converge toward the model set out by these institutions, particularly when these institutions place constraints on domestic policy making.** Domestic policy community members who are active internationally, including state officials, may be expected to use the resources of these international institutions, including information and legitimacy, to enhance their own position within domestic policy networks.

The dissertation also investigates the hypothesis that the higher the degree of international institutionalization, the more transnational activities are expected to flourish, including the formation of transgovernmental coalitions.[76] International institutionalization is expected to ease

[75] This hypothesis is based loosely on arguments made in Keohane and Milner (1996b) and Frieden and Rogowski (1996).

[76] This set of hypotheses is based on Risse-Kappen (1995a).

access to domestic policy making for transnational actors and coalitions by increasing available channels and legitimizing their activities. The higher the degree of international institutionalization, the more we would expect to find the policy goals and methods embraced by transnational actors and/or transgovernmental coalitions circulating within domestic policy communities. Thus, after accessing a domestic policy community, transnational actors are more likely to secure their policy preferences through policy choices when international institutionalization is high because it is more likely that they will succeed in finding domestic partners who share or will adopt their ideas.

C) **If international institutions have a credible scientific component to their activities, such as scientific standard-setting, and science is characterized as neutral within a domestic policy community, we would expect domestic policy choices to reflect the scientific consensus these institutions have endorsed.** Further, domestic policy community members with scientific resources are likely to seek to use the activities of these institutions to enhance their own legitimacy and consolidate the position of neutral science within the domestic arena. In such a situation, the activities of such international scientific institutions have the potential to outweigh the effects of economic internationalization and other non-scientific international institutions. However, if science is contested within a domestic policy community and thus possibly displaced as a primary basis for policy making, the activities of international scientific institutions would be expected to be much less influential on domestic policy choices. These choices would instead by shaped by economic or political internationalization and/or domestic factors.

D) Finally, in the event of findings that one or more of the types of internationalization is present in a policy sector yet policy choices do not converge in the expected direction, attention will be redirected to how domestic policy communities and networks shelter policy making from the pressures and incentives of internationalization. **The dissertation hypothesizes that policy communities equipped with adequate policy capacity are most likely to be able to resist the pressure for convergence toward an external model, if desired.** Adequate policy capacity rests on three interrelated factors: first, state capacity and autonomy; second, access to independent informational / scientific capacity; and third, the capacity to conduct policy making in a manner that will be widely perceived as legitimate.

METHODOLOGY AND ORGANIZATION

The recent arrival of biotechnology as a policy area explains why there were few comprehensive or comparative studies of policy making on biotechnology as of 1998.[77] The subject has garnered more attention in the US than in Canada. For this study, key data sources included transcripts of committee hearings, regulatory policy documents, news releases, background documents, and other government documents. Data on the composition and preferences of members of the American and Canadian policy communities were gathered primarily through committee testimony, web sites, and interviews.[78]

Chapters One and Two sketch the context for policy making, identifying relevant policy legacies prior to 1973 and policy boundaries operating between 1973 and 1998 in agricultural research and regulation. These chapters reflect the recognition that these two policy areas are interdependent and intertwined in both countries.[79] Chapter One argues that Canada and the US have some striking similarities in the history of agricultural research policy and that of regulation of food safety and food labelling. However, the comparison of relevant policy legacies is more interesting for the differences that it reveals. Chapter Two describes the policy boundaries surrounding regulation of plant biotechnology that emerge from innovation in agricultural research policy, the regulation of laboratory work with recombinant DNA organisms beginning in the mid-1970s which was the initial effort to regulate the use of genetic engineering, and the horizontal regulation of biotechnology through the creation of "framework" policies in the mid-1980s and 1990s.

[77] See, for example, Busch et al. (1991), Buttel (1993), Kenney (1989), Krimsky and Wrubel (1996), Krimsky (1985), McIntyre (1990), Miller (1997), Thompson (1997), and Webber (1995). However, even most of these works are edited collections and few have a coherent theoretical framework or a comparative perspective. One exception is Jasanoff (1995a). There has been more coverage in books aimed at popular audiences and in the print media.

[78] Interviews were conducted in person in Ottawa, Washington, New York, Toronto, Winnipeg, Saskatoon, and Regina. Other interviews were conducted by telephone. See the Appendix for a complete list of interviews.

[79] The results of research may provoke regulation, and the nature of regulation may encourage or hinder research progress, or influence the selection of research projects. Further, technical, science-based regulation, at least theoretically, is dependent on research that may suggest the appropriate scope and methods for regulation. Thus, agricultural research policy may well provide boundaries for regulatory policy choices, just as regulatory policy may place boundaries on research policy. For example, in the case studied here, the federal in-house agricultural research branches provide expertise to the regulatory branches. The Agricultural Research Service of the USDA supports the work of Animal and Plant Health Inspection Service (APHIS), while in Canada, the Research Branch supports the work of regulators, housed for many years within AAFC, and since April 1997, in the CFIA. See United States. Department of Agriculture (NDa). Interviews also confirmed the dependence of regulators on their research counterparts. See also Brickman et al. (1985), Chapter Six for a discussion of the effect of research policy on regulation, in the case of regulating toxic chemicals.

Chapter One describes how the governments of both countries played central roles for decades in promoting the application of science to agriculture in pursuit of productivity and efficiency. The basis of this effort was the establishment in each country, in the late nineteenth century, of public agricultural research institutions with the common goal of establishing a viable agricultural industry through continuous innovation and diffusion of advances. In both countries, agriculture became a significant economic activity when industrialization was sweeping the western world. The principles of industrialization, including efficiency through innovation, have shaped its evolution. As a result, agricultural producers in Canada and the US have long been accustomed to adopting the newest techniques and products, including new plant varieties, as somewhat passive recipients.[80] However, the structure of the agricultural research system differed significantly historically between the two countries up to and beyond 1973. Canada's agricultural research system was virtually exclusively public and highly centralized. The American system has been decentralized and a mixed public / private system, particularly since the 1930s. These structural differences help to explain the dominance of the idea of "science-based innovation" in the Canadian agricultural research system compared to the ascendance of "market-based innovation" in the US. The Canadian system also resulted in a much higher degree of federal state capacity and autonomy in agricultural research than the American system. Notable differences can also be found in the historic approach to regulation of new plant varieties. In Canada, the system of variety registration institutionalized the idea of "science-based merit" while the US system favoured the idea of "market-based merit", although both were intended to further economic development.

In contrast, policy legacies in food safety assessment and labelling in Canada and the US appear to be more similar than different. For food safety, there is a similar history of fragmentation of institutional authority and reactive regulation, hampered by inadequate authority and resources. In both countries, there are long-established patterns of cooperation between regulators and the regulated. In the US, the food industry and its scientists have long played a role in shaping policy making by dint of their expertise. Canada has established similar patterns of exchange with the food industry and has a longstanding practice of turning to international expert

[80] This is not to say that all producers have warmly embraced the steady procession of technological advances. Many have not adopted every advance such as the use of agri-chemicals, although most do use mechanization in some form. Some producers have also expressed skepticism about whether these advances benefit them, suggesting that benefits accrue elsewhere, mostly to those who sell the technology and to consumers, since the result is often to lower food prices. This skepticism has been extended to the products of genetic engineering.

bodies for further expertise. Finally, the policy legacies in food labelling also reveal a fragmentation of authority and focus on economic regulation. In both countries and particularly in Canada, food labelling was used historically more to regulate the market than provide health and safety information. Notably, much of food labelling has been aimed at assisting the consumer in making well-informed economic choices. Requirements such as ingredient lists and stating quantities have been intended to provide a "level playing field" in the food industry, which often benefits more reputable firms and excludes those engaged in disreputable practices such as misbranding.

Chapter Two summarizes the significant innovation that has occurred in agricultural research policy, mostly since the late 1980s. The ascendance of technological neoliberalism in both countries through the 1980s and 1990s heightened attention to the potential of agricultural research to contribute to international competitiveness.[81] Firmly based on faith in market liberalism, technological neoliberalism has been institutionalized through change in many policy areas in Canada and the US through the 1980s and 1990s. It builds on the proclaimed trends of economic globalization and the emergence of a knowledge-based economy. Technological neoliberalism provides both guiding ideas, through its central goal of international competitiveness as the foundation of economic growth and prosperity, and programmatic ideas. It is most notable for the purposes of this dissertation for its programmatic edict of pursuing technological innovation, preferably through market-based policy instruments. Technological innovation is portrayed as a necessary condition for securing domestic competitiveness in global markets and thus the maintenance of prosperity.[82] Technological neoliberalism has reinforced existing elements of agricultural research policy that were compatible with its vision and prompted the overhaul of other elements that were in conflict. As a result, the Canadian agricultural research system is moving into closer alignment with the American model, toward market-based innovation and away

[81] The label "technological neoliberalism" is inspired by Manzer's definition of "technological liberalism" which describes the idea that "material well-being, political freedom, and cultural development are already strongly determined by, and in future will be overwhelmingly dependent on, superior capacity for scientific creativity, technological innovation, and economic productivity." See Manzer (1994): 266-267. The popularity of technological neoliberalism was fuelled by the industrial restructuring that occurred in both countries in the 1980s and 1990s.

[82] Evidence of this phenomenon includes the President's Council on Competitiveness in the US under President George Bush, created in 1989, and the federal Prosperity Initiative in Canada of the early 1990s under the Mulroney Conservative government.

from science-based innovation. During the same period, existing trends in the US toward increased private sector involvement and market-based innovation have intensified. However, distinct differences remain for the time being between the two countries, since agricultural research in Canada is still more centralized and more in the public sphere than in the US.

Chapter Two also explores policy boundaries set by early regulatory efforts. In Canada and the US, the initial foray into regulating genetic engineering, through the establishment of guidelines for lab work with rDNA organisms sponsored by federal funding, resulted in regulation remaining largely within the scientific community. The weakness of enforcement provisions left the effectiveness of the guidelines largely dependent on self-regulation by researchers. The institutionalization of the goal of safety as the appropriate intent of regulation of lab work ensured the centrality of science as the basis for regulation, privileging those with scientific expertise in the policy making process. At the same time, the drafting of guidelines set a precedent for the argument that genetic engineering required its own distinct regulatory measures. The subsequent regulatory frameworks for biotechnology that each country issued, in 1986 in the US and in 1993 in Canada, can be largely understood as attempts to shore up state capacity. These horizontal frameworks have provided important boundaries for the appropriate goals, methods, and scope of regulatory responses to specific issues. They endorsed a division of authority for biotechnology regulation that simultaneously reinforced the state's claims of adequate scientific capacity while making its agencies more vulnerable to the demands of societal clients. The common decision to build on existing institutions and legislative authorities has sheltered policy making from the scrutiny of legislatures and tends to maintain existing levels of state capacity and autonomy. Finally, the frameworks endorsed risk assessment as the appropriate means for regulation, which has placed a premium on scientific capacity as a prerequisite to legitimate participation in policy making.

Chapter Three compares policy making and policy choices on three issues arising out of the commercialization of genetically-engineered plants: environmental release, food safety assessment, and food labelling. The evolution of policy making on each issue is briefly sketched and subsequently disaggregated for the purposes of assessing convergence. Broad measures of policy convergence suggest a general trend of Canada converging toward the American model, although the detailed comparison reveals interesting differences. The chapter concludes that the policy

responses to the issue of environmental release show the most divergence. Convergence appears strongest in food labelling, while food safety assessment falls in between the two.

The composition of the two domestic policy communities and their evolution over time is described in Chapter Four. The policy preferences of key groups of actors within the policy communities are summarized, as a backdrop for assessing whose preferences have been incorporated, marginalized, or excluded in policy choices. The chapter also provides an overview of the indicators contributing to the nature of the policy networks surrounding each issue: state capacity and autonomy, the level of organizational development of associational systems, and general patterns of exchange. The chapter concludes with an identification of the nature of the six policy networks emerging around the three issues studied in each country.

To look more closely at the influence of policy communities and networks on policy choices, Chapters Five and Six examine the role of science and the impact of internationalization. Chapter Five examines the role of science in policy making as an idea and, in the form of scientific capacity, as a resource. The chapter examines the starting points for the characterization of science within policy networks and change in that characterization over time. It describes the ways in which science has come into play during the policy process, including through rhetorical battles, the degree of scientific uncertainty, and patterns of exchange of scientific information. The chapter concludes by comparing the role of science across the two countries and its effect on the resources of policy community members. Chapter Six examines the potential degree of internationalization in this policy area, distinguishing between the economic conditions and the political activities that may facilitate it. It explores the depth of international orientation of the key groups of policy community members, including how internationalization appears to have shaped their policy preferences, and their use of international resources. The chapter wraps up with an assessment of the constraints and opportunities for policy making that the degree and nature of internationalization in this policy area have provided.

The concluding chapter assesses the findings of the dissertation and their contribution to our understanding of the influences behind the policy choices observed in Chapter Three. A comparison of the preferences of policy community members with policy choices reveals that biotechnology proponents, particularly plant biotechnology firms and the food industry, have been largely successful in seeing their preferences reflected in those policy choices. Biotechnology

skeptics have been much less successful. At the same time, however, skeptics can claim a partial victory in that their efforts have contributed to precedent-setting regulatory regimes for the environmental release and food safety assessment of new plant varieties and have raised public awareness of the issues surrounding the commercialization of genetically-engineered crop plants. The relative success of biotechnology proponents and critics can be understood largely as a result of the nature of policy networks and more specifically, how ideas working within these networks privilege or marginalize network members.

The conclusion outlines how domestic variables provide more of an explanation of policy choices than the potential for internationalization. In particular, differing policy networks correlate with key differences in the policy responses across countries. The role of science within those policy networks provides greater insight into the nature of relationships among network members. The identification of domestic policy legacies delineates the initial inertia behind policy making. The discussion of key policy boundaries depicts how they place constraints on policy making and affect the influence of policy network members. The examination of internationalization highlights how it shapes policy preferences and resources of policy community members. It also demonstrates that a full understanding of the impact of internationalization can be attained only by exploring its effects within domestic institutions such as policy communities and networks. These conclusions, in combination with the finding of differing degrees of discretion and capacity across issues and countries that result from policy choices, provide lessons about the necessary conditions for policy capacity.

For most agricultural producers and those surrounding them in every link of the agri-food industry, from agricultural researchers to agricultural input firms to food processing companies, the application of genetic engineering to agriculture was initially seen as simply the latest significant innovation in a long series. The critical scrutiny of agricultural biotechnology by environmental organizations and other public interest groups, especially in Europe, came as an unwelcome surprise. It has drawn agricultural producers and the agri-food industry much more closely into the plant biotechnology regulation policy community. But the enlargement of the policy community and adverse consumer reaction to agricultural biotechnology is a much more recent story. To understand the events of the 1980s and 1990s, we must first examine the policy legacies that provided an initial basis for the regulatory response during the earliest days of agricultural

biotechnology, when the issue was the bailiwick almost solely of the research community of each country.

TABLE I-1
Global acreage of genetically-engineered crop plants, 1996-1998[1]

A. Acreage by major crops (millions of acres)

	1996	1997	1998
Canola	0.3	3.0	6.0
Corn	0.7	8.0	20.8
Cotton	1.9	3.5	6.3
Potato	<0.1	<0.3	<0.3
Soybean	1.3	12.8	36.3
TOTAL	7	31.5	70

B. Acreage by country (millions of acres)

	1996	1997	1998
Australia	0.1	0.3	0.3
Argentina	0.3	3.5	10.8
Canada	0.3	3.3	7.0
China	2.8	4.5	n/a
France	n/a	0	<0.3
Mexico	<0.1	<0.3	0.3
South Africa	n/a	0	<0.3
Spain	n/a	0	<0.3
United States	3.6	20.3	51.3

C. Acreage by trait (millions of acres)
(excludes China in 1997 and 1998)

	1996	1997	1998
Herbicide tolerance	1.6	17.3	49.5
Insect resistance (Bt)	2.6	10.0	19.3
Virus resistance	2.8	4.5	n/a
Insect/herbicide resistance	n/a	<0.3	0.8
Quality traits	<0.1	<0.3	<0.3

D. Major crops, by type (percentage of total acres of genetically-engineered crops sown that year)
(excludes China in 1998)

	1996	1997	1998
Herbicide-tolerant soybean	18	40	52
Insect-resistant corn	10	23	24
Herbicide-tolerant canola	4	10	9
Insect (Bt)/herbicide-resistant cotton	28	11	9
Herbicide-tolerant corn	0	2	6

[1] James (1997) and Union of Concerned Scientists (1998). See the web site of the International Service for the Acquisition of Agri-Biotech Applications at http://www.isaaa.cornell.edu/ for the latest statistics.

CHAPTER ONE
POLICY LEGACIES: AGRICULTURAL RESEARCH AND REGULATION UNTIL 1973

The potential of policy legacies to protect existing configurations of ideas and interests suggests that path dependency may explain much of subsequent policy making.[1] When policy choices create institutions premised on a set of ideas or guiding principles about appropriate policy instruments and goals, the combination of institutions and ideas may privilege some interests within a policy community and marginalize others. Such policy legacies can channel policy making by framing problem definition, shaping the policy making process, and placing boundaries on policy choices. By doing so, they may contribute to the relative power of members within policy communities by affecting the importance of their resources, and in turn establishing patterns of interaction. The institutionalization of ideas and interests in policy legacies may provide policy networks with resilience against external and internal challenges from competing ideas and interests. Policy legacies can also play an important role in explaining evidence of distinctive national trajectories in policy making.

The novelty that results when genetic engineering is applied to agriculture has raised new policy issues. However, neither agricultural innovation nor the regulation of the novel processes and products it creates is a new policy area. Regulatory responses to plant biotechnology in Canada and the United States build on the legacy of previous policy choices because both countries have chosen to base their responses to this new technology on existing regulatory authorities and practices. This chapter provides a brief look at relevant policy legacies in agricultural research and regulation prior to 1973 and the age of genetic engineering, focusing on those affecting plant agriculture. These relevant regulatory policy legacies include efforts to govern the import, sale, and use of new plant varieties and seeds, and protect agriculture from pests (the foundation on which environmental safety assessment measures have been built); to increase food safety through penalties for adulteration and, later, selective premarket safety assessment measures; and to promote fair competition and protect consumers from fraud in the food industry through labelling requirements for food products.

The examination of agricultural research policy reveals its role in shaping and supporting

[1] See Hall and Taylor (1996) on the potential effects of policy legacies.

regulatory decisions and its effect on the relative power of public and private agricultural researchers and their organizations within policy networks. The chapter describes the public sector agricultural research system in each country, focusing on the ideas and interests embedded within institutional structures. The division of labour between the public and private sector in agricultural research is also examined to permit an assessment of state autonomy and capacity. Canada and the US share a longstanding public commitment to innovation in agriculture. Both public agricultural research systems are based on the idea of pursuing economic development and productivity through innovation. There have also been important differences over time in the degree of centralization of the public system, in the level of private sector activity, and in the programmatic ideas that shape decisions about appropriate means and policy instruments.[2] These differences suggest that Canadian federal state actors have had more autonomy and capacity than their American counterparts in making agricultural research policy.

Next, the chapter examines the regulation of new plant varieties prior to the advent of agricultural biotechnology. Key differences emerge between the two countries that parallel the differences in agricultural research policy legacies, highlighting the interdependence of the two policy areas. In Canada, regulation of new plant varieties has been centralized and characterized by high levels of cooperation between state officials and seed industry representatives. In contrast, comparable American efforts have been conducted mainly at the state level, rather than by the federal government. The appropriate role of the state has been much more contested in the US, resulting in its redefinition over time. Another notable difference lies in the mix of programmatic ideas. In Canada, through the variety registration system, the principle of science-based merit assessment has been institutionalized and has persisted. In the US, attempts to institutionalize a similar principle at the state level have been less successful, defeated by the increasing prominence of a market-based assessment of merit, which is reinforced by intellectual property provisions. Once again, these differences suggest that historically, Canadian federal state officials have had more autonomy and capacity in regulating the sale and use, and by virtue of the variety registration system, the quality of new plant varieties.

[2] As discussed in the introductory chapter, the dissertation draws a distinction between guiding and programmatic ideas. Programmatic ideas shape policy choices by suggesting specific solutions based on their versions of cause-and-effect relationships which in turn clarify the proper means to achieve policy goals. Public philosophies often incorporate both guiding and programmatic ideas.

In contrast, the comparison of policy legacies in food safety and labelling issues surrounding new plant varieties finds a similar history of minimal regulatory involvement in both countries. A general examination of food safety and labelling regulation shows fragmentation of authority, a reactive approach to implementing food safety measures, inadequate statutory authority and internal scientific resources, and longstanding patterns of interaction among domestic regulators, industry scientists, and international expert bodies that reflect the dependence of regulators on external expertise. This comparison suggests that on issues of food safety assessment and labelling, both the Canadian and American states have encountered a number of obstacles to obtaining adequate capacity to exercise state autonomy.

AGRICULTURAL RESEARCH POLICY LEGACIES

Canada

Historically, Canada's agricultural research effort has been highly centralized and largely conducted within the public sector (see Table 1-1).[3] The federal government has dominated agricultural research, while provincial and private sector efforts have paled in comparison. In 1966, for example, the federal government funded a little more than two-thirds of the total agricultural research effort.[4] Similarly, in 1977, measured by "person-years", the federal effort still accounted for 60 per cent of the research effort, compared to 28 per cent in post-secondary institutions, 5 per cent by the provinces, and 6 per cent by the private sector.[5] The creation of the experimental farm service in 1886 marked the beginning of the extensive involvement of the federal government.[6] Federal employees began to develop and test new agricultural technologies and products for the benefit of agricultural producers with the goal of building a strong agricultural sector. The initiative provided a more systematic basis for innovation than the previous pattern of ad hoc improvements adopted by individual producers. Several decades of growing or stable funding created a strongly institutionalized federal agricultural research system. Between 1886 and 1986, the federal department of agriculture spent approximately $6.2-billion (Cdn) on agricultural

[3] Over time, research efforts at the provincial level have grown, particularly within post-secondary institutions, but the federal government remained the dominant partner in the agricultural research effort into the mid-1990s.
[4] Garland and Hudson (1969): 270.
[5] Brooks and Furtan (1984): 358.
[6] See Anstey (1986) for a comprehensive treatment of the first century of the federal agricultural research effort.

research (in 1984 dollars). Overall, in 1984 dollars, annual spending grew from $1.2-million in 1890 to $263-million in 1985. Centred in recent decades under the Research Branch of Agriculture and Agri-Food Canada, the federal effort has contributed to all major aspects of agricultural research. The distribution of its research stations, which are scattered across the country, has resulted in attention to regional challenges. The department of agriculture, the federal National Research Council and the National Sciences and Engineering Research Council (a federal granting agency) have also funded extramural agricultural research during the last few decades. In 1962, the National Research Council began giving research grants to the private sector for plant breeding, but even into the 1970s, private sector investment in plant breeding was almost non-existent in comparison to public sector efforts.[7] The one exception was work on corn hybrids which marked the beginning of private plant breeding in Canada as firms established their own research stations and hired plant breeders.[8]

The public agricultural research effort is credited with Canada's position during much of the twentieth century as a leading producer and exporter of major agricultural commodities and with its comparatively inexpensive and high-quality food supply. Over time, an extensive agricultural science base has been developed, resulting in continuous innovation in agricultural practices and products. Since the earliest days, a core research area has been plant agriculture. This research has resulted in several well-known achievements, including Marquis wheat, canola, and the development of varieties of corn and soybeans that may be cultivated commercially in the challenging Canadian climate. The achievements of agricultural researchers and findings of a high rate of return on investment, combined with the agri-food industry's status as a major economic sector, maintained political support for public agricultural research and provided protection against critics into the 1970s and 1980s.[9] Unchecked by external political and economic constraints until then, the growth and organization of the federal agricultural research effort historically has been driven by the pursuit of its original mandate. Its mandate--to test and assess systematically animal

[7] Canada. Department of Agriculture (1977): 142, 213.
[8] Canadian Seed Trade Association (1995): 13. The earliest private plant breeding seems to have been conducted by Pioneer in Ontario starting in the late 1940s. Most of the activity began in the 1970s. American seed firm Northrup King opened a research station in Ontario in 1974. Canadian seed firm King Agro had its first corn hybrid licensed in 1978.
[9] On historic rates of return, see, for example, Klein (1985), Zentner (1985), Widmer et al. (1988), and Klein at al. (1996).

breeds, new plant varieties, fertilizers, feeds, seeds, and strategies for combating diseases and insects --remained largely unaltered into the 1980s.[10] The Research Branch's official mandate in 1967 reflected its science-based focus on efficient production and the wide scope of its studies:

> to apply the principles and methods of scientific investigation to the problems of agriculture to the end that farmers become more efficient and prosperous, and may produce and market better quality food products for the nourishment of people.[11]

During these decades, certain guiding ideas became well-entrenched within Canada's public agricultural research institutions, including the legitimacy of a significant federal role, the treatment of research results as a "public good" to be widely disseminated for the benefit of all, and the selection of research projects through a science-driven process tempered by the overarching goal of increasing productivity. While these ideas ostensibly furthered the interests of producers by contributing to agricultural productivity, they also privileged the interests of public agricultural researchers who for decades were relatively free to pursue the accumulation of scientific knowledge. A "common culture" developed among plant breeders, characterized by informal cooperation and based on the willingness and ability to exchange information freely, despite working for different public organizations. Kneen remarks on this lack of institutional chauvinism and attributes it to the fact that the researchers worked in the public sector and knew the results were to be freely distributed and publicly-owned.[12] The Canadian Agricultural Services Coordinating Committee, an institutional mechanism established in 1932 to coordinate and advise on the agricultural research effort, strengthened the links among public researchers.[13]

Up until the 1970s, there were few notable changes in federal agricultural research policy, beyond occasional internal reorganizations and measures reflecting the increasing sophistication of agricultural science (see Table 1-2). None altered the division of labour between the public and private sectors in plant agricultural research or displaced institutionalized ideas. For example, calls for the introduction of intellectual property rights to protect new plant varieties, a market-based

[10] Anstey (1986).
[11] Garland and Hudson (1969): 273.
[12] Kneen (1992): 32-37.
[13] Brooks and Furtan (1984). CASCC's membership was all, or virtually all, drawn from the public sector. It included the federal and provincial deputy ministers of agriculture, federal and provincial agricultural research managers, university representatives, and representatives from the National Research Council I and Statistics Canada. The Agricultural Institute of Canada, a professional association, also held a seat on the committee, which provided the possibility of private sector representation.

policy instrument that might encourage private investment, date back at least to 1923, but no such measures were introduced prior to the adoption of plant breeders' rights in 1990. The sheer breadth and depth of the federal agricultural research effort did provoke harsh criticism from some quarters at times. In the early 1970s, for example, the overwhelming federal role was characterized as paternalistic and blamed for the dependence of the private and other public sector research centres on its efforts. The resilience of the federal agricultural research institution was demonstrated during this brief period of heightened criticism when external evaluations and major conferences, which brought calls for sweeping change in the form of decentralization and greater participation by the private sector, failed to bring about notable adjustment.[14]

United States

Like Canada, the United States has a long history of significant public commitment to agricultural research (see Table 1-2). Similarly sparked by the goal of developing a productive agricultural sector through innovation, a public research infrastructure was established that included the import, development, and testing of new plant varieties that would be transferred to agricultural producers. Soule and Piper argue that American public agricultural research institutions were "born in an atmosphere in which the nation romanticized industry" which explains their incorporation of the industrial goals of productivity and profitability.[15] Innovation has been a fundamental pillar of the US Department of Agriculture (USDA) from its beginnings in 1862 with the mandate:

[14] The main external evaluations were Canada. Science Council of Canada (1970, 1971). There were also at least two major conferences on agricultural research during this time: one in Manitoba and another in Guelph, Ontario, both held in 1971.

[15] Among the strongest proponents of the creation of the USDA were those who wanted to promote innovation, including members of agricultural societies who felt that the US was trailing behind Europe in this area. The US Commissioner of Patents of the time, Henry Leavitt Ellsworth, who was flooded with applications for agricultural machinery and new plant varieties, also believed that an institutional structure was required that could evaluate these innovations as well as diffuse them. See Soule and Piper (1992): 59-61. See also Marcus (1987) on the focus on innovation and productivity. The USDA describes the goal of its historic contribution to creating a public agricultural research system as improvement of the economic situation and quality of life for rural populations, and in particularly for the high proportion that were agricultural producers. See United States. Department of Agriculture (NDa).

> to acquire and to diffuse among the people of the United States useful information on subjects connected with agriculture in the most general and comprehensive sense of that word, and to procure, propagate, and distribute among the people new and valuable seeds and plants.[16]

The public agricultural research system, as in Canada, is credited with increasing agricultural productivity, ensuring an affordable food supply, and providing a high rate of return on investment.[17] This strong public role appears to be an anomaly in the history of American capitalism, provoked by biological and institutional barriers.[18]

In contrast to Canada, the American public sector agricultural research effort has been much more decentralized since its beginnings in the last decades of the nineteenth century. The 1887 federal *Hatch Act* was the centrepiece of a set of USDA initiatives that established a "de facto national system of agricultural research" that removed research from producers.[19] In 1862, federal legislation had been passed to give states land to sell for the purpose of establishing land-grant colleges to provide instruction in improved agricultural methods and other practical training. The *Hatch Act* established the State Agriculture Experiment Stations (SAES), to be associated with the land-grant colleges. The mandate of the SAES at the time of their establishment was to carry out research toward "a permanent and effective agricultural industry" with the goal of obtaining:

> useful and practical information on subjects connected with agriculture and to promote scientific investigation and experiment respecting the principles and applications of agricultural science.[20]

Administratively, the land-grant colleges and the SAES were largely independent of the USDA, but links were forged informally among researchers. During this time, USDA began to fund research

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[16] Soule and Piper (1992): 59.

[17] See, for example, National Research Council. Committee on a National Strategy for Biotechnology in Agriculture (1987): 54. It should be noted that in both countries, agricultural research has also come under fire for its alleged contribution to various perceived ills, including agricultural surpluses that have depressed farm income, and trends toward industrialization, intensification, and concentration within agriculture. Producers, more so in the US than in Canada, have periodically questioned whether public agricultural research and its results were in their best interests.

[18] Kloppenburg attributes the state role in crop research to the ease with which producers, historically, could reproduce much of the seed they required, which made it difficult for firms to invest and operate profitably in producing and selling seed. The lack of private investment spurred state involvement in the nineteenth century when it was decided that the success of agriculture depended on the introduction of new plant varieties. In turn, state involvement tended to discourage private investment, until the development of hybrid varieties. See Kloppenburg JR (1988).

[19] Marcus (1987): 21-22.

[20] Soule and Piper (1992): 60.

at the SAES and to conduct in-house research, which allowed it to promote its own research agenda. American spending on agricultural research has been greater than Canadian spending, in part due to private investment which has grown rapidly in the postwar years (see Table 1-3).[21] One calculation compared American spending at $564-million in 1959 rising to $1.1-billion in 1980 (in constant US dollars), to Canadian spending at $105-million in 1959, rising to $241-million in 1980.[22]

Several developments encouraged the growth of private investment in plant breeding.[23] First, private firms succeeded in convincing the USDA in 1924 to abolish its longtime practice of freely and widely distributing new seed varieties to producers. Second, from the 1930s on, private firms positioned themselves to profit from public sector efforts to develop productive corn hybrid varieties. Hybridization provided a new biological mechanism that much improved the ability of seed firms to profit from the development of new varieties, and resulted in the emergence of large seed firms such as DeKalb and Pioneer Hi-Bred.[24] Third, seed certification programs, which had drastically reduced profit margins because of their levelling effect, inspired seed firms in the 1940s to turn to marketing uncertified seed labelled with a brand name. Firms learned that combining clever marketing with product differentiation achieved by developing new plant varieties through in-house research paid off in profits. By the 1950s, these firms were well-accustomed to taking the high-quality germplasm developed by the public sector and making minor alterations to it to produce proprietary varieties.[25] Fourth, demand for seed was growing rapidly. Finally,

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[21] Table 1-3 provides a statistical overview of American spending on agricultural research since 1972. Private spending on agricultural and food research tripled (in constant dollars) between 1960 and 1992. See United States. Department of Agriculture (NDa).

[22] Schultz (1985): 12. Between 1959 and 1980, net farm income in Canada rose from $1.2-billion (Cdn) to $3.16-billion. In the US, net farm income rose from $11.3-billion (US) in 1959 to $20.1-billion in 1980. These figures are in current dollars; however, the growth in spending on agricultural research in each country largely echoed the growth in net farm income during this period. See United States. Bureau of the Census (1998) and previous years, and Canada. Statistics Canada (1985) and previous years.

[23] Kloppenburg JR (1988) provides a detailed description and analysis.

[24] Hybrids are attractive to the private sector because the firm retains physical ownership of the parent lines from which seed is grown each year. Producers must buy their seed anew each year; saved seed from hybrids is unlikely to be as productive as the first generation. The New Deal of the 1930s brought greater resources to the public agricultural research system, strengthening agricultural science just as research attention was focusing on the potential of corn hybrids. This infusion, somewhat ironically, spurred the development of hybrid varieties which made it easier for the private sector to conduct plant breeding profitably.

[25] Germplasm refers to the hereditary material within germ cells passed on to offspring. Deoxyribonucleic acid (DNA) is the molecular equivalent. See Allaby (1992): 176.

intellectual property rights (IPR) may also have encouraged private investment, although their role has been disputed.[26]

As private plant breeding and the seed industry grew in size and influence during the middle decades of the twentieth century, efforts to renegotiate the appropriate division of labour between public and private sectors intensified.[27] The industry found itself in direct competition with public breeders. Its fundamental goal was to refocus public research priorities. In practical terms, this meant that the public sector should leave commercialization of new plant varieties to the private sector, while continuing to provide quality germplasm for their efforts.

For a brief period, in the earliest days of hybrid research in the 1920s and 1930s, the public plant breeding system had been in a situation of "unambiguous hegemony", as Kloppenburg describes it. The seed industry found itself in a difficult position:

> The new techniques of breeding had begun to show results and were products of the public institutions. If private companies were to pursue these new methods for the production of improved varieties, they would have to obtain their breeders from the public sector. Even then, in the absence of any kind of legal protection for newly developed varieties, there would be difficulty in obtaining adequate returns on research investment. The seed industry was locked into a subordinate position to a public sector aggressive in its approach to applied science and ideologically committed to a mission of serving the farmer.[28]

For example, of the 128 main wheat varieties under cultivation in 1934, more than three-quarters were public. While seed firms were unhappy with this situation, large-scale capital, especially the railroad companies, strongly supported the public agricultural research institutions because these institutions were the only ones with adequate capacity in agricultural science to increase stagnating agricultural productivity.

However, the dominant role of public institutions in plant breeding began to erode even as it reached its height. Fitzgerald portrays the phenomenal success of hybrid corn as the beginning

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[26] For example, Kloppenburg disputes the argument that the *Plant Variety Protection Act* (PVPA) resulted in a significant increase in private investment in plant breeding after 1970. He points out that the expansion of private sector investment goes back at least to 1960 and that increases in demand for seed since the 1970s could easily be used to explain increases in investment in research by seed firms. He also demonstrates that the "relative intensity" of research, measured by the relationship between research investment and sales, flattened out from the 1970s on, rather than accelerating. See Kloppenburg JR (1988): 141.

[27] See Kloppenburg JR (1988) for a detailed account.

[28] Kloppenburg JR (1988): 81. This is not to say that there was no cooperation between seed firms and public institutions. For example, the USDA provided significant long-term support to Funk Brothers, which became a leading seed firm. Seed firm representatives were also active in various advisory committees alongside public plant breeders. See Fitzgerald (1990).

of the loss by public agricultural research institutions of their monopoly on scientific authority. Private agricultural research centres began to garner expertise in hybrids. Land-grant colleges, which had already been experiencing uncertainty about their proper role, were torn between the historic role of responding to producers' needs and an increasing interdependence with seed firms and other agribusiness interests. Hybrid corn was a major catalyst in the changing balance of power between public and private sectors, as a "conjunction of [the] diverse interests" among researchers, producers, and firms resulted in an "ambiguous" relationship from which only the firms emerged unbruised.[29]

Into the 1940s and 1950s, relationships became strained, if not hostile, between seed firms and public breeders. Some seed firms were reselling public varieties under their own labels. The *Federal Seed Act*, which had provisions to prevent such practices, was not being enforced adequately.[30] Less germplasm changed hands, private breeders found themselves unable to visit public experimental fields, and there were even charges of theft. An anecdote about a public researcher who took the bold step of patenting a breeding process for hybrid corn in the 1950s epitomizes the redefining of the implicit consensus on appropriate public and private roles in plant breeding.[31] This patent shocked the research community, which felt that it violated Mertonian scientific ideals of communalism and disinterestedness, *and* the seed industry, which did not want to pay for the research results of the public sector. Although the patent was issued in 1956, the industry resisted paying royalties until 1969 when litigation forced it to pay. Meanwhile, the researcher at the centre of the controversy was censured by the American Society of Agronomy and isolated from his colleagues.

The renegotiation of the division of labour took place through a variety of different institutional fora, focusing on both research and regulatory policy.[32] For example, in 1946, the American Seed Trade Association (ASTA) began an annual conference that brought together public and private breeders. The Agricultural Research Institute, created within the National Science Foundation in 1952, was given the mandate to integrate public and private research activities.

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[29] Fitzgerald (1990), especially pp. 220-223

[30] Provisions of the *Federal Seed Act* required varieties to be sold under their original name; this was intended to prevent false advertising and sale of the same or slightly different seed under new names for marketing purposes.

[31] Kloppenburg JR (1988): 113-115.

[32] Kloppenburg JR (1988): 108-109.

Reflecting the growth of the private plant breeding effort, the National Council of Commercial Plant Breeders was established in 1954 to represent the interests of private breeders. Private breeders and other seed industry representatives began to attend meetings of scientific associations in larger numbers, such as the International Crop Improvement Association, the American Society of Agronomy, and the American Society for Horticultural Science. Further, the private sector was providing substantial funding to public institutions. By 1972, for example, industry funding of the system of agricultural and forestry post-secondary institutions was at $51-million (US), or about 14 percent of the total funding of $374-million.[33] By the 1970s, the seed and plant breeding industry had largely succeeded in recasting the public sector into a role that suited the needs of private seed firms and restricted its ability to set its own research agenda. Public research increasingly focused on basic research at land-grant institutions and produced fewer plant varieties ready for commercialization.[34]

Seed and plant firms also pursued a more favourable climate for their expansion by constant lobbying for stronger intellectual property protection for their research results. In fact, they had asked for some form of protection since at least 1885. In 1930, the *Plant Patent Act* was adopted, covering most asexually reproduced plants. This measure, encouraged in part by the worsening economic conditions following the 1929 stock market crash, reversed the precedent set by an 1889 Patent Office ruling that "products of nature" were not eligible for patenting. To be protected under the *Plant Patent Act*, plants did not have to be useful, only new and distinct. Measures of relative quality or superiority and utility were immaterial to patentability. Expanding IPR measures for plant varieties, the *Plant Variety Protection Act* (PVPA) was adopted in 1970 after a nine-year campaign by seed industry and USDA officials.[35] The PVPA protects plants

[33] National Research Council (1996): 76.

[34] For example, a 1979 study found that the public sector had withdrawn from breeding work on insect and disease resistant varieties of corn and wheat on the assumption that the private sector would step in. See Fowler and Mooney (1990): 135.

[35] These individuals were inspired by the agreement reached in Paris among several European countries to grant reciprocal recognition of plant breeders' rights in 1961. See Doyle (1985) for a detailed account of this campaign. The American Seed Trade Association (ASTA) initially tried to bring these plants under the *Plant Patent Act*. Its attempt was supported by food processors, who wanted new varieties that would be easier to harvest and process mechanically. However, the use of patents was opposed by a variety of actors, including the Crop Science Society of America, horticulturalists, and the Administration, as well as the USDA. The USDA opposed the use of patents because of the tendency of these plants to shift in characteristics across generations, which would make the provisions difficult to enforce.

reproduced by seed, encompassing many major crops. A bill was drafted during a meeting of seed industry officials, SAES directors, and USDA officials in March 1969. Opposition to the PVPA was weak. No agricultural producer or consumer associations appeared during the committee hearings. One congressman asked questions about whether costs would increase for producers and consumers, and wondered why the PVPA was required considering that the agricultural industry had prospered without it. The PVPA also encountered some resistance during the White House review process, but not enough to prevent its passage. For example, the President's special assistant for consumer affairs recommended a veto, noting concerns about the measure possibly resulting in increases in market power and government administration costs. He doubted whether it would actually stimulate innovation as claimed and wondered whether costs to consumers and taxpayers would increase, while benefits would accrue only to plant breeders. The Bureau of the Budget (BOB) initially also recommended a veto. It cited the concerns listed above and expressed doubt about the measure being in the public interest. Its memo suggested that the likely suppression of the information flow between the private and public sectors which might follow would actually hinder innovation, rather than stimulate it. However, at the last minute, BOB director George Shultz ordered the memo changed so as not to prevent approval.[16]

[16] The only possible explanation Doyle was able to find for this reversal was that USDA officials said that the seed industry had a White House contact that helped ensure passage of the law. See Doyle (1985).

Comparing Canadian and American Agricultural Research Policy Legacies

This brief survey suggests that the differences in agricultural research policy legacies between Canada and the US, focusing on plant breeding, are more striking than the similarities. The two countries share a history of significant public commitment to agricultural research, but the mix of ideas, interests, and institutional structures differs. A few tentative conclusions can be made about the potential effect of these policy legacies on future policy networks, including on the degree of federal state autonomy and capacity and the relative power of societal interests. The development of the public agricultural research effort in each country, guided by the strongly-institutionalized idea of pursuing economic development and productivity through innovation, has provided an impressive capacity to deliver. However, the decentralized nature of the American public agricultural research system has weakened the federal government's ability to exercise its capacity, despite its leadership in creating the system. It has been more vulnerable to societal pressures than the Canadian system. The structure of the historic partnership between federal and state governments, with the federal government providing fixed funding while much of the personnel is in the employ of the states, means that state and local priorities have tended to dominate research directions historically.[17] Further, agricultural research priorities at post-secondary institutions have rarely been directed by long-term policy goals. Decentralization appears to have allowed private interests to influence and capture the results of public research, as in the case of hybrid corn. As of the early 1970s, neither the federal executive nor Congress had played an active role in overseeing agricultural research policy, leaving it instead to what one critical report called the "inbred" and "tightly-drawn" land-grant community.[18] The report argued that the community was largely closed to interests outside of the land-grant community, the USDA, and agribusiness.

In the US, the institutionalization of the programmatic ideas of market-driven innovation and market-based merit assessment through the introduction of IPRs has come at the expense of science-based merit assessment. IPR measures institutionalize market-driven innovation because they tie financial reward to commercial success. This idea challenges publicly-funded science-

[17] National Research Council. Committee on a National Strategy for Biotechnology in Agriculture (1987): 52, Fitzgerald (1990). The USDA has made periodic efforts to enhance state capacity. For example, it created an in-house research arm in 1953 (the Agriculture Research Service).

[18] Hightower (1973).

driven innovation through its implicit suggestion that public research may not be necessary in some areas such as developing new plant varieties. Increasing private investment in agricultural research combined with market-driven innovation also restricts state capacity in setting research priorities and in acquiring exclusive scientific resources. Historically, the public sector's development of superior new varieties has countered market-driven innovation by providing some discipline to the seed market because of its commitment to science-based merit assessment; however, the withdrawal of the public sector from producing finished varieties reduces this effect. In contrast, in Canada, science-based innovation and merit assessment remained dominant well into the 1980s, if not into the 1990s.

In summary, American state autonomy and capacity in agricultural research policy at both levels of government appears to have weakened between the 1930s and 1970s. Agricultural research policy increasingly incorporated the preferences of the seed industry through the renegotiation of the division of labour between public and private sectors, the increase in market-driven innovation at the expense of science-driven innovation, and the provision of market-based policy instruments in the form of IPRs.[39] Meanwhile, in Canada, the public agricultural research system went largely unchallenged by private interests. Its institutions protected the scientific autonomy of public researchers and preserved original guiding principles such as science-driven innovation. The federal government's consistent leadership translated into a high level of federal state autonomy and capacity in setting research directions and priorities, based to a large extent on scientific resources.

[39] This effort did not go uncontested by public breeders who, for example, expressed concerns about the potential effects of the PVPA, arguing that it might marginalize public breeding and restrict innovation by reducing the exchange of germplasm. See Kloppenburg JR (1988): 57-61, 139.

POLICY LEGACIES IN REGULATING NEW PLANT VARIETIES

Canada

Sale and Use

For several decades and in close cooperation with the agricultural research community and the seed industry, Canada has regulated the quality of plant varieties used in the cultivation of major crops. The Canadian Seed Growers' Association (CSGA) was created in 1904 to provide producers with quality seed, after the federal agriculture minister declared that setting quality standards and registering stock should be administered by private interests.[40] CSGA has worked closely with the federal department of agriculture ever since. The *Seeds Act* has been the main policy instrument.[41] Under the *Seeds Act*, new plant varieties have had to be tested and licensed prior to import into or sale in Canada.[42] The original *Seed Control Act* of 1905 set out standards only for mechanical purity and germination rates which were voluntarily applied and provincially inspected. In the 1920s, a committee system was established under CSGA which created closer links between seed growers, plant breeders, and the federal department of agriculture. In 1923, when the *Seeds Act* replaced the *Seed Control Act* of 1905, grading of seed and variety registration became mandatory.[43] Under the new *Seeds Act*, CSGA's standards were incorporated into the legislation and the federal government was put in charge of inspection. In 1959, the CSGA was designated as the sole agency to prescribe standards for purity and issue pedigree status.

Variety registration has been required historically for major grain and oilseeds crops to provide assurances of standard quality. Only registered varieties, which qualify as top grades, can enter the commercial grain handling system. Under the variety registration system, committees of experts drawn historically from public agricultural research institutions meet periodically to examine new varieties submitted for registration.[44] The mandate of these committees has been to

[40] Clayton (1995).

[41] The *Seeds Act* is likely to be consolidated under a proposed "Canada Food Safety and Inspection Act", first introduced to Parliament in April 1999.

[42] Canada also has had legislation in place to allow measures to be taken against pests to agriculture since the *Destructive Insect and Pest Act* of 1910, which could be used to prevent the import and distribution of seeds or plants.

[43] The grading system itself dates back to 1874.

[44] Klein (1997): 20. Historically, the members of these committees have been drawn almost exclusively from the public sector, given the nature of the agricultural research effort in Canada. Around the late 1980s, an "edict" came down, presumably from the federal government, that a minimum of 25 per cent of the members of these committees should be drawn from the private sector. See Harvey (1995).

advise regulatory agencies on the legislation and regulations that govern new varieties, to coordinate the conduct of trials to evaluate potential new varieties, and to make recommendations. Varieties that pass the committee's scrutiny and are registered have successfully met or exceeded standards set for agronomic and quality traits such as yield, disease and insect resistance, and end-use quality. While unregistered varieties can be produced and sold, they normally earn less. The rigorous process of variety registration, particularly for wheat, is given credit for the high quality of Canadian wheat and other crops. The standards set for registration also tend to dictate the direction of research on new varieties.[45] Kneen argues that the system of variety registration institutionalizes the principle of equity by providing producers with the assurance that certain varieties meet minimum standards.[46] The system also institutionalizes the principle of science-based assessment of merit and provides indirect state control over research priorities by discouraging development of varieties that are inferior to existing registered varieties.

The variety registration system has required periodic contact between plant breeders, the seed industry, and federal state officials. Crop experts meet regularly through the committee review system where other matters of mutual interest are often discussed, including more recently the regulation of agricultural biotechnology.[47] A seed industry representative described the relationship between the seed industry and state officials in the 1940s and 1950s as cooperative.[48] He stressed the lack of antagonism. The department of agriculture was "a very strong force in the seed industry", he said, and "everyone seemed fairly well-satisfied [with the system] if they played by the rules". Enforcement was adequate and considered simple, inexpensive, and efficient. Amendments to the *Seeds Act* in 1959 further illustrate the close working relationship among the members of this policy community. These amendments made it possible to specify the means by which the legislation was to accomplish its purpose through administrative regulations instead of through legislation. This change was considered by the seed industry as "of great benefit" since it would permit the federal agriculture department to adjust more quickly to changing market

[45] Klein (1997): 18.
[46] Kneen (1992): 67-68.
[47] Personal interviews with agricultural researchers.
[48] Canadian Seed Trade Association (1995): 10. However, it should be noted that the Canadian Seed Trade Association, which represents larger seed firms (in contrast to the CSGA which represents the wide range of seed growers, including family farms) was critical of the *Seeds Act* in the 1920s, and somewhat alienated from the CSGA until the mid-1950s. See Szego (1995): 345.

conditions. Regulations were subsequently developed in consultation with representatives of the seed industry and provincial agricultural departments.[49] Of course, the seed industry and state officials did not always see eye-to-eye. For example, the seed industry was somewhat reluctant to participate in a program promoting the use of improved forage seeds because "the certification tag had an equalization factor eliminating the presumed superiority of one company's brand over another's",[50] and thus restricted a firm's ability to make marketing claims.

Food safety and labelling

Beyond the considerations of plant breeders in the course of developing new varieties, there is no evidence to suggest that the safety of new plant varieties for human consumption was an issue in Canada prior to biotechnology.[51] Responsibility for food safety in Canada at the federal level has generally been shared by several departments and set out in several statutes. Health Canada has had primary responsibility through its standard-setting activities.[52] Other departments, including the agriculture and fisheries departments, have had specific responsibilities regarding grading, inspection, and enforcement.[53] A series of acts since 1907 has governed food safety (see Table 1-4). The major statute--the *Food and Drugs Act*--was introduced in 1920. Historically, the *Food and Drugs Act* has not had provisions requiring a universal approach to food safety assessment that would have brought new plant varieties under its scope. However, some food safety assessment measures have been introduced for specific processes and substances since 1964.[54] Responsibility for food labelling policy in Canada has also been somewhat divided among departments at the federal level. Since 1920, the *Food and Drugs Act* has prohibited the food industry from using misleading labelling, processing or advertising. In 1971, the introduction of

[49] Canadian Seed Trade Association (1995): 24.
[50] Canadian Seed Trade Association (1995): 11.
[51] Interviews with Canadian state officials.
[52] Canada's federal department of health has been called Health Canada since the government reorganization of 1993. Its previous names included Health and Welfare Canada and Department of Health. For clarity, this dissertation will refer to it as Health Canada regardless of the timeframe.
[53] Canada. Auditor General of Canada (1994).
[54] Canada. Health and Welfare Canada. Health Protection Branch (1992). The first specific food safety assessment measure was introduced in 1964 to ensure premarket evaluation of food additives. Food additives must be approved and included on a list of approved substances, before they can be used. Premarket approval is also required for changes in the use of irradiation. Chemical residues in foods, such as from the use of pesticides, are also regulated. Premarket notification is required for new or significantly modified human milk substitutes. All of these measures are designed to evaluate quality, ensure safety, and/or demonstrate nutritional adequacy.

the *Consumers Packaging and Labelling Act* set standards for the labels of all prepackaged food. Food labelling has been intended generally to ensure consumers are provided with accurate information to promote fair competition and product marketability.[55]

The scope of food regulation has evolved since the first federal legislation in 1875 in response to the concerns of the day, which have included reducing adulteration, monitoring incredible claims of miracle cures, and assessing the safety of food additives (see Table 1-4). In 1969, Health Canada's food regulation mandate was reduced when its former duties of monitoring and enforcing labelling regulations were transferred to the Department of Consumer and Corporate Affairs. Its responsibilities were narrowed to include examining the composition of foods, interpreting and enforcing regulations on health hazards, inspecting food processing plants not inspected by the agriculture department, and responding to consumer complaints on safety. Previously, between 1920 and 1969, federal health officials had been responsible for protecting consumers from "misbranding" or false labelling. At times, their duties included screening advertising.

There are indications that the lack of scientific capacity has periodically hampered regulatory efforts in food safety and labelling in Canada. In 1875, there was confusion over the meaning of "adulteration" and many analysts lacked adequate training. The lack of legal standards for food was "a severe impediment" and resulted in the use of American standards.[56] When Canadian officials did draft their own standards in 1909, they based them on standards developed

[55] Canada (1994a). Labelling requirements that existed prior to 1970, such as common name, weight, and ingredients, were intended mainly to protect consumers from misleading claims. Over time, specific provisions were adopted for certain categories of food, such as artificial sweeteners. In the 1990s, detailed provisions were introduced to regulate health and nutritional claims.

[56] Davidson (1950): 44.

in the US and incorporated work done in Europe. Advance copies were sent to manufacturers to avoid controversy, establishing a longstanding pattern of advising industry of proposed regulatory changes. For decades, the standard operating procedure has been to respond to requests for changes in regulations that come from various sources including consumer and industry associations by sending them to an advisory committee. Committee decisions are then communicated to the food industry by a Trade Information Letter which states the problem, the proposed regulatory changes, and asks for comments.[57] Prior to 1970, public hearings were generally not held, with the food directorate instead considering itself accountable through its Minister.

Canadian food regulatory officials also have a long history of collaboration with international committees and other countries. They have been sensitive to developments outside the country.[58] For example, Canada introduced regulations on vitamins in 1939-1940 just as the US was introducing similar measures. In 1948, an internal publication noted that Canadian labs collaborated with labs elsewhere and with associations in other countries. In 1966, lab researchers were actively working with United Nations organizations including the Food and Agriculture Organization and the World Health Organization. And in 1981, another internal publication noted that the recommendations of expert committees at the international level were "always taken into account".

[57] Canada. Department of National Health and Welfare. Food and Drug Directorate (1970).

[58] Canada. Department of National Health and Welfare (1948), Canada. Department of National Health and Welfare. Food and Drug Directorate (1966), and Canada. Department of National Health and Welfare. Health Protection Branch (1981): 33.

United States

Sale and Use

The US has no system similar to variety registration at the federal level that tests merit.[59] USDA regulatory efforts affecting seeds and plants have focused instead on protecting American agriculture from the threats of plant pests and noxious weeds, ensuring fair competition in the seed trade by requiring seed labels to be truthful, providing testing services for seeds on characteristics such as purity and germination rates, setting grading standards, and establishing orderly marketing agreements to ensure uniformity in quality and other cooperative benefits.[60] The *Federal Seed Act*, for example, focuses on the interstate shipment of seeds and seed labelling.

However, the work of crop improvement associations at the state level did encourage improvement in the quality of seeds and plant varieties. Between 1915 and 1930, crop improvement associations were established in most states, affiliated with the State Agriculture Experiment Stations (SAES) and land-grant colleges. Members of these associations were graduates of the colleges and would grow out public varieties for wider distribution. The system was governed by seed certification which ensured a minimum level of quality could be found in the public varieties. Public varieties were not released unless they were superior to existing varieties and were distributed freely. The International Crop Improvement Association was created in 1919 to protect the interests of the seed growers.[61] It rivalled the seed industry association (ASTA) in political influence. Kloppenburg argues that seed firms were excluded deliberately from the crop improvement network by public administrators who were committed to quality and equity, and who opposed the idea of having these firms become the exclusive sellers of their work to producers.[62] With the advent of hybrids, private and public breeders found themselves in full-fledged competition, which made the seed firms even more determined to renegotiate the division of labour and convince public institutions to abandon the development of finished varieties, as noted earlier.

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[59] Lesser (1988).

[60] For example, the US has had plant quarantine legislation since 1912 to prevent the introduction of exotic plant pests. See Hatch and Kuchler (1989). The range of Canadian regulatory activities has been similar, but with the distinctive addition of variety registration.

[61] The International Crop Improvement Association later became the Association of Official Seed Certifying Agencies.

[62] See Kloppenburg JR (1988): 72-82.

Public breeders did not relinquish their role in plant breeding easily. Into the 1950s, many SAES published lists of recommended varieties and new varieties would be certified only if they were superior to existing varieties. Meanwhile, the seed industry lobbied for the removal of these criteria for certification. Instead, it argued, the purchaser of the seed should be the one to judge quality and certification should be limited to guaranteeing seed purity. This change would remove the guarantee of minimum levels of performance which tended to reduce profits. It would allow firms to market on the basis of product differentiation, leaving the variety name and price as the only characteristics on which consumers would base their choices. By the mid-1970s, ASTA had succeeded in eliminating performance as a criterion for certification in all but a few states.[63] As Kloppenburg notes:

> An enduring and ironic theme of efforts to introduce [plant breeders' rights] legislation in the United States has been proponents' insistent assertions that enlarged private investment will result in superior varieties. At the same time, they have just as adamantly rejected the imposition of any regulatory framework intended to ensure that promised quality is in fact realized.[64]

Under the *Plant Patent Act* and the *Plant Variety Protection Act,* novelty rather than scientific merit is the fundamental value determining whether protection is to be granted, which removes scientific resources as an asset contributing to state capacity.[65] Assessment of merit is left to the market in the absence of a variety registration process like that in Canada in which a committee of independent experts or state officials evaluates varieties. The lack of such provisions, combined with the availability of intellectual property right protection based on novelty, has been blamed for the prevalence of "cosmetic breeding" in the US following the PVPA. Cosmetic breeding results in firms producing "variations on a theme" which are sufficiently novel, but do not necessarily offer superior traits.[66]

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[63] Kloppenburg JR (1988).

[64] Kloppenburg JR (1988): 132.

[65] Descriptions of new plant varieties provided in applications for protection under the PVPA are normally accepted at face value, and novelty does not have to be in agronomic traits. See Lesser (1988) who notes that the PVPA appears to have resulted in less difference in protected varieties and reduces incentive to produce better varieties. Kloppenburg has also noted that under the PVPA system, incentives are strong for firms to focus research efforts on creating variations for the sake of novelty rather than improvement. Other critics argue that PVPA has resulted in an explosion in the number of varieties without a corresponding increase in improvement.

[66] See Doyle (1985). Legislative amendments in 1994 were intended to reduce cosmetic breeding.

Food safety and labelling

In the US, the scope of federal food regulation has also changed periodically, mostly in reaction to food safety crises, public pressure, and Presidential priorities.[67] For example, the first federal legislation for food safety was secured not by the twenty-five years of lobbying that preceded it, but by a major food safety scandal. The exposé of unsanitary practices in meat plants in Upton Sinclair's book, *The Jungle*, propelled the long-sought passage in 1906 of the *Pure Food and Drugs Act* and the *Meat Inspection Act.* These two federal statutes were administered initially by the USDA.[68] Since 1927, the Food and Drug Administration (FDA) has had primary responsibility for food safety. In 1938, the FDA's powers were considerably increased through legislative amendments that produced the *Federal Food, Drug, and Cosmetic Act*, which remains the basis for its authority. The 1938 legislation was prompted by an episode of the sale of a new "wonder drug" that had not been adequately tested. The drug fatally poisoned 107 people. At that time, labelling requirements listing the ingredients in some foods were introduced, although they were seldom followed.[69] Until 1958, FDA relied mainly on its postmarket enforcement provisions, which date back to the initial 1906 legislation, to secure food safety by penalizing adulteration once it was discovered. Amendments in the 1950s and 1960s introduced premarket food safety assessment of certain substances such as food additives and pesticide residues. These measures place the onus on producers to ensure the foods they sell are safe and to take the initiative of consulting informally with the FDA when they are unsure about the safety and regulatory status of a new food or food ingredient. Under these provisions, many food ingredients are classified as "generally recognized as safe" (GRAS) and are thus exempted from premarket clearance.

Historically, the FDA did not normally conduct pre-market safety assessments of foods derived from new plant varieties. Many of these foods were being consumed long before the FDA existed. Their safety has been considered by the FDA to be proven based on decades, if not centuries, of human consumption.[70] As well, it has been assumed that plant breeders would assess food safety through their observations about the traits of the new varieties. In some cases where plants were known to pose safety concerns, such as potatoes which contain varying levels of a

[67] Burkholz (1994).
[68] See Table 1-4 for key events in the history of federal food regulation.
[69] Wodicka (1996).
[70] United States. Food and Drug Administration (1992).

toxic substance, tests would be carried out specifically for food safety assessment. The FDA did make an attempt to regulate new plant varieties in the early 1970s, recognizing that increasingly sophisticated breeding methods were sometimes producing significant alterations in the composition of the food derived from the new varieties.[71] The agency was concerned that new varieties might have significant decreases in nutritional value or significant increases in toxin levels. In 1971, regulations were passed stating that a significant decrease in nutrients of 20 per cent or more or an increase in toxin levels of 10 per cent or more would be grounds for review. The measure met with a great deal of resistance, particularly from the agricultural research community and the seed industry. Opponents noted that the lack of basic knowledge about toxin and nutrient levels in food crops would make the measure difficult to implement. To ease implementation, a task force bringing together the USDA, the FDA, and the food industry made recommendations, which included a list of crops for which nutrient levels should be monitored. The American Seed Trade Association, the Crop Science Society of America, and the National Council of Commercial Plant Breeders harshly criticized the recommendations. Their representatives claimed the measures would jeopardize research in plant breeding and would result in the FDA imposing nutritional requirements on other products. A National Academy of Sciences task force added to the criticism, describing the regulations as "unsound, impractical, and regressive", in part because of the ongoing lack of data on which to base them. It appears that the strong opposition had its intended effect because the FDA had not established mandatory monitoring nor enforced these regulations as of early 1984. Subsequently, however, this effort did provide a starting point for the regulation of genetically-engineered plant varieties.

The FDA has an established tradition of turning to outside experts for scientific advice on food safety issues. The resources within the massive American food industry have encouraged the FDA, faced with inadequate financial and scientific means to fulfil its immense mandate, to seek to secure industry cooperation and assistance. For example, when the US Congress passed the Food Additives Amendment in 1958, the question was raised of whether some food additives that were already in use could be considered "generally recognized as safe" (GRAS) and exempted from premarket review. The FDA made up a list of potential GRAS substances and surveyed outside experts to see if they agreed. Jasanoff notes that the FDA has generally had problems attracting

[71] See Kloppenburg JR (1988): 127 and Doyle (1985): 147-153.

and keeping highly-qualified scientists, which encourages reliance on outside experts. It is perpetually understaffed in proportion to its mandate. She argues that its extensive use of expert advisory committees since the late 1960s illustrates the FDA's awareness that its regulatory efforts require legitimation from the wider scientific community.[72] In 1970, when the White House asked for a review of all GRAS substances, the FDA gave the Federation of American Societies for Experimental Biology a contract to do the massive study, which took ten years. Particularly since the 1950s, the FDA's mandate has been pursued in a context of constant scrutiny by the industries it regulates and by consumer advocates, further increasing its challenges. It operates under the simultaneous expectations that it will protect public health effectively and minimize the regulatory burden.[73]

As in Canada, American federal food labelling policy has focused largely on the goal of market regulation rather than ensuring food safety. Prior to 1973, much of food labelling policy was intended to protect fair competition by providing consumers with adequate information to assist their buying choices rather than information about the qualities of a product. For example, an amendment in 1913 required that the quantity be stated on a label. In 1938, labels had to include a food's common name, its net weight and ingredients, and could not make false or misleading statements. In 1966, the federal *Fair Packaging and Labeling Act* was introduced to ensure that goods sold in interstate commerce were labelled accurately so that consumers could make comparisons. Since 1973, there has been more attention to the appropriate use of labelling to make nutritional and health claims, shifting the focus somewhat toward a science-based merit assessment and away from a solely market-based merit assessment. Labelling policy in the late 1990s requires disclosure of information that is "material" to claims made or suggested about the product and the results of its use, but does not require information on the basis of the "consumers' desire to know".[74]

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[72] Jasanoff (1990): 153.
[73] Burkholz (1994): 6.
[74] United States. Food and Drug Administration (1992), United States. Food and Drug Administration. Center for Food Safety and Applied Nutrition (1995).

Comparing Policy Legacies in the Regulation of New Plant Varieties

In comparing Canadian and American policy legacies in regulating the sale and use of new plant varieties, the notable differences are similar to those found in agricultural research policy legacies (see Table 1-5). Regulation in Canada has been centralized at the federal level. The seed industry and state officials worked together on issues of seed certification and variety registration in a cooperative concertation-style relationship that consistently improved the quality of major crops. The variety registration system, in particular, institutionalized the programmatic idea of science-based merit assessment. Evaluation of varieties was done through a science-based process, specifically through the conduct of trials and appraisal by public sector crop experts. State capacity and state autonomy at the federal level were enhanced by the productive relationship with the seed industry and bolstered by access to scientific resources in the public sector. This situation furthered the interests of the agricultural economy generally by building Canada's reputation for quality commodities, which can be seen as a public good. It also enhanced the reputation of public plant breeders by ensuring that varieties met ever-increasing quality standards. It likely deterred private interests from pursuing plant breeding, since variety registration requirements made plant breeding a more difficult endeavour with no assurance of a return on investment. The low levels of private research activity in major crops combined with institutional inertia also appears to explain why the variety registration system did not face challenges powerful enough to have resulted in policy change prior to 1973.

In contrast, in the US, efforts within the public sector to regulate seed and plant variety quality occurred mostly at the state level, reflecting the decentralization of the agricultural research system. From the 1930s on, these efforts were contested by private interests.[75] By the 1970s, the seed industry had succeeded in securing noticeable reductions in public efforts to produce finished plant varieties, thus weakening one policy instrument that could establish minimum quality requirements. The introduction and strengthening of intellectual property rights (IPRs) throughout the century helped to institutionalize market-based merit assessment at the expense of science-based merit assessment. As with agricultural research policy, it appears that the American state has been

[75] It should also be noted that one of the leading seed corn firms, Pioneer, was started by Henry A. Wallace who was subsequently secretary of agriculture from 1933 to 1940, and vice-president from 1941 to 1945. Fitzgerald says that Wallace's influence in national agriculture policy was probably unparalleled during the 1930s. See Fitzgerald (1990): 4.

more vulnerable to societal pressures than its Canadian counterpart. State-level efforts to incorporate performance standards into criteria for development of new varieties were trumped by the preferences of the seed industry and reinforced by the federal decision to provide IPRs.

The lack of efforts in both countries to regulate new plant varieties on the issues of food safety and labelling limits us to drawing a general comparison on food safety and labelling policy. The comparison suggests that Canadian and American food regulators have been hampered by a lack of capacity and autonomy, making them somewhat vulnerable to pressures from the food industry. Authority for food safety and food labelling is fragmented across several departments and statutes in both countries. Combined with the lack of universal food safety assessment measures, this fragmentation which sometimes has separated standard-setting and enforcement capabilities weakens state capacity. Fragmentation has been blamed for reducing the effectiveness of federal food safety efforts, such as Health Canada's inability to ensure whether food safety provisions were being applied fully and effectively.[76] Although Health Canada and the FDA hold mandates to protect human health by pursuing food safety, the adoption of premarket food safety assessment measures appears to have been episodic and reactive. Regulatory authority has existed and been expanded over time, but capacity has not kept pace with a lack of financial and scientific resources. Autonomy may also have been jeopardized by the use of external advisory bodies at the domestic and international levels and reliance on industry cooperation. The FDA's ill-fated attempt in the early 1970s to regulate new plant varieties for food safety illustrates both the lack of scientific capacity, in terms of a database on nutrient and toxin levels, and a lack of autonomy, in that the agency backed away from implementing and enforcing its regulations. In Canada, the absence of efforts to regulate new plant varieties for food safety prior to genetic engineering implies that the department deferred to the judgment of plant breeders. Finally, the evolution of food labelling policy suggests that, up to 1973, institutional fragmentation and the dominant policy goal of market regulation restricted state capacity and autonomy and the potential to pursue

[76] Canada. Auditor General of Canada (1994). However, the establishment of the Canadian Food Inspection Agency in 1997 was expected to remedy some of these ills. On the US, see United States. General Accounting Office (1997b) and United States. General Accounting Office (1996a). For example, the USDA is responsible for the safety of meat and poultry products, while the EPA is responsible for setting tolerance levels for pesticide residues.

consumer protection on safety or quality grounds.[77]

The comparison of regulation of new plant varieties in Canada and the US indicates that federal state capacity and autonomy are enhanced when there is adequate in-house research capacity, scientific resources are centralized, and institutionalized ideas and policy instruments are more science-based than market-based (see Table 1-6). In Canada, these conditions existed historically for the regulation of the sale and use of new plant varieties, but not for food safety or labelling regulation. In the US, the decentralization of agricultural research weakened state capacity and autonomy at the federal level. Capacity and autonomy were further eroded by the increasing role of the private sector and entrenchment of market-based programmatic ideas. In food safety and labelling regulation, state capacity and autonomy have been contingent historically not so much on legal authorities, but on the location of scientific resources in the form of food science expertise.

Conclusion

The policy networks that emerged in the 1980s in Canada and the US in response to issues arising from the commercialization of genetically-engineered plant varieties were built on the foundation of relevant policy legacies in agricultural research and regulation. This chapter has examined these policy legacies to establish the starting points for the policy networks surrounding environmental release, food safety assessment, and labelling of foods containing genetically-engineered plants. It has focused on gauging their expected effects on state capacity and autonomy within the policy networks. Further, the identification of ideas instititutionalized within policy legacies permits conclusions about the ways in which these ideas may privilege some members or encourage patterns of exchange that shape the nature of the policy network.

The nature of policy legacies in agricultural research and regulation suggests that we should expect to find relatively high state capacity and autonomy within the Canadian environmental release policy network. The dominant role of the federal public sector in plant breeding and in the regulation of new plant varieties combined with the institutionalization of science-driven innovation and science-based merit assessment resulted in a cooperative concertation-style relationship

[77] However, in more recent years, with increasing consumer sophistication and interest in nutrition, there have been more animated struggles between regulatory officials and the food industry over claims regarding fat content and health benefits. See, for example, Burkholz (1994) on the FDA's struggle to regulate health claims on food labels.

between seed growers, plant breeders, and federal regulators. Agricultural research and regulation policies were intended ultimately to promote development of the agricultural economy, but institutional arrangements and the prominence of science as an idea in policy choices enhanced the capacity and autonomy of regulators and federal public sector researchers. The concentration of relevant scientific expertise in the federal public sector suggests that it would be difficult for societal interests to challenge the inertia of these policy legacies.

In contrast, American policy legacies have hampered state capacity and the exercise of autonomy in developing agricultural research and regulation policies, leaving the state more vulnerable than its Canadian counterpart to societal pressures. The decentralized structure of agricultural research and efforts at regulation of new plant varieties positioned federal state actors as a weak player among many others and denied any actor a dominant role based on claims of scientific expertise. The growing involvement of the private sector in plant breeding contributed to the institutionalization of market-driven innovation and market-based merit assessment, diluting science as a programmatic idea. This combination of ideas privileged the private sector and restricted state capacity by limiting the scope of its involvement. Carried forward, these policy legacies would be expected to provide advantage to the private sector and help to explain low levels of state capacity and autonomy.

Food safety policy legacies in Canada and the US do not differ as markedly as those relevant to environmental release. Undisrupted, these policy legacies would be expected to favour industry actors and other actors with relevant scientific expertise. In both countries, the fragmentation of authority within and across levels of government has reduced state capacity historically. The lack of capacity and autonomy is illustrated by the fulfilment of the food safety mandate of regulators in a somewhat haphazard and reactive manner. The dominance of market-based guiding and programmatic ideas (policy goals) historically privileged industry actors. The reliance at times on science as a programmatic idea, as for selective premarket food safety assessment provisions for specific products, also made the possession of scientific expertise an important resource. State capacity has also been restricted by a lack of financial and scientific resources. The lack of adequate in-house scientific expertise has encouraged consultation and cooperation with industry during policy making. The few differences in the policy legacies between the two countries are found largely in the sources of external scientific expertise that

regulators have relied on traditionally. In Canada, food safety regulators consistently monitored decisions in food safety regulation in other countries and often relied for guidance on scientific consensus developed elsewhere, especially by international institutions such as those under the auspices of the United Nations. In the US, regulators had the mixed blessing of the growing wealth during the twentieth century of domestic food science expertise within industry and academic institutions. While there was ample expertise available, its location may have made it more difficult for regulators to exercise autonomy. Finally, the highly similar labelling policy legacies in the two countries have provided little advantage to state actors and tend to privilege the private sector. Authority has been fragmented and there has been a heavy, almost exclusive, reliance on market-based ideas.

In the absence of challenge from new ideas or of institutional rearrangement, these policy legacies would be expected to shape problem definitions and policy choices in subsequent policy making through the inertia they contribute to new policy networks. For example, in the case of environmental release in Canada, which added a new dimension to the existing scope of regulation of the sale and use of new plant varieties, one would expect policy choices to pursue economic goals such as competitiveness and market regulation and use science as programmatic idea. Those with scientific expertise within the policy network, such as public sector plant breeders, would have the initial advantage. Within the American policy network surrounding environmental release, policy choices would rely more heavily on market-based guiding and programmatic ideas, providing a greater advantage to the private sector. In food safety policy networks in both countries, the combination of market- and science-based ideas would be expected to provide an advantage to the private sector while also making the possession of scientific expertise an important resource. However, the distinct reliance in Canada on foreign and international sources of expertise might enhance state capacity and autonomy and dilute the influence of the domestic food industry. The differing policy legacies in environmental release across the two countries compared to the virtually identical legacies in labelling and similar legacies in food safety suggest that if policy legacies have influenced subsequent policy choices, we will find the most difference in the two countries' responses to environmental release, less difference in food safety, and little, if any, difference in food labelling. The inertia of policy legacies is, of course, contingent on whether they are challenged, diluted or replaced by new ideas, institutional arrangements, and interests

during subsequent policy making.

TABLE 1-1
Agricultural research funding, Canada

A. FEDERAL FUNDING AND EFFORT

Federal government personnel engaged in research and development activities, 1975-76 to 1996-97, department of agriculture (person-years)[1]

(in natural sciences)	
1975-76	3994
(in natural sciences and engineering)	
1980-81	3788
1981-82	3887
1982-83	3916
1983-84	4804
1984-85	4727
1985-86	4593
1986-87	4425
1987-88	4380
(in research and development)	
1987-88	3617
1988-89	3604
1989-90	3539
1990-91	3453
1991-92	3251
1992-93	3291
1993-94	3327
1994-95	3244
1995-96	2980
1996-97	2783

Spending by federal department of agriculture on natural sciences / research and development, 1976-98 (unadjusted, $millions)[2]

(natural sciences)	
1976-77	117
1980-81	171
1983-84	265
1984-85	292
(research and development)	
1985-86	367
1986-87	372
1987-88	286
1988-89	300
1989-90	307
1990-91	332
1991-92	334
1992-93	319
1993-94	328
1994-95	323
1995-96	327
1996-97	346
1997-98	308

Spending by federal department of agriculture on research and development, 1890-1985, (constant 1984 dollars, $thousands)[3]

1890	1 243
1910	909
1930	8 800
1950	58 835
1970	140 451
1980	190 024
1985	263 267

[1] Canada. Statistics Canada (1983); Canada. Statistics Canada(1988); and Canada. Statistics Canada (1996).

[2] Canada. Statistics Canada (1984); Canada. Statistics Canada (1994); and Canada. Statistics Canada (1997b).

[3] See Anstey (1986): 405.

B. PUBLIC SECTOR ALLOCATION OF AGRICULTURAL RESEARCH EFFORT[1]

Shares of total of "professional full-time equivalent" employees, 1991 and 1996, within the public sector

	Federal	Provincial	University	Total
1991	1024 (44%)	157 (7%)	1123 (49%)	2304
1996	815 (37%)	277 (13%)	1125 (51%)	2218

Efforts by product area by "professional full-time equivalent" employees, 1991 and 1996, within the public sector

	Food and nutrition	Plant breeding
1991	311	169
1996	288	263

[1] Canadian Agri-Food Research Council (1996).

TABLE 1-2
Key historical events, agricultural research policy, (until 1973)

CANADA[1]	UNITED STATES[2]
1859 First school of agriculture established in Canada (in Quebec).	
	1857 First experimental station for agriculture established in Michigan.
	1862 Creation of federal department of agriculture.
1868 Creation of federal department of agriculture.	*Morrill Act* passed by the federal government to give states land to sell for the purpose of establishing land-grant colleges to provide instruction in agricultural sciences and other practical matters.
1886 Federal government passes the Experimental Farm Station Act to create the Experimental Farm System, which expands over the next few decades.	**1887** *Hatch Act* passed by the federal government to grant lands for the establishment of state agriculture experiment stations.
	1914 *Smith-Lever Act* passed by the federal government to create the Cooperative Agricultural Extension Service to improve technology transfer.
	1930 *Plant Patent Act* passed by federal government. It applies to asexually reproduced varieties except those reproduced by tubers (e.g. potatoes) and protects many fruit, nut, and ornamental plants. Major food crops are exempted.
1932 Establishment of the Associate Committee on Agricultural Research by the National Research Council. Dissolved upon creation of the National Advisory Committee on Agricultural Services by the federal department of agriculture in 1935 (renamed Canadian Agricultural Services Coordinating Committee in 1965) to coordinate and advise the agricultural research effort.	
1937 Creation of the Science Service within the federal agricultural research institution to separate "more scientific" basic research from the applied research conducted at experimental farms and research stations.	
1959 Science Service and experimental farms reunited under the Research Branch to encourage greater collaboration. Responsibility for research project selection decentralized within the federal effort, moved from discipline divisions in Ottawa, and given to research station directors.	
	1966 Release of *A National Program of Research for Agriculture*, sponsored by USDA and the National Association of State Universities and Land Grant Colleges. First time that the land grant community, the USDA, and the private sector work together on a comprehensive evaluation and planning effort.
	1970 Federal government passes *Plant Variety Protection Act* to protect varieties reproduced by seed. Excludes hybrids, some vegetable crops, bacteria, and fungi.

[1] Canada. Agriculture Canada. Research Branch (1985), Anstey (1986), and Guitard (1985).

[2] United States. Department of Agriculture (undated b), Soule and Piper (1992), and Marcus (1987).

TABLE 1-3
Agricultural research funding, United States

A. FEDERAL FUNDING AND EFFORT

Federal funding for state agricultural experiment stations, 1975, 1985, and 1994 ($millions US)[1]

	1975	1985	1994
USDA formula funds	81 (58%)	188 (51%)	214 (30%)
Project support			
USDA competitive grants	0	12 (3%)	63 (9%)
USDA special grants	10 (8%)	20 (6%)	69 (10%)
USDA contracts, other	12 (8%)	37 (10%)	87 (12%)
Other federal[2]	35 (26%)	112 (31%)	270 (38%)
Total federal support	138	369	703

Federal funding for agricultural research, from National Institutes of Health (NIH) and the National Science Foundation (NSF), 1972-1992 ($ millions US, nominal dollars)[3]

	NIH	NSF
1972	5.8	4.5
1977	10.4	10.6
1982	10.5	15.2
1987	18.2	19.0
1992	34.1	24.6

B. FUNDING FOR STATE AGRICULTURAL RESEARCH

Sources of support for research activities at the 1862 and 1890 Institutions and Related Colleges, and Schools of Forestry and Veterinary Medicine, 1972-1992 ($millions US)[4]

	Federal	State	Private	Total
1972	118 (32%)	205 (55%)	51 (14%)	374
1977	201 (32%)	341 (54%)	94 (15%)	636
1982	355 (33%)	544 (51%)	169 (16%)	1069
1987	415 (29%)	778 (54%)	253 (17%)	1447
1992	631 (32%)	981 (49%)	380 (19%)	1992

C. PRIVATE SPENDING ON AGRICULTURAL RESEARCH

Expenditures by product areas, 1960-1992, ($millions US, nominal)[5]

	Food and kindred products	Plant breeding	Total agriculture
1960	92 (45%)	6 (3%)	206
1970	206 (44%)	26 (6%)	464
1980	488 (34%)	97 (7%)	1453
1990	965 (32%)	314 (10%)	3012
1992	1038 (30%)	400 (12%)	3416

[1] Fuglie et al. (1996): Table 2, p. 16

[2] Includes National Institutes of Health, National Science Foundation, US Agency for International Development, Department of Defense, Department of Energy, and other non-USDA federal agencies.

[3] National Research Council (1996): 82.

[4] National Research Council (1996): 76.

[5] Fuglie et al. (1996): Table 10, p. 37

TABLE 1-4
Federal regulatory policy events, food safety and labelling, (until 1973)

CANADA[1]	UNITED STATES[2]
1875 First federal legislation containing provisions to analyze and seize food in the effort to reduce adulteration.	**1880** US Chief Chemist Peter Collier recommends a national food and drug law to combat adulteration. Over the next twenty-five years, more than 100 laws are introduced in Congress. None passes until 1906.
1885 First food and drug laboratory.	
1900 Centralization of laboratory analysis efforts.	**1902** Congress supplies funding for the establishment of food standards.
	1906 First federal legislation passes, prohibiting interstate commerce in misbranded and adulterated foods, drinks and drugs.
	1907 First certified colour regulations listing additives suitable for use in food, which were requested by manufacturers.
1909 Advisory board established for creation of food standards.	
	1913 Amendment passed to require quantity of contents to be stated on food packages.
1915 Establishment of regional labs.	
1919 Establishment of federal Department of Health. Transfer of administration of *Fertilizer Act* and *Commercial Feeding Stuffs Act* to Department of Agriculture.	
1920 New *Food and Drugs Act* replaces adulteration legislation, lays down general principles, and leaves details to regulation. Legislation draws the distinction between adulteration (contents) and misbranding (labelling). End of practice of publishing names of manufacturers and retailers found with adulterated foods.	**1927** The Food, Drug, and Insecticide Administration is created as a separate agency, which becomes the Food and Drug Administration (FDA) in 1930.

[1] Davidson (1949) and (1950); and Canada. Department of National Health and Welfare. Food and Drug Directorate (1966).

[2] United States. Food and Drug Administration (1995).

CANADA

1939
Food and Drugs Act amended to make it an offence to advertise food or drugs in a manner likely to create erroneous impressions, in response to growing claims about vitamins, miracle cures, and other products.

1945
Advertising and Labels Division established within department of health to review labels and advertising of all kinds, revives earlier practice of offering opinion on draft advertising scripts and labels. Houses inspection service beginning in 1946.

1957
Consumer Division within the Food and Drug Directorate established.

1964
Advisory Council of Consumers established.

Food additives safety assessment measures introduced.

1969
Responsibility for economic fraud and labelling, inspection at retail level, approval of advertising, and other duties transferred from federal health department to the Department of Consumer and Corporate Affairs upon its establishment.

UNITED STATES

1938
Renewal of national food law through passage of the *Federal Food, Drug, and Cosmetic Act.*

Labelling requirements added such as common name, net weight, name and address of manufacturer. Prohibition of false or misleading claims on labels.

1940
FDA transferred from the Department of Agriculture to the Federal Security Agency when it is decided that the emphasis of food regulation should be less on agriculture and more on health.

1951
The Delaney committee begins to investigate the safety of chemicals in foods and cosmetics, which later results in premarket safety assessment measures regulating the use of food additives and setting tolerances for pesticide residues.

1952
FDA appoints "consumer consultants" to improve communications with consumers.

1958
The Food Additives Amendment is passed, which places the onus on manufacturers to demonstrate the safety of new food additives. The Delaney cause prevents approval of any food additive with carcinogenic effects in humans or animals.

1960
The Color Additive Amendments passed, with similar provisions to the Food Additives Amendment.

1966
Passage of Fair Packaging and Labeling Act. It requires honest and informative labelling for all consumer products in interstate commerce. FDA enforces the provisions on foods, drugs, cosmetics, and medical devices.

1970
Setting of pesticide tolerances transferred to the new Environmental Protection Agency.

TABLE 1-5
Policy legacies for plant biotechnology regulation

AGRICULTURAL RESEARCH POLICY (INNOVATION)-CROP AGRICULTURE

	INSTITUTIONAL	IDEAS	LOCATION OF SCIENTIFIC EXPERTISE
CANADA	centralized	science	public (mostly federal)
UNITED STATES	decentralized	science / market	public / private (especially since 1930s)

	PATTERNS OF EXCHANGE
CANADA	public dominant
UNITED STATES	public-private conflict

SALE / USE OF NEW PLANT VARIETIES

	INSTITUTIONAL	IDEAS	LOCATION OF SCIENTIFIC EXPERTISE
CANADA	centralized	science	public (federal)
UNITED STATES	decentralized	science / market	private / public

	PATTERNS OF EXCHANGE
CANADA	public dominant / private cooperative
UNITED STATES	public-private conflict

FOOD SAFETY

	INSTITUTIONAL	IDEAS	LOCATION OF SCIENTIFIC EXPERTISE
CANADA	federal fragmented / shared	market / science	private / international / public
UNITED STATES	federal fragmented / shared	market / science	private / public

	PATTERNS OF EXCHANGE
CANADA	public-private cooperation
UNITED STATES	public-private cooperation

LABELLING OF FOOD PRODUCTS

	INSTITUTIONAL	IDEAS	PATTERNS OF EXCHANGE
CANADA	federal fragmented / shared	market	alternating cooperation and conflict
UNITED STATES	federal fragmented / shared	market	alternating cooperation and conflict

TABLE 1-6
Market versus science as ideas in policy making

	MARKET	SCIENCE
INNOVATION (what criteria drive innovation)	profitability short-term	advancement of science longer-term goals can be pursued
MERIT ASSESSMENT (basis on which product is evaluated and by whom)	consumer choice	expert evaluation
EXPECTED EFFECT OF CHOICE OF POLICY INSTRUMENTS ON STATE CAPACITY / AUTONOMY	erosion	depends on location of scientific expertise

CHAPTER TWO
CONTEMPORARY POLICY BOUNDARIES: AGRICULTURAL RESEARCH AND REGULATION, 1973-1998

Just as policy legacies may channel policy making in certain directions, contemporary policy making in related areas can establish boundaries. When interdependence exists between two policy areas, as is the case with agricultural research and regulation policies, developments in one may place limits on policy choices in the other. Policy making boundaries can also be established by the existing policy context. Policy making on specific issues is often nested in broader policies and built on responses to similar issues, shaped by the ideas embedded in the institutional structures created by these policy choices.

This chapter describes developments in agricultural research policy in Canada and the United States between 1973 and 1998, focusing on the federal level and plant agriculture. These developments were coincident with efforts to craft a regulatory response to agricultural applications of genetic engineering. The environment for public agricultural research changed dramatically in both countries during this period, both prompting and responding to policy innovation. More so in Canada than in the US, long-institutionalized programmatic ideas and the interests they privileged were challenged and somewhat displaced.

The chapter next explores the policy boundaries set by the initial federal regulatory response to genetic engineering in both countries in the 1970s. Policy choices made at that time, which focused on the safety of working with genetically-engineered organisms within laboratories, provided a starting point for subsequent regulation. The lab safety guidelines of the 1970s did not reflect or respond to the larger debate swirling around the development of genetic engineering, which pondered ethical and socioeconomic issues.[1] Subsequent regulation included the overarching federal "regulatory frameworks" for biotechnology that each country chose to develop in the mid-1980s. By the early 1980s, as the biotechnology industry started to grow rapidly, pressures to use regulation to pursue economic goals had increased as the ascent of the public

[1] Plein (1990) argues that the debate over genetic engineering in the US has passed through three distinct phases. The initial debate, from the late 1960s to the early 1970s, focused on the theoretical potential of genetic engineering and, in particular, the ethics of using these techniques on humans. The second phase began as theory moved into reality, and was distinguished by a focus on health and environmental safety concerns, from the mid- to late 1970s. Into the 1980s, the economic dimensions dominated the debate. Although Plein characterizes these phases as distinct, the debates underlining each of them continued in the 1990s, resulting in biotechnology's status as a multi-issue policy area. Debate in Canada has been much more within closed circles historically, but has a similar multi-issue character.

philosophy of technological neoliberalism intersected with the existing focus of safety entrenched by the lab safety guidelines.[2] The ideas institutionalized in these regulatory frameworks placed boundaries on the policy responses to narrower issues such as those provoked by the commercialization of genetically-engineered plants: environmental safety assessment, and safety assessment and labelling of foods produced from these plants. Regulatory oversight was virtually inevitable given the precedent set by the lab safety guidelines; the battle in the 1980s and 1990s was to be not so much over whether there should be regulation of biotechnology products, but what its goals and methods would be.

AGRICULTURAL RESEARCH POLICY, 1973-1998: INNOVATION UNDER PRESSURE

Given the diverse and important linkages between research and regulation, an understanding of agricultural research policy and its context allows us to identify the boundaries they may place on regulatory policy making. Regulation may affect the progress of researchers and their research priorities; at the same time, researchers are called on by regulatory officials to define problems and provide data on which regulatory responses are based. When researchers are located within the same public institution as regulatory officials, state capacity to regulate may be enhanced. In fact, while agricultural biotechnology is often portrayed as the product of large multinational firms, the public sector in both countries played a fundamental role in encouraging its development by providing funding for research. This reality raises the potential for a conflict of interest between public research and regulatory goals. Researchers working in the private sector also have vested interests, including heightened pressures to commercialize their results so as to produce a return on the significant investment of time and resources. A reliance on their data as the central basis for regulation may weaken state capacity.

Canada

In Canada, there was a brief flurry of debate over the future of the public agricultural research system in the early 1970s, but calls to decentralize the research effort and increase private

[2] The concept "technological neoliberalism" describes the public philosophy ascendant in Canada and the US through the 1980s and 1990s which promotes the goal of international competitiveness. It claims that the achievement of economic growth is contingent on securing international competitiveness and that the surest route to such competitiveness is to be found through technological innovation and market-based policy instruments. Technological neoliberalism comes equipped with its own programmatic ideas which arguably increases its influence. This description relies heavily on the technological liberalism described in Manzer (1994).

sector input into policy making went unheeded. However, from the mid-1980s on, a steady stream of external and internal reviews and policy statements provided the momentum for policy innovation that altered the mix of policy instruments and policy goals (see Table 2-1). The recommendations that emerged from this unprecedented scrutiny included increasing the role of the private sector in setting research priorities and conducting research, increasing collaboration between the private and public sectors in a more formal way, ensuring research met stated policy goals such as competitiveness, and moving toward market-based policy instruments.

Innovation in federal agricultural research policy in Canada focused on introducing policy instruments that would heighten responsiveness to market signals. In 1990, for example, the federal government introduced a market-based policy instrument by passing legislation providing plant breeders' rights (PBR). PBR are a form of intellectual property rights that provides exclusive rights to commercial exploitation of new plant varieties for up to eighteen years.[3] PBR are intended to stimulate private sector investment in agricultural research, although they can also be used by the public sector. Unlike tax credits or direct research grants, PBR do not require significant amounts of government spending. Financial incentives come instead from royalties and sales. Research activity is tied closely to market demand because financial reward is dependent on the degree of commercial success.[4]

The passage of PBR underscored the new direction in Canadian agricultural research policy, reversing decades of societal resistance and government apathy on the matter of providing intellectual property rights to protect new plant varieties.[5] There was opposition to the exclusive ownership rights that PBR would provide for plant varieties that were hitherto regarded as a collective resource and concern about the implications for control of the agri-food system. There had been periodic calls from the seed industry in Canada in support of some such measure since 1925. In the 1970s, lobbying efforts increased as the Canadian Seed Growers' Association sponsored a conference at the University of Guelph in 1971 that led to its members approving the concept of PBR in principle. Agriculture Canada endorsed the idea in 1974. Draft legislation was drawn up in 1978 and introduced in 1980, but never debated. It was delayed by a combination of

[3] See Canada. Canadian Food Inspection Agency (1997) for an explanation of PBR.
[4] Canada. Agriculture Canada. Research Branch (1985).
[5] Resistance to PBRs came from a coalition that included farm, labour, religious, and international development organizations. The coalition was supported by the federal New Democratic Party.

controversy and low political priority. But by 1990, with a mounting emphasis on encouraging technological innovation to secure competitiveness, the balance shifted in favour of its passage.[6]

Other aspects of policy innovation also provided incentives and mechanisms for the private sector to increase its role and influence within the Canadian agricultural research effort. In particular, new institutional mechanisms increased private sector input into public research priorities. First, in 1974, the Canadian Agricultural Research Council (CARC) was created to supplement ongoing coordination efforts within the agricultural research community and meet demands for increased representation of the interests of the users of agricultural research within the private sector. Over time, the proportion of private sector representation within CARC and its committee system grew steadily. Half of its board membership came from the private sector by the late 1990s. Second, in 1988, the Research Branch Advisory Committee was established within the department of agriculture to increase private sector input into the research choices of the federal government.[7] Third, the Matching Investment Initiative (MII) was unveiled in 1995 by the department. This Research Branch program allows the private sector to select research projects and encourages formal public-private research partnerships, with financing shared equally. The federal budget for the MII was $35-million for 1999-2000, to be matched to a total of $70-million by private sector funds. Finally, cultural change was also occurring within the Research Branch during this period. Researchers were encouraged to be more business-like, particularly in pursuing research that could be protected through proprietary measures. The longtime practice of freely distributing research results was sharply curtailed, partly as a result of the increasing number of formal and exclusive research partnerships with the private sector.

During this period, from the mid-1980s through the 1990s, federal dominance in agricultural research began to erode. Funding reductions at the federal level were implemented in

[6] Lesser (1988) argues that Canada's *Seeds Act* did provide some of the protection that PBR has provided since its passage, which may in part explain delay in its adoption. For example, the *Seeds Act* discouraged copying of varieties through the variety registration system because it is not possible to register a near copy. As well, variety owners have been able to protect their varieties through the restriction of sales by variety name to pedigreed (higher quality) seeds and can collect royalties in the transactions with seed growers. However, under the *Seeds Act*, plant breeders had to rely on the government for enforcement while with PBR, they can take action on their own. The lack of PBR also meant that Canadian plant breeders could not expect their varieties to be protected outside of Canada because of the reciprocal international system of plant variety protection. Similarly, Canadian producers were sometimes deprived of foreign varieties because of the reluctance to sell them in a country without such provisions. As of early 1998, 429 PBR certificates had been issued for new plant varieties.

[7] As of 1998, the committee had fifteen members, ten of them from the private sector.

three waves between 1987 and 1998.[8] The federal department of agriculture cut its funding of research from $367-million in 1985-86 to $308-million in 1997-98, a reduction of 16 percent. Funding for the Research Branch, the centre of the in-house federal agricultural research effort, fell from $276.1-million in 1995-96 to $214.7-million by 1997-98, down 22 per cent.[9] To some extent, the significant drop in the number of federal permanent research personnel, from 3617 in 1987-88 to 2783 in 1996-97. was countered by the growth of provincial and private investment. The result was a visible trend toward decentralization and privatization of agricultural research.[10] In the late 1990s, of the total $883-million spent in Canada on agricultural research and technology transfer, the federal share was $311-million, the provincial share was $165-million, universities were spending $213-million, and industry was spending $194-million. These figures reveal that a high percentage of agricultural research in Canada was still publicly funded in the late 1990s, although private funding of publicly-located research was growing.

Much of the policy innovation in the 1980s and 1990s was in fact intended to boost private sector investment and capacity in agricultural research, reflecting the growing popularity of the policy solutions of technological neoliberalism. As noted in Chapter One, private sector investment in agricultural research in Canada was minimal historically compared to the substantial federal effort.[11] In 1967, for example, private sector investment was calculated at a mere 7.4 per cent of the total Canadian effort. In the early 1970s, the federal government-wide policy of "make or buy" resulted in the agriculture department's Research Branch providing funding to the private sector and other public sector research centres for short-term contracts. By the mid-1980s, this funding reached $9-million or 3.4 per cent of the Branch's $263-million budget. However, it was the combination of policy innovation and the lure of the potential of genetic engineering in the late 1980s that finally prompted significant growth in private investment in agricultural research in Canada.[12] Most notably, private investment in *biotechnology* research and development in the agri-

[8] See Table 1-1.

[9] Canada. Agriculture and Agri-Food Canada (1995j).

[10] It has always been difficult to gauge the total private investment in agricultural research. These figures come from a recent effort to measure the agricultural research effort in Canada by the Canadian Agri-Food Research Council. Note that some university funding comes from federal sources, such as NSERC. See Campbell (1998) and Table 1-1. Between 1991 and 1996, there was a decrease of four per cent in the total number of full-time agricultural researchers in Canada.

[11] Guitard (1985): 45-46, Anstey (1986): 104-5, 111-112, and Klein (1985): 8-9.

[12] This growth is more obvious in some research areas than others. In the breeding of new canola varieties, for example, private varieties now vastly outnumber public varieties. See Kneen (1992).

food sector in Canada grew from $14.6-million in 1989 to $35.9-million in 1995.[13] In research on agricultural biotechnology alone, spending grew from $7.4-million to $18.1-million.

The private sector was also encouraged by federal support, political and financial, of the emerging biotechnology industry.[14] The federal government's proactive role was formalized through the 1983 National Biotechnology Strategy (NBS), which set out goals including the development of a strong research infrastructure to ensure that the economic and social benefits of genetic engineering could be captured. The NBS identified plant development as a strategic priority and provided federal funding for research in the private and public sectors. The National Research Council (NRC) was given the mandate to act as the lead federal agency on biotechnology research. Its Prairie Research Laboratory in Saskatoon, established in 1948, was renamed the Plant Biotechnology Institute (PBI) in 1983.[15]

As of 1983, the total Canadian effort in crop biotechnology was relatively small, estimated at one hundred "person-years", including fifty permanent scientists.[16] More than 90 per cent of this effort was based in the public sector. During the late 1980s and early 1990s, federal funding for the PBI slowly increased, although with some loss in real terms to inflation (see Table 2-4). More interestingly, reflecting the growing interest in the private sector and reductions in federal funding, the PBI went from funding external research to being a recipient of significant external funding from other sources. For example, in the mid-1980s, PBI allocated about $1-million annually for external research contracts. In 1987-88, that amount started to decline and funding from external sources climbed steadily, from $4.2-million in 1990-91 to $5.5-million in 1993-94. Much of this external funding supported guest researchers working at the PBI. The NRC attributed the decline in external research contracts to increased costs of contracted-out work compared to in-house costs

[13] Canada. Statistics Canada (1997a).

[14] Comprehensive historical statistics on public funding for agricultural biotechnology in Canada do not appear to be available. During interviews, requests for such information were met with varying responses, including skepticism about the utility of such statistics and arguments about the difficulty of measurement. One official explained that public researchers see biotechnology as a tool, not as a goal. Biotechnology is used to assist plant breeding and it is the plant breeding effort that is measured, not the use of biotechnology.

[15] The Research Branch of the department of agriculture has also spent considerable resources on integrating genetic engineering into its research program. The PBI has focused traditionally on the basic research of plant biotechnology, while Research Branch researchers have worked more on incorporating these basic research results into new varieties. In 1998, an agriculture department official estimated that the Research Branch was allocating about 25 per cent of its crop research resources toward biotechnology-based projects, or about $25-million (Cdn) a year.

[16] Canadian Agricultural Research Council (1983).

and the shortfalls in internal budgets since 1986, which made it impossible to continue the PBI's short-lived "role of national distributor of plant biotechnology research investment".[17] Although the growth in private investment in plant biotechnology in Canada had become increasingly visible, seen in both its rising contribution to underwriting the PBI's research effort and the rapid expansion of the agricultural biotechnology community in Saskatchewan, much of the expertise in plant biotechnology in Canada was still within the public sector as of the late 1990s.[18]

United States

Vigorous debate over the merits and focus of public agricultural research in the US began in the 1970s and continued in the 1980s. The period has been described as that of the greatest controversy and adversity to date for the agricultural research system.[19] Of the series of reports in the 1970s and 1980s that fuelled the debate (see Table 2-1), some took the agricultural research system to task for failing to embrace the latest developments in biological research, particularly genetic engineering.[20] For example, the 1982 Rockefeller Institute/ National Academy of Sciences (NAS) report, *Science for Agriculture*, criticized the US Department of Agriculture (USDA) for ineffective leadership, lack of a coherent research strategy, neglecting cutting-edge research, and for distributing funding according to political demands rather than on an assessment of need or return. It argued for a more efficient allocation of resources, including reducing the number of federal facilities; and a move away from block funding to states toward competitive grants which would provide more control over research priority setting. It warned that without these changes, the US would lose out on the opportunities presented by agricultural biotechnology. In 1987, the National Research Council of the NAS issued a report focused exclusively on agricultural

[17] Canada. National Research Council (1990): 45.
[18] Personal interviews with agricultural researchers.
[19] See Hadwiger and Browne (1987) for a collection of essays inspired by this time of challenge and transition. It was not the first time the merits of agricultural research policy were challenged in the US. See Marcus (1987) for a discussion of earlier debates dating back to the 1860s. Many factors contributed to the intense scrutiny and uncertainty about the system's future role beginning in the 1970s, including increased industrialization and concentration in the agri-food industry; a changing mix of funding for state agriculture experiment stations with more coming from the private sector and state governments; increased pressures for accountability; the declining rural population and the resulting change in the client mix for agricultural research; and the shift by some land-grant colleges away from applied research toward basic "high-tech" research. See Lacy and Busch (1989).
[20] See Kloppenburg JR (1988), Fuglie et al. (1996), Madden (1987), Doyle (1985), and Hightower (1973) for further details.

biotechnology.[21] It called for a long-term increased federal commitment to agricultural biotechnology research, including reallocation of existing USDA funds toward biotechnology research. It argued that the underfunding of basic research on plants and animals was slowing progress in biotechnology research and suggested that $500-million a year be set aside by the federal government to fund competitive grants for agricultural biotechnology research. It concluded that the lack of a significant public commitment to agricultural biotechnology research could jeopardize the "fragile" American competitive advantage in the technology.

Innovation in federal agricultural research policy in the US between 1973 and 1998 came in two key areas: first, the strengthening and broadening of intellectual property rights (IPR), although more so through the courts than deliberate policy initiatives; and second, legislative measures to encourage public-private partnerships and speed commercialization of public research results, in part by encouraging public researchers to use IPR provisions (see Table 2-2 for a chronology). Remarkable change occurred in intellectual property protection for biological inventions through developments that allowed the granting of extremely broad rights.[22] In 1980, the Supreme Court ruling in *Diamond* v. *Chakrabarty* found that a microorganism could be patented. The precedent was established that living things could now be patented on the basis that they had been intentionally altered by human activity. In 1985, a patent office ruling, *Ex parte Hibberd*, found that utility patents could be granted for novel plant varieties. Utility patents, which provide broad and strong protection, began to be awarded for new plants, including seeds, plant parts, plant genes, and tissue culture, and for new breeds of animals (except humans).[23]

Legislative measures adopted in 1980 and refined in 1986 encouraged tighter links between

[21] National Research Council. Committee on a National Strategy for Biotechnology in Agriculture (1987): v.
[22] National Academy of Sciences (1996) and Lacy and Busch (1989).
[23] As of 1994, 286 utility patents had been granted for plants or plants parts. See Fuglie et al (1996): 39. Utility patents are assessed on a standard of "obviousness". Obviousness is defined as whether the claimed subject matter would have been obvious to a person of ordinary skill in the art at the time the invention was made. See National Academy of Sciences (1996). Opposition to these broad patents is widespread and has been led by the Rural Advancement Fund International (RAFI), a non-profit organization that works on issues of ownership and conservation of genetic resources. There also has been considerable commotion in the agricultural biotechnology community because these broad patent rights are placing unprecedented restrictions on research. Agracetus, for example, held rights in Europe to all transgenic soybeans. More notably, it was given a patent in 1992 using a standard technique to genetically engineer cotton, which in theory gave it rights to all genetically-engineered cotton. The courts are now being used to establish the extent of these rights. In the 1990s, there was constant litigation among agricultural biotechnology firms. For example, Pioneer Hi-Bred has sued for patent infringement by DeKalb Genetics, and Mycogen and Monsanto have sued each other.

public and private agricultural research efforts and contributed to cultural change.[24] They reversed the traditional practice of widely and freely distributing research results by allowing and encouraging public sector researchers to use IPR provisions to protect their results. Public researchers were also able to establish cooperative research and development agreements (CRADAs) with private sector partners. Under CRADAs, private sector partners are promised the first option to license research results as an increased incentive to enter into partnerships. In a 1998 article, federal agricultural research official Richard Dunkle said the measure had altered "the focus, direction, and ultimate marketability of publicly-funded research".[25] Previously, with research results widely distributed, the private sector had been less enthusiastic about partnerships with public researchers because there was no guarantee that the private partner would benefit directly from its involvement. Dow Chemical Company official Bill Dowd described CRADAs in the same article as creating a "new relationship between private and public sectors" that has provided "ready access to basic research and the expertise of [USDA in-house] scientists", reducing Dow's research costs and permitting the pursuit of expensive research projects. He called CRADAs "a vehicle for vertical integration of government, academia, and industry" that promotes the exchange of information on research, product development, and marketing, while speeding commercialization.

Congress also attempted to make federal funding for agricultural research more responsive to the preferences of the users of the research by creating the National Agricultural Research and Extension Users Advisory Board in 1977. However, the declining effectiveness of this advisory board, particularly because of the lack of adequate funding, encouraged its merger with two other existing advisory bodies into the National Agricultural Research, Extension, Education, and Economics Advisory Board in 1996.[26] The new board represents the broad spectrum of those interested in agricultural research policy and its results, including commodity, general farm, conservation, consumer and agricultural research organizations.

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[24] National Academy of Sciences (1996). As well, the *Plant Variety Protection Act* was fine tuned in 1980 and 1994, which strengthened the intellectual property protection provided by plant variety protection certificates. Between 1970 and 1994, 3306 certificates were issued for new varieties. See Fuglie et al. (1996): 37.

[25] Lyons-Johnson (1998). Between 1987 and 1995, 500 CRADAs were established in agricultural research and more than 200 licences based on the research results were granted to the private sector. See United States. General Accounting Office (1997a). In 1994, the 227 active CRADAs had a value of $61.3-million (US). Fuglie et al. (1996): 56.

[26] United States. General Accounting Office (1996b).

Meanwhile, the mix of funding for agricultural research changed in the US between 1973 and 1998. Private investment in agri-food research grew significantly, including in plant breeding (see Table 1-3, C). In 1992, the private sector spent $3.4-billion (US) on agricultural research, up from $464-million in 1970. As of 1992, of total spending on agricultural research of about $6-billion (US), almost 60 per cent came from private sources, 25 per cent from the federal government, and 15 per cent from state governments.[27] The growth of private investment, spurred in part by the promise of genetic engineering, accelerated the trend that began in the 1930s and 1940s when the success of hybrid corn varieties fuelled the emergence of major seed firms. Further, during the 1980s and 1990s, private funding for public research grew faster than public funding.[28] For example, in the mid-1990s, about 19 per cent of funding at state agriculture experiment stations (SAES) was coming from private sources, up from 14 per cent in 1972. During the growth in private investment, federal funding remained substantial, although it has not grown in real terms since the mid-1970s.[29] USDA funding through competitive grants increased, as some reports had recommended, but so did funding for special grants (see Table 1-3, A).[30] Unlike fixed formula funding, competitive grants allow the USDA to set research priorities. Special grants, which are earmarked by Congress for specific institutions, increase the influence of legislators on research priorities. In 1994, USDA competitive grants, despite the growth in funding, only contributed 10 per cent of the total federal funding for SAES.

As in Canada, public funding for agricultural biotechnology research in the US grew during the 1980s and 1990s, responding to the criticism of the NAS reports.[31] The agricultural

[27] United States. General Accounting Office (1997a). The GAO notes that agricultural research spending is difficult to measure in the US because of the large number of participants and the proprietary nature of some research.
[28] See National Research Council (1996): 75-76 on these changes. See also Table 1-3.
[29] Fuglie et al. (1996).
[30] In the late 1990s, the USDA annual budget for research activities, both scientific and economic, was about $1.8-billion (US). Of this, $900-million went to in-house research activities, including the Agriculture Research Service, the Economic Research Service, and the National Agricultural Statistics Service. Approximately $935-million went to the Cooperative State Research, Education, and Extension Service, funding state-level activities. Of this later amount, $170-million went to research and education and $270-million for extension services. The remainder was either targeted or distributed by competitive grants. See United States. Department of Agriculture (NDa).
[31] As in Canada, consistent and comprehensive historical funding figures for agricultural biotechnology appear to be unavailable in the US. Differing definitions of biotechnology and the reality that as a process biotechnology may constitute a small or large component of a project both raise questions about how to measure biotechnology research accurately. The General Accounting Office has noted that the national database in the US on public agricultural research does not use biotechnology or sustainable agriculture as a category to measure research. United States. General Accounting Office (1997a). The figures used here are based on periodic efforts to measure funding.

research system provided very little of the initial public funding of biotechnology research. Most of the support came from two federal institutions: the National Institutes of Health (NIH) and the National Science Foundation (NSF).[32] Public funding of basic biotechnological research in the US, largely through the NIH and the NSF, has been substantial and instrumental in American leadership globally in the technology. In the mid-1980s, the federal government was spending about $600-million (US) a year for basic research on biotechnology, while the private sector was investing about $1-billion a year to commercialize the technology.[33]

USDA funding of biotechnology research began with the 1980 Farm Bill; by 1995, it spent $210-million (US). In 1982, the SAES were already spending $41.5-million (US) a year on biotechnology research. Of this amount, $16.2-million (US) came from state sources, $19.8-million from federal sources, and $5.5-million from the private sector. As of October 1984, the in-house USDA research effort, the Agriculture Research Service (ARS), had 183 research projects underway in biotechnology, with a budget of $26.4-million (US). The USDA's extension service, the Cooperative State Research Service, directed $19.2-million (US) of its research grants in 1985, and $18-million in 1986, to biotechnology research. However, despite the growing funding from the USDA and other parts of the agricultural research system, much of the federal money came from other non-agricultural agencies in the mid-1980s. In 1986, for example, the NSF's Directorate for Biological, Behavioral, and Social Sciences funded $72-million in biotechnology research, about 29 per cent of the directorate's total funding budget.[34]

By the late 1980s, the shift toward biotechnology became increasingly visible within the agricultural research system. In the mid-1980s, for example, the SAES added 200 molecular biologists to their staffs, while 115 plant and animal breeding positions were lost.[35] As a group, the SAES chose biotechnology as their number two research priority in 1988 and placed it at the top of annual funding requirements at $130-million (US). Public funding remained significant into the 1990s. Between 1991 and 1993, federal investment in agricultural biotechnology was

[32] National Research Council. Committee on a National Strategy for Biotechnology in Agriculture (1987): 57.
[33] Lacy and Busch (1989): 26. Much of this was on medical applications which began to enter the market in the early and mid-1980s.
[34] National Research Council. Committee on a National Strategy for Biotechnology in Agriculture (1987): 60-64. Table 1-3 illustrates the growing contribution of non-USDA federal agencies to state agricultural experiment stations, including as a proportion of overall federal funding.
[35] Soule and Piper (1992): 216, 220.

estimated to be about $600-million (US).[16] The investment has included the creation of specific programs in plant biotechnology such as the Plant Genome Research Program, the Plant Genome Database, and the Plant Gene Expression Center to encourage basic research on isolating genetic traits.[17] Some observers of the massive shift to investment in agricultural biotechnology by the public agricultural research system argue that it reflects an effort to preserve funding.[18] They suggest that public administrators have exploited the hype over genetic engineering's potential with the ultimate goal of maintaining public institutions and cultivating private sector support for their work.

Comparing agricultural research policies and contexts

This brief comparison suggests that agricultural research policy in Canada has been converging toward the American model since the 1980s. As the summary of developments in Table 2-5 illustrates, Canadian trends of decentralization, privatization, and market-based innovation are somewhat consistent with American trends. Canadian agricultural research policy and the structure of the agricultural research system were more like their American counterparts in the late 1990s than they were in the early 1970s. In each country, agricultural research policy was swept up in the new public management whirlwind of the 1980s and 1990s which fed off the growing popularity of technological neoliberalism in governing circles. Pressures increased for public agricultural research to demonstrate its contribution to competitiveness through innovation in tangible ways. The forces for change were similar, although the timing and degree of their impact differed between the two countries. Policy innovation began earlier in the US and intensified existing trends. It changed the status quo in notable ways but did not result in an abrupt change in direction.[19] In Canada, there was a much more significant move away from the ideas and interests privileged by policy legacies. In both countries, the level of government funding became less predictable while private sector funding grew. Much of the policy innovation in both countries was intended either to increase private sector investment in agricultural research and its role in policy making or to alter the ways in which public research results were to be transferred to the

[16] United States. Department of Agriculture. Economic Research Service (1993).
[17] Young and Asner (1996).
[18] Lacy and Busch (1989).
[19] The term "policy innovation" is used to describe sequential and consistent policy changes over time that result in a significant departure from the status quo.

private sector. However, American private investment in agri-food research in 1992, at $3.8-billion (US), still dwarfed Canadian private investment of about $194-million (Cdn) in the late 1990s.

Those advocating increased support for genetic engineering research within the public sector institutions had a notable degree of success in the 1980s and 1990s at the expense of other research areas. Particularly in the US, the private sector also increased its research role in agricultural biotechnology and underwent a significant transformation as large multinational firms became major players. For example, a 1985 survey found that US firms involved in agricultural biotechnology were employing more than 1000 molecular biologists.[40] In 1988, there were about fifty firms working on agricultural biotechnology in the US, spending about $200-million (US) a year on in-house research. By the early 1990s, firms had invested $1-billion (US) in agricultural biotechnology.[41] A small amount of the private investment funded research within public institutions. In 1984, for example, private firms spent $120-million (US) on research at universities on biotechnology. This funding provided between 20 and 25 percent of total university funding for biotechnology research, much higher than the average of 3 to 5 per cent of funding for university research that came from the private sector.[42] Much of the growth in private investment came in response to the irresistible incentives created by agricultural biotechnology through its potential for innovative and profitable products. These incentives were heightened in the US with reassurances of return on investment through the availability of stronger IPRs.[43]

Genetic engineering brings high costs and requires an extensive knowledge base. In both countries, the decision to promote the integration of genetic engineering into agricultural research encouraged policy change to facilitate public-private research partnerships that provide the requisite financial and technological resources. In Canada, informal collaboration gave way to formal partnerships based on legal agreements that included provisions for ownership of results. In the US, these new relationships began earlier and have been more widespread. They have been

[40] Lacy and Busch (1989): 27.
[41] Soule and Piper (1992): 216, United States. Department of Agriculture. Economic Research Service (1993).
[42] Lacy and Busch (1989): 26.
[43] Kloppenburg (1988): 130-151 argues that the PVPA began this trend. These new factors have caused the fundamental transformation of the seed and plant breeding industry. While this transformation is a global phenomenon, much of it has occurred in the US because it is a pioneer in agricultural biotechnology and is home to three of the five major agricultural biotechnology firms (Dow, DuPont, and Monsanto). More details on this transformation can be found in Chapter Four.

described as "more varied, more aggressive, and more experimental" than collaboration in the past.[44] Examples include private funding for public research in return for exclusive licenses, a greater role for the private sector in shaping public research choices, university-based researchers setting up private firms to commercialize technology created within a public institution, and universities setting up for-profit corporations. Further, the exercise of broad intellectual property rights has created complex webs of technological interdependence between public and private sectors, restructuring traditional roles and relationships. Kloppenburg argues that integrating genetic engineering into agricultural research encouraged the redefinition of the historic division of labour between public and private sectors:

> The emergence of the new biotechnology has been associated with a period of institutional flux in which the responsibilities of industry, state, and university vis-a-vis scientific research...are being redrawn. The current social fluidity has opened space for the operation of interests that intend to transform the agricultural research sector.[45]

More concretely, for example, a single research project may require the combination of various processes and components owned by different organizations, requiring collaboration and/or much licensing of technology because "everyone has pieces of the puzzle".[46]

Implications for regulatory policy making

The comparison of recent change in agricultural research policy in both countries reveals similar implications for policy boundaries and effects on state capacity and autonomy. The institutionalization of technological neoliberalism through policy choices in the 1980s and 1990s is apparent. In Canadian agricultural research policy, the longstanding embedded idea of science-based innovation has been diluted through the embrace of market-based innovation. Kneen describes the change in Canadian agricultural research policy in recent years as a "profound transformation" moving from "an existential speculative or discovery model (a model of tinkering

[44] There has been a great deal of discussion of this trend and its implications for the role of universities, setting research priorities, exchange of scientific information, and the long-term impact on innovation. See, for example, Doyle (1985): 308–309, 339-372. See also Commins (1996), Mestel (1994), and Lacy and Busch (1989). A recent controversial example is a $25-million five-year agreement between Novartis and the University of California, Berkeley. Under this arrangement, announced in 1998, Novartis was to fund basic agricultural genetic research in return for first rights to negotiate for up to 40 percent of the discoveries. This example raised particular concern because the funding covers the entire plant and microbial biology department at the College of Natural Resources.

[45] Kloppenburg JR (1988): 235.

[46] This description came from an American Seed Trade Association official. Personal interview, October 1998.

or invention) to a teleological (end-oriented) model of corporately directed product development".[47] In 1995, the mandate of Canada's Research Branch reflected the new centrepiece of competitiveness, according to the prescription of technological neoliberalism.[48] In the US, policy innovation intensified the existing emphasis on market-based innovation, although there was a weak attempt through the USDA's growing funding of competitive grants to pursue science-based innovation.

Federal state capacity in agricultural research policy can be assessed first, by where research is conducted which identifies the locus of scientific expertise and authority and second, by who has control in setting research priorities. In both countries, the changing division of labour between public and private sectors in agricultural research increased the relative influence of the private sector within agricultural research policy communities, based on its growing financial and scientific resources.[49] At the same time, policy innovation increased private sector input into public research priorities.

Canadian federal state capacity declined as research became more decentralized and privatized. While the public agricultural research system remained centralized in the late 1990s, especially in comparison to the American system, it was becoming more vulnerable to demands from private sector users of agricultural research. New mechanisms to increase private sector input promised more responsiveness. Policy innovation that diluted the long-embedded idea of science-based innovation and the significant drop in federal funding reduced the traditional insulation from

[47] Kneen (1992): 5. Kneen's study is on canola, but his conclusions apply generally to agricultural research in Canada.

[48] The mandate was: "To contribute to the ongoing *competitiveness* of a diversified and environmentally sustainable Canadian food and agriculture sector, including nonfood uses of agri-food products, by developing and transferring *innovative* technologies related to our four areas of business (resources, crops, animals, food) ", in Canada. Agriculture and Agri-Food Canada (1995j): 3 (italics added).

[49] Some public researchers resisted these changes. In the US, there was resistance from SAES administrators and researchers to the reorientation of public research toward private preferences. As well, in response to the 1982 NAS report, some public researchers pointed to other studies showing high returns on investment in public research and evidence that the decentralized system was efficient. See Kloppenburg JR (1988): 17, 237. In Canada, agricultural researchers expressed numerous concerns in personal interviews, including worries about the implications of public funding being increasingly contingent on having a private sector research partner for research priorities. There has also been skepticism about the wisdom of reallocating resources to genetic engineering. Some traditional plant breeders worry that this expensive, albeit dazzling, new technology would divert resources without any guarantee of success. Tensions between molecular biologists and traditional plant breeders in both countries were not uncommon, particularly in the early and mid-1980s.

outside interests that federal researchers had long enjoyed.[50] However, some federal capacity was preserved through the use and design of new policy instruments such as PBR and the MII, which provided new sources of funding and increased research activity within federal facilities.

In the US, federal state capacity has always been weak, given the decentralization of the agricultural research system since its beginnings. Overall, recent developments in agricultural research policy and its context, including the rapid growth in the use of CRADAs, appear to have amplified the historic vulnerability of the American public agricultural research system to local interests and private sector demands and further weakened USDA capacity and autonomy.[51] The rapid growth of private sector investment between the 1970s and 1990s and the decentralization of scientific expertise in plant biotechnology ensured an ongoing minor role for the USDA in setting overall research priorities for the agricultural research system. USDA's capacity in agricultural research policy lies primarily in its in-house research, through the Agricultural Research Service, and its funding of competitive grants for SAES. The funding of these two activities, worth no more than $900-million (US) a year in the mid-1990s, represented only 15 per cent of the approximately $6-billion in total being spent on agri-food research each year in the US during that time. The USDA's capacity has been further weakened by internal factors including a lack of coordination and planning capacity. This problem dates back to at least 1981.[52] As well, within the ARS, the number of research scientists fell from 3400 in 1970 to 1900 in 1998 and the number of laboratories declined from 140 in 1984 to 107 in 1996. During this time, the costs of research rose but Congressional funding did not keep pace in real terms.[53] Rising funding for USDA competitive grants to SAES into the 1990s (see Table 1-3) appeared to be an effort to increase capacity by improving the ability to set strategic research priorities. However, the growth in

[50] These changes are also having an impact on who does what research and therefore research priorities. For example, the introduction of PBR has been linked to the drop in new public varieties of canola while the huge increase in private breeding of new canola varieties has been characterized as an "enormous multiplication of 'me-too' varieties" or, in other words, cosmetic breeding given the minor distinctions among varieties. This description was given by Canadian public plant breeder Julian Thomas, quoted in Rampton (1999).

[51] While some argue that the public system has always been closely aligned with private interests, rather than the public good, others argue that recent change has increased its vulnerability to political demands and reduced the input of science and the "public interest" in setting research priorities. See Soule and Piper (1992): 65, but also Lacy and Busch (1989): 31, 33-34.

[52] Other weaknesses include the lack of internal performance goals and accountability mechanisms and an aging infrastructure. United States. General Accounting Office (1996b).

[53] United States. General Accounting Office (1997a) and ARS web site at: www.ars.usda.gov. In 1998, the ARS annual budget was $745-million (US).

special grants as of the mid-1990s outpaced the growth of competitive grants. Special grants are allocated according to Congressional priorities and thus often go to local interests. Further, Congressional committees have blocked USDA plans to reallocate funding among projects and facilities.

In both countries, state autonomy in agricultural research policy was jeopardized between 1973 and 1998 by the growing research collaboration between public and private sectors. The phenomenon of financial and technological public-private interdependence implied that regulators would have a harder time finding research expertise to tap into that did not have some vested interest in commercialization.[54] As well, the agricultural research policy communities in both countries became more diverse during this period, potentially further complicating the exercise of autonomy. The American policy community, in particular, became more fragmented because of the increase in public interest groups that tracked agricultural research policy.[55] Policy making became more likely to be characterized by contestation and conducted through pluralist policy networks.[56] In Canada, a similar phenomenon occurred, although not to the same extent, as agricultural research policy expanded its focus beyond the needs of agricultural producers to the entire agri-food industry. The popularity of concepts of sustainable development and sustainable agriculture in the late 1980s and into the 1990s also subjected agricultural research policy to heightened scrutiny from environmental and other public interest groups.

These developments in agricultural research policy established similar policy boundaries in both countries for the regulation of genetic engineering. Public funding and political support for the development of genetic engineering ensured that the policy issue would be not *whether*, but *how* commercialization of genetically-engineered products would take place. The

[54] Sheldon Krimsky has argued that when researchers develop financial links to the private sector, they are more likely to become desensitized to the social impacts of science: "the new values emphasizing science for commerce become internalized and rationalized as a public good, the disciplinary conscience becomes transformed. It happens incrementally, without conspiracy or malice." Quoted in Doyle (1985): 363. In Canada, for example, the public sector Plant Biotechnology Institute (part of the National Research Council) counts among its research partners not only other public centres such as the federal department of agriculture and the University of Saskatchewan, but also private partners such as AgrEvo, Monsanto, Dow AgroSciences, DuPont, and the Canola Council of Canada.

[55] The GAO reports from its interviews with agricultural research officials that many interest groups act as watchdogs, citing the Cotton Council as an example. See United States. General Accounting Office (1997a).

[56] Browne describes the varied and increasing number of interests following agricultural research policy in recent years. Often, these interests have competing demands and are not allied, which makes it unlikely that they will be able to achieve significant change. However, he notes, that the more pluralist nature of agricultural research policy communities could result in greater targetting of research without an increase in funding, or cause "policy instability" that could weaken the ability of the public system to secure funding. See Browne (1987): 83-89.

institutionalization of technological neoliberalism provided further impetus for the speedy development and commercialization of innovative genetically-engineered products. Further, it sent regulators the message that any regulation of such products must not delay investment in research or worse, send it to other countries. The emphasis on market-based innovation suggested that the state's role should be to assist the private sector in its agricultural research pursuits, rather than assume a leadership role in setting priorities. Finally, in the US, the decentralization of scientific expertise and authority meant that the problem definitions that would underpin risk assessment and regulatory policy choices were more likely to come from outside the USDA. In Canada, federal expertise in plant breeding research was still dominant during this period, although in decline. Federal state officials were still able to play an important role in problem definition, but the emergence and institutionalization of market-based innovation encouraged them to incorporate the views of those outside their organization, particularly those within the private sector.

In the late 1990s, there was continued momentum behind these changes.[57] Future pressures will likely include calls for stronger intellectual property rights in Canada to pay for the increased costs of research, driven up by the integration of genetic engineering and the cost of accessing proprietary research; calls for the public sector to increase its commitment to the basic biological research that is the essential underpinning of genetic engineering but does not translate into immediate profits; and calls to protect the "freedom to operate" of researchers who find their efforts increasingly circumscribed by the use of proprietary measures and by the new reluctance among researchers to share information and germplasm, who are sometimes prevented from doing so by confidentiality agreements imposed by private sector research partners.[58]

[57] Spillover effects, for example, have included growing pressures to change the variety registration system in Canada. In some ways, it has already been weakened. For example, the registration system for canola is much less rigorous than that for wheat, and the Canola Council of Canada has taken over running the field trials from the public sector. See Griffiths (1996). Arguments have been made that the committee system is incompatible with the changing research environment. They argue it is not responsive enough to market forces. Further, with PBR available, members of the committee may also have individual interests as plant breeders in the outcomes of votes, creating the potential for a conflict of interest. See Klein (1997). In 1998-1999, Canada's variety registration system underwent a formal review in preparation for revision.

[58] For a recent discussion in the US of the impact of IPRs on agricultural research, see National Academy of Sciences (1996). On the costs of research, for example, Calgene spent 10 years and more than $20-million (US) to get the Flavr Savr tomato from lab to kitchen table. See Baker (1994) and Kloppenburg JR (1988).

REGULATION OF GENETIC ENGINEERING

In the early 1970s a group of American researchers called on governments to assess the safety of working with recombinant DNA (rDNA) organisms.[59] This initiative took place before much attention was paid to the specific regulatory issues arising from the use of genetically-engineered plants and when applications of genetic engineering were still confined to laboratories. It created public controversy, but also ultimately allowed rDNA researchers to play a central role in defining the initial goal and scope for regulation in the form of guidelines for laboratory work. The American regulatory model was copied around the world, including in Canada. Later, as the technology developed and products neared commercialization, issues regarding their release and widespread use began to arise. To provide intragovernmental coordination and consistency, the Canadian and American federal governments both chose to issue "regulatory frameworks" which outline guiding principles and divide regulatory responsibility among agencies (see Table 2-6). These documents were intended to be the foundation on which agencies would base their regulatory responses to specific issues such as environmental safety and food safety. In the US, the move to create a regulatory framework in the mid-1980s came from the White House as a response to hesitation, confusion, and disagreement among federal agencies about the nature and coordination of appropriate regulatory responses. The framework was released in its final form in 1986 and refined slightly in 1992. In Canada, calls for improvement in regulatory coordination were channelled through an interdepartmental committee. A regulatory framework was released in 1993. Although the process leading to the release of a regulatory framework differed dramatically between the two countries, the ideas institutionalized through the frameworks are strikingly similar. Notably, the frameworks further institutionalized the goal of human and environmental safety established by the lab safety guidelines, while mixing in economic goals such as international competitiveness.

United States

"Freedom to research" is generally accepted to be a widely-held core value among research scientists. Regulation that constrains research progress or choices is generally viewed as a threat to scientific autonomy. When a group of molecular biologists in the US were the first to sound

[59] As noted earlier, this dissertation generally uses the term "genetic engineering" to refer to rDNA techniques.

alarms publicly about the possible serious risks posed by genetically-engineered organisms, the move was considered a rare event in that researchers were exercising self-regulation. In 1974, in what became a historical turning point for the regulation of genetic engineering, the group outlined its concerns in a letter published in a scientific journal and called for a moratorium on research until some of the safety questions were resolved.[60]

While it appears that the researchers expected the debate to take place within relatively closed scientific circles, it instead took on dramatic proportions with extensive media coverage verging on sensationalism. The media described the potential horrors that genetic engineering could unleash on the world. The furore prompted the 1975 Asilomar conference in the US which brought together leading individuals within the international community of molecular biologists. The conference concluded by issuing a request to the US National Institutes of Health, which was funding a great deal of research on genetic engineering, to draw up lab safety guidelines. In 1976, the NIH released "Guidelines for Research Involving Recombinant DNA Molecules", setting out standards for containment and varying degrees of review according to the perceived level of risk.[61] The NIH Recombinant DNA Advisory Committee (RAC) was established to oversee the guidelines, which applied only to federally-funded research.

The controversy surrounding the risks of genetically-engineered organisms attracted Congressional attention for a few years. Congressional hearings were held every year between 1975 and 1978.[62] Unsuccessful attempts were made to pass legislation that would make the NIH guidelines mandatory for all research on genetic engineering, regardless of who funded it and where it was conducted. At least sixteen bills provoked by the issue were introduced in 1977 and 1978, including one from the Administration. Kloppenburg argues that the growing interest of firms, such as Eli Lilly, Monsanto, and DuPont, in the potential of biotechnology eventually dampened legislative enthusiasm:

> Legislators might have been willing to regulate scientists to prevent hypothetical damage, but they were much more reluctant to delay the cornucopia of products that

[60] For more detailed accounts, see Van Dijck (1998), Jasanoff (1995a), Kenney (1989), Kloppenburg JR (1988), Doyle (1985), and Eddy (1983).

[61] Review at the federal level was reinforced by the establishment of "Institutional Biosafety Committees" at individual institutions which reviewed proposals for rDNA research.

[62] In the 1970s, for example, two reports on the development of genetic engineering were prepared for a Congressional committee. In 1975, there was a Congressional committee hearing on genetic engineering, and specifically, on the "relationship of free society and its scientific community". In 1981, the Office of Technology Assessment issued its first report on genetic engineering, focusing on the "impacts of applied genetics".

> business claimed was just over the horizon. Safety concerns were submerged in the maelstrom of commercial excitement...[63]

Into the 1980s, the NIH guidelines were steadily relaxed. In 1982, the RAC came close to making the guidelines entirely voluntary, but did not because of concerns such action would jeopardize public confidence and trigger greater efforts at the state and local levels to regulate rDNA experiments.[64] While there were a few high-profile cases of violation[65] and although the guidelines were mandatory only for projects receiving federal funding, they have been widely viewed within the research community as a successful example of self-regulation by researchers given the apparent record of few risks to human and environmental safety from laboratory work with rDNA organisms.

In the early 1980s, the NIH began to approve experiments involving deliberate release of rDNA organisms. By 1983, it had approved three applications involving release of genetically-engineered plants and frost-resistant bacteria.[66] However, as products were poised to move beyond the labs, it became increasingly clear to some observers that the guidelines, which had never been intended to govern environmental release, would be inadequate for that task.[67] For example, it was pointed out that the RAC and its Plant Working Group lacked appropriate scientific expertise. The former committee was dominated by molecular biologists and medical researchers and both committees lacked ecologists. Some felt that the RAC review procedure, which consisted of committee members examining information submitted in applications, was not thorough enough. Jeremy Rifkin, a vocal skeptic of genetic engineering, brought the issue to a new level by bringing it to the courts with the help of a coalition. He argued that NIH approval of the experiment involving release of the frost-resistant bacteria violated the requirements of the *National Environmental Policy Act* (NEPA) to conduct an environmental assessment. Claims were made, for example, that the bacteria could alter weather patterns and result in climatic change. Rifkin also argued that the lack of ecologists, plant pathologists, population geneticists, and botanists on the

[63] Kloppenburg JR (1988): 254.
[64] Kenney (1989): 78.
[65] US Congress. House Committee on Science and Technology. Subcommittee on Investigations and Oversight (1986).
[66] United States. House Committee on Science and Technology. Subcommittee on Investigations and Oversight (1983).
[67] United States. House Committee on Science and Technology. Subcommittee on Investigations and Oversight (1983): 31. These observations were made by Geoffrey Kamy, then of the Office of Technology Assessment.

RAC contributed to the committee's "grossly negligent" decision. A federal District Court found in Rifkin's favour in 1984, concluding that NIH consideration of environmental risks was inadequate. The decision was upheld by the Court of Appeals in 1985.[68]

Meanwhile, a turf war was developing over which agency would regulate environmental release instead of the NIH. In July 1983, the Environmental Protection Agency (EPA) claimed jurisdiction over the regulation of some genetically-engineered products, but there was a great deal of uncertainty over the adequacy of its existing statutes which were not intended originally to regulate living organisms. The EPA itself admitted that it lacked the necessary expertise. It stated that there were virtually no appropriate methodologies for safety assessment of genetically-engineered organisms and that it would take several years to develop adequate assessment techniques.[69] EPA was working with the FDA, the USDA, the NIH, and other federal agencies, as well as with the private sector Industrial Biotechnology Association to develop its regulatory response; however, its leadership role was increasingly questioned. For example, the biotechnology industry initially urged NIH to expand its regulatory role, since they feared it might take years for the EPA to prepare its regulations. In February 1984, a Congressional subcommittee called for the creation of a federal interagency task force to examine options for regulating environmental release and to issue guidelines. Responding to the increasingly anxious biotechnology industry, White House officials became involved in the debate over regulation of release in mid-1984. The Office of Management and Budget challenged EPA's claim of jurisdiction. Commerce Secretary Malcolm Baldridge, who worried that EPA regulation would threaten the international competitiveness of American biotechnology firms, had the issue transferred to the Cabinet Council on Economic Affairs which he chaired from the Cabinet Council on Natural Resources and the Environment, chaired by EPA Administrator William Ruckelshaus.

By April 1984, the Administration had launched formal efforts to create a regulatory framework. A draft version was released in December 1984.[70] The intent behind the framework

[68] Doyle (1985): 235-239. However, Rifkin's subsequent efforts in the courts were less successful. Jasanoff argues that the decision made through the federal regulatory framework to rely on existing statutory authorities effectively removed the courts from a central role in shaping biotechnology regulation. See Jasanoff (1995a): 157.

[69] United States. House Committee on Science and Technology. Subcommittee on Investigations and Oversight (1983): 131-132. These remarks were made by EPA official Don Clay.

[70] [United States. Executive Office of the President. Office of Science and Technology Policy (1984). This document included a "regulatory matrix" that identified several existing legislative and regulatory authorities that could be used to regulate environmental release and other aspects of the commercialization of genetically-engineered products.

was to clarify regulatory policy; at the same time, the document recommended that a scientific advisory mechanism be created to assess biotechnology issues. The framework confirmed that the authority to regulate genetically-engineered products, including their release, would be allocated according to existing regulatory duties for the same products created by other means.[71] In November 1985, the Biotechnology Science Coordinating Committee (BSCC) was created to coordinate science issues across the federal government. The final "Coordinated Framework for Regulation of Biotechnology" was released in June 1986.

Despite the release of the framework, however, there was continued confusion about the regulatory regime. Some criticized it as too stringent; others called it too lax. A 1986 report by the General Accounting Office (GAO) identified several problems in federal regulation of biotechnology including differing definitions among regulatory agencies which could be a "significant problem" in coordinating regulation.[72] Another GAO report, in 1988, evaluated the risk management procedures of the USDA, EPA, and FDA. It expressed concern that some categories of genetically-engineered organisms were already being exempted from regulation despite a lack of data on their behaviour in the environment. These criticisms and others, along with the widespread excitement about the economic potential of biotechnology, caused another wave of activity within Congress. Several committee hearings on biotechnology were held in the late 1980s and early 1990s (see Table 2-7). Hearings on regulation centred mostly on the issue of environmental release; other hearings examined "competitiveness" issues, such as the status of biotechnology research. There were attempts to pass legislation to strengthen and clarify the regulatory regime, including the *Biotechnology Science Coordinating Act of 1986.* None succeeded.

Efforts to coordinate and harmonize agency policies fell far short of what was intended by the regulatory framework. The failure of the BSCC to further scientific cooperation and coordination among agencies became an irritant and embarrassment for the Bush Administration, and was an ongoing impediment for developers.[73] Krimsky argues that "basic philosophical

[71] For example, USDA was expected to regulate genetically-engineered plants, the FDA to regulate genetically-engineered drugs and food additives, and the EPA to regulate genetically-engineered microorganisms, including pesticidal and pollution control microorganisms. The EPA's new authority was a departure from its existing mandate, given that its background was in regulating chemical, nonliving substances.

[72] Webber (1995).

[73] Krimsky (1991).

differences toward regulation" among agencies prevented consensus and resulted in continued confusion about the scope of regulatory oversight. By 1990, the BSCC was replaced by the Biotechnology Research Subcommittee, whose less ambitious mandate was to provide scientific expertise to policy makers within the White House Council on Competitiveness. The new subcommittee was also given the job of elaborating the regulatory framework. In 1992, a policy statement was issued in the *Federal Register* to refine the Coordinated Framework. This statement, referred to as the "scope" document, outlined the "proper basis" for *how* agencies should exercise their regulatory authority within the scope of discretion provided by the statutes. The document asserted emphatically that regulation must be risk-based and product-based, and should occur only when the risk is "unreasonable".[74]

Canada

In Canada, lab safety guidelines for rDNA work were released by the Medical Research Council (MRC) in 1977 after consultation with the scientific community. A Canadian researcher had attended the 1975 Asilomar conference on behalf of the MRC. He struck up an ad hoc committee in April 1975 that produced draft guidelines. The process was not publicized and the release of the guidelines drew very little public attention.[75] The guidelines were similar to the NIH guidelines. They specified levels of containment for microorganisms according to the degree of risk, based on the type of research and organisms. The guidelines were revised and relaxed in 1979 and 1980, as experience accumulated with no apparent problems and "consistent with international views".[76] As in the US, the guidelines were mandatory only for those receiving MRC or NSERC funding. Enforcement was limited to withholding funds.

As more and more biotechnology products neared commercialization in the mid-1980s, efforts to regulate them were handled as needed by the federal department that had existing authority over the same products, such as fertilizers, veterinary drugs, or food, that were made by more traditional techniques. Regulatory activity increased steadily from the mid-1980s on and environmental releases began with virtually no public controversy. With more and more federal

[74] "Unreasonable risk" is defined as when the full value of reduction in risk obtained by regulatory oversight exceeds the full cost of the oversight measure. See United States. Executive Office of the President. Office of Science and Technology Policy (1992).
[75] Eddy (1983).
[76] Hollebone (1988): 42.

departments getting involved in the regulation of biotechnology, Cabinet officially requested in July 1988 that these departments develop a coordinated regulatory system. In 1993, the federal regulatory framework was released. It was not Cabinet, but rather two committees that led development of the framework: the National Biotechnology Advisory Committee (NBAC) and the SubGroup on Safety and Regulations of the Interdepartmental Committee on Biotechnology (ICB).[77] The ICB created the SubGroup on Safety and Regulations after concerns were raised about regulatory coordination at a December 1984 meeting.[78]

Through the mid- and late 1980s, the NBAC and the SubGroup reviewed the adequacy of applying existing regulations to the new biotechnology products. Their work "highlighted the need" for regulatory coordination that would clearly outline the role of each federal agency.[79] By 1987, the three central regulatory departments (agriculture, environment, and health) had agreed on a set of working principles, including product-based regulation, building on internationally-developed guidelines, and using risk assessment principles.[80] Meanwhile, the NBAC devoted its entire 1987-88 annual report to the regulatory regime. The report elaborated concerns it had raised about coordination since 1984.

During this time, environmental protection was increasing in importance as a policy issue. The NBAC's heightened concern seemed at least in part to be sparked by the impending passage of new environmental legislation--the *Canadian Environmental Protection Act*--that included potentially broad powers to regulate the products of biotechnology. NBAC argued, for example, that CEPA's proposed regulations would not provide a predictable regulatory climate for development and commercialization of biotechnology products and would be "out of line" with current international experience.[81] The 1990 federal Green Plan for environmental policy provided further impetus. The plan included a commitment to completion of the regulatory framework for biotechnology by 1993, backed by national standards and codes of practice, and called for

[77] In 1983, following the unveiling of Canada's National Biotechnology Strategy, the NBAC was established with public and private sector representation. Its mandate was to monitor the progress of the strategy and encourage development of the biotechnology industry. In 1983, the ICB, composed of federal public servants, was established to allocate the funds of the National Biotechnology Strategy (NBS) among departments and respond to NBAC recommendations.

[78] For a comprehensive account of the NBS, NBAC, and the ICB up until the late 1980s, see McIntyre (1990). McIntyre was one of the original co-chairs of the SubGroup.

[79] Stevenson (1988): foreword, p. 1-2, Hollebone (1993): 4.

[80] Kneen (1992):173.

[81] Canada. Industry, Science and Technology Canada. National Biotechnology Advisory Committee (1989).

regulations to require notification of new biotechnology products prior to their release.[82]

Finally, in January 1993, the regulatory framework was announced by a news release accompanied by a brief backgrounder. The documents clarified the division of responsibility among the nine federal departments involved in biotechnology and provided six guiding principles. A state official involved in developing the framework said the timing of its release simply reflected the time it took for all the relevant departments to get ready internally, which varied by department.[83] According to state officials and government documents, the regulatory framework was released to provide consistency within government and clarification for developers, trading partners, and the public. It was intended to send a "strong message" that "clear rules and requirements [would] be put in place in a timely fashion to encourage product development in Canada".[84] One former agriculture department official involved in the creation of the framework said a formal statement was needed to provide a "strong rationalization" for existing regulatory practices and to ensure that federal departments and agencies were operating by the same principles. The renewed Canadian Biotechnology Strategy, released in August 1998, replaced the 1983 NBS. The new strategy made no changes to either the principles or the institutional arrangements outlined by the 1993 regulatory framework.[85]

Comparing regulatory responses to biotechnology and their implications

The Canadian and American policy responses to concerns about the safety of working with genetically-engineered organisms in labs were virtually identical. Their subsequent federal regulatory frameworks are broadly similar, with some subtle differences (see Table 2-8).[86] Both frameworks pursue the dual goals of encouraging development of biotechnology and securing health and environmental safety. The American documents more clearly express the goals of ensuring that regulations do not adversely affect competitiveness and promoting international

[82] Canada. Agriculture and Agri-Food, Health Canada, and Environment Canada (1993): 8.
[83] Personal interview, August 1998.
[84] Hollebone (1993): 5.
[85] Canada. Industry Canada. Bio-Industries Branch (1998). The renewed strategy includes a commitment to ongoing work to increase public awareness and understanding of the regulatory regime for biotechnology.
[86] Framework principles differ on two points which appear to be attempts to counter specific weaknesses. Canada makes an explicit commitment to be open and consultative during development and enforcement of its regulations, while the US first highlights the room for agency discretion and then, increasingly over time, its expectation for consistency across agencies.

harmonization of regulations. The Canadian framework principles refer vaguely to developing regulations "in harmony" with "national priorities" and "international approaches". However, as described in this chapter, Canadian officials have emphasized in other ways that biotechnology regulation is intended to help achieve the goals of competitiveness and international harmonization. Both countries outline a "status quo" approach of relying on existing statutory authorities and establish risk assessment as the central policy instrument. Through the 1990s, the status quo approach has resulted in the use of guidelines, amendments to existing regulations, or new regulations to respond to the issues examined in this study, rather than new legislation. Legislatures have had a minimal role, confined largely to oversight through committee hearings.[87]

State capacity and autonomy

In both countries, the lab safety guidelines did little to increase state capacity or autonomy for the purpose of biotechnology regulation. The institutional design of this regulatory response, combined with its fairly speedy relaxation in subsequent years, resulted in a situation close to self-regulation for researchers.[88] However, the lab safety guidelines did establish the central importance of scientific expertise and authority as resources within agricultural biotechnology regulation policy communities by institutionalizing a definition of safety based solely on risk assessment. This definition of safety made science the fundamental basis for regulation (as a programmatic idea) and thus made the possession of scientific expertise a key component of state capacity and autonomy. This development was of more benefit to Canadian regulators than American regulators, given the differing locations of expertise in plant breeding and biotechnology.

Somewhat in contrast to the lab safety guidelines, the federal regulatory frameworks for biotechnology appeared to be an attempt to shore up state capacity, if not autonomy. Both countries chose to divide jurisdiction for biotechnology regulation across several agencies, according to the agencies' existing expertise in regulating similar products made through more traditional processes. The decision has allowed agencies to make more credible claims of possessing adequate scientific capacity to regulate genetically-engineered products. It also has

[87] In the US, reflecting institutional differences at the national level, there have also been several unsuccessful attempts to pass federal legislation to regulate biotechnology, as noted earlier.

[88] The guidelines were backed by national oversight committees with some participation by non-scientists, but the weakness of enforcement measures at the national level resulted in heavy reliance on local oversight measures and voluntary compliance. At the national level, enforcement measures were limited to withdrawing funds and there was no capacity for inspections to determine levels of compliance. Eddy (1983).

served to keep policy making somewhat sheltered from the more public arena of the legislature, which may contribute to state autonomy. However, the fragmentation of jurisdiction also appears to increase the vulnerability of individual agencies to their specific societal clients.

In both countries, the frameworks' identification of risk assessment as a central policy instrument further entrenched the importance of independent scientific capacity in contributing to state capacity and autonomy.[89] At the same time, the ongoing dual role of the state in both countries of promoting biotechnology development and crafting a regulatory response, combined with the increasing interdependence of public and private researchers, has raised the question of whether there is an institutionalized conflict of interest that makes it difficult or impossible for regulators to access independent scientific capacity.[90] Those who believe there is a conflict of interest find plenty of ammunition in the government documents of both countries, which sometimes engage in earnest promotion of biotechnology. For example, Kneen comments that the first public document in Canada that detailed regulatory provisions for biotechnology, issued in 1991, "came out sounding a bit like a youthful cheerleader unburdened by the responsibilities of adult living".[91]

Policy boundaries created by institutionalized ideas

Canadian and American policy choices about the initial and broad principles for regulation of genetic engineering institutionalized similar ideas about appropriate goals for regulation and the means to achieve them. In both countries, the lab safety guidelines entrenched the identical goal of managing risks to human and environmental safety in the mid-1970s. By the mid-1980s, however, when products were ready for commercialization, the underlying public philosophy was changing in both countries. It was shifting toward technological neoliberalism which places a premium on achieving international competitiveness to ensure economic growth and endorses technological innovation and market-based policy instruments as the appropriate means. As a result, policy responses institutionalized official problem definitions[92] which broadened the original

[89] Independent scientific capacity is supplied by adequate expertise in-house at a regulatory agency and/or by access to researchers without vested interests in development of the technology.

[90] McIntyre (1990) also makes this argument. Note also that USDA housed its regulatory responsibilities for plant and animal health within its Agriculture Research Service until 1971, when the Animal and Plant Health Service was created. See Hightower (1973): 60.

[91] Kneen (1992): 174.

[92] The term "official problem definition" refers to the definition adopted by state officials during policy making.

focus of regulation from human and environmental safety to include economic goals.

The ascent of technological neoliberalism was evident in the public discussion about biotechnology regulation in both countries. The concept of the new "knowledge economy" based on services, information technology, and technological innovation plays a major role in the popularity of technological neoliberalism. Significant economic restructuring in the 1970s and 1980s encouraged policy makers to favour the transition to the knowledge economy, seeing it as crucial to maintaining the relative economic prosperity of their countries. Biotechnology is slated to play a central role in the new knowledge economy. It has been treated by policy makers as a strategic priority. Its proponents have spared no effort in promoting its potential benefits. They have used the wide scope of possible applications to dazzle policy makers with forecasts of a vibrant and significant new industry that could contribute to economic growth and skilled employment. As an additional incentive, biotechnology has also been depicted as a more environmentally-friendly and efficient technology that is likely to supply less-costly processes and innovative, superior products.

In the US, during debate over the regulatory framework, state officials often depicted biotechnology regulation as an issue of protecting public safety without compromising innovation, framing it within the goal of competitiveness. The focus on competitiveness began early in the 1980s. For example, Congress asked the Office of Technology Assessment to conduct a study in 1981 to assess where the US stood in relation to other countries on biotechnology development. The resulting report warned that while the US was the world leader in biotechnology, there was no guarantee that it would remain the leader.[93] Similarly, the mandate of the working group that drafted the federal regulatory framework for biotechnology was to develop a "coordinated and sensible regulatory review process that will minimize uncertainties and inefficiencies that can stifle innovation and impair the competitiveness of US industry".[94] Subsequently, the proposal for a Coordinated Framework noted that:

> The tremendous potential of biotechnology to contribute to the nation's economy in the near term, and to fulfil society's needs and alleviate its problems in the longer term makes it imperative that progress in biotechnology be encouraged. While the potential benefits of biotechnology are widely acknowledged, legitimate concerns about safety have also been raised as additional products of biotechnology move from contained research laboratories into full contact with the public and the

[93] Doyle (1985): 333-334.

[94] United States. Executive Office of the President. Office of Science and Technology Policy (1984): 50857.

environment through commercial testing and applications in the environment."[95]

Regulatory certainty was portrayed as a necessary component of competitiveness. In April 1985, Dr. Bernadine Healy, then Office of Science and Technology Policy (OSTP) Deputy Director and who played a key role in development of the framework, said in response to a question about the impact of regulation on competitiveness: "....if we have regulatory chaos, that is going to be our worst enemy in terms of our economic advantage and our international competitiveness".[96] The discussion of the appropriate scope for regulatory intervention was consistently punctuated by reminders that if regulations were too stringent, developers would simply move operations to another country.

Into the 1990s, the focus turned to deregulation in the US. The American 1992 "scope" document acknowledged its intellectual debt to the "formative role" played by a series of policy statements and reviews issued prior to its release.[97] These statements promoted and reflected a changing, less prescriptive, and less onerous approach to regulation. They specified new means that regulators were to use, which included not dictating to the regulated the means by which they were to meet their regulatory obligations. For example, the 1990 "President's Principles" for biotechnology regulation included: basing regulation on the product, not the process; minimizing the regulatory burden while protecting public health and welfare; and having flexible regulation that accommodates development of the technology and encourages its use by basing regulation on desired ends rather than also prescribing means. The 1991 *Report on National Biotechnology Policy* of the President's competitiveness council emphasized the priority placed by the executive on eliminating "unneeded regulatory burdens for all phases of the development of new biotechnology products", arguing that existing regulatory structures were adequate "in those

[95] United States. Executive Office of the President. Office of Science and Technology Policy (1984): 50856.
[96] Healy is quoted in [US Congress. House Committee on Science and Technology. Subcommittee on Investigations and Oversight (1986): 6.
[97] United States. Executive Office of the President. Office of Science and Technology Policy (1992). The statements include the "President's Principles of Regulatory Review for Biotechnology", approved by President Bush in August 1990; a September 1990 EPA report on risk assessment and environmental protection; the February 1991 *Report on National Biotechnology Policy*, published by the President's Council on Competitiveness; and the Council on Competitiveness's "Fact Sheet on Critical Technologies", issued in April 1991.

limited instances where private markets fail to provide adequate incentives to avoid unreasonable risks". Finally, the "Fact Sheet" of the Council on Competitiveness recommended certain principles for regulation. These principles included regulating only when there was evidence that potential benefits would exceed potential costs; relying on voluntary standards and disclosure where possible instead of inflexible regulation; using health, safety, and environmental regulations to address ends rather than means: and that regulations should be based on scientific risk assessment procedures and used to address real and significant risks rather than hypothetical and remote risks.[98] Based on these recommendations, the 1992 US "scope" statement provides guidelines to agencies on the ways in which regulation is to be conducted that are much more specific than anything in the Canadian regulatory framework.

In Canada, improving federal regulatory coordination to provide clarity, predictability, and consistency became a more pressing policy issue following the 1983 release of the National Biotechnology Strategy. The NBAC in particular worked to identify and promote conducive conditions for development and commercialization of biotechnology.[99] The creation of the SubGroup on Safety and Regulations in 1985 appears to have been the first formal response by state officials to calls for regulatory coordination. As in the US, coordination was portrayed by state officials primarily as a competitiveness issue. Confusion among developers and the public about the scope of regulation and the division of authority among departments, and concerns about the slow pace of regulatory development were portrayed by proponents as serious impediments to exploiting the commercial potential of biotechnology. NBAC, for example, stated in its 1987-88 annual report that it had already urged and continued to urge the government to "move quickly to clarify the coverage of biotechnology products", noting that the:

> development of an appropriate regulatory system which covers environmental introduction and use of such products will, in large measure, determine whether the commercial benefits from the substantial private and public investments which have been made to date will be reaped in Canada.[100]

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[98] United States. Executive Office of the President. Office of Science and Technology Policy (1992).

[99] NBAC was composed of approximately twenty senior representatives from government, industry, and universities, with about one-third of the membership coming from the federal government. Its problem definitions are thus a mix of public and private versions. Kneen argues that biotechnology regulation was first placed in the context of international competitiveness in Canada in 1980, through the publication of a joint Science Council of Canada / Institute for Research on Public Policy report on the prospects for biotechnology in Canada. See Kneen (1992): 171-172.

[100] Canada. Industry, Science and Technology Canada. National Biotechnology Advisory Committee (1989): 3.

State officials described regulatory policy making for agricultural biotechnology as a challenge of crafting rigorous, yet not overly restrictive, regulations that would not jeopardize competitiveness and cause developers to move elsewhere as had occurred in Germany where a temporary moratorium had been placed on field trials.[101] In Canada, the focus into the 1990s was not so much about lightening regulation as in the US, but rather about incorporating competitiveness into existing regulations.[102]

Within the boundaries set by technological neoliberalism, biotechnology regulation is to be used in pursuit of the overarching goal of encouraging development of the technology, in tandem with intellectual property rights, direct research funding, and indirect subsidization of research through various tax credits and incentives. In this view, the assurances of safety provided through regulation provide the basis for consumer acceptance and facilitate international trade. Regulation is to be developed as a competitive advantage and in such a way that international harmonization is possible. Technological neoliberalism condones regulation based narrowly on risk assessment because science-based regulation should be more amenable to international harmonization and less vulnerable to trade challenges than regulation that incorporates "political" goals. Further, regulation's importance in the biotechnology development toolbox was increased by fiscal restraint in both countries through the 1980s and 1990s. As a policy instrument, regulation can be relatively inexpensive compared to other measures such as research funding and tax credits. In this context, it is simple to understand why the regulatory frameworks were intended to ensure that biotechnology, *as a technique and technology,* was not discriminated against.

The boundaries placed on regulatory policy by the institutionalization of technological neoliberalism are clear in the two countries' regulatory frameworks. Technological neoliberalism endorses the narrow risk-based definition of safety, requires regulatory policy instruments to be flexible and thus responsive to changing technology and market demands (according to the image of a nimble state in a globalized economy), and promotes the crafting of regulation to provide competitive advantage to domestic economic sectors. Further, Canada's regulatory framework

[101] For example, see Hollebone (1988): 37.

[102] In Canada, the 1992 federal Budget announced a government-wide regulatory review. The intent was for regulatory agencies to rejustify their regulations publicly. The goals were to use resources more efficiently; reduce the costs of regulations to government, industry, and consumers; conduct cost-benefit assessments of regulations, and ensure that regulations did not reduce industry competitiveness, and in particular, industry's ability to respond to market demands. To integrate competitiveness, regulations were examined with a view to increasing simplification, responsiveness, and harmonization. See Canada. Health Canada. Health Protection Branch (1993).

with its broad principles sets certain parameters for regulation. Placed squarely within those parameters are human and environmental safety; risk-based assessment; a favourable climate for development of biotechnology; an open, consultative policy making process; and, as expressed by state officials, a priority of national and international harmonization. Excluded from the scope and intent of regulation, for example, are ethical concerns extending beyond safety about the development and actual use of the techniques of genetic engineering;[103] using regulations to impose criteria of social utility such as encouraging development of the technology toward provision of specific "public good" benefits such as improving agricultural sustainability, food quality, or food safety;[104] and, finally, distinguishing products created through genetic engineering from those produced through other techniques, or in other words a process-based approach. This last omission weakened the rationale for creating a new "biotechnology regulatory agency" or drafting new legislation to deal exclusively with genetic engineering. The exclusion of these issues in the regulatory framework has set and reinforced existing boundaries between legitimate and illegitimate issues for regulation. As will be seen in the specific cases below, these issues are considered as either outside the scope of regulation or incompatible with the existing policy framework. The American regulatory framework sets virtually identical boundaries on the scope and intent of regulation.

Conclusion

Policy boundaries in agricultural research and regulation have provided the broader context for policy responses to specific issues of commercialization such as environmental release and food safety. The ascendance and gradual institutionalization of technological neoliberalism in policy

[103] While Canadian state officials largely sidestepped the ethics of genetic engineering in regulatory discussion, one exception was a technical background paper on labelling genetically-engineered foods. It noted that governments can be involved in ethical issues, but the nature of an appropriate role was not yet clear. It stated that in Canada, regulators make choices on rational scientific data, while in some European countries, ethical issues received more attention. See Canada (1994): 12.

[104] The discussion of comments received on the proposed regulatory amendments clarifying AAFC authority for environmental assessment notes that two respondents recommended that, before evaluation occurs, products covered by these provisions should be shown to have clearly defined benefits to the environment, consumers, and farmers. This suggestion was rejected by AAFC as inconsistent with approaches already taken. AAFC noted that it is the responsibility of firms to explain benefits to consumers, who will then make the choice as to whether to purchase the product. See Canada. Minister of Public Works and Government Services Canada (1997): 37.

choices has reinforced market-based ideas and diluted the science-based ideas of policy legacies. It has provided the private sector with additional influence in policy making, while weakening state capacity and autonomy. The lab safety guidelines initially made risk and science the basis of regulation. By positioning scientific expertise at the centre, they privileged policy community actors with such expertise. However, the direction of innovation in agricultural research policy and the federal regulatory frameworks for biotechnology placed greater pressures on regulation to contribute to economic goals. The regulatory frameworks built on the lab safety guidelines, but placed regulatory science in the service of economic development for the purpose of achieving international competitiveness. The visible financial and political commitments by Canadian and American governments to the development of agricultural biotechnology and increasing collaboration and interdependence between public and private sector researchers placed additional limits on the options for regulation. Commercialization would proceed and regulation would be designed to facilitate it.

Insulated from the economic dimensions of biotechnology regulation, the lab safety debate of the 1970s was "a bid for control of the scientists, by the scientists, for the scientists". It was a debate about which institutions would "decide questions of safety".[105] It appears that rDNA researchers initially won the day with their scientific autonomy barely crimped by the guidelines.[106] However, another effect of the lab safety guidelines was to set a precedent for special regulatory oversight of genetically-engineered products. If a technology was risky enough to be regulated in the lab, then the public would expect some degree of oversight of its widespread use. Regulation of genetic engineering was now in the public and political arena.

Into the 1980s, the agricultural biotechnology regulation policy community began to expand. The nascent biotechnology industry, along with environmental and other public interest groups concerned about the risks of biotechnology, called for more explicit regulation of the release and use of products. In the US, the biotechnology industry wanted the federal government to take charge. It hoped federal regulation would preempt its personal nightmare of a potpourri of

[105] Eddy (1983): 40-41.

[106] The guidelines were not particularly stringent in either country: they applied generally only to those receiving federal funding, were voluntary for the private sector, and were quickly relaxed. In the US, firms often did conform to the guidelines after 1978, since they found that it was relatively easy to do so. Kenney (1989).

local efforts.[107] As specific issues regarding use began to arise such as environmental safety, food safety, and labelling of genetically-engineered foods, new policy networks sprang up to deal with them. Canada and the US responded to all three of these issues. Chapter Three examines and compares their policy choices.

[107] Local efforts had sprung up during the lab safety issue. In the mid-1980s, it looked like the same thing might happen with environmental release of genetically-engineered products.

TABLE 2-1
Major reports and statements on agricultural research policy Canda and the United States (since 1970)

CANADA

1970
Science Council publishes *Agricultural Science in Canada*, a background study for its 1971 report (below): Advocates increased focus on applied research, decentralization to provinces, higher transfers to private sector for research, and overall increase in private sector involvement in policy making.

1971
Science Council publishes *Two Blades of Grass: C*alls for the creation of an "Agricultural Research Coordinating Council" with a broad membership and a mandate to set priorities, assess programs and improve collaboration. It recommends that the council have direct control of the allocation of federal funding and provide contracts to the private sector.

1986
Nielsen Task Force Report: Agricultural research should be reoriented toward client needs; private sector should have more direct influence, including through shared-cost funding of research.

National Agriculture Strategy issued by Canadian ministers of agriculture: Signals move to market-based policy instruments and commitment to competitiveness as a policy goal in all aspects of agricultural policy, including research.

UNITED STATES

1972
Hightower Report: Public agricultural research system privileges agribusiness and industrial agriculture at expense of smaller producers.

Pound Report, (National Academy of Sciences): USDA research program behind the times and underfunded.

1981
Office of Technology Assessment publishes *An Assessment of the United States Food and Agricultural Research System*: Identifies need for increased support for the system, a lack of well-defined goals, inadequate process for priority setting, and inequitable distribution of costs and benefits among states. Calls for stronger USDA research program on national interest issues.

1982
Winrock Report, *Science for Agriculture*, NationalAcademy of Sciences: USDA research should be more strategic, change funding strategy to pursue cutting-edge research.

1987
National Research Council, National Academy of Sciences, *Agricultural Biotechnology: Strategies for National Competitiveness*: Calls for more strategic research priorities, including a long-term and significant commitment to agricultural biotechnology.

CANADA

1988

Research Branch publishes *Canadian Agriculture Research and Technology Transfer: Planning for the Future, Part 5, Research Branch Proposal For Action*, in response to the *National Agriculture Strategy*, announcing its willingness to increase private sector involvement in policy making and to promote public-private partnerships.

1989-1990

Growing Together policy review: Agricultural research important to competitiveness of agri-food industry, support for strengthening coordination of private and public partnership, while maintaining strong federal role.

1990

Report issued by Task Force on Competitiveness in the Agri-Food Industry, as part of the Growing Together review, calling for greater collaboration in agricultural research.

1991

National agricultural research conference, "Partnerships: A Focus on Technology".

Research Branch publishes *Canadian Agriculture Research and Technology Transfer: Planning for the Future, Part 9, Strategic Directions.*

1992

First comprehensive strategy published, representing consensus of Canadian agricultural research community: *A National Strategy for Agri-Food Research and Technology Transfer.*

Science Council study on sustainable agriculture includes recommendations for agricultural research. Criticizes Research Branch for being slow to respond to changing priorities.

1993

Auditor General's report faults Research Branch for weaknesses in measuring whether its research results were meeting stated policy goals such as competitiveness and higher rates of technology transfer.

1998

House of Commons Standing Committee on Agriculture and Agri-Food, *Capturing the Advantage: Agricultural Biotechnology in the New Millennium.* Makes six recommendations including increased funding for long-term basic research to keep Canada at the forefront of biotechnology developments and continued implementation of an intellectual property framework that will foster the development of biotechnology products.

UNITED STATES

1989

National Research Council (National Academy of Sciences): *Investing in Research: A Proposal to Strengthen the Agricultural, Food, and Environmental System.* Calls for major increase in use of competitive grants. Says that agricultural research is underfunded.

1997

General Accounting Office: *Agricultural Research: More Efficient and Accountable System Could Better Respond to New Challenges.* Recommends making the system more efficient by reducing federal facilities and increasing collaboration between the public and private sectors, and by increasing accountability to encourage better quality research.

TABLE 2-2
Agricultural research policy and context
Canada and the United States (since 1973)

CANADA	UNITED STATES
1974 Creation of the Canadian Agricultural Research Council (now the Canadian Agri-Food Research Council) to assist the Canadian Agricultural Services Coordinating Committee, for the purpose of coordinating technology transfer and building consensus on research priorities. In recent years, the percentage of private sector representatives has gone from about twenty-five to fifty per cent of members.	**1977** Congress establishes two advisory boards to improve coordination of the public agricultural research effort: the Joint Council on Food and Agricultural Sciences, and the National Agricultural Research and Extension Users Advisory Board
	1980 Amendments to the *Plant Variety Protection Act* (PVPA) to include more plant varieties. The period of protection was lengthened from seventeen to eighteen years, to bring it into conformity with international standards for plant breeders' rights.
	Supreme Court ruling, *Diamond v. Chakrabarty*, finds that a genetically-engineered microorganism can be patented, setting the precedent that livings things can be patented on the basis of being altered by human activity
	Federal *Bayh-Dole Act* permits researchers to patent and grant licenses for federally-funded research
	Federal *Stevenson-Wydler Act* permits cooperative research and development agreements between public researchers and private organizations
1983 Establishment of the Plant Biotechnology Institute in Saskatoon by the National Research Council, (previously the Prairie Regional Laboratory), following release of the National Biotechnology Strategy	**1985** Patent office ruling, *Ex parte Hibberd*, finds that patents can be granted for novel plant varieties. This ruling and others set the precedent for the granting of broad utility patents for new plants and new breeds of animals
	1986 Passage of the *Federal Technology Transfer Act* makes it easier for public and private researchers to work together. Allows Agricultural Research Service (USDA) to give private sector research partners the first option to market the research results
1987 Establishment of the Industry Relations Office within the Research Branch of the federal department of agriculture	

1988
First meeting of the Research Branch Advisory Committee. Majority of the members represent the private sector

Federal minister of agriculture authorizes worldwide licensing and collection of royalties for all plant varieties developed by Agriculture Canada[1]

1990
Passage of plant breeders' rights legislation marks first provision in Canada of intellectual property rights for plant breeding

1990
Congress establishes the Agricultural Science and Technology Review Board, to provide advice on new technologies

1994
PVPA amended to discourage "cosmetic breeding" by preventing protection from being granted to new varieties that had only minor distinctions from existing varieties. Protection extended to tuber crops and first-generation hybrids. Agricultural producers must obtain a license to sell seeds of varieties protected under the PVPA.

1995
Launch of federal program: Matching Investment Initiative that promotes formal research partnerships between the public and private sectors

[1] Canada. Agriculture Canada. Research Branch (1989): 22.

TABLE 2-3
Private sector investment in biotechnology researh, Canada

Private sector annual spending on biotechnology research and development, 1989-1995[1]

by major sectors, percentage

	1989	1993	1995
Agrifood	13.9	13.5	11.0
Health	62.5	57.8	56.6
Services*	8.4	15.0	24.2

(*clinical trials, contracts, mostly biopharmaceutical)

by major sectors, $million

	1989	1993	1995
Agrifood	14.6	27.6	35.9
Health	63.7	117.2	177.5
Services	8.8	30.7	65.2

[1] Canada. Statistics Canada (1997a).

TABLE 2-4
Agricultural biotechnology research, Canada

A. Biotechnology research and development by the private sector, 1989-1995, ($million)[1]

	1989	1993	1995
Current expenditures			
Agrifood	14.6	27.6	35.9
By subsector			
Agriculture	7.4	13.5	18.1
Food processing	4.8	12.5	13.9
Other	4.0	4.4	5.4

B. Funding for the Plant Biotechnology Institute, National Research Council, Canada, 1983-1995 ($millions, current dollars)[2]

1983-84	8.6	(expenditures)
1984-85	11.5	(expenditures, including $1.1 million in external research contracts and special expenses of $4.3 million in building construction)
1985-86	7.5	(expenditures including $1 million in external research contracts)
1986-87	7.6	(expenditures including $900,000 in external research contracts)
1987-88	9.4	(expenditures including $500,000 in external research contracts)
1988-89	10.5	(expenditures, including $600,000 in external research contracts) (value of contract work for industrial clients rises to $400,000)
1989-90	10.5	(NRC funding, not including contract work for industrial clients with a value of $500,000)
1990-91	10.5	(federal funding, not including $4.2 million in funding from research partners, including universities)
1991-92	16	(total funding, including NRC share of 11.6 million, and 4.4 from other sources)
1992-93	16.3	(total funding, including NRC share of 11.2 million, and 5.1 million from other sources)
1993-94	16.9	(total funding, including NRC share of 11.4 million, and 5.5 from external
1994-95		(no annual report issued)
1995-96	9.2	(federal funding, no figures on external funding provided, hosting 53 guest researchers from industry, and 17 from universities, vs PBI core staff of 108)
1996-97	10.4	(expenditures)
1997-98	10.7	(PBI hosting 72 guest researchers from industry and 27 from universities vs core staff of 110)

[1] Canada. Statistics Canada (1997a).

[2] Annual Reports of the Plant Biotechnology Institute, National Research Council, 1983-1995. Figures for 1996-1998 are from the web site: www.pbi.nrc.ca.

TABLE 2-5
Agricultural research policy innovation, 1973 to 1998
Canada and the United States

	CANADA	UNITED STATES
INSTITUTIONAL		
Location of research	Private investment increasing Federal role declining Provincial / university role increasing	Private investment increasing Federal role increasing State role declining
Control of research priorities	Federal declining, provincial increasing, Private increasing	Federal stable / increasing State declining, Private increasing
POLICY INNOVATION		
Private sector input	Canadian Agricultural Research Council (1974) growing private sector representation primarily intopolicy making and research priorities	National Agricultural Research and Extension Users Advisory Board, established in 1977, private sector membership
	Research Branch Advisory Committee (1988) private sector input into federal department of agriculture's research priorities	Merged with two other general advisory committees, following passage of 1996 legislation, into National Agricultural Research, Extension, Education, and Economics Advisory Board, which includes private sector representation
	Matching Investment Initiative (1995) shared-financing projects initiated by private sector	
Public-private research collaboration	Increased and formalized since 1987 eg., Industry Relations Office (1987)	Legislation in 1980, 1986 facilitates and encourages collaboration through Cooperative Research and Development Agreements (CRADAs)
	Matching Investment Initiative (1995)	
Intellectual property rights	Introduction of plant breeders' rights (1990) for new plant varieties	*Plant Variety Protection Act* finetuned (1980, 1994) Utility patents (1985)

TABLE 2-6
Chronology: Regulating genetic engineering
Laboratory safety and regulatory frameworks

CANADA	UNITED STATES
	1971 Researchers begin to discuss concerns about safety of working with genetically-engineered organisms.
	1974 Recombinant DNA Advisory Committee (RAC) established by the National Institutes of Health (NIH) to advise on safety issues of working with potentially hazardous genetically-engineered in laboratories. The Office of Recombinant DNA is established to support RAC's work.
	1975 **February** International conference of scientists in Asilomar, California, concludes that while some experiments should be deferred, most rDNA work can go ahead safely under appropriate conditions.
1975 **April** Medical Research Council forms ad hoc committee to discuss lab safety guidelines.	**December** First publication of guidelines by NIH for working with rDNA techniques in labs. Over the next several years (1978, 1982, 1983), these guidelines are periodically revised and made less restrictive.
	1976 NIH guidelines are extended to all federal agencies that fund research, by a presidential order.
1977 Guidelines for working in laboratories with recombinant DNA, animal viruses, and cells released by the Medical Research Council. Revised and relaxed in 1979 and 1980.	
1980 Private sector Task Force on Biotechnology established to advise federal government on how to proceed with biotechnology. Recommends a National Strategy, including long-term federal funding and stimulation of the private sector.	
1983 National Biotechnology Strategy released, based on recommendations of Task Force.	
National Biotechnology Advisory Committee established to advise Minister of State for Science and Technology.	
Interdepartmental Committee on Biotechnology (ICB) established to monitor progress under National Biotechnology Strategy.	

1984
April
The White House Cabinet Council on Natural Resources and the Environment forms the Working Group on Biotechnology to study potential conflicts between public safety concerns and the development of the industry. This group issues a proposed regulatory framework on December 31.

1985
ICB establishes the Sub-Group on Safety and Regulations.

1985
October 30
OSTP establishes the Biotechnology Science Coordinating Committee (BSCC) to improve coordination among federal agencies on scientific issues.

1986
ICB commissions the 1986 *Coordinated Study on Government Processes in Safety and Regulation of Modern Biotechnology.*

1986
June 26
Coordinated Framework for Regulation of Biotechnology issued by the White House science office and five federal agencies. Finalizes 1984 draft policy.

1988
Cabinet directs all federal departments involved with biotechnology to create a plan of action for a coordinated regulatory framework.

Attempt to strengthen regulatory coordination by creating a National Biotechnology Regulatory Coordination Office within the Department of Industry, Science and Technology does not go forward.

1990
BSCC replaced by the Biotechnology Research Subcommittee of the Committee on Health and Life Sciences, a standing interagency committee of the Federal Coordinating Council on Science, Engineering, and Technology.

August
Release of President's Principles For Regulatory Review of Biotechnology, requiring a risk-based approach.

1990
The federal Green Plan confirms the intention to establish a regulatory framework for biotechnology within five years.

September
EPA Report: *Reducing Risk: Setting Priorities and Strategies for Environmental Protection*, endorses and recommends risk-based approach.

1991
February
Release of *Report on National Biotechnology Policy* by the President's Council on Competitiveness.

1992
Federal government-wide regulatory review intended to ensure regulations do not impede industry competitiveness.

April
Council on Competitiveness issues Fact Sheet on Critical Technologies, which endorses risk-based approach.

1992
February 27
OSTP publishes "scope" document which details *how* federal regulatory agencies are to proceed in regulating biotechnology. A strong emphasis is placed on a risk-based approach, and a strong justification of the product-based approach.

1993
January 11
Announcement of new regulatory framework (approved by Cabinet in December 1992).

1998

August

Release of renewed Canadian Biotechnology Strategy, to replace 1983 strategy. No change to regulatory framework or principles. Main components are creation of an independent, expert, Canadian Biotechnology Advisory Committee, to integrate social and ethical aspects along with environmental, health and regulatory issues. This is a wider mandate than that given to NBAC.

The new strategy places a greater emphasis on public awareness and participation, and strengthens interdepartmental coordination.

TABLE 2-7
Legislative hearings on "biotechnology"
Canada and the United States, up to 1998

CANADA

PARLIAMENT

ISSUE: BIOTECHNOLOGY REGULATION
1) During review of *Canadian Environmental Protection Act*, regulation of biotechnology is raised, resulting in 1996 hearings (below), 1995
2) Several days of hearings and roundtable discussions. Report issued in November: *Biotechnology Regulation in Canada: A Matter of Public Confidence*, 1996
House of Commons Standing Committee on Environment and Sustainable Development

ISSUE: AGRICULTURAL BIOTECHNOLOGY
1) One day hearing on implications for agriculture, including regulatory regime, 1996
2) One day hearing on "update" on agricultural biotechnology, 1997
House of Commons Standing Committee on Agriculture and Agri-Food

ISSUE: RENEWAL OF CANADIAN BIOTECHNOLOGY STRATEGY
Four days of hearing. Resulted in report issued in May, *Capturing the Advantage: Agricultural Biotechnology in the New Millennium*, 1998
House of Commons Standing Committee on Agriculture and Agri-Food

UNITED STATES

CONGRESS[1]

REGULATORY ISSUES

A. Focus on environmental implications
1) Environmental Implications of Genetic Engineering
June 22, 1983
Subcommittee on Investigations and Oversight; Subcommittee on Science, Research, and Technology of the Committee on Science and Technology
U.S. House of Representatives

2) The Potential Environmental Consequences of Genetic Engineering
September 25 and 27, 1984
Subcommittee on Toxic Substances and Environmental Oversight of the Committee on Environment and Public Works
U.S. Senate

3) Biotechnology Regulation
December 11, 1984
(Focus on environmental release, especially the quality and adequacy of the existing scientific database on which regulation will be based)
Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce
U.S. House of Representatives

[1] It is hoped that this list is comprehensive, although it may not be exhaustive. It was compiled by searching the index of American government publications from 1970 to 1996.

4) Planned Release of Genetically-Altered Organisms: The Status of Government Research and Regulation
December 4, 1985
Subcommittee on Investigations and Oversight, of the Committee on Science and Technology, U.S. House of Representatives

5) Releasing Genetically-Engineered Organisms into the Environment
May 16, 1986
Subcommittee on Toxic Substances and Environmental Oversight of the Committee on Environment and Public Works
U.S. Senate

6) Field Testing Genetically-Engineered Organisms
May 5, 1988
Subcommittee on Natural Resources, Agriculture Research and Environment of the Committee on Science, Space, and Technology
U.S. House of Representatives

B. Focus on regulatory framework

1) Coordinated Framework for Regulation of Biotechnology
July 23, 1986
Subcommittee on Investigations and Oversight; Subcommittee on Natural Resources, Agriculture Research and Environment; Subcommittee on Science, Research and Technology; of the Committee on Science and Technology
U.S. House of Representatives

2) The Use and Regulation of Biotechnology in Agriculture: Joint Hearing on the Potential of Biotechnology and America's Competitive Position
November 4, 1987
Committee on Agriculture, Nutrition, and Forestry, and the Subcommittee on Technology and the Law, of the Committee on the Judiciary
U.S. Senate

3) Federal Oversight of Biotechnology
November 5, 1987
Subcommittee on Hazardous Wastes and Toxic Substances, of the Committee on Environment and Public Works
U.S. Senate

C. Non-regulatory issues

1) Biotechnology and Agriculture
April 16 and 17, 1985
[Focus on how U.S. farm policy can be adapted to provide for the advances of biotechnology, while minimizing disruption to the farm economy]
Subcommittee on Investigations and Oversight of the Committee on Science and Technology
U.S. House of Representatives

2) Biotechnology Development
December 18, 1985
[Focus on updating committee on status of U.S. biotechnology policy]
Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce
U.S. House of Representatives

3) Biotechnology Development and Patent Law
November 20, 1991
Subcommittee on Intellectual Property and Judicial Administration of the Committee on the Judiciary
U.S. House of Representatives

4) Competitiveness of the U.S. Biotechnology Industry
March 23, 1994
Subcommittee on Science, Technology, and Space of the Committee on Commerce, Science, and Transportation
U.S. Senate

D. Committee reports on regulation

Issues in the Federal Regulation of Biotechnology: From Research to Release
Report prepared by the Subcommittee on Investigations and Oversight, transmitted to the Committee on Science and Technology, December 1986
US House of Representatives

E. Hearings on legislative initiatives on biotechnology regulation and/or research

1) The Biotechnology Science Coordination Act of 1986
June 4,5, 1986
Subcommittee on Natural Resources, Agriculture Research and Environment, Subcommittee on Science, Research and Technology, of the Committee on Science and Technology
U.S. House of Representatives

2) Review of Current and Proposed Agricultural Biotechnology Regulatory Authority and the Omnibus Biotechnology Act of 1990
October 2, 1990
Subcommittee on Department Operations, Research, and Foreign Agriculture of the Committee on Agriculture
U.S. House of Representatives

3) Agricultural Research Act of 1988; and the Biotechnology Competitiveness Act of 1988
August 10, 1988
Subcommittee on Department Operations, Research, and Foreign Agriculture
U.S. House of Representatives

4) Biotechnology Patent Protection Act of 1991
November 21, 1991
Subcommittee on Intellectual Property and Judicial Administration of the Committee on the Judiciary
U.S. House of Representatives

TABLE 2-8
Comparative policy choices, regulatory frameworks

CANADA[1]	UNITED STATES[2]
PRINCIPLES (in 1993 regulatory framework)	**PRINCIPLES** (in Federal Register statements, 1984, 1986, 1992)
Policy goals (guiding)	**Policy goals (guiding)**
Safety Maintaining Canada's high standards for the protection of human health and the environment (1993)	**Safety** Legitimate concerns about safety have been raised. The regulatory process should adequately consider health and environmental safety consequences. (1984) Regulation should seek a balance between ensuring health and environmental safety while maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry. (1986)
Economic development through innovation Fostering a favourable climate for development, accelerating innovation and adoption of sustainable Canadian biotechnology products and processes (1993)	**Economic development through innovation** Modern biotechnology offers vast potential for benefits, such as new services and superior products that will be more effective, convenient, safer or more economical. "The tremendous potential of biotechnology to contribute to the nation's economy in the near term, and to fulfill society's needs and alleviate its problems in the longer term makes it imperative that progress in biotechnology be encouraged." (1984)
Open consultations, framed by national priorities (competitiveness) and international approaches (harmonization) Promoting development and enforcement of Canadian regulations in an open and consultative manner, in harmony with national priorities and international approaches (1993)	**Competitiveness** Recognition that the way in which regulations are implemented will affect the competitiveness of developers and the future development of basic science. Regulation should minimize uncertainties, delays, overlaps, and inconsistencies. (1984) **Harmonization** Promotion of international harmonization, including scientific cooperation to achieve mutual understanding of regulatory approaches and international agreement on technical issues, such as principles for risk assessment. Harmonization will also assist in reducing barriers to trade in biotechnology. The framework takes into account the goals for regulation outlined by the OECD.[3] (1984)

[1] Canada (1993).

[2] United States. Executive Office of the President. Office of Science and Technology Policy (1984), (1986) and (1992).

[3] The work of the OECD in putting forward principles for regulation is discussed in Chapter Six.

Policy means (programmatic)

Status quo-efficiency, federalism
Building on existing legislation and institutions, clarifying jurisdictional responsibilities and avoiding duplication (1993)

Risk-based assessment
Developing guidelines, standards, codes of practice, and monitoring capabilities for pre-release assessment of the risks associated with release to the environment (1993)

Developing a sound scientific data base, upon which risk assessments and evaluations of products can be made (1993)

Policy means (programmatic)

Status quo-flexibility
Existing statutes provide the basic network of agency jurisdiction and provide for product-based regulation. As experience is gained, the framework is expected to evolve. (1984)

Science-based assessment
Regulatory decisions should be based on the best available science. (1984)

Each agency will develop its own review criteria and procedures, based on historical experience and scientific databases developed from reviewing other products with similar uses. (1984)

Risk-based assessment
Regulation should distinguish among organisms that require more or less review. (1986)
Regulation must be risk-based and focused on the product, not the process. Regulatory resources should be allocated according to degree of risk. Regulation is to occur only when there is evidence that the risk is "unreasonable", defined as when the full value of reduction in risk obtained by oversight exceeds the full cost of the oversight measure. Evidence includes information on the characteristics of the product, the type of use, and the target environment. (1992)

Agency discretion - consistency
Each regulatory agency decides whether its statutes apply to biotechnology products. (1984)
Regulation across agencies and, within agencies, across products, should be consistent. All agencies will adopt a case-by-case approach, at least initially. Agencies should adopt consistent scientific definitions and should apply reviews of equal scientific rigour. (1986)
Recognition of the need for agency discretion and flexibility within parameters set by the "scope" document. (1992)

CANADA

INSTITUTIONAL ARRANGEMENTS

"Stretch" existing mandates and legislative authorities.

For cases examined:
1) Environmental safety assessment: plants with novel traits
AAFC / CFIA through:
Feeds Act, Seeds Act, Plant Protection Act

2) Food safety assessment: novel foods
Health Canada through:
Food and Drugs Act

3) Labelling of food containing "novel" ingredients, including plants with novel traits
For safety aspects, Health Canada through:
Food and Drugs Act

Fragmentation of regulatory authority among several departments and agencies, according to existing responsibilities for products produced by other methods.

Interdepartmental coordination through the Interdepartmental Committee on Biotechnology and its sub-committees, since 1983. Key interdepartmental forum for regulations is the Sub-Group on Safety and Regulations.

POLICY INSTRUMENTS

Extension of existing regulatory authorities through amendments. Addition of government-wide definition of biotechnology to some statutes to clarify that authority exists over products produced using biotechnology. Amendments also explicitly outline information requirements for developers.

Provision of guidelines to developers for scientific considerations.

Use of risk assessment techniques, such as applying the concept of "substantial equivalence".

No new legislation.

UNITED STATES

INSTITUTIONAL ARRANGEMENTS

"Stretch" existing mandates and legislative authorities.

For cases examined:
1) Environmental safety assessment: plants with novel traits
USDA through:
Federal Plant Pest Act, Federal Noxious Weed Act
National Environmental Policy Act[4]

2) Food safety assessment: new plant varieties
Food and Drug Administration through:
Federal Food, Drug, and Cosmetic Act

3) Labelling of food containing "novel" ingredients, including plants with novel traits
Food and Drug Administration through:
Federal Food, Drug, and Cosmetic Act

Fragmentation of regulatory authority among several departments and agencies, according to existing responsibilities for products produced by other methods.

Interagency coordination of science issues through Biotechnology Science Coordinating Committee (1985-1990) and subsequently the Biotechnology Research Subcommittee.

POLICY INSTRUMENTS

Use of policy statements through the Federal Register to clarify authority, and, in one case (environmental safety), new regulations that extend existing regulatory authorities.

Provision of guidelines to developers for scientific considerations.

Use of risk assessment techniques and risk-based resource allocation strongly promoted in 1992 GST "scope" document.

No new legislation.

[4] NEPA requires all federal agencies to prepare an analysis before any actions that may significantly affect the environment. Depending on the action, the agency may have to prepare either an environmental assessment and/or an environmental impact statement.

CHAPTER THREE
REGULATING GENETICALLY-ENGINEERED PLANTS: COMPARING POLICY MAKING AND POLICY CHOICES

This chapter examines how Canada and the United States have responded to three policy issues arising from the commercialization of genetically-engineered plant varieties: environmental release, food safety assessment, and labelling. In some situations, the policy response has been tailored for genetically-engineered plants. In others, a blanket policy response has been put in place for all genetically-engineered organisms, all novel foods, or all plants with novel traits. The focus on policy responses affecting genetically-engineered crop plants in this case study simplifies the cross-national comparison by excluding policy responses specific to microorganisms, animals, and other genetically-engineered products. Since this case study uses the concept of policy network which focuses on the nature of interaction among policy community members, the chapter focuses on points of comparison that capture both key aspects of the policy making process and policy choices. A brief history of the development of the regulatory response in each country introduces the examination of each issue. Specific points of comparison are then made: first, issue arrival and problem definition by state officials; second, consultation and information gathering procedures; and third, policy choices, disaggregated into policy goals, institutional frameworks, and policy instruments. The discussion of policy choices includes the identification of central policy principles that provide policy goals (guiding ideas), prescribe policy means (programmatic ideas), and establish the scope of regulation. Together these details provide a relatively broad index of comparison of the policy making process and policy choices.

Issue arrival, which is part of the process of "agenda setting", is a chronological measure used here to mark recognition of the issue on the part of state officials.[1] Problem definition may encompass arguments about causes and consequences, as well as a problem's components.[2] Problem definition may precede issue arrival, when it begins within society at large, but what is important is how the problem is defined by state officials as of issue arrival. At that moment, the selection of an official problem definition begins to shape the policy response. Policy community members may hold competing problem definitions among themselves and seek to secure

[1] It is often difficult to pinpoint the exact moment of issue arrival. In the absence of personal recollections, reliable evidence can be found sometimes through government documents that mention the establishment of committees or other institutional structures with a mandate to deal with the issue. See Howlett and Ramesh (1995): 105-121 for a discussion of agenda setting and problem definition.

[2] Rochefort and Cobb (1993).

recognition of their favoured definition within the official definition.[3] The parameters of the official definition draw boundaries between legitimate and illegitimate policy goals and methods. The stakes can be high in the debate over problem definition. As Portz remarks, "a well-crafted definition--with visibility, sponsorship, and a solution--is a source of power that few can match in the policy world."[4] For example, the way in which a problem is classified can determine which actors or institutions take responsibility for solving it and what solutions are available.[5] Further, problem definitions may play a decisive role in determining key aspects of the policy process. The problem definition may affect which societal actors join the policy community and how much public attention the issue gathers. Issues characterized by technical complexity may be framed as technical, ethical or social problems.[6] When they are framed as technical problems, experts can dominate policy making. In contrast, when ethical or social aspects are included within the official problem definition, a broader range of participants may be involved. Consultation and information gathering procedures are also briefly described in this chapter for the purposes of determining the extent to which there are recurring patterns of information exchange. Problem definition and information exchange patterns provide insight on the nature of the policy community and policy networks, and on the role of scientific expertise in policy making, topics explored further in Chapters Four and Five.

The disaggregation of policy choices into policy goals, institutional frameworks, and policy instruments assists in the completion of the comparative task. Following guidance from literature on the role of ideas in policy making, principles underpinning policy choices are classified by distinguishing between guiding ideas which identify goals, programmatic ideas which outline the appropriate means by which to achieve those goals, and ideas which explicitly set limits on the scope of regulation. Outlining choices about institutional frameworks and policy instruments allows us to assess the degree of continuity with policy legacies and the impact of policy boundaries. The chapter concludes by summarizing key similarities and differences in policy making processes and policy choices between the two countries and across the three issues, and determining whether there is evidence of policy convergence.

[3] The existence of competing problem definitions for the issues examined in this case study is explored further in subsequent chapters.
[4] Portz (1996): 382.
[5] Kingdon (1984): 207.
[6] Baumgartner and Jones (1991).

ENVIRONMENTAL RELEASE: Is it "safe" to release genetically-engineered plants with novel traits into the environment?

Canada: Tracing policy making

One of the earliest policy issues raised by the pursuit of the application of genetic engineering to agriculture, and in particular to major crops, was whether and how to regulate release of genetically-engineered plants into the environment. More and more questions were asked in Canada during the 1980s about the environmental impact of plants with novel traits such as herbicide tolerance or insect resistance, at a time when environmental issues had taken on a heightened salience. Skeptics worried that these plants could become noxious weeds or have other adverse impacts on biodiversity through "gene escape"--the transfer of their traits to wild relatives.[7] Policy makers were called on to craft an appropriate regulatory response to calm these fears, which extended to other organisms such as genetically-engineered microorganisms which were perceived to pose even greater potential problems for monitoring and control than plants.[8]

As of the early 1980s, while an assessment mechanism was in place in Canada to evaluate the merit of some new plant varieties through the variety registration system under the *Seeds Act*, there were no provisions requiring formal environmental assessments prior to the release of new plant varieties. In 1985, the Science Council noted the absence of such requirements for genetically-engineered seeds. It recommended that the federal department of agriculture work with the federal departments of health and the environment to develop policy guidelines for field testing of seeds ultimately intended for commercial use.[9]

By 1988, the first year of small-scale field trials of genetically-engineered plants, Agriculture and Agri-Food Canada (AAFC) was well-embarked on regulating the confined release of these plants and had issued its first guidelines (see Table 3-1 for a chronology).[10] At the time,

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[7] The debate about environmental risk is examined in more detail in Chapter Five.

[8] This perception is based in part on the fact that while cultivation of genetically-engineered plants might be on a large scale, plants are more visible than micro-organisms and thus appear to be easier to control. There is also expertise in both countries in the eradication of plants, built up over decades of implementing statutes covering plant quarantine, plant pests, and plant health.

[9] Canada. Science Council of Canada (1985): 42.

[10] In 1993, Agriculture Canada became Agriculture and Agri-Food Canada (AAFC). In 1997, the department's regulatory responsibilities were spun off to the Canadian Food Inspection Agency. This case study refers to AAFC for events prior to 1997.

the lack of resources was slowing the pace of regulatory development. According to its own appraisal, the department was "partly prepared" in 1988 with guidelines at various stages of development.[11] More resources were needed to develop the "diagnostic capability" to ensure quality control, environmental safety, and food safety.

Into the 1990s, AAFC refined its environmental safety guidelines, acting under existing statutory authority. However, its assertion of its authority to conduct environmental safety assessments was challenged. Environmental organizations have argued that the *Canadian Environmental Protection Act* (CEPA), which came into force in 1988, should govern the regulation of all biotechnology products and processes, including new plant varieties. By the mid-1990s, as the issue of unconfined release loomed, AAFC took steps to clarify its authority in response to demands from developers and environmental groups for more certainty and formality. As a counterweight to the challenges from environmental groups, the Department of Justice confirmed in 1993 that the statutes administered by AAFC, including the *Seeds Act*, had sufficient authority to regulate biotechnology products. The issue reemerged during the CEPA review process of 1994-1995, resulting in a clarification from Cabinet that CEPA was only to govern regulation of those products of biotechnology not already regulated by other statutes. AAFC argues that its regulatory provisions are equivalent to standards set under CEPA and meet the requirements of the *Canadian Environmental Assessment Act.*[12]

To further reinforce AAFC's authority, the regulations of the *Seeds Act* and other relevant statutes were amended in January 1995 simply to include a definition of biotechnology in order to clarify that existing statutory authority extended to biotechnology products.[13] Two years later, in January 1997, AAFC's environmental safety assessment process for plants with novel traits (PNTs) was set out in a second set of regulatory amendments, providing a broad outline of the process and scientific information requirements.[14] This measure introduced greater formality to the

[11] Hollebone (1988): 45, 47.

[12] Since Environment Canada has agreed that these measures are equivalent, AAFC is not required to report its approvals of field trials or unconfined releases to CEAA administrators. Canada. Minister of Public Works and Government Services Canada (1997): 24.

[13] Canada. Minister of Supply and Services Canada (1994). The other statutes whose regulations were amended at the same time to clarify the extension of their authority to the products of biotechnology are the *Feeds Act*, the *Fertilizers Act*, the *Health of Animals Act*, and the *Pest Control Products Act.*

[14] In 1994, AAFC decided to refer to "plants with novel traits" (PNTs) rather than genetically-engineered plants, reflecting its subsequent formal policy choice of "novel trait" as a regulatory trigger.

approval process for unconfined releases that had begun in 1995.[15]

In the first decade of field trials in Canada, the number of approved trial sites accelerated from 14 in 1988 to 812 by 1997, dipping to 515 in 1998. In March 1995, AAFC issued its first "decision document" confirming the determination of the environmental safety of a PNT. By doing so, it granted permission for the first unconfined release of a genetically-engineered plant. At the end of 1998, almost 4400 field trials had been approved and 28 decision documents approving unconfined release had been issued, including a handful for PNTs not produced through genetic engineering (see Table 3-2). Compared to Europe, where anti-biotechnology activists held frequent demonstrations and destroyed field trials of genetically-engineered plants, there was relatively little public protest in Canada in the 1980s and 1990s and very few episodes of physical attacks on field trials. Into the late 1990s, AAFC's environmental safety measures continued to be challenged periodically by environmental groups and other public interest groups. Media attention was low and sporadic, confined largely to the agricultural press, until the close of the decade when the advent of widespread cultivation began to capture greater public attention.[16]

Disaggregating policy making
Issue arrival and problem definition

AAFC's policy response to the issue of environmental safety began in the mid-1980s as state officials began to assess the technology and gather information, provoked by questions from developers of genetically-engineered agricultural products. In 1987, the issue officially arrived with the establishment of the Branch Biotechnology Working Group, within the Food Production and Inspection Branch, Agriculture Canada's regulatory branch. That same year, the federal Interdepartmental Committee on Biotechnology established an ad hoc committee to study the issue of environmental release.

AAFC / CFIA has defined the issue of environmental release consistently as a safety

[15] The January 1997 amendments were made to the regulations of the *Feeds Act*, the *Fertilizers Act*, the *Health of Animals Act*, and the *Seeds Act*.

[16] See Mittelstaedt (1999). In 1998, MacArthur (1998) reported the discovery of herbicide-tolerant canola plants in fields in Alberta where none had been planted, confirming theories about the possibility of the spread of volunteers that could cause weed problems. There was also coverage of confusion about proper cultivation practices with Bt plant varieties given concerns about their contribution to development of insect resistance to the pesticide. Button (1998). In early 1999, the CFIA issued a notice that clarified this issue. Approvals of unconfined release of Bt corn became conditional on implementation of the Resistance Management Plan submitted by the Bt Corn Coalition, which calls for a minimum 20 per cent non-Bt refuge. See Canada. Canadian Food Inspection Agency. Plant Biotechnology Office (1999).

problem within the context of the competitiveness of the biotechnology industry. As a problem, environmental safety was new to regulators who had never formally included this issue within the scope of their evaluations. However, in the late 1980s, the increased focus on environmental issues combined with questions about new products convinced regulators to incorporate environmental safety generally into their regulation of new products.[17] In 1988, a state official described the task of regulation as responding to demands for regulations that would protect human and animal health, and the environment, but would not chase away developers. Canada was best to avoid the German example, where a five-year moratorium on field trials had resulted in the movement of trials to "more favourable" regulatory climates, including France and the Netherlands.[18] In 1993, government documents recognized not only the potential of biotechnology to "improve conditions and increase services for mankind", but also "concerns about potential adverse effects to human and animal health and to the safety of the environment."[19] In 1995, AAFC defined the problem as assuring the safety and efficacy of these new products, by developing "the best and safest ways of benefiting from biotechnology". AAFC summed up its role as "to balance public concerns for safety with those of industries that wish to use technology to create national prosperity".[20]

Consultation and information gathering

Consultation in the 1980s and 1990s was the domain of the bureaucracy and very little was done in the way of public consultation through the federal Parliament. The lack of new legislation to regulate the agricultural products of genetic engineering meant that discussion by elected officials was largely confined to occasional committee hearings (see Table 2-6).[21] AAFC officials state that extensive national and international consultations have taken place since 1987 on the safety

[17] Interview with CFIA official, August 1998.
[18] Hollebone (1988): 37.
[19] Canada. Agriculture and Agri-Food Canada. Committee on Biotechnology Regulation (1993).
[20] Canada. Agriculture and Agri-Food Canada (1995b): 1.
[21] While two committee reports have been issued with recommendations for biotechnology policy, only that by the Standing Committee on Environment and Sustainable Development made recommendations on environmental release. The committee called for regulation by other departments to be consistent with requirements laid out in the *Canadian Environmental Protection Act*--to ensure equivalent treatment of the notification, assessment, and regulation of risks to the environment and human health. See Canada. House of Commons. Standing Committee on Environment and Sustainable Development (1996).

assessment process for environmental release.[22] Most of the domestic consultation occurred in the early and mid-1990s. First, the department used various advisory committees such as the multistakeholder Plant Biotechnology Advisory Committee.[23] Second, the department solicited comment directly by sending draft regulations in 1994 to more than 2000 organizations and individuals, and revised regulatory amendments in 1996 to 1500 organizations and individuals, allowing for a sixty-day comment period. Third, the department provided notice of its regulatory amendments through the 1995 Federal Regulatory Plan. Finally, there was a major national workshop in 1993 on regulating agricultural products of biotechnology. The 1993 multistakeholder workshop was a departure from AAFC's original focus on consulting within the agricultural research community and with federal and provincial government officials. At the 1993 workshop, AAFC acknowledged that its consultations had focused initially on gathering technical input from the scientific community and that it recognized the importance of consulting other interested individuals and organizations.[24]

AAFC officials report that information gathering apart from consultations has also been extensive. It has been conducted through domestic scientific networks, through international fora such as the Organisation for Economic Cooperation and Development (OECD), and bilaterally, for example, with US Department of Agriculture (USDA) officials. For example, in 1988, an AAFC official noted that recent information exchange on the techniques and science of molecular biology had included a bipartite Canadian-American meeting, a seminar run by the developer firm Monsanto to inform Canadians about its American experience with field trials, and a training program for the regulators in AAFC's Seed Division involving Research Branch colleagues.[25]

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[22] See Canada. House of Commons. Standing Committee on Agriculture and Agri-Food (1996a).

[23] Canada. House of Commons. Standing Committee on Agriculture and Agri-Food (1996a): 32. The use of multistakeholder consultations and advisory bodies has been more common in Canada since the late 1980s, particularly in developing environmental and other social regulatory policies. Multistakeholder mechanisms are intended to include a much more complete range of those interested in and / or affected directly or indirectly by policy choices. In the past, consultations would often be restricted to those regulated by policy choices, encouraging the perception of the capture of regulatory agencies by their direct clientele.

[24] Canada. Agriculture and Agri-Food Canada, Health Canada, and Environment Canada (1993).

[25] Hollebone (1988): 46.

Policy choices: Policy goals

AAFC chose the guiding ideas for its regulatory response long before the release of the 1993 federal regulatory framework. The framework simply reinforced those guiding ideas and the department's programmatic ideas about policy means (see Table 3-3). AAFC's focus has been safety within the context of competitiveness. AAFC has called its approach "safety-based" because it assesses the risks of each product. Regulation is product-based because it examines the risks stemming from the novel traits of a product and thus sidesteps an exclusive focus on the process of genetic engineering.[26] In pursuing the goal of competitiveness, AAFC officials have also placed an emphasis on harmonization. Policy documents repeatedly stress that policy choices are consistent with ideas and standards endorsed by international organizations such as the OECD and major trading partners, including the US.[27] AAFC has also suggested that meeting its scientific information requirements may provide developers with a competitive advantage since they will have information on hand that customers in other countries may want. It has predicted that its 1997 regulations, by contributing to regulatory certainty, will encourage development of the biotechnology industry.

Institutional framework

Regulation of the sale and use of new plant varieties has traditionally been centred at the office within the federal department of agriculture responsible for administering the variety registration system under the *Seeds Act*. Genetically-engineered plant varieties were dealt with initially by regulators responsible for other new plant varieties within the Food Production and Inspection Branch, the regulatory branch of Agriculture Canada. As of 1998, evaluation was handled by the Plant Biotechnology Office within the Variety Section of the CFIA.[28] In 1987, the department established a Branch Biotechnology Working Group to coordinate efforts among the many divisions (e.g., seeds, feeds, fertilizers) being confronted with the new biotechnology products. In 1993, the Biotechnology Strategies and Coordination Office at AAFC was formally

[26] However, AAFC has recognized that the use of genetic engineering to introduce foreign genes could result in unintended effects. Notably, information requirements for both confined and unconfined release include data on the methods used to achieve the expression of the novel trait(s).

[27] See, for example, Hollebone (1988), Canada. Agriculture and Agri-Food Canada (1995b), and Canada. Minister of Public Works and Government Services Canada (1997).

[28] The name change reflects internal reorganization more than a change of location or personnel.

established to take over the increasing workload of the Working Group. It was renamed the Office of Biotechnology, after its move in April 1997 to the Canadian Food Inspection Agency (CFIA).[29] In the late 1990s, the Office began to focus increasingly on interdepartmental work and other external relations but continued to work closely with other offices within CFIA including the Plant Biotechnology Office. According to state officials in both departments, AAFC and Environment Canada have worked together closely over several years on the issue of environmental release of agricultural products. In 1988, the two departments negotiated a Memorandum of Understanding to guide their collaboration. It established procedures in cases of overlap and confirmed AAFC's status as the lead agency regulating agricultural products of biotechnology.[30]

Policy instruments

To implement its regulatory response, AAFC / CFIA initially used existing institutions and legislation, supplemented by regulatory guideline documents. This strategy is consistent with the "status quo" approach chosen in the late 1980s.[31] The decision in the mid-1990s to amend existing regulations came only when the department decided that greater clarity and a reinforcement of its authority to conduct environmental safety assessments was necessary.[32] The second set of regulatory amendments in 1997 set out the process and general information requirements for the safety assessments, formalizing the department's approach. CFIA justified its choice of amending the regulations of existing statutes to provide for environment safety assessments, rather than continuing with guidelines or transferring responsibility to Environment Canada, as the option which "most closely reflects the principles of the [federal regulatory framework], fits the mandate of the department, and provides a cost effective use of resources".[33]

The scientific aspects of environmental safety assessment are based on the regulatory trigger of "novel trait" and provisions requiring developers to submit data on risks to the

[29] A CFIA official noted in August 1998 that this internal coordinating body was initially expected to be shortlived.
[30] Hollebone (1988): 47.
[31] Hollebone (1988): 44-45.
[32] Personal interviews with state officials, 1998.
[33] Canada. Minister of Public Works and Government Services Canada (1997): 27.

environment and human health.[34] The regulatory trigger of novel trait means that the scope of regulation focuses on all plants with novel traits (PNTs) and thus encompasses both plants produced by genetic engineering and other, older methods such as mutagenesis. To conduct its evaluations, CFIA reviews information from the developer and, when necessary, may conduct a search for other relevant information. Developers must first receive approval for confined field trials.[35] Data gathered through field trials are used when the new plant variety is evaluated for environmental safety prior to approval for wide-scale cultivation, called "unconfined release". Imported plants with novel traits are normally assessed to determine whether they pose a plant pest risk. If a PNT undergoes an environmental safety assessment which includes a pest risk assessment, the requirement for an import permit under the *Plant Protection Act* is waived. The concept of substantial equivalence guides the risk assessment process. Products with novel traits are compared when possible to their conventional counterparts.[36]

Throughout the 1990s, approvals for field testing and environmental safety assessments were issued on a case-by-case basis. The twinning of the concepts of novelty and substantial equivalence allows regulators to decrease or waive information requirements from developers for subsequent safety assessments of similar products as knowledge of products with novel traits increases. If the product has already been assessed and approved, its "novelty" status disappears, eliminating the need for subsequent review of similar new products in most cases because these new products can be assessed as substantially equivalent to the already-approved variety.

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[34] "Novel trait" is defined as a characteristic of the seed intentionally selected, created or introduced into a distinct, stable population of cultivated seed of the same species through a specific genetic change, and based on valid scientific rationale. It is not substantially equivalent, in terms of its specific use and safety both for the environment and for human health, to any characteristics of a distinct, stable population of cultivated seed of the same species in Canada, having regard to weediness potential, gene flow, plant pest potential, impact on non-target organisms and impact on biodiversity. See Canada. Minister of Public Works and Government Services Canada (1997): 53.

[35] Field trials are considered a "confined release" because measures are taken to minimize gene escape, whether through pollen, seed, or other means. Canada. Agriculture and Agri-Food Canada (1995f).

[36] For example, a canola variety with the novel trait of tolerance to a specific herbicide would be compared to its conventional counterpart which lacks this specific trait. The new variety would be compared on matters such as its potential for weediness, gene flow, plant pest risk, and impact on non-target organisms and on biodiversity.

United States: Tracing policy making

Just as the initial concerns about the safety of working with rDNA organisms in the lab had mostly disappeared from the political agenda and the NIH lab safety guidelines were being increasingly relaxed, the issue of environmental release emerged in the United States. Public concern began to grow in the early 1980s. At least six congressional committee hearings examined the issue between 1983 and 1988, and one committee issued a report.[37] The 1986 report made fifteen recommendations, including further review of the adequacy of existing institutional mechanisms, guidelines, and data for the purpose of assessing risks associated with environmental release. The General Accounting Office (GAO) also periodically examined the issue, examining both the USDA's role in research and the adequacy of its regulatory efforts.[38] USDA officials described the GAO's almost constant scrutiny as an "open-book test" that drew their attention to issues that had been overlooked or underestimated. The 1985 GAO study's revelation that the USDA was funding at least eighty-seven agricultural biotechnology research projects that would involve environmental release heightened congressional interest in the adequacy of regulatory measures.

The first major public controversy involving environmental release arose not over a new plant variety, but rather over a genetically-engineered bacterium designed to make plants resistant to frost. Between 1981 and 1983, the Recombinant DNA Advisory Committee of the National Institutes of Health approved a few experiments involving environmental release, including that involving the frost-resistant bacteria. The testing was planned for the fall of 1983 in California. However, the release was opposed by a coalition led by Jeremy Rifkin and his Foundation on Economic Trends. The experiment was delayed through litigation and local publicity campaigns for almost four years, with the release occurring only in April 1987.[39] The controversy prompted the biotechnology industry to call for a clear regulatory regime to limit the damage to public confidence and reduce its own liability. The White House decision to create a federal regulatory framework handed USDA the responsibility to regulate several agricultural products of

[37] See Table 2-6. For the report, see U.S. Congress. House Committee on Science and Technology. Subcommittee on Investigation and Oversight (1986).
[38] United States. General Accounting Office (1985), United States. General Accounting Office (1986), and United States. General Accounting Office (1988).
[39] For more detailed accounts, see Jasanoff (1995a), Kloppenburg JR (1988), Doyle (1985), and Bureau of National Affairs (1989).

biotechnology, including genetically-engineered plants.

The USDA appeared initially to be reluctant and confused in developing its response. The issue of liability was looming large, the Reagan administration had a strong deregulatory bent, and two main groups within Congress were pressuring USDA--one toward environmental protection and the other toward minimal regulation. As well, researchers were split into two camps; those working with large firms that had a history of working within the constraints of regulatory regimes favoured explicit regulations and researchers in the public sector who had a history largely of self-regulation and were not so keen about that prospect. It was, as one USDA official described it, a "very yeasty time".[40] The 1986 GAO report noted that the USDA was hesitant because it did not want to impose regulations that might stifle the biotechnology industry. It was also waiting for the finalization of government-wide coordination efforts by the Office of Science and Technology Policy (OSTP) in the form of a regulatory framework. The several lawsuits surrounding environmental release had created anxiety within the USDA and "a high level of legal consciousness and a desire to do things so that legal questions do not become major issues".[41] The GAO described the USDA approach to biotechnology regulation as lacking formality and specific provisions both generally and for approval of environmental release. Within USDA, there was also uncertainty about where responsibility for regulation would lie. Struggles were occurring between regulators and researchers over who would be given primary responsibility, with researchers worried that regulators would control their research.

The USDA had stated its intention in 1984 to rely on its existing authorities combined with the NIH lab safety guidelines for the purposes of biotechnology regulation. It asserted that genetically-engineered agricultural products could be regulated in the same way as their conventionally-produced counterparts. After receiving comments on its 1984 statement and in an atmosphere of constant scrutiny, the USDA acknowledged in 1986 that its 1984 statement had "left unanswered some questions about the means for review and approval of various genetically-engineered products".[42] In 1987, it issued new regulatory provisions under its existing authority to regulate plant pests. These provisions outlined criteria for the purpose of determining which genetically-engineered organisms would be "regulated articles". Developers would be required to

[40] Personal interviews with USDA officials, October 1998.
[41] United States. General Accounting Office (1986).
[42] United States. Department of Agriculture (1986).

supply specific data to regulators about these "regulated articles".[43] Most of the comments USDA received supported its 1987 measure, but others suggested that the department lacked authority to regulate environmental release and lacked provisions to require review *prior* to release. USDA rejected these comments, arguing that it had adequate authority under the *Federal Plant Pest Act.* The first field trials for genetically-engineered plants took place in 1987, at five sites. In 1997, field trials were conducted at more than 3700 sites (see Table 3-4).

After 1987, the USDA progressively relaxed its regulatory oversight of genetically-engineered plants. In 1992, the department again was uncertain about the future direction for its regulations. It was an election year and regulation was an unpopular concept, reinforced by the activities of the President's competitiveness council. From some quarters, there were calls to scrap the regulations on the release of genetically-engineered plants completely. The USDA issued its first proposal to relax its regulations that year and received comments from eighty-four individuals and organizations.[44] The majority of the comments favoured a reduction in regulatory oversight. These supportive comments came from industry, the academic research community, and state governments. However, a majority also opposed two specific proposals as being premature moves toward self-regulation and deregulation; one would have given researchers much more autonomy and the second would have allowed notification of field trials on the day of the release. The proposed amendments became final in 1993, exempting some plants from the permit system and placing them under a notification system. They introduced provisions to allow for the determination of "nonregulated status" or, in other words, no further regulation. In 1997, further amendments allowed most of the genetically-engineered plants falling at the time under the scope of the regulations to be introduced by notification as long as they met certain standards, allowed for nonregulated status to be extended to other similar plants, and reduced field test reporting requirements.[45] These revisions received comments from fifty individuals and organizations. Sixty per cent expressed general support for the changes, but one-third opposed any revision.

As in Canada, the cultivation of genetically-engineered plants with novel traits continued to

[43] United States. Department of Agriculture (1987).
[44] United States. Department of Agriculture. Office of the Secretary (1993).
[45] United States. Department of Agriculture. Animal and Plant Health Inspection Service (1997).

be controversial into the late 1990s.[46] For example, EPA's efforts to regulate plant pesticides such as Bt incorporated into plant material were mired in controversy through the 1990s. In September 1997, a coalition led by Greenpeace that included the International Federation of Organic Agriculture Movements filed a petition against the EPA.[47] It called on the EPA to cancel all registrations of genetically-engineered Bt plants, to cease evaluating new applications for registration, to confirm that these plants cause "unreasonable adverse effects to the environment", and to conduct a review for an environmental impact statement assessing the EPA's policy for Bt crops. In February 1999, the coalition launched a lawsuit against the EPA when the agency failed to respond to the petition. Meanwhile, in January 1999, the National Corn Growers' Association and several of the major firms selling Bt corn (Monsanto, Dekalb, Dow AgroSciences, Mycogen Seeds, Novartis Seeds and Pioneer Hi-Bred International) bypassed the EPA and reached an "agreement-in-principle" intended to reduce confusion among producers about proper cultivation methods of Bt crops to reduce the development of insect resistance. The agreement was to come into effect in the year 2000 and includes refuge requirements, clearer agreements between seed firms and growers, and monitoring provisions.[48]

Disaggregating policy making
Issue arrival and problem definition

In the US, the issue of environmental release emerged when the National Institutes of Health (NIH) lab safety guidelines were still the centrepiece of federal regulatory efforts. When the NIH's advisory committee began to approve experiments involving environmental release in the early 1980s, it was treated as a logical progression of its oversight effort until a series of lawsuits created public controversy. The Office of Technology Assessment (OTA) had warned in 1981 that a regulatory regime for environmental release would be necessary and suggested a

[46] Producers are keen to use the new Bt corn and cotton plant varieties, while environmentalists and organic growers worry about the development of insect resistance and the loss of Bt as a pest management tool. Media attention continues. See, for example, Benson et al. (1997).

[47] See Greenpeace International's web site at http://www.greenpeace.org/~geneng/ for details.

[48] See the National Corn Growers' Association web site at www.ncga.com. The development of insect resistance to pesticides, whether chemical or biological, is a perennial challenge for agricultural producers. Organic farmers have long relied on topical applications of Bt, as a biological pesticide, to avoid using chemical pesticides. The widespread and intense use of Bt in genetically-engineered plants may rapidly accelerate the development of insect resistance to Bt, thus rendering obsolete one of organic farming's key pest management tools. Refuge requirements are being required on the belief that they may slow the development of insect resistance.

number of options. The OTA report provoked discussion both within industry and within federal agencies, but little was done because the need was not seen as compelling and the Reagan administration was philosophically opposed to regulation.[49] However, the industry began to be interested in some form of regulation as a buffer against liability. Before the release of the coordinated framework, USDA had been involved in regulatory discussions. For example, it had consulted with NIH on issues of mutual interest such as the environmental release of genetically-engineered plants. It also established the Agriculture Recombinant DNA Advisory Committee (renamed the Agriculture Recombinant DNA Research Committee, or ARRC, in 1984) in 1976 to provide scientific advice and work with NIH and the National Science Foundation. Shortly after the release of the draft framework in December 1984, ARRC recognized that USDA would begin to receive requests for approval for release.[50]

USDA's 1984 policy response that it would incorporate the new genetically-engineered products under its existing regulatory regime suggested that it did not see these products as creating any specific policy issues.[51] The department argued that there were no unique safety issues arising from the use of genetic engineering, a position that translated into no discrimination against the use of the technology. In 1983, USDA Assistant Secretary for Science and Education Orville Bentley, in replying to the question of what potential environmental dangers were posed by the release of new genetically-engineered organisms, had declared that no "unique" dangers were expected to result "as long as existing oversight procedures are fully utilized".[52] USDA's focus was on ensuring that whatever regulation did occur did not impede domestic or international competitiveness and on encouraging harmonization on regulatory standards to avoid trade barriers. However, by 1986-1987, bowing to pressures for an explicit regulatory response to the use of genetic engineering and sobered by environmental lawsuits, the USDA introduced its new regulations with the implied recognition that the use of genetic engineering could result in the introduction of plant pests that might threaten agriculture and the environment. In 1988, however, its view of the issue was still strongly based on competitiveness:

[49] Kenney (1989): 83-85.
[50] This point was raised in a January 1985 meeting of ARRC. See United States. General Accounting Office (1986): 37.
[51] United States. Executive Office of the President. Office of Science and Technology Policy (1984). See pages 50897-50904 for the USDA's statement.
[52] United States. House Committee on Science and Technology. Subcommittee on Investigations and Oversight (1983): 257.

> Biotechnology offers great potential in many areas, particularly in continuing improvement of our capacity to develop products that are of critical importance to the future of American agriculture. It is vital that products of biotechnology be regulated based on firm scientific principles and meet the same high standards of safety and efficacy as do those products made through conventional technology. Thus, we seek to foster a regulatory climate that encourages innovation, development, and commercialization of beneficial new agricultural products derived from biotechnology, while implementing a responsible policy that limits potential of real risks.[53]

Consultation and information gathering

USDA focused much of its consultation and information gathering within the scientific community, both through USDA advisory committees such as ARRC and its successor ABRAC, and through institutions of the wider agricultural research and regulation community.[54] For example, in the late 1980s and early 1990s, the USDA worked through the National Plant Board, an association of state-level plant pest regulatory agencies. A series of federal-state conferences were held to discuss regulation of genetically-engineered plants, using these existing relationships within the plant pest regulation network. USDA officials say that the public and representatives of public interest groups have been able to express policy preferences and concerns through various existing consultation mechanisms such as meetings within the National Plant Board system and agricultural extension activities. State officials have also had less formal meetings with interested organizations, including some of the public interest groups that are skeptical about the use of genetic engineering in agriculture. The USDA has been an active participant in meetings and discussions within the federal government about recombinant DNA research since the early 1970s.[55] Beyond its domestic information gathering activities, USDA regulatory officials have actively gathered information by convening and attending bilateral and international workshops on specific technical issues.

After 1984, when the USDA began to publish notices and rules regarding regulation of genetically-engineered organisms in the *Federal Register*, consultation was broadened and included a more formal element. USDA officials say that they generally have not solicited public comment proactively beyond the *Federal Register* process in part because of the mandatory timeframes

[53] U.S. Congress. House Committee on Science, Space, and Technology. Subcommittee on Natural Resources (1988): 80. This statement was made by Kenneth Gilles, then assistant secretary, marketing and inspection services, USDA.

[54] Personal interviews with USDA officials, October 1998.

[55] United States. General Accounting Office (1986).

within regulations for action. For example, petitions for determination of nonregulated status are published for a sixty-day comment period. USDA did solicit information for one petition, but found the process unworkable and subsequently decided that it would be better to direct information-gathering internally. It has also used expert advisory committees to help with development of regulations, such as the notification system for field trials, but has found them difficult to use at times because of confidential business issues.

Policy choices: Policy goals

USDA's policy response incorporated the goal of safety, but largely in pursuit of the initial goal of competitiveness, rather than balanced against it (see Table 3-3). Given its focus on "plant pests", the USDA's definition of "safety" appeared to be focused more on avoiding or reducing economic harm to agriculture than on protecting human or environmental health. Subsequent policy choices to relax and streamline regulatory requirements simply reinforced the institutionalization of the goal of competitiveness. As part of its commitment to competitiveness, the USDA also sought to further harmonization internationally, based on the promotion of scientific consensus.[56]

Institutional framework

Since the mid-1980s, the USDA's inspection branch, the Animal and Plant Health Inspection Service (APHIS), has been responsible for regulation of genetically-engineered plants. As of 1998, evaluation was handled within the Plant Protection and Quarantine branch of APHIS. To improve internal coordination within USDA on biotechnology policy and to coordinate USDA's interaction with other departments and levels of government, an Office of Agricultural Biotechnology (OAB) was established in 1986.[57] Observers noted that the OAB helped to bridge disagreements between regulators and agricultural researchers within the department. The OAB operated for almost a decade, until it and its Agricultural Biotechnology Research Advisory Committee (ABRAC) were shut down abruptly in early 1996, almost a year before the initial

[56] These international activities are explored further in Chapter Six.

[57] See United States. Department of Agriculture (1986) for a description of OAB's mandate and duties. The OAB's duties included coordination of the new National Biological Impact Assessment Program, proposed by the agricultural research community as a mechanism to evaluate the impact of the products of genetic engineering on the environment and other safety issues.

schedule.[58] While some argued that these measures reflected deregulatory pressures from Congress, others also noted the lack of resistance within the USDA. The USDA stated at the time that the functions of the OAB that remained necessary would be continued through other means. Throughout the 1980s, the USDA worked with and negotiated agreements with other regulatory agencies, especially the EPA and the FDA, to clarify areas of jurisdictional overlap. Regulatory officials and interest group representatives say that relationships among the regulatory agencies in the late 1990s have generally been productive. In 1998, for example, USDA officials were holding monthly teleconferences with EPA and FDA officials on matters of mutual concern.

Policy instruments

The USDA made few comments in regulatory documents describing the means by which it would achieve its regulatory goals, although in 1984 it said it would use a "formal and logical process" and would adapt its approach as experience accumulated.[59] This suggestion of adopting a a science-based approach was elaborated subsequently. In 1991, the USDA issued voluntary and detailed research guidelines for the release of organisms with "deliberately modified hereditary traits" that outlined a process of determining the "level of safety concern" and revealed its current thinking on scientific assessment.[60] A close reading of the USDA's regulations on environmental release reveals a strong focus on procedural commitments, such as description of various applications and petition processes, timeframes for responses, provision for public comment and appeals, rather than on the scientific assessment process.

The USDA did move quickly to draft new regulations for the specific purpose of governing the release of genetically-engineered plants and other organisms that could pose a plant pest threat, once it had decided that its initial position of no new regulatory measures was untenable. The USDA has relied mainly on its authority under the *Federal Plant Pest Act,* which it argues provides extremely broad powers to prevent the release of plant pests and, if necessary, to eradicate them. The USDA's choice of regulatory trigger, which combines the process of genetic engineering along with the potential of plant pest risk, appears narrow in comparison to Canada's "novel trait". However, USDA officials argue that the definition of regulated article, which allows them to

[58] Fox (1996). ABRAC had existed in some form since 1976 when the first advisory committee on rDNA research was first set up by USDA.

[59] United States. Executive Office of the President. Office of Science and Technology Policy (1984).

[60] United States. Department of Agriculture. Office of the Secretary (1991).

review organisms that they have "reason to believe" could cause a plant pest threat, provides broad discretion. Like Canada, the USDA uses a "stepwise" process, moving from field trials to unconfined release. Initially, the USDA relied on a permit system that required developers to submit applications including the scientific information requirements outlined in the regulations. By 1993, it reduced the scope of permit requirements by allowing some products to be introduced through a notification system. It also introduced procedures for the determination of "nonregulated status" or, in other words, allowing unconfined release of previously-regulated articles. By 1997, through further regulatory amendments, many of the new genetically-engineered plant varieties could move directly to field trials under the notification procedure. As it relaxed its regulatory requirements, the USDA also announced its intention in the *Federal Register* to begin issuing guideline documents for technical matters that would include recommendations on procedures and protocols.[61] It stressed that these guidelines were voluntary and that following them would not necessarily ensure approval. USDA's regulatory activities are governed by the *National Environmental Policy Act* (NEPA). USDA has met NEPA's requirements by preparing environmental assessments prior to issuing permits for field trials and for determinations of non-regulated status.

FOOD SAFETY ASSESSMENT: Is it "safe" to eat these products?

Canada: Tracing policy making

Many of the new plant varieties of the first generation produced through genetic engineering are intended ultimately for human consumption. Health Canada refined its regulatory approach for foods produced through genetic engineering throughout the 1990s (see Table 3-5).[62] Compared to the issues of environmental safety and labelling, food safety assessment had not attracted much public attention in Canada into the late 1990s. However, this situation began to change in 1999, as more products entered the marketplace and increasing consumer resistance to genetically-engineered foods in Europe was seized on by biotechnology skeptics to capture

[61] United States. Department of Agriculture (1995).

[62] Health Canada had already been regulating pharmaceutical products produced through genetic engineering for years before it began to deal with foods and food ingredients produced through genetic engineering. It approved its first genetically-engineered drug, human insulin, in January 1983. A wide range of therapeutic products have been produced since the early 1980s through genetic engineering. Other applications of genetic engineering in the medical field include gene therapy and xeno-transplantation. See Canada. Industry Canada. Canadian Biotechnology Strategy Taskforce (1998) for a brief summary of the contribution of biotechnology in the medical field.

Canadian media attention.[63] Health Canada's focus on "novel foods" has somewhat obscured the fact that most of the novel foods falling under the scope of regulation are derived from genetic engineering. This focus, combined with the current labelling policy, likely reduced consumer awareness.

In the fall of 1999, Health Canada published the final version of the regulations it first proposed in 1992. These regulations require premarket notification for the sale of foods meeting the definition of novel foods. Notification was thus voluntary for several years, although Health Canada officials said that, as of 1998, all novel foods had passed through its assessment process before being sold in Canada. As a result, between 1994 and 1998, thirty-eight new plant varieties received food safety approval from Health Canada (see Table 3-6). Most had new traits conferring herbicide tolerance, insect resistance, or changes in composition, such as modified oil characteristics. Into the first decade of the new century, Health Canada expects to be evaluating rising numbers of "functional foods" derived from new plant varieties, which have enhanced nutritional or medicinal properties.

The pace of regulatory development demonstrates Health Canada's cautious approach. Health Canada officials have periodically noted that they have advanced slowly so as not to be "out of step" with developments elsewhere in the world and to ensure a comprehensive, well-founded approach.[64] However, turmoil inside the department and more specifically, within the Health Protection Branch, in the 1990s may also have contributed to their caution. The branch was stung by criticism and hampered by funding cuts. Its problems raised questions about whether it had adequate capacity and autonomy from those it regulated to fulfil its health protection mandate.[65] Throughout much of the 1990s, Health Canada was under constant pressure from the food industry to narrow its proposed definition of "novel foods" upon which its regulatory response is

[63] Recent mainstream media coverage in Canada includes, for example, Colapinto (1998), Dyer (1999), and Black (1998). A 1998 news story reported polling results of an Angus Reid survey of 1000 Americans and 1000 Canadians that found that most were not aware of the use of genetic engineering and had limited understanding of biotechnology. See Briere (1998).

[64] See Canada. Agriculture Canada (1993). This approach was also described in a personal interview with a Health Canada official.

[65] Media coverage was heavy in late 1998 and into early 1999. Some of the controversy has focused on Health Canada's long delayed decision on the use of a genetically-engineered bovine growth hormone, used to increased milk production, which finally resulting in rejection of the product in early 1999. On the travails of the branch, see for example, McIlroy (1998), McBane (1998), Winsor (1998), Eggertson (1997a), Eggertson (1997b), and *The Globe and Mail* (1998).

based.[66] The definition was revised three times between 1992 and its 1999 version. It was narrowed in its scope through a more specific definition and revised to make it easier to incorporate data regarding food safety acquired in other countries.

Disaggregating policy making
Issue arrival and problem definition

Health Canada's 1992 "information letter", sent out to interested parties, was its first public document on the issue of food safety assessment of genetically-engineered foods, including those from plant varieties. Discussion inside the department, however, began at least as early as 1988, according to Health Canada officials. In its policy statements, Health Canada has stated that genetically-engineered foods raise safety issues and suggested that safety assessments should be conducted to limit negative effects on the well-being of consumers.[67] It has also argued that the adequacy of food safety assessment would be important to consumer acceptance of the new foods. Health Canada has taken a consistently cautious tone, noting scientific uncertainty about the food safety of genetically-engineered food and the need in some cases for government review. It has expressed concerns that while novel foods and food processes could increase quality and nutritional value, they could also have side effects such as reductions in nutritional value, or introduction of harmful substances with toxic effects, increased levels of existing toxicants, and substances producing allergic reactions in some individuals.

Consultations and information gathering

For the most part, Health Canada has conducted consultation through invitation for comment and by communicating directly with firms, industry associations, consumer groups, and individuals. Its more formal consultation measures included the 1992 "Information Letter", and co-sponsoring the major 1993 multistakeholder Workshop on Regulating Agricultural Products of Biotechnology and a 1994 multistakeholder workshop on the technical aspects of labelling novel foods. Its publication of the proposed regulations in 1995 and 1998 in the *Canada Gazette* also provided a formal consultation process. Information gathering has been extensive with much of it conducted at the international level through organizations such as the Food and Agriculture

[66] The constant renegotiation of the definition of "novel food" is examined further in Chapter 5.
[67] Canada. Health and Welfare Canada. Health Protection Branch (1992) and Canada. Health Canada. Health Protection Branch. Food Directorate (1994).

Organization and the World Health Organization of the United Nations, and the Organisation for Economic Cooperation and Development, as well as from other countries.[68] Health Canada's regulations, for example, are based somewhat on the approach adopted in the United Kingdom. The department has used a wide range of existing conferences and other venues for informal consultation and information gathering, including attending meetings of several organizations interested in its regulatory response such as consumer and industry groups.[69]

Policy choices: Policy goals

Health Canada's regulatory response throughout the 1990s has focused on the central goal of ensuring that the use of genetic engineering does not jeopardize food safety. The slow pace of regulatory development has allowed it to keep an eye on developments in both scientific standards and choice of policy instruments internationally and in other countries. Harmonization, or at least compatibility, with internationally-accepted standards has been a key goal. The delay in settling on a more concrete regulatory response is seen by regulatory officials as insurance against having to make substantial revisions should international consensus shift.

Health Canada has also kept the government-wide goal of competitiveness in mind through its focus on harmonization and its choice of the premarket notification option which in some cases will trigger premarket review. This option reduces barriers to commercialization for developers compared to across-the-board safety assessments. Premarket approval for each product was seen to be overly onerous and not necessary. A listing procedure similar to that used to approve food additives, which would require regulatory amendments to be updated, was also rejected. Both of these options were seen to impede innovation by slowing down commercialization, while not providing additional safety. The notification option, in contrast, allows developers to sell their product as soon as the internal Health Canada assessment process is complete.[70]

Institutional framework

[68] In 1991, Health Canada's food directorate sent documents regarding food safety assessment of genetically-engineered food to US state officials for their comments including Dr. James Maryanski, FDA biotechnology coordinator, who replied favourably and encouraged ongoing Canadian-American contact. Letter dated October 23, 1991, from Maryanski to Dr. Bill Murray, chair of the food directorate, posted by the Alliance for Bio-integrity at www.bio-integrity.org

[69] Interview with Health Canada official, September 1998.

[70] Canada. Minister of Supply and Services Canada (1995). This point was reemphasized in a personal interviews with a Health Canada official.

Evaluating genetically-engineered foods had brought little change to Health Canada's institutional framework for food safety assessment as of 1998. Health Canada has sole responsibility for setting food safety standards and fulfils this responsibility within the Health Protection Branch. Although its regulation focuses on novel foods, it has created an Office of Food Biotechnology which coordinates evaluations internally and is the contact point for developers, public interest groups, and individual citizens. There is also an internal biotechnology working group for coordination within the food directorate of Health Canada. Health Canada has consistently participated in interdepartmental committees on biotechnology.

Policy instruments

Since late 1999, Health Canada has required premarket notification for all foods falling under its definition of "novel food". Prior to the finalization of regulations, it relied on voluntary compliance by developers, apparently quite successfully, and issued technical guidelines to assist developers in their own safety assessments. These guidelines include decision tree charts that list questions about the intended use of the product and the ways in which it is novel. Depending on the answers to the questions, developers can determine whether review by Health Canada is advisable.

When it does conduct safety assessments, Health Canada's approach is risk-based and applies the concept of substantial equivalence. It compares the novel food to its conventional counterpart which usually has a long history of safe use in humans. The focus is on similarities and differences in composition, including nutritional value and toxicity. If the novel food contains an element that does not have a long history of safe use, such as a new protein resulting from the introduction of genetic material from another source to obtain the new trait(s), evaluators may also use more in-depth studies. For example, they may conduct an in-depth toxicological assessment of the new protein, similar to that done for new food additives. The concept of substantial equivalence, by combining various evaluative procedures, facilitates the case-by-case approach and allows for the variation of assessment according to the potential risk. As Health Canada argues:

> The variety of ways by which plants can be modified, and the degree of modification that can be produced, preclude standardization of the means to assess safety. The methods and extent of genetic modification, in part, determine both the type and quantity of information required to make an assessment.[71]

As is the case with AAFC/ CFIA's choice of the regulatory trigger of "novel trait" for environmental release, the definition of "novel food" provides a built-in flexibility that reduces regulatory oversight as evidence accumulates. It also extends the scope of regulation beyond products resulting from the use of genetic engineering, although virtually all of the approved novel foods to date involve the use of genetic engineering.[72] This approach does not discriminate overtly between novel foods produced through genetic engineering techniques and those produced through other means.

United States: Tracing policy making

Like Health Canada, the United States Food and Drug Administration (FDA) had considerable experience regulating the medical products of biotechnology before turning its attention to foods from new plant varieties produced through genetic engineering. While concerns have been raised about the safety of genetically-engineered foods by public interest organizations such as the Consumers Union and the Union of Concerned Scientists (UCS), public controversy in the US has focused more on the labelling issue than on the process of food safety assessment. As well, the food safety of genetically-engineered plants has received relatively little mainstream press compared to the significant media attention surrounding the issue of the use of genetically-engineered bovine somatotrophin (BST), a bovine growth hormone to increase milk production in cows.[73]

With the release of the Coordinated Framework documents in 1984 and 1986, the FDA asserted that genetically-engineered foods could be regulated in the same way as other foods and

[71] Canada. Health Canada. Health Protection Branch. Food Directorate (1994).

[72] Interview with Health Canada official, September 1998.

[73] On the issue of BST/BGH, see, for example, Hiss (1994), Kleiner (1994), and Coghlan (1994). Opposition to BST in the United States has been stronger in certain regions, including New England, and has been a major focus of the "Pure Food Campaign" linked to Jeremy Rifkin's Foundation on Economic Trends. Some states have tried to put in place mandatory labelling for milk produced with the assistance of synthetic BST. Monsanto has sued some companies that have advertised their product as "BST-free" or similar claims because such labelling suggests their product is unsafe. The FDA issued guidelines in 1994 to state regulatory agencies recommending that dairies should not be obliged to inform consumers whether cows are treated with BST. As of 1996, approximately 10 per cent of American dairy cows were receiving BST treatment, according to a USDA survey, much lower than forecast by some analysts. See Lewis (1996).

that adequate authority for regulation was available under the *Federal Food, Drug and Cosmetic Act* (FDCA). In response to demands from industry, government agencies, academia and the public for more details on its policy on genetically-engineered foods, a policy statement was issued in 1992 on the specific issue of "foods from new plant varieties" (see Table 3-5 for a chronology).[74] Representatives of public interest groups are quick to point out that the FDA's policy was actually announced by the Council on Competitiveness, chaired by Vice-President Dan Quayle. The Council's press release described the intent of the policy: to "ensure the safety of [genetically-engineered] foods while facilitating their availability as quickly as possible", describing the potential of these foods to be tastier, more varied, more wholesome, and produced more efficiently than conventional counterparts.[75]

The 1992 policy statement was still the FDA's working policy in 1998, although there had been some unsuccessful attempts to refine it. The 1992 policy provoked more than 4000 comments, one of the largest responses to any food policy in the history of the FDA. Many of the comments were critical.[76] They expressed concern about the safety of novel plant foods, including the potential inclusion of allergens, animal or human genes; the lack of labelling requirements; and that the FDA would not be able to keep track of most of the novel foods entering the market because no notification system was planned. As the FDA began its first review of a safety assessment of a genetically-engineered plant food product, Calgene's Flavr Savr tomato, groups like the UCS urged the agency to finalize its policy, assuming that it would respond to the critical and widespread reaction. In 1994, the FDA did contemplate moving to premarket notification. Observers of the premarket notification initiative believe that the agency was seriously committed to the idea, but withdrew from it when the Republican landslide in 1994 produced a renewed deregulatory fever.[77] The initiative for premarket notification had come from Vice-President Al Gore's office and was criticized by the new Republican Congress in 1995 until it was abandoned.

The detailed experiments conducted by the developer of the Flavr Savr tomato and their

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[74] United States. Food and Drug Administration (1992).
[75] Quoted in Kneen (1992): 179
[76] Mellon (1994).
[77] Soon after the Republican electoral victory in 1994, food industry associations were expressing their hopes for relaxed regulation of food labelling, a more science-based risk assessment process that would eliminate the Delaney Clause which had a zero tolerance approach to the inclusion of potential carcinogens in foods, and quicker approval of biotechnology foods. See Van Wagner (1995).

review by the FDA resulted in the conclusion that the new tomato had not been significantly altered and was therefore safe for consumption.[78] For the biotechnology industry, approval of the Flavr Savr tomato marked a significant turning point in the battle for public acceptance. Carl Feldbaum, president of Biotechnology Industry Organization, said at the time: "The biotech industry isn't holding its breath anymore. Demystification of genetic engineering is being accomplished at a rapid rate."[79] Since approval of the Flavr Savr tomato, developers have had the option of providing summaries of their own safety assessments to the FDA for the purpose of notification or as the basis for consultations to discuss safety or regulatory issues (see Table 3-9). The FDA publishes a list of new plant varieties produced through genetic engineering for which it has completed "final consultations" with the developers, meaning that there are no scientific or regulatory issues outstanding. While consultations are voluntary, developers consistently do consult with the FDA for their own protection.

The FDA continued to explore some of the scientific issues arising from genetically-engineered foods through the 1990s, including allergenicity and the use of antibiotic resistance marker genes in plants.[80] Developments in Europe and at home toward the end of the decade suggest that the FDA's policy may come under more intense public scrutiny into the new century. For example, in May 1998, a lawsuit was launched against the FDA under the auspices of the "Alliance for Bio-Integrity".[81] The alliance brought together scientists, religious leaders, chefs, and medical professionals. The lawsuit calls for mandatory safety assessments and labelling of all genetically-engineered foods. It alleges that the FDA's policy violates religious freedom and the FDA mandate to protect public health and provide consumers with relevant information.

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[78] The review of the Flavr Savr tomato concluded that the only new substance found in the tomato was the marker gene protein, APH(3')II, which has antibiotic resistant properties but is considered to be quickly inactivated by stomach acid and digestive enzymes. Its low concentration in the tomatoes tested and its dissimilarity to known food allergens and toxins resulted in the determination of safety for food consumption. For a thorough discussion of the review, see United States. Food and Drug Administration. Center for Food Safety and Applied Nutrition (1995).

[79] Quoted in Baker (1994).

[80] See United States. Food and Drug Administration. Center for Food Safety and Applied Nutrition (1998). Margaret Mellon of the National Wildlife Federation (later of the Union of Concerned Scientists) had urged the FDA to investigate these two safety issues further in 1992. See National Wildlife Federation (1992).

[81] See the Alliance's web site (http://www.bio-integrity.org/) and Vorman (1998).

Disaggregating policy making
Issue arrival and problem definition

While the FDA outlined its general approach to biotechnology regulation in the Coordinated Framework documents of 1984 and 1986, it made its first formal statement specifically on foods derived from new plant varieties, incorporating those produced through genetic engineering, in 1992. In 1990, a journal article by FDA officials central to the regulatory development process discussed the regulatory issues posed by genetically-engineered foods. It stated their belief that in crafting its regulatory response, the FDA would want to "balance protecting and informing the public with encouraging innovation" and to "find solutions that will ensure the safety of the food supply, but will not stifle innovation of new technologies."[82] The article acknowledges the scientific uncertainty surrounding genetically-engineered foods but suggests that scientific investigation and the accumulation of adequate data should reduce "initial uncertainty to a reasonable certainty that no harm will occur".

In policy statements and other documents, the FDA and its officials rarely explicitly identify a problem that their policy response is intended to solve. The tone of these statements is matter-of-fact and they are highly descriptive, rather than attempting to be persuasive. In particular, the 1992 statement is explained as a response to requests from the policy community for "clarification of regulatory status", rather than a proactive move by the agency. The statement is intended to respond to questions such as whether premarket approval would be required, what scientific information the FDA would like to see as part of a safety assessment, and whether special labelling would be necessary. There is no mention in the 1992 statement of public concerns about the safety of foods produced through genetic engineering. More recent documents widen the scope of the issue and are more explicit about the goal the FDA has established for its regulatory activity. A 1995 document, for example, states that the goal of safety assessment is to confirm that new foods are "as safe" as foods currently available and acknowledges that "in spite of the technical advantages of using recombinant DNA techniques", questions have been asked about the safety of foods derived through these techniques.[83]

[82] Ronk et al. (1990).
[83] United States. Food and Drug Administration. Center for Food Safety and Applied Nutrition (1995).

Consultations and information gathering

The FDA's 1984 statement made only a brief reference to genetically-engineered foods, focusing almost exclusively on its regulatory requirements for human drugs and biologics.[84] It received thirty-four comments on the 1984 statement, twelve from manufacturers of regulated products, sixteen from associations, and six from individuals. These comments requested further guidance for certain biotechnology products including foods. The FDA agreed in 1986 to consider providing such information. In 1992, the FDA acknowledged receiving and examining comments from industry and the public. It referred to arguments in letters from industry and environmentalists, and to a scientific article published by the International Food Biotechnology Council in 1990. It also noted that it had examined scientific research papers.[85] The 1992 policy statement partially fulfilled the 1986 commitment of further information by providing technical guidance regarding the food safety assessments of new plant varieties. The 1992 statement asked for comments and, as noted earlier, received more than 4000.

The consultation process for developers was discussed during a 1994 public meeting of the FDA's Food Advisory Committee and Veterinary Medicine Advisory Committee. These two committees are staffed with external experts. After a FDA presentation on the safety of genetically-engineered foods and animal feeds, the committee members endorsed the consultation process as an appropriate oversight mechanism. However, a member of the public interest community who attended the meeting noted that it was unclear whether the meeting had been convened to discuss approval of the Flavr Savr tomato, which occurred shortly afterwards, or the safety assessment process generally, but that the committees' approval has been used by FDA since 1994 to endorse its overall approach.[86] At the meeting, Margaret Mellon of the Union of Concerned Scientists expressed the belief of many observers, based in part on media reports, that the FDA was bowing to pressure from Flavr Savr developer firm Calgene to approve the tomato since the application had been before the agency for more than two years. Mellon argued at the time that approval of the tomato would be premature until FDA responded to the scientific and policy issues raised in the comments it received on its 1992 policy. The FDA also held a public meeting of its advisory committees later in 1994 on the premarket notification option. The FDA has never published a

[84] Biologics include vaccines and other biological products used to create immunity to infectious diseases or other harmful substances of biological origin.
[85] United States. Food and Drug Administration (1992).
[86] Personal interview, November 1998, and Mellon (1994).

summary of the comments it received on its 1992 policy or a response to them, or for subsequent public meetings it held in 1994 on its safety assessment process and the option of premarket notification. However, the agency has been more proactive in consulting within the scientific community.[87]

Policy choices: Policy goals

As in Canada, the FDA's response to assessing the food safety of genetically-engineered plants and other products pursues the goals of safety along with competitiveness and harmonization (see Table 3-7). The FDA has stated its commitment to the promotion of international scientific cooperation on biotechnology issues. It has also sought to reduce barriers to trade in biotechnology products by encouraging harmonization of national regulatory measures to the greatest extent possible. "Attention is being paid" to achieve consistency nationally and harmonization internationally to avoid creating a competitive disadvantage for American developers.[88] The FDA's response further embeds its historic emphasis on industry responsibility for safe food. The FDA acknowledges the public's reliance on its expertise and authority to ensure a safe food supply; at the same time, it is frequently stated in policy documents that the onus for safe food is on the developer or manufacturer.[89] In other words, while the FDA recognizes food safety as part of its mandate, it does not accept primary responsibility. This position is similar to the approach FDA has taken for granting "generally recognized as safe" (GRAS) status to food ingredients.[90]

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[87] For example, it held a conference in April 1994 with the USDA and EPA on concerns about allergens in genetically-engineered foods, and conducted consultations in 1996-1997 on antibiotic resistant marker genes.

[88] See United States. Executive Office of the President. Office of Science and Technology Policy (1984) and United States. Executive Office of the President. Office of Science and Technology Policy (1986).

[89] See, for example, United States. Food and Drug Administration. Center for Food Safety and Applied Nutrition (1995).

[90] The manufacturer is given options about how to seek or claim GRAS status: by formally seeking an FDA opinion; using an ingredient listed in FDA regulations as having GRAS status; or choosing to make an "independent determination", without seeking FDA concurrence. Korwek (1986).

Institutional framework

The Center for Food Safety and Applied Nutrition (CFSAN) within the FDA handles the regulation of genetically-engineered plant varieties and other foods. The Office of Premarket Approval within CFSAN and the Office of Surveillance and Compliance of the Center for Veterinary Medicine contribute the individuals who form the Biotechnology Evaluation Team which administers consultations with developers.[91] The FDA collaborates with the USDA and the EPA on some aspects of its food safety assessment. For example, when it has to prepare an environmental assessment, it will check to see if documentation has been prepared by other agencies that may have already dealt with the product, such as the USDA. Similarly, while the EPA has primary responsibility for assessing the food safety of plant pesticides, the FDA may also be involved depending on the product.

Policy instruments

The FDA relies on existing provisions under the *Food, Drug, and Cosmetic Act* that give it authority to remove adulterated foods from the marketplace and to require a pre-market approval of foods falling under the category of "food additives". The FDA has stated that it does not expect to use its pre-market approval authority frequently. It would use it only, for example, when a new plant variety includes substances that are substantially different than those with a safe history of human consumption. For example, newly-introduced proteins will not normally have to undergo pre-market approval if they come from food sources that are substantially equivalent to existing food substances, are not associated with food safety concerns such as toxicity, and will not be consumed in significant quantities. Conversely, substances that have a GRAS status, but have been produced through a new process such as genetic engineering, may have to be approved prior to sale if the process has resulted in the product being altered to the extent that it is no longer recognized as safe.

The scientific policy instrument the FDA relies on is the "guidance" section of its 1992 policy statement which sets out a voluntary process for developers.[92] The guidance section, which

[91] For an explanation of how the Biotechnology Evaluation Team works, see United States. Food and Drug Administration. Center for Food Safety and Applied Nutrition (1997). The core team will be supplemented with additional expertise as needed.

[92] FDA has also published a document providing detailed guidance on consultation procedures for developers. See United States. Food and Drug Administration. Center for Food Safety and Applied Nutrition (1997).

is based on criteria used in traditional plant breeding, includes flow charts to assist producers in determining when it would be advisable to consult with the FDA. It outlines key considerations for food safety assessment including the nature of the genetic modification, the identity and function of any new substances such as proteins, and any unexpected effects that result from the genetic change such as alterations in levels of toxins or nutrients, or the presence of food allergens.

Consistent with its past practices in food regulation, the FDA has chosen not to focus on the method of production as a trigger for safety assessment. Although its 1992 policy statement was provoked by questions about new plant varieties derived through genetic engineering, the policy extends to new plant varieties produced through any means. The FDA makes it clear that food safety assessment does not eliminate risk. It notes that regardless of the method by which foods are produced, "foods are not inherently safe" and "a level of absolute safety for a food cannot be achieved or expected".[93] Like the USDA, the FDA must meet the requirements of the *National Environmental Policy Act* (NEPA). For this issue, the NEPA requirement for an environmental assessment would be triggered only when a product falls under section 409, requiring pre-market approval, and a new food additive regulation is put in place. Observers believe that the FDA had not used section 409 to regulate genetically-engineered foods as of 1998. FDA has stated that it will provide guidance to developers who are submitting petitions under section 409 to help them meet requirement for an EA.

LABELLING: Do consumers need to know, or have a right to know, whether they are eating foods developed with the use of genetic-engineering?

As more and more products containing ingredients from genetically-engineered plants and other products entered the market in the 1990s, the issue of whether labelling should be required to indicate the use of genetic engineering moved from a theoretical discussion to one with practical implications. Many of those involved in the vigorous labelling debate agree that when genetic engineering has altered a conventional product in unexpected and invisible ways, such as significant changes in the level of nutrients or the introduction of novel genetic material that could provoke an allergic reaction, this fact should be included on a product's label. However, there is a deep divide between those who feel that mandatory labelling should be used only for such health

[93] United States. Food and Drug Administration. Center for Food Safety and Applied Nutrition (1995): 4.

and safety purposes and those who wish to see labels on all food resulting from the use of genetic engineering or made from genetically-engineered ingredients. Mandatory labelling is seen as the last hope for those who wish to avoid buying or consuming genetically-engineered food in North America, given the often-heard argument that the introduction of genetically-engineered food ingredients into the commercial food system is so far along as to be irreversible. Much of the debate revolves around the question of whether the consumer has a "right to know" or a "need to know" that food or some of its ingredients have been produced with the use of genetic engineering.

The labelling debate and policy making efforts to move it forward have occurred at the domestic and international levels. The potential effect of labelling provisions as an intended or unintended trade barrier, combined with the logistical difficulties of segregating genetically-engineered food, have focused Canadian and American attention in the late 1990s on the development of labelling policy in Europe and Japan. Since 1997, the labelling issue has become a significant trade irritant between the US and Europe, with Canada tagging along for the ride. Hopes for a resolution through the work of Codex Alimentarius, a United Nations body, have been dimmed by the glacial rate of progress. Canada chairs the Codex Committee on Food Labelling which meets annually in Ottawa but, as of 1998, the effort to reach a consensus could point to little success. These international developments are explored further in Chapter Six. In the meantime, Canada and the US have established informal domestic labelling policies.

Canada: Tracing policy making

In Canada, policy making on the labelling of genetically-engineered foods in the 1990s was filtered through a series of managed consultations with an eye on developments internationally (see Table 3-9). The 1993 multistakeholder workshop resulted in a consensus supporting mandatory labelling for health and safety purposes. It also demonstrated that labelling was a highly contentious issue. Another multistakeholder technical workshop devoted solely to labelling was held by federal regulatory officials in 1994, which resulted in more detailed guidelines. In April 1997, AAFC issued an Information Letter that summarized comments on the guidelines developed from the 1994 consultations. These guidelines now form the basis for Canada's labelling policy which regulatory officials treated as still under development as of 1999.

Media attention in Canada regarding the issue of labelling was periodic and increased in the late 1990s, sparked annually by the Codex food labeling meetings held in Ottawa. Coverage has

also been prompted by developments in the European debate in the late 1990s.[94] Otherwise, the debate has been largely among representatives of the food industry, biotechnology developer firms, some public interest groups, the "health food" lobby, and regulators.[95] Labelling was discussed during the 1996 hearings on biotechnology regulation by the House of Commons Standing Committee on Environment and Sustainable Development, although the committee made no recommendations specifically on labelling. In May 1998, the House of Commons Standing Committee on Agriculture and Agri-Food recommended, in a report on agricultural biotechnology, that Parliament review Canadian policy on labelling.[96] As of 1998, no genetically-engineered products had triggered mandatory labelling.

Disaggregating policy making
Issue arrival and problem definition

The federal government's concerted attempt in 1994 to deal with the labelling issue through its technical workshop confirmed the issue's arrival. For regulatory officials, the problem was the lack of consensus across interested societal organizations that had emerged during the 1993 workshop. It hoped its 1994 workshop would secure that consensus and reduce disagreements about certain aspects of the debate, such as the extent of the consumer's "right to know" or the importance of harmonizing labelling provisions with those of major trading partners. The background paper prepared for the workshop provided some parameters for the discussion. It noted Health Canada's concerns that novel foods produced through genetic engineering could pose health and safety concerns, such as allergenicity or altered nutritional composition. Regulatory officials speaking at the workshop outlined their mandate to ensure the marketability of food and their focus on food safety and quality as a means to achieve their mandate. They also pointed out

[94] These developments included Prince Charles' criticism of genetically-engineered food and the controversy over the proposed use of a bovine growth hormone in dairy cows. See, for example, Evenson (1998), Wilson (1998b), *The Western Producer* (1998).

[95] The term "health food" lobby is used here to describe those who take an active interest in the nutritional and other health aspects of food, including those who buy and sell "natural" and "health food" products. The health food lobby has not been formally represented in consultations, although some of its membership overlaps with that of active public interest groups. Specialized health food publications such as *alive* frequently run stories on developments in food biotechnology and generally support mandatory labelling. See also Herriott (1998) as an example of articles in health-focused popular periodicals.

[96] The government's response to the committee report in December 1998 noted that CFIA and Health Canada would be pleased to assist in any further study of labelling policy. Canada. House of Commons. Standing Committee on Agriculture and Agri-Food (1998).

that the purpose of the workshop was to incorporate consumer and industry concerns, while also seeking compatibility with policies being developed outside Canada. Participants at the workshop were asked to consider three questions:

> 1) Should special labelling for genetically-engineered foods be considered and if so, what are the factors or guiding principles that would determine the need for special labelling; 2) if special labelling is required, at what point(s) in the introduction of a recombinant gene should labelling be considered; and 3) once a need for labelling has been determined, what factors or principles should guide the application of mandatory or voluntary labelling?[97]

Consultations and information gathering

Consultations have been an integral part of the development of Canada's labelling policy. The 1993 and 1994 consultations, as managed multistakeholder workshops, provided a relatively broad spectrum of views. Prior to the 1994 workshop, a twelve-member steering committee was established, with seven federal government representatives, two food industry representatives, a consumer representative, and two representatives of the dietitian / nutritionists community. The committee drafted a background report and decided that the workshop should be technical in focus. About sixty participants attended the 1994 workshop.[98] The 1995 communique and the 1997 information letter, which compiled the comments from the 1994 consultations and outlined a set of guiding ideas, were widely distributed. The result was a consultation process similar to that achieved through the *Canada Gazette*. Industry Canada also sponsored a workshop on labelling issues, held by the non-profit information organization, the Food Biotechnology Communications Network, in December 1995.

Not surprisingly, given Canada's chairmanship of the Codex Committee on Food Labelling, Canadian regulatory officials have been particularly attentive to the development of labelling policies outside the country. The 1994 background document, for example, included a brief survey of developments in labelling elsewhere, including in Australia, the United Kingdom, the US and Europe.

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[97] Canada (1994a): 5.
[98] Canada (1994a): 1-5.

Policy choices: Policy goals

Canada's labelling policy for novel foods, including those with ingredients from genetically-engineered plants, is closely tied to food safety assessment with its requirement of special labelling only for alterations in foods that pose health and safety risks. With the exception of these additional labelling requirements, this policy is akin to that for all other food products. Policy choices on labelling pursue the economic goal of competitiveness and the historic goal of fair market competition (see Table 3-10). They include an explicit commitment to pursue harmonization of labelling policies. They also permit food manufacturers to use positive or negative labelling regarding the use of genetic engineering as long as the information is considered truthful by regulators. These policy choices do not discriminate against genetic engineering as a technology and have thus reduced the need for segregation in food processing for food products heading to Canadian and American markets.

Institutional framework and policy instruments

Policy choices have maintained existing institutional arrangements and policy instruments for food labelling. Health Canada and the CFIA share responsibility for food labelling policy, with Health Canada setting health and safety standards and the CFIA setting marketplace standards. The CFIA enforces labelling policy and has taken the lead in developing the labelling policy for novel foods. However, the labelling policy relies heavily on Health Canada's food safety assessment process to ensure detection of the alterations and risks that must be labelled. Beyond Health Canada's process, enforcement remains a challenge. Although tests are being developed to identify the presence of novel proteins and other genetic material in otherwise conventional foodstuffs, not all genetically-engineered products can be identified. Unless strict segregation practices had been followed, claims that food products were free of the use of genetic engineering were sometimes difficult or impossible to verify given the state of detection technology in 1998.

United States: Tracing policy making

The FDA has not spilled much ink on the issue of whether special labelling should be required for foods and food ingredients produced through genetic engineering. For the most part, it has chosen to treat the option of labelling of foods containing genetically-engineered ingredients as a non-issue. The 1992 policy statement summarized its position on labelling in four paragraphs, with some references to the need for special labelling in the scientific guidance section. As in Canada, the FDA chose to extend existing labelling requirements to cover genetically-engineered foods. Special labelling is required only when the product has been substantially altered from its conventional counterpart so that it is no longer appropriate to call it by the same name, or if there are safety concerns, such as allergenicity.

The labelling issue also garnered attention at the state level; by 1993 attorneys-general in eight states had called on the FDA to require mandatory labelling.[99] At least one local government got involved in the issue. For two days, in the fall of 1993, the city of Chicago had an ordinance in place requiring labelling of genetically-engineered produce.[100] Observers of the federal labelling policy said in 1998 that no special labelling had been used or required yet for genetically-engineered plants, but expected it to come soon for new traits such as modified oil composition.[101]

Disaggregating policy making
Issue arrival and problem definition

The FDA's first acknowledgement of public concern about the labelling of genetically-engineered food appears to have been its discussion in the 1992 policy statement. As noted earlier, the FDA did not portray labelling as a problem. Its 1992 discussion of labelling was simply in response to "several inquiries" it had received about labelling requirements. It noted at the time that it did "not believe that the method of development of a new plant variety (including the use of new techniques including recombinant DNA techniques) is normally material information...and would not usually be required to be disclosed in labeling".[102]

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[99] Consumers Union (1993). In 1998, the National Food Processors Association was not aware of any states that required labelling of genetically-engineered food.

[100] The alderman behind the ordinance said that people did not want this food "forced down their throats" and did not trust federal government approval. The ordinance was quickly reversed, at the alderman's request, possibly because of the "intense letter writing campaign" by the biotechnology and food processing industries, as claimed by the Industrial Biotechnology Association. *The New York Times Magazine* (1993).

[101] Personal interviews with representatives of industry associations and public interest groups, 1998.

[102] United States. Food and Drug Administration (1992).

Consultation and information gathering

The FDA solicited comments twice on its labelling policy through the *Federal Rgister* process prior to 1999, in 1992 and 1993.[103] Those who have examined the 4000 comments the FDA received in response to its 1992 statement say that many of them commented on the labelling policy. Some of the calls for mandatory labelling were based on religious or ethical concerns about consuming foods with genetic material and/or traits derived from animal or human sources. The second request for comments, in April 1993, consisted of a long list of detailed questions and received an estimated thirty comments, far fewer than the 1992 policy. One observer attributes the small response to the technical nature of several of the questions posed by the FDA. For example, the FDA asked respondents to comment on: how genetic engineering should be defined; what specific characteristics of foods derived from genetically-engineered plants distinguish them from other foods; whether the intended technical modification should have any bearing on whether labelling is required; what labelling, if any, should be required for a food derived from a plant that contains multiple traits that originate from different lines; and what labelling, if any, should be required for plant cultivars developed by traditional techniques (such as cross hybridization), when one (or both) parent line(s) was developed using genetic engineering, or when one (or both) parent line(s) is derived from a progenitor line that was developed using genetic engineering.[104] Respondents were also asked specific questions about how to label different products; how to enforce labelling requirements, such as whether the FDA would be able to enforce a requirement that the source of transferred DNA be noted on a label; how to label for food allergies; and to comment on the logistical and economic aspects of labelling genetically-engineered foods.

[103] The FDA organized a public meeting on labelling for early 1994 that was cancelled suddenly two weeks before the set date, and never rescheduled. Details on information gathering are unavailable since the FDA was unable to consent to a research interview because of the 1998 lawsuit pending against its food safety and labelling policy for genetically-engineered foods. No information gathering for the purpose of developing its food labelling policy was found in its published policy documents.

[104] These questions are taken verbatim from the full list. For the full list and discussion of these questions, see Consumers' Union (1993). The observation that these technical questions deterred comments was made by a representative of the Union of Concerned Scientists.

Policy choices: Policy goals, institutional framework, and policy instruments

The FDA's labelling policy rests squarely on its approach to food safety assessment policy and its sole stated goal is safety (see Table 3-10). The FDA has recognized in its more general discussions of regulating genetically-engineered food that regulations may affect competitiveness, but does not link this observation explicitly with its labelling policy. However, FDA's policy does not discriminate explicitly against the use of genetic engineering. In fact, it takes pains to underline that the method by which new plant varieties are developed is not relevant information for labelling. The agency's policy choices do not alter the existing institutional framework for food labelling policy. They maintain the FDA's historic primary responsibility for setting and enforcing labelling requirements for most foods, including new plant varieties. To implement its policy, the FDA relies on the guidance section of its 1992 policy statement that suggests to developers what characteristics of a product might trigger special labelling requirements. The choice is left to the developer as to whether to consult with the FDA.

COMPARING POLICY PROCESS AND POLICY CHOICES

This comparative look at responses to three specific issues arising from the regulation of genetically-engineered plants reveals a remarkably high level of similarities and a few notable differences between Canada and the US. On the issues of environmental release and labelling, issue arrival occurred first in the US. On food safety, issue arrival occurred in the same year, although the American policy statement was issued in May while Health Canada's information letter was issued in August. Differences are clear in official problem definitions. In Canada, safety is the core of the problem, to be balanced with the goals of competitiveness, harmonization, and market regulation. In the US, ensuring competitiveness by not hampering innovation was the central problem raised by regulation, until pressures from public interest groups forced a more explicit response to specific safety concerns about the use of genetic engineering. Both Canada and the US have used existing scientific networks and advisory committees for consultations and information gathering. They have occasionally created new scientific advisory bodies. For wider public consultations, Canada has relied more on managed but proactive multistakeholder consultations. The US has relied on its *Federal Register* process, supplemented by occasional

public meetings. Both countries have been active in information gathering at the international level, a topic explored further in Chapter Six.

Convergence or divergence?

To move beyond a comparison of similarities or differences and to assess whether convergence in policy choices has occurred between the two countries, we need to determine whether there is evidence of policies becoming more alike over time. Measuring convergence is not an easy task, but past efforts provide some useful guidelines. First, disaggregation of aspects of policy making makes measurement easier and more precise. Previous work has compared specific policy choices such as goals, policy instruments, and outcomes, as well as policy styles.[105] Case studies suggest that there can be variation in the degree of convergence across aspects of policy making. While convergence may occur, for example, in the choice of policy goals, there may not be convergence in policy styles or policy instruments. Second, to measure convergence, we can construct measures that attempt to track the "change in difference over time" by placing aspects of policy making on a scale over at least two points in time.[106] These measures can provide a general indication, although they obscure details. The assessment of convergence is hampered by the reality that much of policy making is not amenable to quantification without the imposition of arbitrary measures.

This study assesses convergence from the point of the first serious recognition by policy makers to 1998.[107] For the issue of environmental release, a relatively long time frame is available beginning in 1983 when the National Institutes of Health advisory committee on rDNA research issued its first approvals of experiments involving release. For food safety and labelling, the time frame begins in 1990 at the first indications of government action in the US on the issue of food safety which is closely linked to the issue of labelling. In disaggregating policy choices, we would expect to see less change in some aspects than others. Given the usual inertia associated with

[105] For example, Coleman (1994) examines convergence in policy making styles or processes and finds more convergence in the membership of policy communities than in the structure of policy networks. Bennett (1992) examines policy principles and policy instruments, and finds more convergence on principles than on instruments. Finally, Brickman et al. (1985) compare policy process and policy choices, and finds more divergence in processes than in objectives and outcomes.

[106] Seeliger (1996).

[107] The timeframe within which convergence is assessed influences results and thus, evidence of convergence or divergence is not necessarily a permanent trend. Seeliger (1996).

institutional frameworks once created and policy ideas once institutionalized, there may well be less change in these aspects than in the details of policy instruments.

To compare policy ideas and examine convergence, we can examine policy principles in the form of ideas guiding policy goals, the appropriate means to achieve goals, and the appropriate scope of regulation. While this comparison obscures subtle differences, we can match similar ideas and compare when these ideas were first articulated.[108] There may be evidence in a study of several countries that one country stands out as a pioneer with other countries converging to its model.[109] Or, by matching ideas chosen domestically with ideas endorsed in international organizations, there may be evidence of the influence of international activities.[110]

Turning to institutional frameworks, we might well expect to find policy choices built on policy legacies unless new institutions are created without reference to existing structures and mechanisms. In this case study, the commitment of the two federal regulatory frameworks to rely on existing institutional frameworks and policy instruments limits the possibility of radical change, let alone convergence. It eliminated the option, which was often suggested in both countries and pursued unsuccessfully through draft legislation in the US, of creating a new institution to regulate the use of genetic engineering and / or new comprehensive legislation. Instead, we see the persistence of historic institutional similarities and differences between the two countries.

While the choice of policy instruments has been framed by the commitment of the federal regulatory frameworks to use existing legislative authorities where possible, there has still been room to manoeuvre within those boundaries. Legal authority flows from the general provisions of existing statutes and their regulations. However, to deal with specific issues, since the reliance on existing authorities prevents a regulatory vacuum, policy makers have had options about the degree of regulation or intervention they impose on developers and users, and about the flexibility or ease of revision of the policy instruments they have chosen. There have also been options regarding the content of the specific measures established. Keeping in mind this set of options, we can examine policy choices for convergence. To assess convergence, two simple scales are used here. The first scale is used to assess the degree of regulation, ranging from 0 to 2, with 0 representing no

[108] It should be noted that the first published evidence of articulation by policy makers may come well after an internal decision to adopt certain policy ideas.
[109] See Bennett (1992) for a study that reaches this conclusion.
[110] This task is undertaken for this study in the final chapter.

specific regulation of the issue, 1 representing a response that relies on voluntary compliance, and 2 representing mandatory compliance. The second scale examines the degree of flexibility in adapting regulatory content, on scale of 0 to 3, with 0 representing no measures, 1 for the use of guidelines which can be easily changed in-house, 2 representing regulations which must go through a more formal approval process, and 3 representing legislation which must pass the scrutiny of legislative bodies.

Findings from these measures have implications for state capacity. Whether regulation is voluntary or mandatory will likely affect the degree of state capacity. With voluntary regulation, state capacity to achieve regulatory goals may be jeopardized. Even mandatory regulation may not translate into state capacity if enforcement mechanisms are weak. However, the nature of the policy network combines with the degree of regulation to affect state capacity. A policy network with a history of close state-societal cooperation may allow the state to achieve its policy goals even in a situation of voluntary regulation. Similarly, the degree of flexibility in regulation can contribute or detract from state capacity. The ease of revision of guidelines can provide autonomous state actors with a great deal of discretion which can translate into capacity and reinforce autonomy. However, if the state is captured by a key societal actor, the ease of revision may result in capacity but not autonomy, as the state finds itself obligated to respond to societal demands. Similarly, choosing not to use legislative measures can have either positive or negative effects on state capacity.

Environmental release

In the case of environmental release, as summarized in Table 3-11, the two countries have several similar broad policy goals, including environmental safety, protection of the agricultural sector, harmonization, and competitiveness. The timing of the articulation of these ideas suggests that Canada has converged with American ideas.[111] However, Canada is alone in its goal of market regulation and the use of the OECD concept of substantial equivalence.[112] There is also an unusual mix of differences in the choice of regulatory trigger and the position on the novelty of genetic

[111] The time lag between Canada and the US may be less than indicated because this table relies on Canadian policy statements accompanying regulatory measures since 1993, given the lack of formal policy making statements prior to this date. However, earlier measures in Canada, such as the guidelines issued from 1988 on, still occurred after the first American statements.

[112] However, regulatory officials in the two countries say that the scientific approach of their safety assessment is virtually the same.

engineering, which set the scope for regulation.[113] In terms of regulatory outcomes, these choices have meant that Canadian review occasionally includes non-genetically-engineered plants with novel traits while American review, by incorporating the criteria of plant pest, occasionally excludes genetically-engineered plants.

Institutional frameworks reflect historic differences in the focus of federal regulation of new plant varieties. In Canada, responsibility was handed to the variety registration section in 1987. In the US, it was given to the plant protection and quarantine office in 1985. However, both departments created internal coordinating bodies to bring together expertise from other regulatory branches encountering new genetically-engineered products and/or from the agricultural research community. The US created its coordinating mechanism in 1986, while Canada created its version in 1987. Both used existing advisory committees and established new biotechnology committees.

Of the three issues examined, policy responses to the issue of environmental release have resulted in the greatest difference between the two countries in the details of the policy instruments. Statutory instruments differ since the US has no equivalent to the variety registration system under the *Seeds Act*. Canada has no equivalent to the *National Environmental Policy Act*, although the passage of the *Canadian Environmental Protection Act* (CEPA) has placed additional pressures on AAFC / CFIA to demonstrate that its environmental assessment process is equally rigourous to one that would be conducted under CEPA. As well, the Canadian regulations state that the minister (or person acting on his or her behalf) must consider risks to the environment and human health in making a decision.

Further differences are revealed in comparing the content of the regulations. Canada's regulations are relatively brief in comparison to the American regulations. Scientific information requirements are summarized and details are reserved for the accompanying guidelines documents. The regulations also contain grounds for waiving of scientific information requirements. In the US, the regulations reflect a more formal approach. They incorporate, for example, a thorough outline of procedures, timelines for approvals, and appeals; detailed scientific information requirements; and prescriptive requirements about the marking and containment of genetically-

[113] In Canada, the regulatory trigger focuses on novel traits which extends the scope of regulation beyond genetic engineering. In the US, the regulatory trigger explicitly includes genetic engineering even while it is repeatedly stressed that genetically-engineered products are not fundamentally different from those produced by more conventional techniques.

engineered organisms. In contrast to the US, the Canadian regulations have no provisions for public comment periods or appeals of decisions. Both sets of regulations have built-in flexibility in terms of the scope of regulation, but it is achieved differently. In Canada, flexibility comes through the concept of novelty. The degree of novelty, which is determined by the evaluator, determines the degree of regulation. In the US, the flexibility that does exist in the scope of regulation is achieved through a more formal, explicit approach. The scope of regulation is determined by classification which appears to set limits on the discretion of evaluators. Whether the USDA must be approached for a permit, notified, or need not be informed at all prior to release depends on the classification of the genetically-engineered plant. Classification rests on detailed criteria outlined in the regulations. Even the discretion available to evaluators in regulating products that they have "reason to believe" may pose a plant pest threat is limited by the list of plant pests included in the regulations that developers may petition to amend.

In examining convergence, we can apply the two scales mentioned above to environmental release. Table 3-12 shows how the US moved earlier to respond to the issue. It subsequently changed direction, while Canada has been more cautious and consistent. From these relatively crude measures, we see evidence of Canada converging toward the US until 1997 when Canada finalized its regulations on environmental safety assessment while the US pursued deregulation. On the flexibility of regulatory content, Canada converges slowly toward the US lead of using regulations. Both countries have avoided enshrining environmental safety measures in legislation.

Food safety assessment

In food safety, there is more evidence of convergence and less of a time lag. Guiding ideas are mostly similar, with Canada adopting most of its ideas shortly after the US has already done so. As Table 3-13 shows, the two countries share goals of safety, protecting public confidence, harmonization, and competitiveness. Their programmatic ideas are also similar, including employing the concept of substantial equivalence, a science-based and risk-based approach with built-in flexibility, and the encouragement of industry consultations. However, the US is alone in stressing industry responsibility for the safety of food products.

As is the case with environmental safety, the US and Canada differ on their combination of regulatory trigger and position on the novelty of genetic engineering. Canada provides a clear

definition that sets out the scope of regulation while the US leaves the scope of regulation much more vague and very much up to developers to sort out. In each country, the issue of food safety of genetically-engineered plants and other genetically-engineered food sources has prompted the creation of special institutional structures within larger existing frameworks. At Health Canada, an Office of Food Biotechnology has been established within the existing Health Protection Branch. At the FDA, a Strategic Manager for Biotechnology has been appointed within the Center for Food Safety and Nutrition (CFSAN).[114]

In both countries, regulators encourage informal consultations and provide detailed scientific guidance documents to help developers decide when to consult. The notable difference in policy instruments is Canada's requirement of mandatory premarket notification for novel foods. The initial definition of novel foods suggested that Canadian review would be much broader than its American equivalent, encompassing foods that were new to Canada, even if they had been consumed elsewhere with no adverse effects. However, the final regulations stated that evidence of safe consumption from other countries would be considered during safety reviews.

In applying the two convergence measures to the issue of food safety, Table 3-14 shows that on the degree of regulation, the two countries were briefly synchronized. In 1992, Canada issued its proposal for regulation of novel foods and the US issued a guidance document that suggested the need for FDA review of specific products. In 1995, however, Canada proposed regulations for mandatory notification. On flexibility, the US moved earlier to release a guidance document while Canada was still soliciting comment through an information letter. By 1994, Canada issued its own guidance document and in 1999, with the finalization of its regulations, again increased the formality of its policy response.

Labelling

Both countries have adopted relatively informal and flexible labelling policies. The US issued its policy statement earlier, which it considers its working policy. The Canadian policy, outlined in a set of guidelines, is described as interim, awaiting developments internationally. As Table 3-15 shows, the issue of labelling genetically-engineered foods has the highest degree of

[114] In the US, the EPA has primary responsibility for setting and enforcing standards for the food safety of plant-pesticides (plants developed with insect-resistant traits). There is no similar division of responsibility in Canada, although personnel within the Pest Management Regulatory Agency are consulted when necessary by CFIA and Health Canada.

similarity in ideas about policy goals and policy instruments. Canada and the US share the goals of safety and truthful labelling. They also agree that the process behind the product is irrelevant information for labelling, limiting the scope of labelling to product characteristics. They have adopted the same regulatory trigger, unlike the other two issues. The American declaration that the consumer's desire to know is not an adequate basis for putting in place labelling requirements is arguably similar to Canada's conclusion that religious dietary restrictions are outside the scope of its labelling policy and are adequately addressed elsewhere. However, Canada is alone in making an explicit commitment to harmonization.

The choice of institutional framework differs, again reflecting policy legacies. The FDA has remained the primary federal agency and has subsumed labelling within its food safety assessment policy. In contrast, the division of responsibility for food labelling in Canada has resulted in fragmentation. Health Canada sets health and safety standards. The CFIA administers economic regulations and enforces all labelling requirements. However, both countries rely mainly on existing, similar authorities for food labelling. One exception is that Canada's guidelines provide more explicit parameters of the policy response. The convergence measures show Canada becoming more similar to the American example on the degree and flexibility of regulation. As of 1998, both countries had a de facto voluntary labelling policy, which would be triggered only if a product went through the safety assessment process or consultations and was pinpointed for mandatory labelling (see Table 3-16).

Conclusion

Similar domestic factors and the pressures of internationalization encourage expectations of similar policy responses and evidence of convergence between Canadian and American policy responses to the same issues. The detailed comparison in this chapter does reveal high levels of similarity and some convergence, particularly in broad policy goals. However, institutional frameworks differ. These differences are consistent with policy legacies whose continued effect was reinforced by federal regulatory frameworks for biotechnology that endorsed the use of existing institutions and legislative authorities. The most interesting results of the comparison are found in the details of policy instruments and their implications for state capacity and autonomy. In this last element of comparison, the greatest difference is found in the two countries' responses

to environmental release. Less difference is found in the response to the issue of food safety and virtually no difference in the response to labelling. All three cases show some evidence of convergence of Canadian policy choices toward American models, with labelling showing the most convergence. The notable divergence that does exist is found in the degree of regulation in environmental release and food safety, while important differences are found in the scope of regulation (largely due to regulatory triggers) and the degree of discretion given to regulators to handle the issues of environmental release and food safety.

The findings in this chapter are consistent with the policy legacies outlined in Chapter One. The most distinct policy legacies between the two countries were those relevant to environmental release--the issue to which policy responses in the two countries differed most notably. Policy legacies that were more similar between the two countries, in food safety and labelling, correlate with more similar policy responses to these two issues. The consistency between policy legacies and policy choices suggests that domestic factors may have played a primary role in shaping policy choices, raising the possibility of path dependency. Chapter Four explores the nature of policy networks which will determine whether the expected effects of policy legacies on these networks have been carried forward during policy making.

Policy choices in environmental release, food safety, and labelling also reflect the limits of policy boundaries imposed by innovation in agricultural research policy, the creation of lab safety guidelines, and the content of the federal regulatory frameworks for biotechnology. These boundaries encouraged and reinforced the central position of policy principles of international competitiveness, harmonization, science, and risk in policy choices. Chapters Five and Six take a closer look at the dynamics created within and external to policy networks during policy making through the role of science and the nature of internationalization.

TABLE 3-1
Chronology of regulatory events, environmental release and safety assessment of genetically-engineered plants Canada and the United States, 1980-1998

CANADA[1]	UNITED STATES
(Canada has guidelines in place for research with rDNA organisms but these do not cover environmental release.)	**1980** First request to Recombinant DNA Advisory Committee (RAC) of National Institutes of Health for permission to test genetically-engineered maize. RAC approves experiment, but subsequently decides to defer action.
	1981 Report by the Office of Technology Assessment, *Impacts of Applied Genetics*, mentions issue of deliberate release. Genetically-engineered corn plant approved for use in the environment by RAC, but experiment does not proceed.
	1982 NIH guidelines revised, with further reduction of restrictions. Deliberate release of rDNA organisms into the environment moves from a prohibited category to requiring review and approval by RAC.
	1983 First congressional hearings on the issue of deliberate release into the environment. RAC approves three experiments involving environmental release. Rifkin coalition launches lawsuit against NIH guidelines.
	1984 EPA claims jurisdiction over deliberate release. Draft coordinated framework document released, clarifying allocation of jurisdiction among federal agencies. USDA holds jurisdiction over environmental release of genetically-engineered crop plants.
1985 Science Council recommends that the federal departments of agriculture, health, and the environment work together to create a policy to govern release of genetically-engineered seed.	**1985** **July** *Federal Register* notice of delegation of responsibility for biotechnology within USDA. Regulation of biotechnology goes to the Assistant Secretary for Marketing and Inspection Services and agricultural biotechnology research to Assistant Secretary for Science and Education, within the USDA. **September** *Federal Register* notice of USDA policy on treatment of confidential business information concerning biotechnology.

[1] This chronology relies heavily on Canada. Agriculture and Agri-Food Canada (1996b).

1986
July
Office of Agricultural Biotechnology created to coordinate within USDA and administer biotechnology policy. Assisted by Committee on Biotechnology in Agriculture which coordinates at a policy level.

1987
Food Production and Inspection Branch, the regulatory branch of Agriculture Canada, establishes the Branch Biotechnology Working Group.

1987
Interdepartmental Committee on Biotechnology establishes ad hoc Committee on Environmental Release.

1988
First field trials of genetically-engineered crops, regulated by Agriculture Canada.

Seed Division of Agriculture Canada publishes guidelines, *The Regulation of Plant Biotechnology in Canada Part I*.

1989
First ad hoc advisory meeting for Seed Division on field testing of "biotechnology" plants, including reproductive isolation issues (subsequent meeting in 1990).

Seed Division publishes The *Regulation of Plant Biotechnology in Canada Part II.*

1991
Revision of guidelines for information requirements in publication *Field Testing Genetically Modified Plants in Canada.*

1992
Refinement of regulation through development of the "safety-based approach" and "the step-wise approach".

1987
First field trials of genetically-engineered crops, regulated by USDA.

June 16
New USDA regulations to require reviews of genetically-engineered organisms posing plant pest risks through a permit system (in effect July 16).

October
Agricultural Biotechnology Research Advisory Committee established by USDA, comprised of scientists outside USDA, for purpose of conducting special reviews.

1991
USDA publishes voluntary guidelines for contained release during research work on deliberately-modified organisms in the *Federal Register.*

1993
Various consultations including on guidelines for confined and unconfined release, which endorse Agriculture Canada's regulatory approach, including November multistakeholder meeting (below).

Confirmation from the Privy Council Office that the *Seeds Act* provides adequate authority for Agriculture Canada to conduct environmental assessments of genetically-engineered plants.

Food Biotechnology Workshop held by AAFC to explore impact of biotechnology on existing inspection and food safety activities.

June
Biotechnology Strategies and Coordination Office established to lead AAFC consultations on regulation.

November
Workshop on Regulating Agricultural Products of Biotechnology, held by departments of agriculture, health, and the environment.

1994
AAFC's advisory committee on plant biotechnology expresses support for approach to regulation.

Change of term from "genetically-modified plants" to "plants with novel traits" (PNTs).

First applications received for unconfined release of PNTs.

Environment Canada publishes proposed information requirements under the *Canadian Environmental Protection Act* (CEPA) for PNTs (Agriculture Canada considers these to be duplication).

June
Release of guidelines document *Assessment Criteria for Determining the Environmental Safety of Plants with Novel Traits*. Consultations begin, and the document is subsequently revised and reissued.

1993
March
USDA amends regulations to relax regulation of six genetically-engineered crops (corn, cotton, soybeans, potatoes, tomatoes, and tobacco) so that notification of field trials is sufficient, rather than approval by permit. It also establishes provisions to allow consideration of petitions to grant individual genetically-engineered organisms "non-regulated status" which provides permission for unconfined release.

1995
January
Environment Canada agrees that proposed regulations under *Seeds Act* meet CEPA requirements for exemption.
Amendment of regulations under *Seeds Act* to clarify that it regulates biotechnology plants, using CEPA's definition of biotechnology.

April
Agriculture Canada's proposed regulations for environmental safety assessment are ready for publication, but do not proceed.
Environment Canada intends to publish information requirements under CEPA; these do not proceed either.

CEPA review causes uncertainty at AAFC about whether the existing regulatory approach will be changed.

First approvals of PNTs for unconfined release and variety registration.

1996
August
Draft amendments to regulations for environmental safety assessment published, including those for Puts under the *Seeds Act*.

1997
January
Regulations on environmental safety assessment finalized.

1997
May
Amendments to regulations published in the *Federal Register*:

- allow APHIS to extend nonregulated status to additional organisms that resemble an organism which has already been "deregulated" (an existing determination)
- extend the notification system to enable field testing under performance standards for most crop plant species
- announces intention to develop guidelines on various topics such as extending an existing determination of nonregulated status
- reduces paperwork requirements

September
Petition launched against EPA by Greenpeace International coalition on issue of contribution of Bt crops to the development of insect resistance.

1998
New requirements regarding cultivation of Bt crops established.

TABLE 3-2
Environmental releases, plants with novel traits field trials and environmental safety decisions Canada, 1988-1998[1]

A. Number of submissions and actual field trials, by year

YEAR	SUBMISSIONS	FIELD TRIALS
1988	10	14
1989	28	44
1990	40	76
1991	39	174
1992	40	298
1993	88	489
1994	111	774
1995	127	529
1996	155	665
1997	148	812
1998	191	515
TOTAL	977	4390

B. Most common crops for field trials

YEAR	ALFALFA	CANOLA	CORN	FLAX	POTATO	SOYBEAN	WHEAT
1988	0	8	0	2	0	0	0
1989	1	21	0	4	0	0	0
1990	2	26	2	3	3	0	0
1991	2	29	1	2	4	0	0
1992	6	23	0	3	5	1	0
1993	7	58	6	2	7	3	0
1994	0	74	8	4	12	2	2
1995	8	70	18	4	14	4	3
1996	26	79	16	0	19	2	2
1997	7	537	20	0	156	57	19
1998	61	224	16	1	126	30	13
Total	120	1149	87	25	346	99	39
Percentage of all trials	3%	26%	2%	<1%	8%	2%	<1%

[1] Source is CFIA web site: http://www.cfia-acia.agr.ca/english/plant/pbo/home_e.html

C. Most common novel traits in field trials

YEAR	BR	FT	HT	IR	NUT	OIL	STRESS	VR
1988	10	0	5	0	2	1	0	0
1989	24	0	24	0	2	0	0	0
1990	35	0	32	0	2	0	0	3
1991	35	0	30	1	0	0	0	4
1992	35	0	25	3	1	1	5	3
1993	59	2	58	9	11	9	7	5
1994	13	0	66	0	2	8	9	9
1995	9	4	63	21	3	23	13	9
1996	9	10	66	18	10	22	21	9
1997	0	63	521	148	20	58	14	141
1998	48	36	198	130	30	66	42	117
Total	277	115	1088	330	83	188	111	300
Percentage of all trials	6%	3%	25%	8%	2%	4%	3%	7%

Note that some plant varieties have more than one trait.

D. Environmental safety decision documents, by crop and developer[1]

Crop	Trait	Date Authorized	Developer	Document number on web site
Canola	HT	1995	AgrEvo	1
Canola	HT	1996	AgrEvo	11
Canola	Oil	1996	Calgene	8
Canola	HT	1995	Monsanto	2
Canola	HT	1996	Monsanto	7
Canola	HT	1998	Monsanto	21
Canola	HT	1995	Pioneer Hi-Bred	3
Canola	BR	1995	Plant Genetic Systems	4
Canola	HT	1998	Rhone-Poulenc	25
Corn	HT	1998	AgrEvo	22
Corn	HT	1996	BASF	13
Corn	IR	1996	Ciba Seeds / Mycogen	9
Corn	HT	1996	Dekalb	15
Corn	IR	1998	Dekalb	23
Corn	IR	1998	Dekalb	26
Corn	IR	1997	Monsanto	19
Corn	IR	1996	Northrup King Seeds	12
Corn	HT	1996	Pioneer Hi-Bred	10
Corn	IR	1997	Pioneer Hi-Bred	18
Corn	BR	1996	Plant Genetic Systems	16
Corn	HT	1998	Zeneca Seeds	27
Cotton	IR	1996	Bollgard (Monsanto)	14
Flax	HT	1998	Crop Dvpm Centre, USask	24
Potato	IR	1996	NatureMark (Monsanto)	6
Potato	IR	1997	NatureMark (Monsanto)	20
Rapeseed	BR	1996	Plant Genetic Systems	17
Soybean	HT	1995	Monsanto	5
Wheat	HT	1999	Cyanamid	28

[1] Note that some decision documents review more than one plant line when the lines are very similar and developed by the same firm or organization.

E. Most common crops for environmental safety determinations, 1995-1998

YEAR	CANOLA	CORN
1995	4	0
1996	3	6
1997	0	2
1998	2	4
Total	9 (32%)	12 (43%)

F. Most common traits for environmental safety determinations, 1995-1998

YEAR	HT	IR
1995	4	0
1996	4	4
1997	0	3
1998	5	2
Total	13 (46%)	9 (32%)

G. Most common developers for environmental safety determinations, 1995-1998

YEAR	AgrEvo / PGS	Monsanto / Calgene / DEKALB	Pioneer / DuPont
1995	2	2	1
1996	3	5	1
1997	0	2	1
1998	1	3	0
Total	6 (21%)	12 (43%)	3 (11%)

ABBREVIATIONS

BR=breeding traits such as marker genes and male sterility
FT=fungicide tolerant
HT=herbicide tolerant
IR=insect resistant
NUT=nutritional traits
OIL=oil composition
SE=substantially equivalent
STRESS=stress tolerant
VR=virus resistant

TABLE 3-3
Comparative policy choices: Environmental release and safety assessments for plants with novel traits / genetically-engineered plants

CANADA[1]	UNITED STATES[2]
PRINCIPLES	**PRINCIPLES**
1. Policy goals (guiding)	**1. Policy goals (guiding)**
Safety / market Protection of health and the environment. (1993)	Safety / market / economic harm To date, no unique or safety problems have been associated with products of genetic engineering, conventional or modern. In achieving national consistency and international harmonization, regulatory decisions can be made in a socially responsible manner, protecting human health and the environment, while allowing US producers to remain competitive. (1984)
To ensure a "safe release" into the environment. (1994)	Genetic alteration may create a plant pest new to and not widespread in the US. It is necessary to establish appropriate safeguards to prevent the introduction of genetically-engineered organisms that pose a threat to agriculture. USDA recognizes the importance of ecological effects and the need for developing procedures responsive to public concerns about safety. (1986)
The purpose of regulation is to assure the protection of human, animal, and environmental health, in addition to protecting the agricultural and forestry sectors of the Canadian economy. It also assures commercial interests that competitors will market new products that are safe and make accurate claims. (1995)	

[1] Canada. Agriculture and Agri-Food Canada. Committee on Biotechnology Regulation (1993), Canada. Agriculture and Agri-Food Canada. Food Production and Inspection Branch. Plant Industry Directorate (1994b), Canada. Agriculture and Agri-Food Canada (1995b), Canada. Agriculture and Agri-Food Canada (1995g), Canada. Minister of Public Works and Government Services Canada (1997). The principles listed for both countries are either direct quotes or slightly revised for clarity and brevity.

[2] United States. Executive Office of the President. Office of Science and Technology Policy (1984), United States. Department of Agriculture (1986) and United States. Department of Agriculture. Office of the Secretary (1991).

Policy goals

Harmonization / trade

Assessment criteria reflect general concepts of risk assessment used both nationally and internationally. (1994)

[AAFC] strives to ensure that regulatory requirements are consistent with those of recognized international scientific groups and other national governments. This approach assists in the maintenance of the quality and safety of agricultural products that are traded internationally. (1995)

The regulatory approach adopted by AAFC, including regulations and guidelines, has been developed in full consideration of international approaches, such as those endorsed by organizations including the OECD. (1997)

Competitiveness

The flexibility of the product-based novel trait approach and the concept of substantial equivalence, by allowing products to lose their novel status, may help developers in Canada "gain a competitive edge in foreign marketplaces" compared to developers elsewhere who are subject to a process-based approach. (1997)

These amendments will encourage fair competition in the global marketplace and set a clear path for developers to follow so that they can bring safe products to market. (1997)

Without gathering data on product characteristics and on environmental and health safety questions, developers will be unable to put new products on the market and will be less competitive with companies in other countries. (1997)

Policy goals

Competitiveness / harmonization

The manner in which regulations for biotechnology are implemented will have a direct impact on the competitiveness of US producers in both domestic and world markets. Inconsistent or duplicative domestic regulation will put US producers at a competitive disadvantage. Certification systems which favor domestic products, if adopted by our trading partners, will create substantial nontariff barriers to trade and block market access. Therefore, attention is being paid to the need for achieving consistently in national regulation and international harmonization.

With respect to international harmonization, the US is seeking to promote scientific cooperation, mutual understanding of regulatory approaches, and international agreement on a range of common technical problems. (1984)

2. Policy means (programmatic)

Science-based risk assessment (1993)
Establish appropriate safety levels based on the best scientific information. Safety is defined not as the complete absence of risk, but rather as the level of "acceptable risk". (1995)

A "stepwise" approach, moving from contained laboratory work, to confined release (field trials), to unconfined release. (1993)

Substantial equivalence / familiarity
Familiarity is the knowledge of similar products according to their traits and usage. If the proponent identifies that the product is familiar according to the guidelines, an assessment for substantial equivalence is made. (1995)

Status quo
Product-based regulation that includes a review of process. Builds on existing legislation. (1993)

Industry and public consultations
Developers encouraged to call appropriate regulatory official "early in the development process" if there are questions. (1995)
Regulatory approach developed in consultation with the public and all interested stakeholders. (1997)

3. Scope of regulation

Regulatory trigger
Review is triggered when the new plant variety has a "novel trait". (1993)

Novelty
Regulatory review is required if a product contains novel traits and the risk is not known. The method of production has created intrinsic novelty, even though the traits of the product are the same as those already commercially available (e.g., the introduction of new genes). (1995)

2. Policy means (programmatic)

Science-based assessment
The USDA will use a formal and logical process to ensure the continual integration of safety concepts and other principles.
The USDA will constantly reevaluate its regulatory position as the state of the art of biotechnology evolves. (1984)

Risk-based safety evaluation
Evaluation should include determination of "level of safety concern" for parental organism, then evaluation of the effect of the genetic modification on safety, which leads to the determination of the level of safety concern for the modified organisms (USDA voluntary guidelines for research involving organisms with deliberately-modified hereditary traits). (1991)

Status quo
The existing regulatory framework of USDA, combined with the NIH guidelines, is adequate. Should any new process or products require additional regulatory measures, USDA will amend its regulations or will request additional authority. (1984)

3. Scope of regulation

Regulatory trigger
Review is triggered when new plant variety is produced by genetic engineering and there is reason to believe that it may pose a plant pest risk. (1986)

Novelty
The products of "modern" biotechnology (genetic engineering) are not fundamentally different from products obtained by conventional technology. (1984)

CANADA

INSTITUTIONAL FRAMEWORK

Plant Biotechnology Office handles reviews, within Variety Section, of CFIA.

Internal coordination:
1) Branch Biotechnology Working Group, within the Food Production and Inspection Branch of AAFC.
2) Succeeded by Biotechnology Strategies and Coordination Office, within the Food Production and Inspection Branch of AAFC which becomes Office of Biotechnology, within the CFIA.

Use of existing mechanisms for evaluation of new crop varieties (variety registration system), combined with new formal information requirements for environmental safety assessment purposes.

Establishment of Plant Biotechnology Advisory Committee, and use of other external scientific and multistakeholder committees within specific divisions (Seeds, Feeds, Fertilizers, etc).

Research oversight: separate provisions for contained research. Scientists and institutional biosafety committees are responsible. Guidelines have been available and revised over time since 1977.

POLICY INSTRUMENTS

Regulatory amendments (1995, 1997) and technical guidelines (1988).

Statutes:[1]
Seeds Act and Regulations

[1] The *Plant Protection Act* regulates the import of plants with novel traits and requires a pest risk assessment prior to import.

UNITED STATES

INSTITUTIONAL FRAMEWORK

Reviews handled within Plant Protection and Quarantine section of Animal and Plant Health Inspection Service within USDA.

Internal coordination:
Establishment of Office of Agricultural Biotechnology (closed in 1996) to administer all of USDA's biotechnology responsibilities and coordinate the National Biological Impact Assessment Program (a new advisory structure).
Establishment of Committee on Biotechnology in Agriculture within USDA.

Use of existing mechanisms for evaluation of new crop varieties such as the National Germplasm Advisory Board.

Establishment and use of internal and external scientific advisory bodies, including the Agriculture Recombinant DNA Research Committee, and the Agriculture Biotechnology Recombinant DNA Advisory Committee (eliminated in 1996).

Division of authority for biotechnology within USDA: regulation delegated to Assistant Secretary for Marketing and Inspection Services and research to the Assistant Secretary for Science and Education (July 1985).

Research oversight: NIH guidelines and local Institutional Biosafety Committees for containment measures. USDA developed guidelines for research confinement (outside contained facilities), released in 1991.

POLICY INSTRUMENTS

New regulations (1987) and technical guidelines (1997). Voluntary guidelines for contained release during research (1991).

Statutes:
Federal Plant Pest Act and Regulations
Plant Quarantine Act and Regulations

The *National Environmental Policy Act* (NEPA) requires the USDA to prepare an environmental assessment, and if necessary, an environmental impact statement, to "evaluate the environmental effects of its action at the point of commitment". APHIS has interpreted this requirement by preparing environmental assessments prior to issuing a permit for the release into the environment of a regulated article. It uses internal procedural guidelines (revised most recently in 1995) to implement NEPA.

CANADA

Amendments to Seeds Regulations of the *Seeds Act*, Part V "Release of Seed"[4]
Provisions

Regulatory trigger , section 107(1)
Meets the definition of novel trait

" 'Novel trait', in respect of seed, means a characteristic of the seed that
a) has been intentionally selected, created or introduced into a distinct, stable population of cultivated seed of the same species through a specific genetic change, and
b) based on valid scientific rationale, is not substantially equivalent, in terms of its specific use and safety both for the environment and for human heath, to any characteristic of a distinct, stable population of cultivated seed of the same species in Canada, having regard to weediness potential, gene flow, plant pest potential, impact on non-target organisms and impact on biodiversity."

Explicit exemptions, section 108
For seeds falling within certain categories, including seed already grown prior to these regulations and constituting a distinct stable population in the Canadian environment; seed grown in containment; and seed derived from a distinct stable population or already authorized for unconfined release, and is substantially equivalent, in terms of use and safety for the environment and human health, to seed of the same species, with respect to weediness potential, gene flow, plant pest potential, impact on non-target organisms and impact on biodiversity.

Built-in flexibility
Through the concept of novelty. The degree of novelty determines the degree of regulation.

Approval / notification, section 109
Notification must be provided in writing and authorization received for either confined or unconfined release of seed.

Flexibility in information requirements, section 110 (4)
Information requirements vary according to whether approval is requested for a confined or unconfined release. Minister may waive certain information requirements if certain conditions are met. The same information does not need to be supplied more than once. Information used for environmental assessment in other countries will sometimes be accepted toward Canadian environmental assessments, if the data is applicable to Canada.

[4] Canada. Minister of Public Works and Government Services Canada (1997): 53-57

UNITED STATES

New regulations, 7 CFR Part 340[5]
Provisions

Regulatory trigger, section 340.1
Meets the definition of "a regulated article", which it is produced through genetic engineering and is or may be a plant pest, with some exemptions.

A "regulated article" must fall under certain categories:
1) an organism altered or produced through genetic engineering, AND
2) IF the donor or recipient organism, or the vector or vector agent, belongs to any genera or taxa on a list of plant pests, and meets the definition of plant pest OR
3) is an unclassified organism, or contains an unclassified organism OR
4) is any other organism or product altered by genetic engineering which the Administrator determines is a plant pest or has reason to believe is a plant pest.

Explicit exemptions, section 340.2(b)
Detailed exemptions for specific plant pests if certain conditions involving their characteristics and/or handling are met.

Built-in flexibility, section 340.5
Allow petitions to be filed requesting additions or deletions from list of plant pests, and for determinations of non-regulated status.

Approval of introduction of regulated articles, section 340.4
Granted through application for a permit, accompanied by specific information requirements.

Notification option, section 340.3
Provides for notification, accompanied by specific information requirements, instead of permit in certain cases and for certain crops, when specific safety and performance/handling criteria are met (e.g., criteria regarding weediness and toxicity to non-target organisms, transmission of disease, viruses, animal / human pathogens; stable expression, end use, containment and disposal methods.

[5] United States (1997).

Transition to unconfined release
Information requirements are somewhat different for unconfined release, compared to confined release.

Decision process, section 111
States that Minister will consider information provided and will make a decision to authorize confined release or unconfined release, or to refuse the application, after evaluating risk to environment and to human health. Outlines risks Minister must consider: effects of release on the environment, the magnitude of the exposure to the environment of the seed involved in the proposed release; and assess whether the seed is toxic.

New information requirements, section 112
If developer becomes aware of any new information regarding risk to the environment, including risk to human health, the new information must be provided immediately to the Minister. New information will be evaluated and the decision adjusted accordingly. If the risk appears lower, the Minister may maintain, change or remove conditions regarding release. If risk is greater, the Minister may impose additional conditions, change the conditions or refuse authorization, or if release is underway, require the release to be stopped, and appropriate action taken to eliminate or minimize the risk.

Public comment periods prior to final decisions
CFIA considers public consultations to have occurred prior to finalizing regulations.

Provision for appeals
None stated in regulations.

Transition to "nonregulated status", section 340.6
Petitions can be filed, accompanied by specific information requirements, to request consideration of granting "nonregulated status" for a plant.
Nonregulated status may also be "extended" to other regulated organisms that are similar to an organism already granted nonregulated status, by determination of the Administrator or through an outside request.

Decision process
Regulations outline procedures, deadlines, and time frames. No specific references to content of risk assessment, as in Canada.

New information requirements
Beyond requirement to submit field test reports, which should include any observations of deleterious effects on plants, nontarget organisms, or the environment, no explicit obligation to supply any new information regarding risks to the environment.

Public comment periods prior to final decisions
To notify the public and solicit comments, USDA will publish in the *Federal Register*, requests to amend the list of plant pests (no time frame given for comment period). Petitions for determination of nonregulated status will be published initially for a sixty-day comment period. Preliminary decisions to extend a determination of nonregulated status will be announced in the *Federal Register* thirty days before the decision becomes final

Provision for appeals, changes to regulations
If a permit is denied for introduction of a regulated article or a petition for determination of nonregulated status is denied, an appeal may be made within ten days. Conflicts regarding material facts will be resolved through a hearing.

Prescriptive requirements
Marking and identity, section 340.7
Container requirements for movement, section 340.8

TABLE 3-4
Environmental releases, regulated articles under 7 CFR 340 field trials and "nonregulated status" determinations United States, 1987-1998[1]

A. Number of approvals and actual field sites, 1987-1997

YEAR	PERMITS	NOTIFICATIONS	PERMITS AND NOTIFICATIONS	FIELD SITES
1987	5	N/A	5	5
1988	16	N/A	16	16
1989	30	N/A	30	40
1990	51	N/A	51	81
1991	90	N/A	90	155
1992	160	N/A	160	381
1993	117	189	306	905
1994	69	515	584	1926
1995	87	620	707	3859
1996	114	490	604	2988
1997	104	643	747	3735
1998	n/a	n/a	1073	n/a
Total	843	2457	4373	14091

B. Most common crops for field trials, 1987-1997

Crop	Number of approvals, permits and notifications	Percentage of total approvals
Corn	1420	43
Cotton	237	7
Melon / Squash	120	4
Potato	332	10
Rapeseed	81	2
Soybean	329	10
Tobacco	114	3
Tomato	369	11

C. Most common novel traits covered in approvals (permits and notifications), 1987-1998[2]

Trait	Approvals	Percentage of total approvals
Agronomic properties	259	5.1
Fungal resistant	243	4.7
Herbicide tolerant	1459	29.6
Insect resistant	1204	23.8
Product quality	985	20.2
Virus resistant	436	9.9

[1] Source is USDA / APHIS web site: http://www.aphis/usda.gov/bbep/bp. The site does not supply detailed data on field trials by year.

[2] Categories used here for traits are those used by APHIS. Percentages are those supplied by APHIS.

D. Determinations of Nonregulated Status, by crop and developer, 1992-1999[1]

Crop	Trait	Year of Determination	Developer
Beet	HT	1998	AgrEvo
Beet	HT	1998	Novartis
Corn	HT	1995	AgrEvo
Corn	HT / IR	1998	AgrEvo
Corn	IR	1995	Ciba Geigy
Corn	HT	1995	Dekalb
Corn	IR	1997	Dekalb
Corn	IR	1995	Monsanto
Corn	IR	1996	Monsanto
Corn	HT	1997	Monsanto
Corn	HT / IR	1997	Monsanto
Corn	IR	1996	Northrup King
Corn	BR / HT	1998	Pioneer Hi-Bred
Corn	BR	1996	Plant Genetic Systems
Cotton	HT	1994	Calgene
Cotton	HT / IR	1997	Calgene
Cotton	HT	1996	DuPont
Cotton	IR	1995	Monsanto
Cotton	HT	1995	Monsanto
Papaya	VR	1996	Cornell
Potato	IR	1995	Monsanto
Potato	IR	1996	Monsanto
Potato	IR/ VR	1998	Monsanto
Potato	IR / VR	1999	Monsanto
Rapeseed	HT	1998	AgrEvo
Rapeseed	Oil	1994	Calgene
Rapeseed	HT	1999	Monsanto
Radicchio	BR	1997	Bejo
Soybean	HT	1997	AgrEvo
Soybean	HT	1998	AgrEvo
Soybean	HT	1998	AgrEvo
Soybean	Oil	1997	DuPont
Soybean	Oil	1994	Monsanto
Squash	VR	1996	Asgrow
Squash	VR	1994	Upjohn
Tomato	PR	1996	Agritope
Tomato	PR	1992	Calgene
Tomato	PR	1994	Calgene
Tomato	PR	1994	Calgene
Tomato	PR	1995	Calgene
Tomato	PR	1995	Calgene
Tomato	PR	1996	Calgene
Tomato	PR	1995	DNA Plant Technology
Tomato	PR	1995	Monsanto
Tomato	IR	1998	Monsanto
Tomato	PR	1995	Zeneca

[1] APHIS records receiving a total of sixty-four applications as of March 1999. Of these, forty-six were approved, eleven were withdrawn by the developer and five were pending or under review for completeness.

E. Most common crops for nonregulated status determinations, 1994-1998

YEAR	Corn	Cotton	Potato	Rapeseed	Soybean	Tomato
1994	0	1	0	1	1	2
1995	4	2	1	0	0	4
1996	3	1	1	0	1	2
1997	3	1	0	0	1	0
1998	2	0	1	1	2	1
Total	12	5	3	2	5	9
Percentage of approved determinations (/46)	26	11	7	4	11	20

F. Most common traits for nonregulated status determinations, 1994-1998[4]

YEAR	HT	IR	PR	VR
1994	2	0	2	1
1995	3	4	5	0
1996	2	3	2	2
1997	3	3	0	0
1998	7	3	0	1
Total	17	13	9	4
Percentage of approved	37	28	20	9

G. Most common developers for nonregulated status determinations, 1994-1998

YEAR	AgrEvo / PGS	Monsanto / Calgene / DEKALB	Novartis[5]	Pioneer / DuPont
1994	0	5	0	0
1995	1	8	1	0
1996	2	3	1	1
1997	0	4	0	1
1998	5	2	1	1
Total	8	22	3	3
Percentage of approved	17	48	7	7

ABBREVIATIONS

BR=breeding traits such as marker genes and male sterility
FT=fungicide tolerant
HT=herbicide tolerant
IR=insect resistant
OIL=oil composition
PR=processing, handling such as delayed ripening
VR=virus resistant

[4] Note that some varieties have more than one novel trait.
[5] Ciba Seeds and Northrup King have merged under Novartis Seeds.

TABLE 3-5
Chronology of regulatory events, food safety assessment of novel foods / new plant varieties Canada and the United States, 1984-1999

CANADA	UNITED STATES
	1984-86 FDA states its intention in the Coordinated Framework documents to regulate genetically-engineered foods in the same way as foods produced through other processes.
	1988 Under contract to the FDA, the Federation of American Societies for Experimental Biology establishes two groups to make recommendations for FDA food policy, including the Ad Hoc Expert Panel on Criteria for Determining the Regulatory Status of Food and Food Ingredients Produced by New Technologies.
	1989 Release of FDA action plan promising to speed up approval of biotechnology products.
1988-1992 Health Canada studies issue of genetically-engineered foods, gathering information and holding internal discussions.	**1990** FDA issues its first approval for a recombinant DNA-produced food ingredient, fermentation-derived chymosin (rennet).
	1992 **May** FDA issues a policy statement that foods derived from new plant varieties produced by genetic engineering will be regulated no differently than foods created by conventional means, unless special circumstances apply. Guidelines are released to help firms decide whether FDA review is advisable for specific products.
1992 **August** Health Canada releases an Information Letter to solicit comment on its proposed approach for safety assessment of novel foods.	

CANADA	UNITED STATES
1993 **November 8-10** Workshop on Regulating Agricultural Products of Biotechnology (multistakeholder consultation conducted by Agriculture Canada, Health Canada, Environment Canada, and Industry and Science Canada).	
	1994 **April** Workshop held by FDA, EPA, and USDA on "Scientific Issues Related to Potential Allergenicity in Transgenic Food Crops". FDA holds a public joint meeting of its Food Advisory Committee and Veterinary Medicine Committee to review its approach to food safety assessment.
1994 **September** Health Protection Branch publishes *Guidelines for the Safety Assessment of Novel Foods.*	**May** Calgene Flavr Savr tomato is the first genetically engineered plant product to receive FDA approval. **November** FDA holds a public joint meeting of its Food Advisory Committee and Veterinary Medicine Committee to discuss pre-market notification consultations on the option of moving to pre-market notification, but does not proceed.
1995 **August** Health Protection Branch publishes proposed new regulations for safety assessment of novel foods under *Food and Drugs Act.*	**1996** **June** FDA issues guidance document on consultation procedures for developers of new plant varieties (revised in October 1997). **November 1996 - February 1997** FDA consults with external experts on whether and when it should recommend that certain antibiotic resistance genes not be used in crops intended for food.
	1998 **May** Alliance for Bio-Integrity launches a lawsuit against FDA's food safety assessment and labelling policies for genetically-engineered foods.
1998 **September** Republishes proposed new regulations with some revisions.	**September** FDA issues draft guidance document for the use of antibiotic resistance marker genes in plants.
1999 **October 27** Regulations finalized, publication in the *Canada Gazette*	**1999** **October** FDA announces intention to hold three public meetings on its food safety policy before the end of the year.

TABLE 3-6
Food safety assessment, approvals of novel foods by Health Canada, 1994-1998[1]

A. Approvals of novel foods, 1994-1998, by date authorized

Crop	Trait	Date Authorized	Company Name
Maize	HT	May 30, 1994	Pioneer Hi-Bred International
Canola	MS	Sept. 8, 1994	Plant Genetic Systems
Canola	HT	Nov. 21, 1994	Monsanto Canada
Canola	HT	Feb. 16, 1995	AgrEvo Canada
Tomato	CP	Feb. 17, 1995	Calgene
Canola	HT	Apr. 25, 1995	Pioneer Hi-Bred
Canola	Breeding	Aug. 17, 1995	Plant Genetic Systems
Potato	IR	Sept. 21, 1995	Monsanto Canada
Tomato	CP	Nov. 2, 1995	DNA Plant Technology
Corn	IR	Dec. 19, 1995	Ciba Seeds
Soybean	HT	Apr. 9, 1996	Monsanto Canada
Cotton	IR	April 9, 1996	Monsanto Canada
Canola	CP	Apr. 9, 1996	Calgene
Tomato	CP	June 28, 1996	Zeneca Plant Science
Corn	IR	Aug. 15, 1996	Northrup King Co.
Canola	CP	Aug. 15, 1996	Pioneer Hi-Bred
Cotton	HT	Aug. 16, 1996	Calgene
Cotton	IR	Nov. 8, 1996	Monsanto Canada
Potato	IR	Nov. 8, 1996	Monsanto Canada
Corn	HT	Dec. 19, 1996	DEKALB Genetics Corp
Cotton	HT	Dec. 19, 1996	Monsanto Canada
Corn	IR	Dec. 19, 1996	Pioneer Hi-Bred
Corn	HT	Feb. 14, 1997	BASF Canada
Canola	HT	Feb. 17, 1997	AgrEvo Canada
Corn	IR	Feb. 17, 1997	Monsanto Canada
Canola	MS	Mar. 12, 1997	Plant Genetic Systems
Corn	HT	April 3, 1997	AgrEvo Canada
Corn	IR / HT	April 3, 1997	DEKALB
Corn	HT	July 8, 1997	Zeneca Seeds
Corn	MS	July 8, 1997	Plant Genetic Systems
Canola	HT	July 8, 1997	Rhone-Poulenc Agriculture
Canola	HT	Sept. 12, 1997	Monsanto Canada
Corn	IR / HT	Sept. 12, 1997	Monsanto Canada
Flax	HT	Feb. 16, 1998	Crop Development Centre, U Sask
Squash	VR	Apr. 16, 1998	Seminis Vegetable Seeds
Squash	VR	Apr. 16, 1998	Seminis Vegetable Seeds
Corn	HT	June 8, 1998	Pioneer Hi-Bred
Cotton	IR/HT	Dec. 14, 1998	Monsanto Canada

[1] Source: Health Canada's web site: www.hc-sc.gc.ca/datahpb/datafood/english/main_e.htm. According to a Health Canada official, the list of approved novel foods on Health Canada's web site does not include some categories of foods falling within the department's definition, such as those produced through novel processes. A few of the approved foods on the list come from plants altered through mutagenesis, rather than genetic engineering.

B. Approvals for most common crops

Year	Total approvals	Canola	Corn / maize	Cotton	Tomato
1994	3	2	1	0	0
1995	7	3	1	0	2
1996	12	2	3	4	1
1997	11	4	7	0	0
1998	5	0	1	1	0
Total	38	11 (29%)	12 (32%)	5 (13%)	3 (8%)

C. Approvals for most common novel traits
(note that some plants have more than one novel trait)

	Total approvals	Breeding*	HT	IR	CP
1994	3	1	2	0	0
1995	7	1	2	2	2
1996	12	0	4	5	3
1997	11	2	8	3	0
1998	5	0	3	1	0
Total	38	4 (11%)	19 (50%)	11 (29%)	5 (13%)

*Breeding category includes male sterility trait

D. Approvals by most common developers

	Total	AgrEvo / PGS	Ciba / Northrup	Monsanto / Calgene / DeKalb	Pioneer / DuPont
1994	3	1	0	1	1
1995	7	2	1	2	1
1996	12	0	1	7	2
1997	11	4	0	3	0
1998	5	0	0	1	1
Total	38	7 (18%)	2 (5%)	14 (37%)	5 (13%0

Note: Ciba Seeds and Northrup King have merged under Novartis Seeds.

Abbreviations:
CP=composition / processing characteristics (such as oil characteristics, delayed ripening, etc.)
HT=herbicide tolerance
IR=insect resistance
MS=male sterility (this trait is sometimes combined with a fertility restorer trait)
VR=virus resistance

TABLE 3-7

Comparative policy choices: Food safety assessment of novel foods / foods from new plant varieties

CANADA[1]

PRINCIPLES

1. Policy goals (guiding)

Safety

Genetically-modified plants should undergo a food safety assessment. (1992)

Safety assessment will be necessary for some novel foods. (1994)

Public confidence

Public satisfaction with the safety assessment mechanism is important to achieve consumer acceptance of novel foods. (1995)

Harmonization

The regulatory approach is similar to that in the US and being considered in the European Union. It incorporates safety assessment concepts developed by the Group of National Experts on Food Safety of the OECD. (1995)

Competitiveness

Pre-market notification chosen over the pre-market approval option because the latter would introduce unnecessary impediments to the marketing of novel foods without providing a corresponding increase in the level of consumer protection. (1995)

Pre-market notification will enhance the possible successful marketing of such products by providing a degree of assurance to the public regarding their safety as food. (1995)

[1] Canada. Health and Welfare Canada. Health Protection Branch (1992), Canada. Health Canada. Health Protection Branch. Food Directorate (1994), and Canada. Minister of Supply and Services Canada (1995). The principles listed for both countries are either direct quotes or slightly revised for clarity and brevity.

UNITED STATES[2]

PRINCIPLES

1. Policy goals (guiding)

Safety

1992 policy statement issued "to ensure that relevant scientific, safety, and regulatory issues are resolved prior to the introduction of such products into the marketplace". (1992)

Public confidence

The public relies on FDA for assurance that foods are safe and wholesome. (1995)

Harmonization

Attention is being paid to the need for achieving consistency in national regulation and international harmonization. (1984)

Scientific principles used for food safety assessment are consistent with those set by the OECD and the FAO/WHO Joint Consultation. (1992)

Competitiveness

Recognition that regulations can have a direct impact on the competitiveness of American producers in domestic and world markets. (1984)

[2] United States. Food and Drug Administration (1992) and United States. Food and Drug Administration. Center for Food Safety and Applied Nutrition (1995).

PRINCIPLES

2. Policy means (programmatic)

Substantial equivalence
Assessment is based on comparing novel foods to their traditional counterparts, according to the OECD's concept of substantial equivalence, where appropriate. Findings of substantial equivalence reduce regulatory requirements, while findings of substantial differences increase the degree of regulatory review. (1994)

Science-based
Guidelines provided are flexible, assessment is done on a case-by-case basis, and are expected to be revised as information accumulates. (1994)

Risk-based
The degree of review and information requirements will vary with the product and its degree of substantial equivalence. (1994)

Industry consultations
Developers are encouraged to consult in the early stages of product development. (1994)

PRINCIPLES

2. Policy means (programmatic)

Substantial equivalence
Scientific concepts in guidance section of 1992 policy statement are consistent with the concept of substantial equivalence being discussed by the Group of National Experts on Safety in Biotechnology of the OECD. (1992)

Science-based
Regulation by FDA must be based on the rational and scientific evaluation of products, not on *a priori* assumptions about certain processes. (1984)
Because scientific developments in this field are occurring rapidly, FDA will refine its policy, if circumstances warrant. (1992)
We are continuing to consider issues regarding allergenicity, labeling, and pre-market notification. (1995)

Risk-based
Substances with a history of safe use would generally require less or no review while substances that raise safety concerns would receive closer scrutiny. (1992)

Industry consultations
Producers can informally consult with FDA prior to marketing new foods. (1992)

Industry responsibility
The burden of proof of safety and effectiveness of products rests with the manufacturer. (1984)

PRINCIPLES

3. Scope of regulation

Regulatory trigger
Review is triggered when the product falls under the definition of "novel food". (1992)

Novelty
It is generally agreed that the application of genetic modification does not inherently increase or decrease the risk associated with an organism. However, the wide variety of modifications possible through genetic manipulation, and the potential for the introduction of toxic compounds, unexpected secondary effects, and changes in nutritional and toxicological characteristics may give rise to safety concerns.....it is considered important that an appropriate mechanism be developed for the safety assessment of foods derived through the application of genetic modification technology. (1994)

PRINCIPLES

3. Scope of regulation

Regulatory trigger
The regulatory status of a food, irrespective of the method by which it is developed, is dependent upon objective characteristics of the food and its intended use, although the method used to produce the food may be relevant to the safety assessment. (1992)

Novelty
There is no information the agency is aware of to indicate that the use of genetic engineering techniques to produce new plant varieties raises any different or greater safety concerns than the use of traditional techniques. (1992)

CANADA

INSTITUTIONAL FRAMEWORK

The Canadian Food Inspection Agency is designated as the lead agency for regulation of agricultural biotechnology; Health Canada is responsible for food safety standards and assessment.

Health Canada has authority under the *Food and Drugs Act* to control the sale of food to ensure a safe food supply.

Office of Food Biotechnology created within the Health Protection Branch of Health Canada to administer the policy; internal biotechnology committee established to coordinate within the Food Directorate.

POLICY INSTRUMENTS

Informal consultations: Health Canada encourages developers to consult with them early in the process of product development.

Guidelines for developers detailing scientific considerations for safety assessments, including product characteristics that would trigger the requirement for pre-market notification and/or a safety assessment by Health Canada. Charts provided to assist developers in assessing need for notification and review. (1994)

Amendments to the Food and Drug Regulations for "novel foods". (1999)
Main provisions:

1. Definition of novel foods

2. Pre-market notification required for novel foods

3. Safety assessment may be required. Decision is made by senior Health Canada official, after reviewing notification data. Developer may have to provide evidence of safety.

UNITED STATES

INSTITUTIONAL FRAMEWORK

Food and Drug Administration has authority through the *Food, Drug, and Cosmetic Act* to ensure the safety of most foods, including food produced from new plant varieties.[1] Administration of policy is based within the Center for Food Safety and Nutrition. A Biotechnology Evaluation Team handles reviews as necessary.

POLICY INSTRUMENTS

No new procedures or requirements proposed. (1984)

"Informal notifications" and voluntary regulation: FDA recommends that developers notify them of new products. (1992)

Guidance documents for developers detailing scientific considerations for safety assessments, including a "decision tree" approach to be used to determine need for "informal notification" of, and consultations with, FDA. (1992)

"Initial" and "final" consultations: FDA publishes a list of new plant varieties for which final consultations have been completed, indicating that all safety and regulatory issues have been resolved. (1992)

Two sections of the *Food, Drug and Cosmetic Act* are used as needed:
1. Section 402(a)(1): adulteration provisions provide post-market authority for enforcement.
2. Section 409: food additive provisions provide pre-market authority.

The *National Environmental Policy Act* applies to all pre-market approvals of FDA regulated products for new uses of products, and new products.

[1] In the US, the EPA has primary responsibility for setting and enforcing standards for the food safety of plant-pesticides (plants developed with insect-resistant traits). There is no similar division of responsibility in Canada, although personnel within the Pest Management Regulatory Agency are consulted when necessary by CFIA and Health Canada.

TABLE 3-8
Final consultations, foods derived from new plant varieties produced through recombinant DNA technology, Food and Drug Administration, 1994-1998[1]

A. Final consultations, by year and company

Crop	Trait	Year	Company Name
Squash	VR	1994	Asgrow Seed Co.
Tomato	CP	1994	Calgene
Cotton	HT	1994	Calgene
Tomato	CP	1994	DNA Plant Technology
Soybean	HT	1994	Monsanto
Tomato	CP	1994	Monsanto
Potato	IR	1994	Monsanto
Tomato	CP	1994	Zeneca Plant Science
Canola	HT	1995	AgrEvo
Corn	HT	1995	AgrEvo
Canola	CP	1995	Calgene
Corn	IR	1995	Ciba-Geigy Corp.
Cotton	HT	1995	Monsanto
Canola	HT	1995	Monsanto
Cotton	IR	1995	Monsanto
Tomato	CP	1996	Agritope
Corn	HT	1996	DEKALB Genetics
Cotton	HT	1996	DuPont
Potato	IR	1996	Monsanto
Corn	IR	1996	Monsanto
Corn	HT / IR	1996	Monsanto
Corn	IR	1996	Northrup King
Oilseed rape	MS	1996	Plant Genetic Systems
Corn	MS	1996	Plant Genetic Systems
Canola	HT	1997	AgrEvo
Radicchio	MS	1997	Bejo Zaden
Corn	IR	1997	DEKALB
Soybean	CP	1997	DuPont
Squash	VR	1997	Seminis Vegetable Seeds
Papaya	VR	1997	Univ. of Hawaii / Cornell University
Soybean	HT	1998	AgrEvo
Sugar beet	HT	1998	AgrEvo
Corn	IR / HT	1998	AgrEvo
Canola	MS / HT	1998	AgrEvo
Cotton	HT / IR	1998	Calgene
Tomato	IR	1998	Calgene
Corn	HT	1998	Monsanto
Potato	IR / VR	1998	Monsanto
Potato	IR / VR	1998	Monsanto
Sugar Beet	HT	1998	Monsanto / Novartis
Corn	MS	1998	Pioneer Hi-Bred
Flax	HT	1998	Univ. of Saskatchewan

[1] Source is FDA web site http://vm.cfsan.fda.gov/~lrd/biocon.html. Specific dates for the final consultations are not provided on FDA's web site.

B. Most common crops

Year	Total	Canola	Corn / maize	Cotton	Potato	Soybean	Tomato
1994	8	0	0	1	1	1	4
1995	7	3	2	2	0	0	0
1996	9	0	5	1	1	0	1
1997	6	1	1	0	0	1	0
1998	12	1	3	1	2	1	1
Total	42	5 (12%)	11 (26%)	5 (12%)	4 (10%)	3 (7%)	6 (14%)

C. Most common novel traits
(note that some plants have more than one novel trait)

	Total	Breeding*	CP	HT	IR	VR
1994	8	0	4	2	1	1
1995	7	0	1	4	2	0
1996	9	2	1	3	4	0
1997	6	2	1	1	1	2
1998	12	2	0	8	5	2
Total	42	6 (14%)	7 (17%)	18 (43%)	13 (31%)	5 (12%)

*Breeding category includes male sterility trait

D. Consultations by most common developers

	Total	AgrEvo / PGS	Ciba / Northrup	Monsanto/ Calgene / DeKalb	Pioneer / DuPont
1994	8	0	0	5	0
1995	7	2	1	4	0
1996	9	2	1	4	1
1997	6	1	0	1	1
1998	12	4	0	6	1
Total	42	9 (21%)	2 (5%)	20 (48%)	3 (7%)

Abbreviations:
CP=composition / processing characteristics (such as oil characteristics, delayed ripening, etc.)
HT=herbicide tolerance
IR=insect resistance
MS=male sterility (this trait is sometimes combined with a fertility restorer trait)
VR=virus resistance

TABLE 3-9
Chronology of regulatory events, labelling of novel foods / new plant varieties Canada and the United States, 1992-1999

CANADA	UNITED STATES
	1992 **May** As part of its policy statement on foods from new plant varieties, FDA states that labelling requirements for new plant varieties will be the same as required with conventional plant varieties, except if the composition of the food differs significantly from its conventional counterpart.
	1993 **April** FDA solicits comments on labelling of genetically-engineered food in *Federal Register* notice.
1993 **November** Workshop on Regulating Agricultural Products of Biotechnology, a multistakeholder consultation conducted by regulatory departments. Minimal consensus reached on labelling at this workshop; need for further consultations on labelling identified.	
1994 **November** Technical Workshop on the Labelling of Novel Foods Derived Through Genetic Engineering held, a multistakeholder workshop intended to produce consensus on general principles.	
1995 **December** AAFC issues *Communiqué: Labelling of Novel Foods derived through Genetic Engineering* which outlines a set of proposed guidelines for labelling policy.	
	1996 **February** FDA schedules, then abruptly cancels, meeting of Food Advisory Committee on labelling genetically-engineered foods.
1997 **April** CFIA issues *Information Letter: Summary of Comments on the Communiqué* which summarizes comment on the 1995 communique and presents guidelines which are the basis for Canada's labelling policy. The policy is still under development since no final policy has been issued.	
	1998 **May** Alliance for Bio-Integrity launches a lawsuit against FDA's food safety assessment and labelling policies for genetically-engineered foods.
1999 Canadian General Standards Board forms a committee to develop guidelines for voluntary labelling of biotechnology foods.	
	1999 **October** FDA announces three public meetings to discuss its policy on food safety and labelling.

TABLE 3-10

Comparative policy choices: labelling of novel foods / foods derived from new plant varieties

CANADA[1]	UNITED STATES[2]
PRINCIPLES	**PRINCIPLES**
1. Policy goals (guiding)	**1. Policy goals (guiding)**
Safety Labelling is required if genetic engineering has resulted in the presence of potential health and/or safety risks; and/or significant nutritional or compositional changes from the traditional food source. (1995)	**Safety** Labelling is required if a food from a new plant variety differs from its traditional counterpart to the extent that the common name no longer applies, or if a safety or usage issue exists, such as a potential allergic reaction. (1992)
Harmonization Domestic and international needs must be considered. Consistency with the principles of major trading partners and international standards should be sought. (1995)	
2. Policy means (programmatic)	**2. Policy means (programmatic)**
Linked with food safety assessment (science-based) Food safety assessment process will identify when food has characteristics that require special labelling. (1995)	**Linked with food safety assessment (science-based)** Food safety assessment process will identify when food has characteristics that require special labelling. (1992)
3. Scope of regulation	**3. Scope of regulation**
Focus is on novel foods and novel food ingredients. (1995)	The method used to develop new plant varieties is not relevant information for labelling. The FDA is not aware of any information that foods derived from genetic engineering techniques differ from foods produced in other ways in any meaningful way. (1992)
It is not necessary to inform consumers through labelling that genetic engineering has been used, unless significant changes have been made. (1995)	Labelling must be truthful and not misleading. (1992)
Labelling should be understandable, truthful and not misleading; voluntary positive and negative labelling is acceptable, if factual. (1995)	The consumers' "desire to know" is not on its own an adequate basis for requiring disclosure through labelling. (1995)
Religious dietary restrictions are outside the current mandate and are adequately addressed by the regulatory framework of religious groups. (1995)	

[1] Canada. Agriculture and Agri-Food Canada. Biotechnology Strategies and Coordination Office (1995).

[2] United States. Food and Drug Administration (1992) and United States. Food and Drug Administration. Center for Food Safety and Applied Nutrition (1995).

CANADA

INSTITUTIONAL FRAMEWORK

Primary responsibility for food labelling is shared by the Canadian Food Inspection Agency (CFIA) and Health Canada. Health Canada has primary responsibility for health, safety, and nutrition labelling considerations under the *Food and Drugs Act*. The CFIA administers non-safety labelling considerations such as misrepresentation, and enforces all food labelling requirements. Industry Canada administers the *Consumer Packaging and Labelling Act* which sets out some labelling requirements to ensure uniform labelling. CFIA has taken the lead on coordinating development of the labelling policy for novel foods, including genetically-engineered foods.

POLICY INSTRUMENTS

Labelling of novel foods is based on the principles of the guidelines outlined above and the general labelling requirements of the *Food and Drug Act* regulations. (1997)

In particular, subsection 5(1) of the *Food and Drugs Act* states:
"No person shall label, package, treat, process, sell or advertise any
food in a manner that is false, misleading or deceptive or is likely to
create an erroneous impression regarding its character, value, quantity,
composition, merit or safety".

UNITED STATES

INSTITUTIONAL FRAMEWORK

The Food and Drug Administration has primary responsibility for setting and enforcing labelling requirements for most foods, except meat and poultry. Much of its authority comes from the *Food, Drug and Cosmetic Act* (FDCA). The *Fair Packaging and Labeling Act* and the *Nutrition Labeling and Education Act* provide additional authorities.

POLICY INSTRUMENTS

Guidance section of 1992 policy statement suggests possible situations when special labelling may be required and recommends consultation with FDA.

Labelling requirements for foods derived from new plant varieties produced through the use of genetic engineering techniques will be identical to those for all other foods, as outlined in the FDCA.

In particular, subsection 403(i) of the FDCA requires food producers to describe the food by its common name, or by an appropriately descriptive term; and to "reveal all facts that are material in light of representations made or suggested by labelling or with respect to consequences which may result from use".[1] Therefore, labelling would be required if a food differs significantly from its traditional counterpart, or if there are safety or other issues that should be brought to the attention of consumers through labelling.

[1] United States. Food and Drug Administration (1992).

TABLE 3-11

Comparative policy choices: environmental release / safety assessment principles
Canada and the United States

SIMILAR

GOALS:
Environmental safety (1986U, 1993C)
Protection of agricultural sector (1986U, 1995C)
Harmonization (1984U, 1994C)
Competitiveness (1984U, 1997C)

MEANS:
Science-based assessment (1984U, 1993C)
Use of existing authorities (1984U, 1993C)

DISTINCT

GOALS:
Market regulation (1995C)

MEANS:
Explicit use of concept of substantial equivalence (1995C)
Determination of "level of safety concern" (1991U)
Explicit commitment to industry and public consultations (1995C)

Regulatory trigger
Genetic engineering and plant pest (1986U)
Novel trait (1994C)

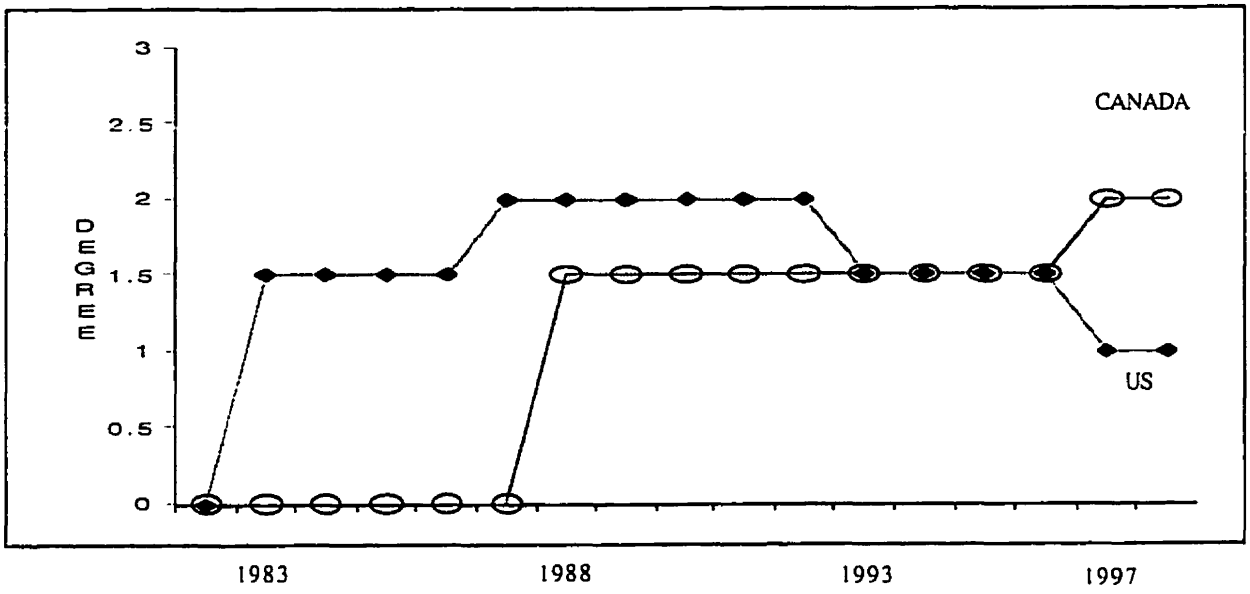
Novelty
Products of genetic engineering are not fundamentally different from those produced otherwise (1984U)
Method of production can create intrinsic novelty (1995C)

C=Canada
U-United States

TABLE 3-12

Comparing degree and flexibility / formality of regulation, environmental release / safety Canada and the United States

Environmental release / safety -- Degree of regulation



United States

1983=1.5
(NIH guidelines mandatory for some, voluntary for others)
1987=2
(USDA review mandatory if triggered)
1993=1.5
(USDA narrows scope of mandatory review)
1997=1
(USDA further narrows scope of mandatory review)

Canada

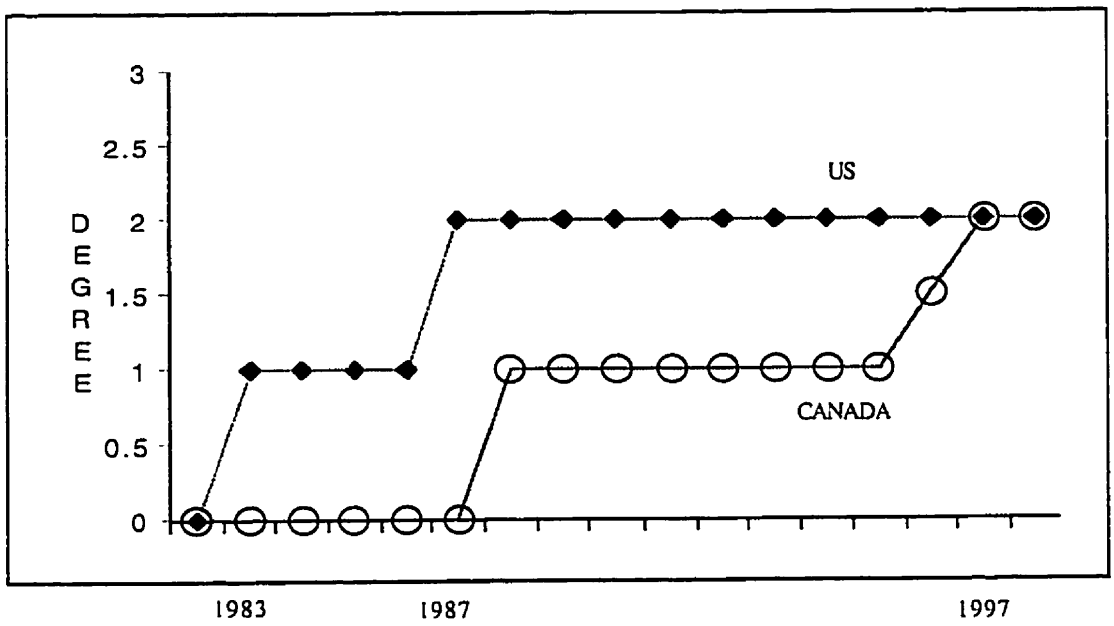
1988=1.5
(AAFC issues guidelines, but enforcement available through *Seeds Act* and other statutes
1997=2
(AAFC / CFIA review mandatory if triggered)

Scale

0=no specific measures for environmental release
1=voluntary compliance
2=mandatory compliance

TABLE 3-12
Comparing degree and flexibility / formality of regulation, environmental release / safety
Canada and the United States

Environmental release / safety -- Flexibility / Formality



UNITED STATES
1983=1, guidelines
1987=2, regulations

CANADA
1988=1, guidelines
1996=1.5, proposed regulations
1997=2, regulations

Scale
0=no policy
1=guidelines
2=regulations
3=legislation

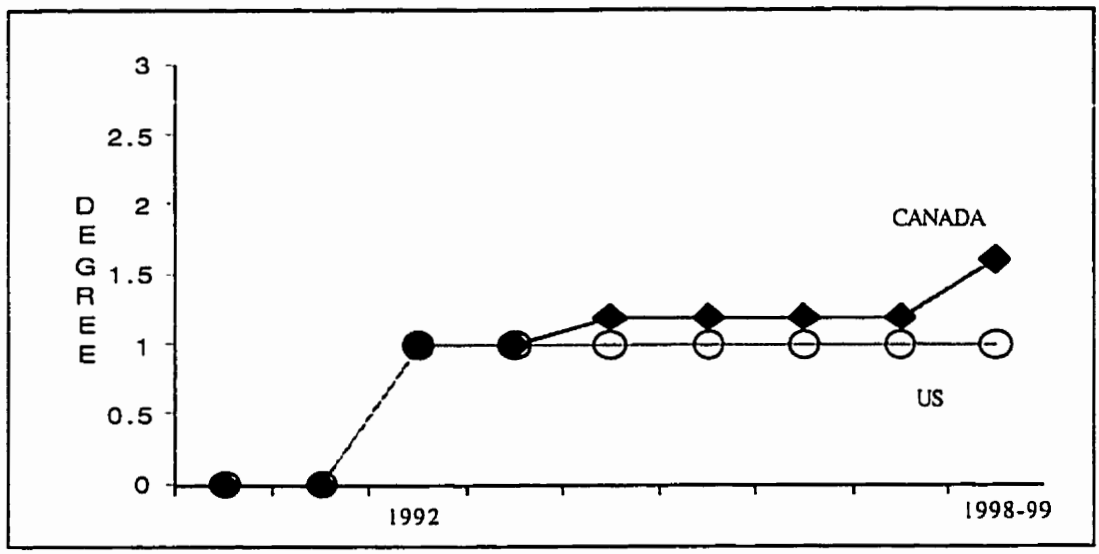
TABLE 3-13
Comparative policy choices: food safety assessment principles

SIMILAR	DISTINCT
GOALS:	**MEANS:**
Safety (1992 C and U)	Industry responsibility (1984 US)
Public confidence (1995 C and U)	
Harmonization (1992 US, 1995 C)	**Regulatory trigger**
Competitiveness (1984 US, 1995 C)	*Novel food definition (1992 C)
	*Product characteristics (1992 US)
MEANS:	**Novelty**
Substantial equivalence (1992 US, 1994 C)	*Genetic modification can cause safety concerns because of its potential (1994 C)
Science-based flexibility (1992 US, 1994 C)	*Genetic engineering does not appear to raise any greater or different safety concerns than the use of traditional techniques (1992 US)
Risk-based (1992 US, 1994 C)	
Industry consultations (1992 US, 1994 C)	

C=Canada
U=United States

TABLE 3-14
Comparing degree and flexibility / formality of regulation, food safety assessment
Canada and the United States

Food safety assessment--degree of regulation



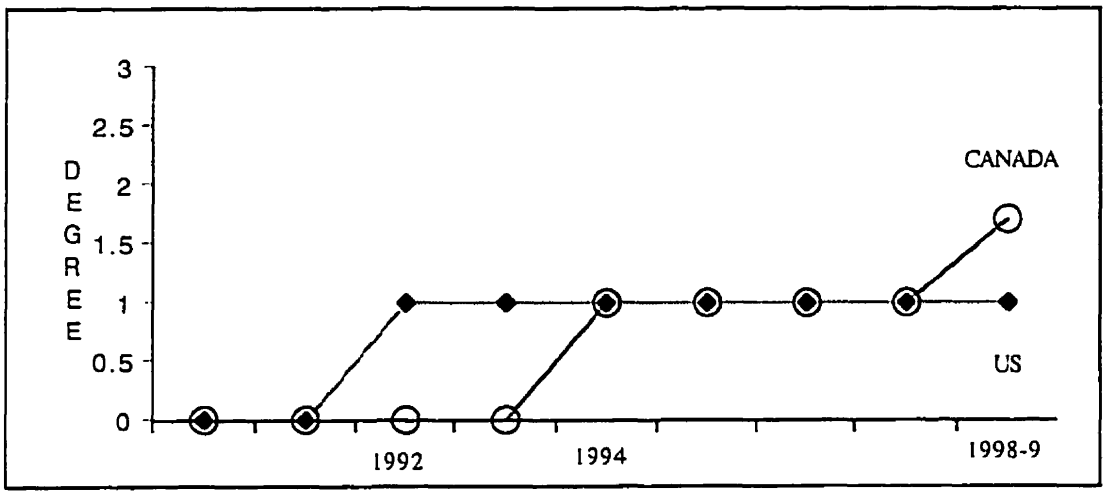
UNITED STATES
1992=1, policy statement with guidance

CANADA
1992=1, proposal of premarket notification and safety assessment
1994 / 95=1.2, scientific guidelines issued,
proposed regulations issued
1998=1.6, proposed regulations reissued (finalized in 1999)

Scale
0=no policy
1=voluntary compliance
2=mandatory compliance

TABLE 3-14
Comparing degree and flexibility / formality of regulation, food safety assessment
Canada and the United States

Food safety assessment -- Flexibility / Formality



UNITED STATES
1992=1, policy statement with guidance

CANADA
1994=1, scientific guidelines issued
1998=2, proposed regulations near final version

Scale
0=no policy
1=guidelines
2=regulations
3=legislation

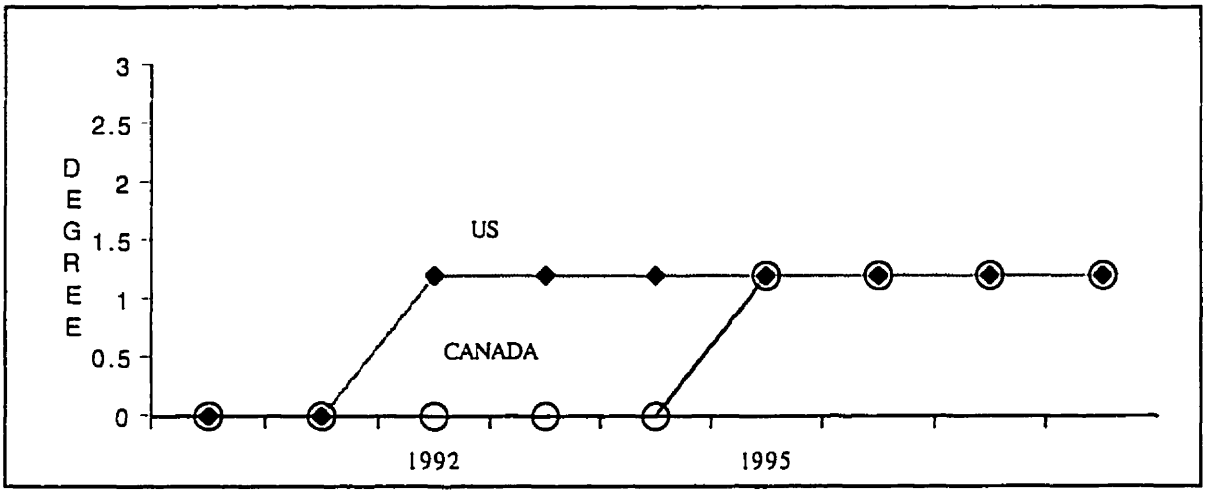
TABLE 3-15
Comparative policy choices: labelling principles

SIMILAR	DISTINCT
GOALS: Safety (1992U, 1995C) Labelling must be truthful (1992U, 1995C)	**GOALS:** Explicit commitment to harmonization (1995C)
SCOPE: The process is irrelevant information for labelling purposes (1992U, 1995C)	**SCOPE:** Focus on novel foods (1995C) The consumer's desire to know is not an adequate basis for labelling requirements (1995U) Religious dietary restrictions are adequately addressed by the regulation put in place by religious groups (1995C)
Regulatory trigger Labelling is required for clear health and safety concerns, such as significant alteration in nutritional composition or the presence of potential allergens (1992U, 1995C)	

C=Canada
U=United States

TABLE 3-16
Comparing degree of regulation and flexibility / formality, labelling
Canada and the United States

Labelling -- Degree of regulation



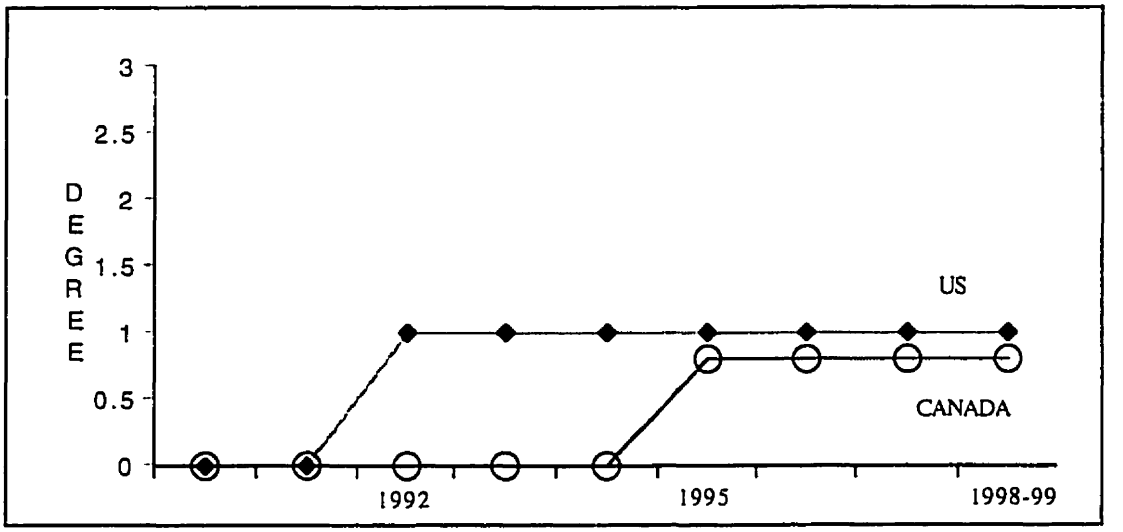
UNITED STATES
1992=1.2, mandatory requirements in limited circumstances

CANADA
1995=1.2, mandatory requirements in limited circumstances

Scale
0=no policy
1=voluntary compliance
2=mandatory compliance

TABLE 3-16
Comparing degree of regulation and flexibility / formality, labelling
Canada and the United States

Labelling -- Flexibility / Formality



UNITED STATES
1992=1, policy statement with guidance

CANADA
1995=0.8, interim guidelines

Scale
0=no policy
1=guidelines
2=regulations
3=legislation

CHAPTER FOUR
POLICY COMMUNITIES AND POLICY NETWORKS

Specialization characterizes much of policy making in recent decades across industrialized countries. Many state officials and interest groups focus their work on narrow policy issues and rarely interact routinely with those from other policy areas. The concepts of policy community and policy network reflect this reality and help to impose order on the complexity of modern policy making for analytic purposes.[1] These concepts acknowledge that interaction between state and societal actors within a given sector is very much a function of their internal resources and their degree of interdependence. Static levels of internal resources create regular patterns of interaction and exchange, or policy networks, which can shape the process of policy making and its outcomes. These patterns of exchange may also illustrate dependency within a policy community that flows, for example, from the need to acquire scientific information or political legitimacy. This chapter describes the policy communities and policy networks surrounding the regulation of plant biotechnology as the first step in moving toward an assessment of their influence on policy choices. The following two chapters take a closer look at the role of science and its effect on patterns of exchange within policy networks and the degree and nature of internationalization working within and through policy communities and policy networks.

This chapter begins by sketching the evolving composition of the Canadian and American policy communities. It next summarizes the regulatory policy preferences of key groups of policy community actors to reveal the degree to which their preferences have been included or excluded during policy making. To permit a description of the policy networks arising around the issues of environmental release, food safety assessment, and labelling, two broad indicators are examined. These indicators are: first, the capacity and autonomy of key sectoral state actors; and second, the level of organizational development of societal interests active in the policy community. Given the high degree of overlapping membership across the three policy networks in each country, these indicators need only be examined once for the entire policy community. The chapter concludes by comparing the six policy networks that have arisen across the two countries on the issues of environmental release, food safety, and labelling.

[1] Kenis and Schneider (1991).

EVOLVING POLICY COMMUNITIES

Policy communities surrounding the regulation of plant biotechnology emerged in both countries in the early to mid-1980s.[2] A policy community includes:

> all actors or potential actors with a direct or indirect interest in a policy area or function who share a common 'policy focus' and who, with varying degrees of influence, shape policy outcomes over the long run.[3]

Regulation of agricultural biotechnology became distinct from the 1970s issue of regulating research in laboratories as research progressed on agricultural applications. The formal recognition of a new policy area by the state often occurs through the creation of one or more institutional mechanisms, such as cabinet minister positions, departments, or special administrative units, to manage it.[4] These new institutional mechanisms confer legitimacy on the new policy area. The need to coordinate regulation of agricultural biotechnology was formally recognized in both countries by the mid-1980s.[5]

Researchers, regulators, and a handful of biotechnology skeptics (including environmentalists) formed the original core of the policy communities in both countries. The new policy community emerged from the intersection of existing agri-food regulation and agricultural research policy communities (see Table 4-1). Evolution has been driven primarily by the changing mix of regulatory issues (see Table 4-2).[6] As new issues arose in the 1990s, including consumer resistance overseas that translated into lost exports and demands for mandatory labelling of all genetically-engineered foods, the policy communities expanded dramatically in both countries. The newer members included a more diverse mix of public interest groups, agricultural producer

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[2] The focus of this study on crop plants excludes those organizations whose focus is solely on animal or other non-plant applications. This split reflects the traditional division of disciplines in agricultural science. For both research and regulatory purposes, these divisions are largely maintained in biotechnology applications.

[3] Coleman and Skogstad (1990b): 25-26.

[4] Knoke et al. (1996): 9.

[5] For example, Agriculture Canada established a Biotechnology Working Group in 1987 within its regulatory branch, while the USDA established its Office of Agricultural Biotechnology (OAB) in 1986. Both institutional structures were intended to improve internal coordination on biotechnology policy, including regulation. See United States. Department of Agriculture (1986) for a description of the OAB's mandate and duties.

[6] The central importance of issues in shaping the evolution of plant biotechnology regulation policy communities to date suggests that this influence will continue. Much of the first wave of genetically-engineered plants, developed in the 1990s, was engineered to carry novel agronomic traits such as herbicide tolerance and insect resistance. Into the next century, researchers expect to commercialize plants that will produce pharmaceuticals, plastics, or other products normally produced in labs; and plants that will perform novel functions such as extracting toxic wastes from soil. The next waves of genetically-engineered products are likely to continue to create new and more complex issues, which will likely attract the interest of other organizations and individuals.

associations, and agri-food associations.

Plant biotechnology industry

As Chapter Two has outlined, the public sector has made an important contribution to the development of the plant biotechnology industry in both countries. However, from the 1980s on, the private sector has played a dominant role in the US and a growing role in Canada.[7] Further, closer links between public and private sectors in the 1980s and 1990s through research partnerships and other means have blurred the traditional division that once existed, especially in Canada. The current oligopolistic structure of the crop plant biotechnology industry has been achieved by a breathtaking series of acquisitions and mergers (see Table 4-3). In the late 1990s, a handful of large firms dominated the industry globally: AgrEvo, Dow AgroSciences (Dow Chemical Company), DuPont, Monsanto, and Novartis Seeds (Novartis) (see Table 4-4). All but AgrEvo and Novartis were based in the US. In the 1990s, each of these firms increased its commitment to the "life sciences", driven by the potential of genetic engineering. This heightened focus on life sciences, which often includes a focus on biopharmaceuticals, has been accomplished through a mix of methods. These methods have included creating new firms through joint ventures or mergers (AgrEvo, Novartis), spinning or selling off other business lines (DuPont, Monsanto), and acquiring part or all of major seed companies and smaller plant biotechnology companies (AgrEvo, Dow AgroSciences, DuPont, Monsanto). Each country also has several tiny firms working away in obscurity, overshadowed by these life sciences giants. that often become widely known only when they are bought up or linked up with the bigger players.

[7] For example, private investment in biotechnology research in the agri-food sector in Canada more than doubled between 1989 and 1995, reaching $35.9-million (Cdn). Canada. Statistics Canada (1997a). Beyond the investment of multinational firms such as Monsanto and AgrEvo, the Saskatchewan Wheat Pool was likely the largest Canadian organization involved in plant biotechnology research in the late 1990s. Most of the other Canadian firms are much smaller. Several have aligned themselves with or been bought up by larger firms during the last decade, including Performance Plants, Biotechnica, and Allelix Crop Technologies. For example, in September 1998, Performance Plants, a small firm begun by a group of scientists from Queen's University in Ontario, established a research and marketing alliance with Dow AgroSciences.

Plant biotechnology and the agri-food industry

The arrival of plant biotechnology has affected each link in the agri-food industry. Seed and agri-chemical firms have become virtually synonymous. Producers have had to assess the agronomic performance and economic returns promised by the new products, while hoping that processors and consumers will embrace them. Processors and retailers are intrigued by the potential genetic engineering offers to enhance nutritional and other qualities of food. For all of these links in the agri-food industry, regulation plays an important role in determining the supply of and demand for these products, in part by contributing to consumer acceptance.

Plant biotechnology is also contributing to structural change in the agri-food industry by reconfiguring relationships.[8] Most notably, it is drawing the links in the industry closer together--in part through more formal, contractual arrangements. For example, the potential to provide plant varieties with specific traits creates incentives for "identity-preservation" (IP) growing arrangements in which producers contract with their customers to grow a specific variety and keep it segregated.[9] Producers are also signing more contractual agreements with their input suppliers. Some firms, including Monsanto, have asked producers to sign "technology use agreements" which are intended to protect the firm's investment in technology and place various obligations on producers that may include, for example, on-farm inspections.

Through plant biotechnology, the business interests of agricultural chemical and seed firms are becoming intertwined. Large agri-chemical firms have become significant developers and suppliers of genetically-engineered plant varieties, aided by their acquisition of seed companies and smaller plant biotechnology companies. In 1997, the largest seed firms in the world, in terms of their revenue, were Pioneer Hi-Bred (an American seed firm now owned by DuPont), Monsanto, and Novartis.[10] Beyond their financial consolidation and their links through associational systems,

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[8] For a description of increasing concentration in the American agri-food industry and the argument that biotechnology is contributing to the formation of a few "clusters" of firms that dominate the industry, see Heffernan (1999).

[9] The growing use of IP arrangements has been encouraged by delays in regulatory approvals for genetically-engineered plant varieties in major markets and by the practices of food firms such as Quaker Oats and Frito-Lay who seek a guaranteed supply of high quality commodities. These arrangements sometimes cut out large "middlemen" companies such as Cargill, when large food processing firms deal with agricultural producers directly. Bill Leask of the Canadian Seed Trade Association calls this development the "third wave" of the evolution of the seed industry. See Canadian Seed Trade Association (1995) for a summary of his description of this trend and its implications for the industry.

[10] Rural Advancement Foundation International (1998).

plant biotechnology and seed firms such as Monsanto, Pioneer Hi-Bred, DeKalb Genetics, DuPont, Mycogen, Calgene, and AgrEvo also have been drawn into a tight web of technological interdependence. Complex interlinkages are now common, either by working together on a project or licensing technology. They are also often unavoidable when one firm holds exclusive rights to an important process or gene, such as Monsanto's Roundup Ready gene.

Given the central role of their members in first using and later selling the products of agricultural biotechnology, it may be surprising that agricultural producer associations were generally not active in the agricultural biotechnology regulation policy communities until the mid-1990s, Representatives of these associations explain that there was initially no apparent need for significant involvement. Those who were more active in the policy community, including plant biotechnology firms and regulators, reassured producer associations that adequate regulatory safeguards were in place or would be in place in time for commercialization.[11] For several producer associations, the perception that regulations were "science-based" meant there was nothing to worry about. Genetic engineering was simply the latest wave of innovation in agriculture and producers were content to sit cheerfully on the sidelines as they often had in the past during introductions of new technologies. The unhappy realization that some of their important export markets, notably Japan and some European countries, could and have refused genetically-engineered crops has fuelled their interest.[12]

For food industry associations in Canada and the US, the commercialization of genetically-engineered plants was not initially considered to be a major issue, coming after the introduction of genetically-engineered microorganisms which were already in widespread use to produce various foods, including cheese. These associations have consistently kept an eye on efforts to regulate new food technologies of potential benefit to their members, such as irradiation. Their involvement in the policy communities has intensified during development of food safety

[11] Personal interviews, 1998.

[12] For example, because half of the Canadian acreage of canola in 1998 was in genetically-engineered varieties, European markets have been lost at least temporarily until these varieties are approved in Europe. Exports of canola to the European Union, which reached $424-million (Cdn) in 1994--a third of all canola exports that year--had dropped to $2-million by 1998. The degree of consumer resistance in Europe during the mid- and late 1990s appears to have been largely unanticipated by agricultural producers. Much of the effort of their associations, in response, has been focused on events at the international level. This focus recognizes that regulatory regimes in export markets may be influenced by international agreements such as the United Nations Biosafety Protocol and the activities of international institutions such as Codex Alimentarius. Commodity associations representing export-reliant producers of crops who have planted substantial acreages of these varieties since the mid-1990s, particularly canola in Canada, and soybeans and corn in the US, have been the most active.

assessment measures and the peaks of the ongoing labelling debate.

Public interest groups

The mix of public interest groups in each policy community has changed somewhat over time as issues have ebbed and flowed.[13] These groups have been most active on the issues of environmental release and labelling. They have been less active on food safety assessment, with the exception of vigorous activity on a single product not examined in this case study: a genetically-engineered synthetic bovine growth hormone that can be injected into cows with the intent of increasing milk production.[14] In Canada, many of the active public interest groups, some of which are otherwise single-issue or regional in scope, have worked together through the Canadian Environmental Network's (CEN) biotechnology caucus.[15] In the US, the Biotechnology Working Group (BWG), which existed for about a decade and was wound up in 1998, performed a similar function.[16]

Much of the activity carried on under the banner of public interest groups has been led by a small core of dedicated individuals.[17] Canada's Brewster Kneen, for example, has worked on agricultural biotechnology issues for several years. He has been allied with the Canadian Environmental Network's biotechnology caucus and the Toronto Food Policy Council.[18] Kneen is probably Canada's closest equivalent to the American activist Jeremy Rifkin--the most well-known skeptic of genetic engineering in the US. Rifkin created the Foundation on Economic Trends

[13] The height of involvement came during the late 1980s and early 1990s, although it was growing again in the late 1990s. Since the mid-1990s, a few individuals and groups have played a leadership role within the public interest group community, while others have become passive, interested observers.

[14] The Environmental Defense Fund, the Union of Concerned Scientists, and the Consumer Policy Institute of the Consumers Union, all in the US, have followed food safety assessment decisions. The Canadian Institute of Environmental Law and Policy has supported calls for mandatory labelling. A somewhat unusual member of Canadian and American policy communities--the Natural Law Party, a political party active in various countries over the last several years that advocates meditation--has taken a keen interest in the food safety and labelling issues. Their campaign in Canada is called the "Consumers Right to Know Campaign".

[15] In 1996, more than eighty organizations belonged to the CEN biotechnology caucus, ranging from the more well-known Canadian Labour Congress, the Council of Canadians, the National Farmers Union, and the Sierra Club, to the more obscure Citizens for Renewable Energy (Ontario), the Environmentally Sound Packaging Coalition (British Columbia), and the Stop Incineration United in Yards Anywhere (Ontario).

[16] Members of the BWG included consumer, environmental, labour, and religious organizations.

[17] In Canada, these individuals include Brewster Kneen, Burkhard Mausberg, and more recently Mark Winfield; in the US, they include Jeremy Rifkin and his one-time colleague Andrew Kimbrell, Margaret Mellon, Jane Rissler, Michael Hansen, and Rebecca Goldburg.

[18] Kneen publishes *The Ram's Horn*, a monthly newsletter that takes a skeptical look at developments in the industrial agri-food sector, and published a book on agricultural biotechnology, titled *Farmageddon*, in 1999.

(FET) in 1977 for the express purpose of scrutinizing the development of genetic engineering.[19] In the US, Margaret Mellon has worked on agricultural biotechnology issues since the mid-1980s, at the Environmental Law Institute, the National Wildlife Federation, and most recently the Union of Concerned Scientists (UCS).[20] Rebecca Goldburg of the Environmental Defense Fund and Michael Hansen of the Consumer Policy Institute (CPI) of Consumers Union have both been active since the late 1980s.[21]

POLICY PREFERENCES

Comparing policy preferences against policy choices is a first step in assessing which policy community members appear tp have had more success in influencing policy choices. It must also be noted that congruence between preferences and choices does not automatically permit a conclusion of direct causality. As others have observed, summarizing the policy preferences of key actors can be tricky.[22] The assumption can be made that each actor's top priority is to maximize his/her own economic gain and other tangible benefits. Skeptics of public interest groups suggest that even these seemingly altruistic actors have their self-interest at heart, waging campaigns to ensure a steady stream of donations and funding. For those who believe that the motivation driving policy actors is often a complex mix of deeply-held values, the political and economic context, and enlightened self-interest, a favoured option may be to interview actors and identify their preferences through their statements. The policy preferences displayed below in Table 4-5 have been gathered from interviews, public documents, statements in media reports, and

[19] Rifkin uses his books, including *Who Should Play God* (1977), *Algeny* (1983), and most recently *The Biotech Century* (1998), litigation, and public speaking tours to broadcast his message. One of Rifkin's colleagues, Andrew Kimbrell, recently left FET to lead the International Center for Technology Assessment (CTA). The CTA is administering the lawsuit launched in 1998 against the Food and Drug Administration on its safety assessment policy for GE food, and is involved in the 1997 lawsuit against the EPA on Bt crops.

[20] Mellon, who has done work in molecular virology and has a doctorate in biology as well as a law degree, works at UCS with Jane Rissler who has a background in plant pathology. At the UCS, Mellon and Rissler have submitted several briefs to American regulatory agencies on genetically-engineered plants. They have also published books on these issues, including Rissler and Mellon (1996).

[21] In the early days, another prominent individual was Jack Doyle of the Environmental Policy Institute (EPI). Doyle's book, *Altered Harvest*, included an examination of the impact of genetic engineering on American agriculture. Doyle is no longer active and EPI has since merged with Friends of the Earth. For the book, see Doyle (1985).

[22] Knoke et al. (1996): 78-80. Pontusson suggests drawing a distinction between policy preferences and "interests" of actors, with preferences as the means to secure interests. See Pontusson (1995): 136 . In this discussion, the two are both treated as policy preferences.

committee testimony, and thus avoid the bias of an outside observer.[23] The discussion that follows blends these stated preferences with those objective interests actors would be expected to pursue.

Policy community members are grouped into broad categories to reduce the detail involved in discussing policy preferences. Important differences of opinion within these groups will be noted, where they exist. Table 4-5 summarizes policy preferences of representative policy community members on key aspects of regulation, including basic principles, the role of science, sensitivity to economic internationalization, and labelling. The table illustrates at a glance both the relatively high degree of consensus among the majority of policy community members and the polarization in policy preferences. Very few policy community members have stated policy preferences that fall on both the "A" and "B" side of the table. Those that do tend to be public interest groups and have in-house scientific expertise. Accompanying this congruence in policy preferences is the tendency for members to use the same phrases and concepts, such as "sound science" and "harmonization", in expressing their preferences. The majority of policy community members have expressed their policy preferences in the vague language of broad guiding principles. Very few (including researchers, Greenpeace, the Environmental Defense Fund, and the Union of Concerned Scientists), have presented detailed technical recommendations or criticisms.

Agricultural Researchers / Biotechnology Developers

Individual researchers from both the private and public sector have been active in the policy communities since the earliest days of regulatory development.[24] A few of the large biotechnology developer firms have been the most visible actors.[25] There are varying opinions

[23] As well, during interviews, information on policy preferences was obtained by asking open-ended questions rather than asking individuals to comment on a series of specific preferences.

[24] There are some important distinctions between public and private sector researchers. The interests of public sector researchers are often represented by the individuals themselves and rarely by a formal organization. Individual public sector researchers are more likely to be viewed as independent experts. In contrast, the interests of private sector researchers are largely subsumed under the interests of their employers--plant biotechnology firms. Public and private sector researchers clearly have some interests in common--particularly their objective of ensuring that regulation does not impede research unduly. It is not uncommon for individual researchers to work in both public and private sectors, although many spend their entire career in one sector.

[25] Large firms including AgrEvo, DuPont, and Monsanto have expressed their policy preferences both on their own and through various industry associations. DuPont's activities appear to have been restricted to the US through the 1990s, while AgrEvo has been more active in Canada. Other firms such as Dow AgroSciences and Novartis have kept a lower profile. Representatives of smaller firms such as Agracetus and Calgene, as well as the large firms, have testified at US committee hearings. Most of these smaller firms are now aligned or part of the larger firms.

about the environmental and human health risks posed by genetically-engineered plants. Many have argued the risks are negligible for most products developed to date and rarely greater than those with conventionally-produced varieties. For these individuals and organizations, the risks of genetically-engineered plants did not warrant a distinct regulatory response. However, once it became evident that some regulatory response was forthcoming, the top priority has generally been to ensure regulation does not unduly impede the progress or commercialization of research, or limit the choice of research projects. A related priority, pursued by developer firms in particular, has been to secure efficient regulatory regimes that smooth the path toward commercialization by providing consumer acceptance. The incentives for involvement may be greater for such firms than for public sector researchers since their need for profitability requires successful commercialization of their products.

For example, when Monsanto made its decision to invest in plant biotechnology in the late 1970s, it realized that there could be controversy.[26] It worked proactively to encourage regulators to develop a regulatory framework and called on other firms to do likewise. Particularly in Canada, where a private sector biotechnology association was created only in 1987, Monsanto found itself almost alone among biotechnology developers in its regulatory efforts in the early and mid-1980s. In contrast, public sector researchers have generally been less visible. They have provided expert advice by testifying at committee hearings, sitting on advisory committees, and reviewing regulatory proposals. In Canada in particular, where much of the expertise in plant biotechnology was found within the public sector in the early days of regulatory development, some public sector researchers were periodically called on to provide advice.

Among agricultural researchers and developer firms, there appears to have been general consensus on the fundamental principles that should guide regulatory development through the 1980s and 1990s. There has been agreement that regulation should be based on existing legislation and institutional arrangements rather than creating new ones focused exclusively on genetic

[26] Personal interview, February 1998.

engineering.[27] This preference is based on the beliefs that first, existing measures would provide a more efficient path to commercialization and second, that biotechnology is too wide an application to be well-regulated by a single entity. There has also been strong support for regulation designed with built-in flexibility to respond to the accumulation of knowledge about the risks of products.

There has been some disagreement on whether regulation should be "product-based", which means focusing on the characteristics of the product and the risks they may pose, or "process-based" which singles out the use of genetic engineering and the risks it may bring.[28] Researchers interviewed believe that most of their colleagues support a product-based approach rather than a process-based approach that would draw attention to the use of genetic engineering.[29] However, some have opposed a product-based approach, concerned that it might greatly expand the scope of regulation and bring older products under heightened scrutiny. At least one firm wanted it both ways to reduce the scope of regulation. In the early 1990s, Allelix Crop Technologies, a small Canadian plant biotechnology firm acquired by Pioneer Hi-Bred in 1990, stated its preference for a product-based approach but also argued that only genetically-engineered plants should be regulated. It did not want plants produced through mutagenesis, for example, to be regulated.[30]

Differences of opinion have usually been quickly replaced by consensus. For example, in the early to mid-1980s, before the final Coordinated Framework which delegated authority was released in the US, there was some debate over which agency was best suited to regulate

[27] One major difference of opinion has been about the wisdom of creating specific regulatory measures to govern the use and products of genetic engineering, especially new plant varieties. This difference was largely between larger developer firms, who tended to prefer specific regulations and who were accustomed to dealing with regulatory paperwork and safety assessments for other products such as pesticides and pharmaceuticals; and public sector researchers who were not so accustomed and did not see a need for special measures. DuPont initially stated, in 1983, that no new legislation or regulation would be necessary beyond the existing NIH lab safety guidelines and the decentralized system of Institutional Biosafety Committees. See United States. House Committee on Science and Technology. Subcommittee on Investigations and Oversight (1983). Increasingly over time, however, the larger developer firms came to agree that regulation was an important tool. For example, AAFC reported that during consultations, several firms expressed great concern about the lack of regulations on environmental assessments for genetically-engineered products which they believed was hindering their competitiveness. Canada. Minister of Public Works and Government Services Canada (1997).

[28] This distinction is rather artificial and more of a rhetorical device, given that current regulatory regimes tend to focus attention on the process of genetic engineering and often include a consideration of the process used in safety assessments. This point is discussed further in Chapter Five.

[29] A 1995 survey of 1,257 researchers in the US working on rDNA projects found that only 11 per cent supported a process-based approach. Rabino (1996).

[30] The technique of mutagenesis, which normally involves using radiation or chemicals to alter traits, has been used for several decades. For Allelix's position, see Kneen (1992): 165.

genetically-engineered organisms.[31] Initially, some of the firms which had a history of working with the Environmental Protection Agency (EPA) supported the idea of giving the agency the responsibility for regulating the release of genetically-engineered organisms, in part because they believed this would be the fastest route to commercialization. However, the academic agricultural science community expressed doubts about using the "chemical paradigm" behind regulation of inert toxic substances to regulate living products. It felt that the USDA and its supporting network of expertise was better equipped to handle the task. Ultimately, the 1986 Coordinated Framework document handed USDA primary responsibility for most genetically-engineered plants and EPA primary responsibility for most genetically-engineered microorganisms

Clashes of opinion within the plant biotechnology industry continue to surface from time to time. For example, in February 1997, Novartis announced its intention to label its genetically-engineered plant products and its support for the consumer's "right to choose"--a position not supported by many of its competitors.[32] Another rift in the industry emerged in November 1997, when the seed firm Pioneer Hi-Bred announced publicly its decision not to carry Monsanto's Roundup herbicide tolerance gene in corn because of the restrictive terms set by Monsanto, despite more than two years of negotiation.[33]

Representatives of the plant biotechnology industry and national biotechnology associations had few complaints in the late 1990s about the Canadian and American regulatory regimes.[34] Their priority instead has been to influence the development of regulatory regimes elsewhere and promote harmonization. In June 1998, for example, Monsanto president Hendrik Verfaillie called for a single international regulatory policy on genetically-engineered food in order to "avoid trade

[31] Personal interview, USDA officials, October 1998.
[32] Reuters Newswire, America Online, Feb. 24, 1997
[33] Pioneer stated that it could not accept Monsanto's terms which would have included charging producers a "substantial" technology fee and which would allow Monsanto to determine which additional traits could be included in the herbicide tolerant hybrids and how much to charge for them. Pioneer suggested that Monsanto's demands would limit the "number of traits, genes, and technologies" that Pioneer would be able to provide to its clients. The press release was titled "Pioneer announces decision on herbicide resistance in corn" and released November 13,1997.
[34] Personal interviews, 1998. A 1995 survey of 1,257 researchers in the US working on rDNA projects found that 62 per cent oppose mandatory labelling of genetically-engineered foods, while 33 per cent favour it. Sixty-two per cent supported the statement that scientists should develop products, like Bt crops, even if they could involve risks if misused, but 64 per cent also say that publicly-funded researchers should be legally obligated to consider the potential environmental risks of their research. Rabino (1998).

impasses that could hinder global food security."[35] In the US, the Biotechnology Industry Organization (BIO) aimed its sole criticism of the domestic regulatory regime in 1998 at the EPA's efforts to regulate Bt crop plants.[36] The Canadian biotechnology industry association, BIOTECanada, has described the Canadian regulatory regime as very pragmatic and providing adequate flexibility. It has suggested that Canadian regulators could streamline their regulatory process by reevaluating whether the questions they are asking are necessary as new scientific information becomes available. It would also like Canadian regulators to consider accepting data packages from other countries for issues such as food safety that are not related to geographical context.

Canadian public sector researchers are relatively satisfied, but also express hopes that regulation will be streamlined and relaxed over time.[37] The regulatory regime is seen as overly cautious, but it is also recognized that, compared to other countries, it is efficient and is allowing commercialization. The Canadian regime is seen to be largely science-based. What are perceived as excessive information requirements tend to be attributed to "political" considerations such as public perception. Their American counterparts also appear to be satisfied. A 1995 survey found that more than half of the researchers surveyed who were working in government or academia rated the USDA and FDA's efforts at regulating rDNA products generally as good or excellent.[38]

Agricultural producer associations

Most agricultural producer associations in both countries endorsed the idea of genetically-engineered plant varieties through the 1980s and into the 1990s--some with more enthusiasm than others. Their policy-related concerns have been focused primarily on the contribution of biotechnology to competitiveness and more recently on protecting market access.[39] They have generally been passive observers of regulatory development. Beyond their detailed interest in

[35] Le Gras (1998).

[36] BIO has no complaints about the USDA or the FDA. It would like to see the regulatory process move more quickly but sees no "major disastrous flaws" in the American regulatory regime. Personal interview, October 1998.

[37] Personal interviews, 1998.

[38] They do grumble about inefficiency, insufficient expertise, and lack of clarity, but only 12 per cent of researchers felt that the shortcomings of US regulatory agencies were sufficient to provide an advantage to competitors elsewhere. Rabino (1996).

[39] Associations that have a mandate to increase export sales, such as the Canada Grains Council and the US Grains Council, took a keen interest in the biosafety protocol negotiations which in the late 1990s were perceived as a serious threat to grain exports.

market access issues, producer associations have generally kept their policy preferences focused on broad principles. They have aligned themselves with plant biotechnology firms and food industry associations.

Canada's major producer federation, the Canadian Federation of Agriculture (CFA), has endorsed agricultural biotechnology although with a note of caution sparked by concerns about increased input costs. CFA members have a long history of adopting new technologies. Genetic engineering has been viewed, at least initially, as yet another new technology.[40] Its members place much confidence in the Canadian regulatory system and are comfortable with deferring to regulators on risk assessment of new technologies.[41] The CFA sees the products of genetic engineering as providing useful new tools that will help to maintain competitiveness. In 1993, for example, the CFA's president stated that the federation's members wanted to be first globally with biotechnology products so to take advantage of markets for them and called for a regulatory system in conformity with international rules.[42] At the same time, he underlined the importance of public confidence in the safety of biotechnology products and keeping input costs reasonable for producers. The CFA also worried that if Canada said "no" to biotechnology, it would be developed and used elsewhere. The American Farm Bureau Federation (AFBF) has taken a position very similar to that of the CFA. It has supported the use of biotechnology in agriculture, although there is concern about the degree of concentration in the plant biotechnology industry.[43] In 1997, the AFBF president outlined the federation's views on biotechnology and its support for the domestic regulatory regime, noting that:

> International acceptance and movement must be assured as approved biotech products become more common. Science is science. *When the scientific community approves a product, that should be the end of the discussion.* A product should be able to move through trade channels without facing pseudo-scientific barriers or charges of imaginary health dangers.[44]

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[40] In fact, CFA members generally took a while to understand why consumer resistance to genetically-engineered foods has arisen because they are accustomed to using new varieties, such as hybrids, and do not see genetically-engineered plants as much different. Personal interview, July 1998.

[41] CFA also sees support for biotechnology as helping it to meet client demands and important in maintaining a strong agricultural research base in Canada. It also has a strong preference for seeing AAFC / CFIA maintain responsibility for regulating agricultural inputs, rather than dealing with Environment Canada as would have occurred if responsibility had been placed under the *Canadian Environmental Protection Act.*

[42] Canada. Agriculture and Agri-Food Canada, Health Canada, and Environment Canada (1993): 17.

[43] Personal interview, November 1998.

[44] The date of this statement is March 3, 1997. The column can be found at http://www.fb.com/news/fn1997/fn0303.html. Italics are added to the original.

Commodity associations representing export-reliant producers, including the Canola Council of Canada, the American Soybean Association (ASA), and the National Corn Growers Association (US) have been among the most enthusiastic proponents of genetically-engineered plant varieties, given the potential for novel traits. Their policy preferences and concerns have not diverged much from those of the CFA and the AFBF, except that their members have been on the frontline of market access battles. These market access troubles disrupted the tacit alliance between plant biotechnology firms and their initially eager customers from the mid-1990s on.[45] Further, commodity associations have become increasingly annoyed that regulators seem unwilling or unable to take measures that would avoid market access problems.

In the late 1990s, several commodity associations began to adopt a more defensive posture toward genetically-engineered plant varieties. There is concern about whether producers will cooperate to ensure these varieties do not enter export markets, should the need arise.[46] Problems with market access have also encouraged some associations, including the ASA and the Canola Council of Canada (CCC), to search for a way to include export market approval in existing regulatory regimes as a prerequisite for commercialization of genetically-engineered plants. The CCC explored various options in the late 1990s, such as making variety registration contingent on regulatory approvals in major markets.[47] Meanwhile, in 1995-96, when the ASA realized that plant biotechnology firms were selling producers soybean varieties that had not yet secured regulatory approval in major export markets, it became "sensitized to the risks of not being proactive".[48] The ASA asked the USDA to help warn producers that exports might be jeopardized. The USDA's refusal led the ASA to put out grower advisories by itself. In 1997-98, the ASA became even more proactive. It sent a letter to plant biotechnology developer firms that outlined its desired conditions for commercialization. It requested that varieties not be commercialized until

[45] Commodity association representatives complained in the late 1990s that the plant biotechnology firms were not always helpful, and some refused to provide any assistance in assuring segregation of varieties, perhaps because of a fear of liability.

[46] Interviews suggest that a few associations and their producers are more interested in using the new varieties and reaping their perceived benefits than worrying about trade issues. For example, in the US, the soybean associations are more cautious than the corn associations, reflecting the relative dependence on export markets. In 1996, 37 per cent of the soybean crop was exported compared to 19 per cent of the corn crop.

[47] *The Western Producer* (1999), and personal interview, September 1998. In early 1999, the Canadian committee that evaluates new canola and rapeseed varieties voted to ask the federal government to amend the *Seeds Act* to incorporate sensitivity to approvals in export markets. The Canadian Wheat Board called for similar measures in October 1999 for genetically-engineered wheat and barley.

[48] Personal interview, October 1998.

approvals were in place in all major soybean markets and that if such approvals were not in place, these firms ensure that soybeans did not enter export channels and thus jeopardize exports.[49]

In both countries, there are also some agricultural producer associations that are more skeptical about biotechnology. In Canada, the National Farmers Union has expressed concerns about biotechnology's link to rising input prices and increased corporate and multinational control of the agri-food industry. Some of its members have adopted genetically-engineered varieties, but association staff also began to hear more in the late 1990s from worried and dissatisfied producers. In the US, the National Family Farm Coalition has expressed general concerns and signed on to the 1997 Greenpeace-led petition calling on EPA to reconsider approval of Bt crops.[50] Finally, organic producers in both countries began to monitor the use and regulation of genetically-engineered plants much more closely in the late 1990s. There is considerable support within the organic movement to exclude genetically-engineered organisms from the definition of organic.[51] Organic producers worry, for example, that their organic crops may be contaminated by pollen from genetically-engineered varieties in neighbouring fields. Such incidents have been reported, but there were no provisions in either country as of the late 1990s to inform organic producers whether genetically-engineered varieties were being cultivated nearby.

Like agricultural producers, the mainstream food processing and retailing industry in Canada and the US has generally taken a passive recipient approach to the use of genetically-engineered plants in food. Through its associations, it has been supportive of new biotechnology foods. It has also been aware of the importance of consumer acceptance and the role of regulation in securing that acceptance. Major food industry associations, including the Food and Consumer Product Manufacturers of Canada, the National Food Processors Association (US), and the Grocery Manufacturers of America generally support their domestic regulatory regimes. In Canada, some frustration has been expressed over the delay in finalizing both food safety assessment and labelling measures, which has been blamed largely on the use of multistakeholder

[49] In 1998, AgrEvo announced that it was working with the ASA on this issue, and would withhold a variety from commercialization for a year as a result. ASA reports that this strategy has helped to avoid problems so far, although it anticipates continuing this strategy until market access problems are resolved.

[50] The National Family Farm Coalition is a relatively new organization, established in 1986, to bring together grassroots organizations whose goal is to preserve and strengthen family farms.

[51] For example, a 1998 USDA proposal for national organic standards that would have not have explicitly excluded genetically-engineered foods sparked 280,000 protest letters, in part because of opposition to this aspect of the proposal. USDA withdrew the proposal.

consultations. One food industry association representative stated bluntly that "we would rather have a date for an outcome than a decision in our favour".[52]

Public Interest Groups[53]
Consumers

As the final link in the agri-food chain, consumers have had a mixed set of reactions to biotechnology foods, from uninformed or informed acceptance and apathy, to skepticism and rejection.[54] On their behalf, the major Canadian and American consumer organizations have become involved in the debate. The expressed policy preferences of the national wing of the Consumers' Association of Canada (CAC) and its endorsement of the Canadian regulatory regime places it virtually in opposition to the preferences put forward by the research institute of the major American consumer organization, Consumers Union, and the international consumers' group, Consumers International. Within CAC, however, there have been divisions of opinion. Some of the provincial organizations have expressed much more skepticism about biotechnology than Chris Mitchler, the volunteer Chair of the National Food Committee (CAC-NFC), who acted as a major spokesperson throughout much of the 1990s. One significant division within the CAC comes over labelling policy. The CAC-NFC has aligned itself with the agri-food industry position of labelling only for health and safety purposes while some provincial groups, such as the Quebec wing, want mandatory labelling.[55] The CAC-NFC has described mandatory labelling as a "problematic and impractical way" to meet the consumer's "need to know" when it comes to genetic engineering.

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[52] Personal interview, July 1998.

[53] The Natural Law Party, which is a political party, is included here under the category of public interest group since it often finds itself aligned with these groups in terms of its policy preferences. Some of the party's supporters have called for mandatory labelling and a fifty-year moratorium on genetically-engineered foods until long-term effects are known. These individuals believe that consumption of these foods could potentially result in the creation of new diseases, toxins and allergens through "unnatural gene transfer" between species, and transfer dangerous diseases across species barriers. The Natural Law Party has not minced words when expressing concerns, suggesting in a pamphlet that "the entire population is in a dangerous global experiment in the interests of short-term commercial gain by giant transnational biotech companies".

[54] There is, of course, no completely accurate measurement of consumer opinion on the commercialization of genetically-engineered plants. Many public opinion surveys and focus groups have been conducted; often with differing questions and goals and sometimes with differing results. See Appendix.

[55] This division, a CAC representative said, is responsible for the vague language in its 1994 policy statement on regulation of agricultural biotechnology, which hardly takes a position beyond very broad principles. For example, the statement says: "The principal objectives of biotechnology regulations must be to ensure human health and safety, environmental protection, and product quality and value." Consumers' Association of Canada (1994). See Consumers' Association of Canada (1996) for an overview of CAC's position.

CAC-NFC's position is well-represented in this 1996 excerpt:

> Some groups have indicated that ethical and social concerns, in addition to health and safety and environmental concerns, must also be mandatory on a label. It is our understanding that no other product is required by regulation to justify its existence on moral, ethical and other grounds. In addition, it is difficult to see how such information could be conveyed on a label....If the end product is exactly the same as its conventionally grown counterpart in terms of its composition and attributes, does the consumer need to know through a mandatory label how it was grown? Do consumers ask how other food products were produced, such as how beefsteak tomatoes are bred and grown? Provided the product is safe to humans, animals and the environment, and has tangible benefits to the consumer who buys it, will the consumer care how it was produced?[56]

The CAC-NFC has argued that mandatory labelling would be meaningless, given predictions that genetically-engineered food will be integrated into the agri-food system in such a pervasive way.[57] In contrast, the Consumer Policy Institute within the Consumers Union supports premarket notification and testing, and mandatory labelling of genetically-engineered food, although it is not opposed to the use of genetic engineering per se. Unlike the CAC, the Consumers Union has presented detailed, technical policy papers on these issues to regulators within FDA, EPA, and USDA.

Environmental groups

In Canada, environmental groups have expressed several distinct policy preferences and have channelled them largely through the Canadian Environmental Network's biotechnology caucus.[58] Not all are opposed to genetic engineering across the board, but they generally support calls for a more stringent regulatory regime that is far more precautionary. Their preferences have included: shifting the onus for proving the safety of biotechnology products to their developers; broadening environmental assessments to include criteria such as the potential effectiveness of the

[56] Consumers' Association of Canada (1996): 4-5

[57] The CAC-NFC has stated that labelling is only one of a set of potential communication tools for educating consumers about genetically-engineered food. It recommends the use of other methods such as point-of-purchase information, and 1-800 numbers--an argument common among biotechnology proponents. It has also argued that a logo notifying the consumer of the presence of ingredients resulting from genetic engineering would not provide sufficient information and would simply confuse consumers, even to the point of distracting them from other more important labelling information.

[58] Individual groups and representatives of the CEN biotechnology caucus have expressed their views at legislative committee hearings and multistakeholder consultations. For example, a document titled *For Whose Future?: A Response to the Proposals of the Government of Canada on the Regulation of Biotechnology under the Canadian Environmental Protection Act* was prepared for the caucus in March 1996 by Mark Winfield of CIELAP and Brewster Kneen.

product and the availability of alternative means of achieving the product's purpose which have a lower likelihood of harming the environment or human health; increasing public notification and opportunities for public comment during regulatory decision making; improved access to information including a database documenting all environmental releases of biotechnology products in Canada; extending the scope of the *Canadian Environmental Protection Act* to all biotechnology products; and full cost recovery of the costs to regulators of commercialization. Most of these groups also support mandatory labelling of all genetically-engineered foods. Underlying much of this concern are broader questions about the distribution of costs and benefits of the technology and the perception that regulatory approval is being rushed, "stampeded by the ideological rubric of competition".[59]

In the US, members of the Biotechnology Working Group (BWG), which folded in 1998, also generally agreed on policy preferences such as premarket notification and testing for genetically-engineered foods, a more precautionary approach to environmental release, and mandatory labelling. The key division was among those groups which were fundamentally opposed to genetic engineering and those which were not. Within the BWG, some groups and projects have focused on specific issues.[60] The Environmental Defense Fund (EDF) and the Union of Concerned Scientists (UCS) are probably the two environmental organizations that have been the most consistently active on biotechnology regulation from the mid-1980s through the 1990s. Both organizations have commented on the adequacy of regulatory measures for environmental release, food safety, and labelling. For example, EDF argued through much of the 1990s that the FDA's food safety policy was failing to protect consumers adequately, particularly from the risks of new allergens. It has stated that the 1992 policy weakens significantly the requirements on industry to demonstrate the safety of substances added to the food supply by genetic engineering in comparison to regulatory requirements for chemical food additives. More recently, on the issue of environmental release, the EDF petitioned the EPA in July 1999 to require specific management measures to reduce the development of Bt resistance expected as a result of the widespread cultivation of Bt crops.

[59] This quote comes from Brewster Kneen, during the 1993 multistakeholder consultation. Canada. Agriculture and Agri-Food Canada, Health Canada, and Environment Canada (1993): 28-29.

[60] For example, in 1990, the BWG published a book expressing concerns about herbicide-tolerant crops. Among other measures, it recommended ending public funding for the development of such crops while increasing funding for other, non-chemical methods of pest control. Goldburg (1990).

Like the EDF, the UCS is not opposed to genetic engineering per se, but does have serious reservations about some agricultural applications.[61] It would like to see much more research on the risks and benefits of genetically-engineered plants prior to commercialization. It believes there is no harm in slowing the current rush to approve new varieties which are not desperately needed. More recently, in the late 1990s, UCS focused its comments on the adequacy of the science behind USDA regulatory decisions.[62] It has argued, for example, that the small scale of field trials does not provide sufficient data to assure the safety of large-scale environmental releases. It also believes that USDA deregulation in the 1990s has been premature since it is "way ahead of the science". It is not opposed in principle, however, to relaxing measures when an adequate scientific basis exists. During the mid-1980s, prior to her arrival at UCS, Margaret Mellon criticized the inadequacy of USDA's existing statutes for the purpose of environmental assessment. She called for a new comprehensive law regulating all environmental releases, reinforcing similar arguments made by the EDF about the need to strengthen and fill gaps in regulatory measures.[63] She pointed out that the *Federal Plant Pest Act*, for example, had no provisions for standardized data gathering and no standards for establishing what constituted an acceptable risk. Prior to the finalization of USDA's new regulations for environmental release, Mellon noted in 1986 that the *Plant Pest Act* and the *Noxious Weed Act*, as remedial statutes, lacked explicit authority to require testing of organisms to determine whether they fell under the definitions of plant pest or noxious weed, which were to be the regulatory triggers allowing the department to take action. Further, the existing language of the statutes referred to organisms that "can" rather than "may"

[61] UCS twins its concerns about agricultural biotechnology with its advocacy of more sustainable agricultural practices. It describes its approach as utilitarian--as weighing benefits against risks, while also considering alternatives. UCS believes that while the risks involved in agricultural applications vary according to product, they include both human health risks (new allergens in food supply, transferring of antibiotic resistance given use of marker genes with this property, and the production of new toxins) and environmental risks (increased weediness, novel gene transfer to wild or weedy relatives, widespread use of herbicide-tolerant crops resulting in accelerated development of herbicide resistance, requiring development of new, perhaps more environmentally harmful herbicides; acceleration of the development of insect resistance through widespread use of pesticides incorporated into plants, such as the Bt crop varieties; unintentional poisoning of wildlife; and creation of new or more harmful viruses).

[62] These concerns are discussed further in Chapter Five.

[63] See U.S. Congress. House Committee on Agriculture. Subcommittee on Department Operations (1991), U.S. Congress. House Committee on Science and Technology. Subcommittee on Investigations and Oversight; Subcommittee on Natural Resources, Agriculture Research, and Environment; Subcommittee on Science, Research, and Technology (1987), U.S. Congress. Senate Committee on Environment and Public Works. Subcommittee on Toxic Substances and Environmental Oversight (1986).

cause injury, which could have easily excluded from USDA's jurisdiction any organisms whose effects on the environment were unknown. As Mellon noted, this flaw would have undercut USDA's ability to establish a thorough pre-release review program.[64]

This brief summary of policy preferences suggests that biotechnology proponents, bolstered by the tacit support of agricultural producers and the agri-food industry, have been more successful than biotechnology skeptics in securing their policy preferences in policy choices. Possible explanations for their success, including the nature of policy networks, the role of science within those policy networks, and the effects of internationalization are explored in subsequent chapters and assessed in the conclusion.

POLICY NETWORK INDICATORS

A policy network, as a relational concept of power, draws attention to the mutual dependency of policy community members and recurring patterns of interaction among them.[65] Coleman and Skogstad define a policy network as "the properties that characterize the relationships among the particular set of actors that forms around an issue of importance to the policy community".[66] The relative power of policy community members is determined by their internal resources and characteristics, including the nature of organization within the state and of associational systems at the sectoral level. The following section discusses and examines indicators of state autonomy and capacity and organizational development of societal actors for members of the plant biotechnology regulation policy communities in Canada and the US.

State autonomy and capacity

State autonomy and capacity can vary across sectors within a single state; the concepts of policy community and policy network facilitate disaggregation to allow for assessment of state actors within a specific sector.[67] The degree of state autonomy can be evaluated by examining the independence that state actors appear to have in conducting policy making, including defining

[64] This problem has presumably been somewhat resolved by the use of the phrase "reason to believe" in regards to plant pest risks in the finalized USDA regulations, which regulators say provides wide scope to assess the risks of genetically-engineered plants.
[65] Knoke et al. (1996) and Smith (1993).
[66] Coleman and Skogstad (1990b): 26.
[67] Coleman and Skogstad (1990b): 15-16

problems and making policy choices. For example, when state actions appear to match the policy preferences of key societal actors closely and consistently, we may suspect a lack of autonomy. State capacity is an important ingredient in state autonomy but is not absolutely necessary and does not guarantee the exercise of autonomy. An autonomous state actor may lack capacity to implement its own policy preferences. State capacity is assessed by examining the degree to which the state has adequate resources to develop and implement policies to achieve policy goals. To provide a relatively detailed assessment of state capacity and the potential for state autonomy, this section examines three categories of indicators: first, institutional characteristics that determine where authority resides and that affect coherence of action; second, the existence and content of institutionalized ideas, such as a clear political mandate and guiding and programmatic ideas that help to shape policy goals and instruments; and third, indicators of capacity that underpin authority, including the adequacy of financial resources, policy instruments, and expertise.[68] All three indicators can contribute to the potential for state autonomy, while institutional characteristics and capacity indicators are most useful in gauging state capacity.

First, institutional characteristics can be assessed by locating the locus of authority and analyzing the coherence of action of state actors. Coherence of action depends somewhat on whether decision making power is concentrated or diffused among state officials. When authority is diffused or overlaps across departments or levels of government, the existence and strength of coordinating interdepartmental or intergovernmental mechanisms may compensate.[69] Coherent and authoritative action is facilitated when a single state actor dominates policy making and can acquire necessary information from societal actors. Coherence is usually enhanced when state actors have internal institutional mechanisms, such as committees or working groups, that encourage interaction and permit longer-term planning. These institutional mechanisms can provide a degree of independence from the demands of societal actors, if it is desired. The lack of such mechanisms may contribute to ad hoc, short-term policy making that is more likely to be vulnerable to political pressures.

Second, when sectoral state actors have a clear vision of their mandates that is underpinned by a well-institutionalized and coherent set of guiding and programmatic ideas, they can use it as

[68] The choice of indicators examined here is largely based on Atkinson and Coleman (1989): 51-53.
[69] Smith et al. (1993) argue for a greater research focus on the contribution of relationships across departments in shaping policy making.

insulation against the demands of societal actors if and when there are differing views between the two. The content of institutionalized ideas is also important. Compatibility between ideas specific to a policy area and the overarching public philosophy of the time may facilitate autonomous action and provide resilience against the challenges of societal actors. When strong political support exists for the state's mandate, the potential for state autonomy is greater. However, when institutionalized ideas are congruent with the interests of key sectoral groups, at least the appearance, if not the exercise, of state autonomy is reduced.

Third, a strong sectoral state actor is aided greatly by adequate internal capacity to back up claims of authority and efforts to act autonomously. It must have appropriate policy instruments to achieve its goals. Control over policy instruments allows a state actor to make choices that determine its role and authority in relation to societal actors. A strong state actor may be able to impose and administer rules affecting societal actors without the need for negotiation, leaving little room for these groups to contest interpretation or implementation. State actors have more potential to act autonomously when they have the capacity internally to produce the necessary information, scientific or otherwise, to implement policy and defend policy choices. Of course, the level of financial resources often determines whether state actors are equipped adequately with personnel and informational resources. State actors who lack capacity and must depend on societal actors for information, or who find themselves constantly negotiating with societal groups about content, interpretation, and implementation of rules, are likely to have more difficulty in acting autonomously.

The following assessment focuses on state actors central to the issues examined in this study and their interdepartmental relationships: Agriculture and Agri-Food Canada / the Canadian Food Inspection Agency (AAFC / CFIA), Health Canada, the US Department of Agriculture (USDA), and the US Food and Drug Administration (FDA). Institutional, ideational, and capacity-affecting characteristics can be separated for analytical purposes; however, the discussion that follows reveals their overlapping nature in practice. Further, as policy choices are made, they may also contribute to state capacity and potential for autonomy.

Agriculture and Agri-Food Canada / The Canadian Food Inspection Agency[70]

Environmental safety assessment of the release of new plant varieties and a leadership role in food labelling policy, including the labelling of novel foods, are new responsibilities for Agriculture and Agri-Food Canada and the Canadian Food Inspection Agency (AAFC / CFIA). These responsibilities date back respectively to the mid-1980s and the early 1990s. AAFC / CFIA has tapped into its historic experience and expertise in regulation and research to bolster its capacity to handle these new responsibilities. It has done so more credibly and overtly for environmental release than for food labelling. AAFC / CFIA has decades of experience in regulating agricultural inputs, including new plant varieties, and in exercising its authority to control plant diseases and pests that pose economic threats to agricultural producers.[71] Its variety registration system is described as rigorous, but essential to maintaining the historic quality of Canada's major crops. The department's authority in this area has rarely been challenged.[72] In contrast, AAFC / CFIA lacks experience and exclusive authority in food labelling policy. Its coordinating role in food labelling is relatively new, emerging after departmental restructuring in 1993.[73] Authority is divided between AAFC / CFIA and Health Canada, with the former focusing on economic aspects of food labelling such as fraud and the latter on health and safety standards.

Capitalizing on its experience and existing capacity, AAFC became the lead agency for agricultural biotechnology regulation by the late 1980s--a designation made following the decision

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[70] Upon the creation of the Canadian Food Inspection Agency in 1997, the responsibilities of the regulatory branch of Agriculture and Agri-Food Canada were transferred to it.

[71] The department has been responsible for administering several statutes that provide its authority, including the *Seeds Act*, the *Feeds Act*, the *Plant Protection (Quarantine) Act*, and the *Fertilizers Act*. In April 1999, a bill called "the Canada Food Safety and Inspection Act" was introduced in Parliament. The bill is the fruit of the CFIA's effort, in cooperation with Health Canada, to consolidate and modernize existing statutes regulating food safety and inspection. The bill consolidates the *Canada Agricultural Products Act*, the *Meat Inspection Act*, the *Fish Inspection Act*, the *Seeds Act*, the *Feeds Act*, the *Fertilizers Act*, and the food-related provisions of the *Food and Drugs Act* and the *Consumer Packaging and Labelling Act*. An analysis of the likely effect of this consolidation on the capacity and autonomy of the CFIA is beyond the scope of this study.

[72] One recent exception was the transfer of responsibility for pesticide regulation to the Pest Management Regulatory Agency, under Health Canada's jurisdiction, in 1995. The move resulted in the transfer of responsibility for the *Pest Control Products Act* from AAFC to Health Canada. The variety registration system has also been the focus of pressures for change in recent years as the private sector takes a larger role in developing new varieties.

[73] This role is arguably compatible with the department's historic food inspection and grading activities

to adopt a single window approach.[74] However, the commercialization of genetically-engineered plant varieties has provoked challenges from environmental groups regarding the capacity of regulators within AAFC to conduct environmental assessments adequately. These groups pointed out that, prior to the 1997 regulatory amendments, the statutory authority to regulate the use of seed of new plant varieties did not contain an explicit mandate to conduct environmental assessments nor did AAFC have any experience in conducting such assessments.[75]

The historic mandate of the federal department of agriculture has been to stabilize and promote the development of the agricultural economy as an economic development strategy, particularly for Western Canada. Political support for this mandate has fluctuated over time, but remained relatively high until the 1990s. The mandate positioned AAFC historically as a clientele department, serving agricultural producers primarily. However, in agricultural research and regulation, as Chapter One suggests, science-based programmatic ideas were well-institutionalized and contributed to state capacity and autonomy. Historically, the department lacked neither scientific nor financial resources to fulfil its regulatory duties adequately. For example, AAFC has been able to tap into the scientific expertise of its in-house Research Branch and that of variety registration committees which, until recently, were comprised largely of public sector researchers.[76] In contrast, on food labelling policy, market-based ideas have been predominant historically. Labelling policy has traditionally been used as a tool to achieve market regulation rather than food safety, reducing the scope of regulation and resulting in relatively minimal state involvement and capacity.

CFIA's potential to exercise autonomy in regulating agricultural biotechnology hinges largely on the capacity emerging from its institutional framework and policy instruments. Its

[74] The department's regulatory branch, long called the Food Production and Inspection Branch (FPIB), held primary responsibility after the mid-1980s, although the Research Branch also took an active interest. In April 1997, the regulatory functions and much of the personnel of the FPIB were transferred to the new Canadian Food Inspection Agency. The single window approach also explains why CFIA is the designated lead agency on labelling of genetically-engineered foods rather than Health Canada, which plays a supporting role.

[75] These statutes were written long before environmental assessment became a well-known concept and began to be institutionalized within the federal government. During interviews, it was pointed out that in the past, plant breeders may have incorporated such considerations as potential for weediness and outcrossing into their evaluation of new varieties prior to submission for variety registration. As well, researchers may have studied such environmental effects on an ad hoc basis, prior to the popularization of the concept of formal "environmental assessments". Environmental groups have argued that all biotechnology regulation should instead fall under the *Canadian Environmental Protection Act,* which is administered by Environment Canada.

[76] Further, public sector agricultural research was dominated by the federal government until recently.

mandate, in contrast, exposes it to capture by its clientele. On the issue of environmental release, policy choices have buttressed the department's ample capacity historically and its potential for autonomy in regulating the use of new plant varieties. The federal regulatory framework for biotechnology, by sanctioning the "stretching" of existing legislation and institutional arrangements, reinforced AAFC / CFIA arguments about its capacity. The department argued that its strong research base, its regulatory experience, and the long history of safe use of new varieties provided an adequate foundation to govern environmental release of genetically-engineered plants, even though it had never before conducted such standardized environmental assessments.[77] Further, the initial decision to use guidelines and a case-by-case approach provided regulators with the potential flexibility to fine-tune its response as desired, without consultation, and thus enhance internal capacity. On the issue of labelling genetically-engineered foods, Canada's interim guidelines have provided little extra capacity to CFIA or Health Canada. For example, there are no provisions requiring premarket screening of the labelling on genetically-engineered foods entering the marketplace to ensure that the health and safety labelling expectations outlined in the guidelines are actually followed.

Developments in the late 1990s appear to be weakening capacity and the potential for autonomous action within the CFIA. First, the longstanding federal near-monopoly in agricultural research and scientific expertise is declining. Fiscal restraint has reduced the level of in-house scientific expertise and made it difficult to attract young scientists familiar with the cutting edge of biotechnology research. As a result of the 1995 federal Budget, the Research Branch of AAFC lost about 28 per cent of staff by the late 1990s, including many senior scientists. Fiscal restraint combined with the novelty of the products of genetic engineering is fuelling concerns that in-house scientific capacity is inadequate to fulfil the regulatory mandate. CFIA is perceived by many researchers in the private and public sector as struggling to keep its science up to date with the newest products. BIOTECanada, for example, expressed its concerns about CFIA's resources in 1998.[78] It noted that CFIA had:

> few permanent employees dedicated to risk assessment of biotechnology products, which makes it difficult for them to establish and maintain their technical expertise. The federal government needs to allocate additional resources, both human and

[77] Canada. Agriculture and Agri-Food Canada, Health Canada, and Environment Canada (1993): 7.

[78] This comment was made in a submission to the consultations on the renewal of the National Biotechnology Strategy. See BIOTECanada (1998).

> financial, to the CFIA and other regulatory agencies so that they can manage existing and future workloads.

Further, the growing role of the private sector in producing new plant varieties and on variety registration committees is eroding the traditional public sector monopoly on claims of scientific expertise regarding new varieties, and thus reducing capacity and potential for state autonomy.[79]

Second, the changing client mix, from a focus largely on agricultural producers to the much broader range of the agri-food industry, shifts the relative allocation of financial and scientific resources between state and societal actors within the larger agricultural policy community to the disadvantage of state officials.[80] For the issue of food labelling, this shift also results in CFIA regulating one of its new core constituencies--the food processing and retailing industries. New market-based measures, reflecting the shift from a state-assisted paradigm to a "market liberal paradigm", are also increasing the influence of AAFC / CFIA's client groups on policy making.[81] This influence is increasing through new institutional mechanisms, such as advisory committees and the Matching Investment Initiative research partnership program, and initiatives such as cost-recovery provisions and delegation of activities such as food inspection and seed certification to non-governmental actors.

Finally, critics have argued that close links between federal regulators and researchers within AAFC and the growing interaction between federal and private sector researchers in the 1990s is creating unacceptable institutionalized conflicts of interest that weaken the potential for state autonomy from the plant biotechnology industry.[82] The dramatic reduction in financial transfers to producers from the state, particularly since the 1995 federal Budget, is also encouraging the growth of public-private links. There is more pressure on the department to

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[79] Kirk (1997).

[80] This shift was formally accomplished in the renaming of the department from Agriculture Canada to Agriculture and Agri-Food Canada in 1993, as part of an overall restructuring of federal departments. As well, CFIA's official mandate is to ensure a safe food supply, protect the health of animal and plant resources, and facilitate trade in these products, giving it a diverse client base that includes consumers, agricultural producers, and the food industry.

[81] Skogstad (1996) and Coleman and Skogstad (1995). See Chapter Two for further details.

[82] Critics argue that the Research Branch is "pro-biotechnology" which compromises the ability of regulators to assess the risks of the technology in a neutral fashion. They also point to links between Research Branch scientists and the industry, which are seen to heighten the conflict of interest. For example, between 1990 and 1995, the Research Branch worked closely with AgrEvo to produce the first herbicide tolerant canola released in Canada. The Research Branch provided the germplasm and the transfer technology, while AgrEvo provided the gene conferring the novel trait of herbicide tolerance. Further, some argue that the spinoff of CFIA is largely a cosmetic change which does nothing to alleviate the potential for conflict of interest, particularly since the CFIA has trade promotion within its official mandate.

ensure that its remaining activities, including research and regulation, achieve the policy goals of economic development and competitiveness.[83]

Health Canada

Health Canada's capacity in food safety and labelling appears to have been historically inadequate in relation to its mandate. Already insufficient, its capacity deteriorated in the late 1990s. Health Canada has often shared jurisdiction for food safety and labelling with other federal departments, as statutory authority was fragmented through much of the twentieth century.[84] The lead role played by AAFC / CFIA in agricultural biotechnology regulation has relegated Health Canada to a supporting agency, even while AAFC / CFIA is dependent on Health Canada to set food safety standards. Health Canada's primary hope for capacity and autonomous action may well lie with its mandate as a regulatory agency to protect public health. That mandate appears to have been diluted by a recent government-wide effort to institutionalize new guiding ideas within regulatory efforts. The 1992 federal Budget launched an in-depth regulatory review across the federal government, including within Health Canada. Its goals were to reduce the costs of regulation to government, industry and consumers; institutionalize cost-benefit assessments of regulations; and ensure that regulations would not impede industry competitiveness and its ability to respond to market demands. An emphasis was placed on increasing simplification and harmonization of regulations.[85]

Health Canada's capacity in food safety assessment has suffered from a lack of internal financial and scientific resources.[86] In response, the department has traditionally reinforced its scientific capacity through close consultations with the food industry and its active monitoring of standards and measures endorsed internationally. However, the commercialization of biotechnology products during a period of significant fiscal restraint has caused new problems. A 1998 Health Canada document noted that the growth of the biotechnology industry has resulted in

[83] The 1995 Budget projected a reduction in AAFC's budget from $2.1-billion (Cdn) to $1.6 billion by 1998-99, a reduction of about 25 per cent.

[84] See Chapter One for further details.

[85] Canada. Health Canada. Health Protection Branch (1993).

[86] An earlier assessment of the Health Protection Branch noted that an effort in the late 1970s to create a national toxicology lab with the intent of reducing dependence on foreign testing data was unsuccessful because of a lack of availability of new federal spending. Further, the Branch's agenda was described as driven by a "hazard-of-the-week" syndrome--heavily influenced by media coverage which in turn was triggered by the release of studies by American or international organizations. See Doern (1981), especially pp. 73-78.

an increased workload for regulators, who are dealing with more applications and increased complexity.[87] Fiscal restraint has also fuelled worries that the department lacks the resources to fulfil its mandate. In particular, the Health Protection Branch has been scrutinized since 1997, when research scientists voiced their concerns publicly about the accumulated impact of budget cuts and cost-recovery programs on the scientific integrity of evaluation.[88] In July 1997, the government announced cuts intended to eliminate much of the research effort within the Branch on both drugs and food. The cuts would have resulted in the loss of 123 positions and a reduction of $7-million (Cdn) in the budget for the food directorate, equal to about one-quarter of its staff. The cuts were to be on top of previous cuts in funding, for a total decline in the Branch's budget from $237-million (Cdn) in 1993-94 to $118 million by 1999-2000. The scientists argued that Health Canada would no longer be able to fulfil its mandate of protecting the public health and would instead have to rely increasingly on the scientific data of those it was regulating, becoming captive to the interests of developers. The controversy resulted in a decision by the Health Minister to reinstate the funding for the research labs for an indeterminate period, while establishing a science advisory board of prominent individuals to consider the matter.[89]

US Department of Agriculture

Like its Canadian counterpart, the American federal department of agriculture has long had an exclusive position within the federal government in regulating agricultural inputs and products. The USDA has also been active on issues of agricultural biotechnology since the mid-1970s. For example, in 1976, the USDA established the Agriculture Recombinant DNA Research Committee (ARRC) to coordinate research policies on rDNA research. ARRC brought together departmental officials with officials from the National Institutes of Health and the National Science Foundation. The mandate of the USDA is "to protect and enhance agriculture and forestry in the United States". As in Canada, development of agriculture has been pursued through regulation and financial

[87] Canada. Industry Canada. Canadian Biotechnology Strategy Taskforce (1998).
[88] Eggertson (1997a, 1997b) and Winsor (1998).
[89] The Health Protection Branch began a "transition" process of fundamental review in August 1997 which was expected to take two or three years and may have delayed a final decision. However, the 1999 federal Budget allocated $65-million (Cdn) over three years for measures to improve food safety regulation and science. The February 2000 federal budget allocated $46-million for biotechnology regulation at Health Canada. A newspaper article in November 1999 suggested that internal reorganization was beginning which would reduce in-house food research but also would include the recruitment of prominent scientists to boost internal expertise. See Winsor (1999).

support of research, as well as through income support payments and other subsidies. The USDA's role is seen to be largely promotional, furthering the interests of the agricultural industry and even, some argue, the interests of large agribusiness over those of smaller firms and producers.[90] From this viewpoint, USDA's regulatory activities have been intended to protect consumers against misrepresentation while ensuring fair competition in the market. Most of its regulatory programs have been voluntary for producers who may comply if they wish to improve the "marketability" of their products. USDA's regulatory authority has been challenged periodically in the past, largely on charges of conflict of interest. As a result, it lost responsibility for regulation of food purity in the 1920s and regulation of pesticide residues in the 1960s.[91]

The USDA's claims of adequate capacity to regulate the release of genetically-engineered plants rest squarely on its history. For example, its responsibility for protecting American agriculture from plant pests through plant quarantine measures and pest eradication authorities dates back to 1912. The USDA has also argued that the history of plant breeding and the successful release of new varieties in previous decades without major safety problems provides a solid foundation for the regulation of genetically-engineered varieties:

> -scientists have long been able to create new gene combinations within single organisms--even creating new species--through mutagenesis, cross-hybridization, and other breeding techniques. USDA has vast amounts of expertise and scientific data relevant to the evaluation of safety and efficacy of organisms or other products derived from modern biotechnology procedures, because these products are not fundamentally different from products obtained by conventional technology.[92]

However, the USDA's capacity was weakened in the mid-1980s by coordination problems within the agency. In 1986, the General Accounting Office highlighted the lack of clarification of roles, the lack of intradepartmental coordination, and the lack of authority and direction within the department's committee on rDNA research. It suggested that there was a struggle over which office or branch would hold primary responsibility.[93] The subsequent creation of the Office of Agricultural Biotechnology to improve coordination and a revamped advisory committee, renamed

[90] Bastian (1990).

[91] In these two cases, USDA was judged ultimately to be in a conflict of interest because of competing regulatory and promotional roles. In the case of pesticide registration, it lacked authority to require manufacturers to register their products. See Bastian (1990).

[92] United States. Executive Office of the President. Office of Science and Technology Policy (1984): 50897-50898. However, the US has never had a system of evaluation of new plant varieties similar to the variety registration system in Canada.

[93] United States. General Accounting Office (1986). See also Chapter Three on the uncertainty within the USDA during the 1980s and into the 1990s.

the Agricultural Biotechnology Research Advisory Committee, appear to have been defensive measures taken by the USDA to resolve these problems.[94] Policy choices have done little to improve the USDA's capacity, particularly after the deregulatory measures of 1993 and 1997. As discussed in Chapter Three, the scope of regulation and the discretion regulators can exercise in setting the level of regulatory review are highly circumscribed by the detailed criteria within the regulations.

US Food and Drug Administration

The Food and Drug Administration (FDA) has long held primary responsibility for food safety and food labelling in the US. However, many other departments and other levels of government have shared jurisdiction on these issues, thereby weakening state capacity and autonomy.[95] The FDA's mandate to protect public health through food safety and other measures should reinforce its autonomy, but the regulatory agency appears to be more vulnerable to changing political tides than its Canadian counterpart. It has lacked political support at times for the exercise of its mandate and appears to avoid taking action as a result.[96] Further, the aggressive and proactive oversight of the FDA's activities by congressional committees, industry associations, and public interest groups places the FDA under near-constant scrutiny. In contrast, Health Canada's appearances in a more public sphere are generally limited to major crises. For example, when the FDA appeared to show some hesitation about how to regulate genetically-engineered foods, the agency and its commissioner endured heavy criticism:

> [The FDA] blinked, hesitated, prevaricated, and backed away from fairness and scientific principle, filling the vacuum with silence and studied ambiguity. At the root of [FDA Commissioner David] Kessler's equivocal approach, to agricultural biotechnology especially, appears to have been a deep-seated suspicion of recombinant DNA technology and its purported effects, a skepticism that went well beyond the need to reassure a wary public about new and controversial food products.[97]

Ultimately, as described in Chapter Three, uncertainty during the mid-1990s about biotechnology foods within the FDA was quickly shelved and consideration of measures such as premarket

[94] Both of these institutional mechanisms were abruptly closed in 1996. They had been scheduled for closure in 1997, but Congress eliminated the funding early.
[95] See Chapter One
[96] One longtime FDA observer pointed out that during the "Republican Revolution" of the mid-1990s, the FDA was under great pressure to reduce its regulatory intervention.
[97] Hoyle (1997).

notification disappeared under the deregulatory pressures of the period.

Given the lack of institutional coherence and inadequate political support for its mandate, the FDA's potential for autonomous action lies largely in the capacity of its policy instruments. Like its Canadian counterpart, the FDA has turned consistently to outside experts to bolster its in-house scientific capacity and sometimes also to compensate for lack of adequate funding. In one example unrelated to genetic engineering, the FDA had to respond to a White House recommendation that food labels reveal nutritional information. Since the FDA lacked adequate funding and skills to solicit consumer opinion on options for how to present the information, it worked with a major food industry association, the Grocery Manufacturers of America (GMA). The GMA co-designed the survey with FDA, chose a research organization, and funded an extensive survey.[98] Through much of the 1990s, the FDA's capacity has been severely limited; budgetary restraint combined with an enlarged mandate has threatened its ability to maintain programs.[99]

Policy choices creating a voluntary regulatory regime have done nothing to improve the FDA's capacity. Despite, or perhaps because of, this relatively weak regulatory regime, the FDA has felt it necessary to insist that it has ample legal authority to regulate. In its 1992 policy statement, for example, the FDA describes its existing statutory authority through the *Food, Drug and Cosmetic Act* (FDCA) as "fully adequate" for the purpose of regulating new plant varieties, regardless of whether genetic engineering or more traditional techniques are used to develop them. It argues that its authority is adequate because statutory provisions place a "clear legal duty" on producers for food safety, provide post-market enforcement powers, and permit the FDA to

[98] Wodicka (1996). Wodicka, who provides these examples, is a former Director of the FDA's Bureau of Foods.
[99] Within the FDA, the Center for Food Safety and Applied Nutrition (CFSAN), where regulation of genetically-engineered foods is housed, has lost 20 per cent of its staff over the last two decades. The director of CFSAN, Joseph Levitt, said in late 1999 that "every program is struggling." The FDA's total budget, at $1.1-billion (US) in 1999, has not increased during the 1990s to reflect the FDA's new responsibilities during the same period, which result from more than twenty-four pieces of legislation. The situation has encouraged some industry associations to lobby Congress to increase funding for the FDA. See Carey (1999).

require premarket review and approval as necessary.[100] However, the absence of mandatory premarket notification has left the FDA dependent on the developer's judgment about whether to approach the FDA for consultations, review, or approval before a new food enters the food supply. This dependence on the voluntary compliance of the food industry is an extension of the longstanding practice of the FDA to consult informally with the industry, while placing the onus on the industry for safety. In contrast to the USDA, the FDA's arguments about its capacity are based more on the strength of its statutory authorities, rather than on its own experience in assessing the food safety of new plant varieties. The agency has never routinely tested new plant varieties for food safety. It has relied instead on the fact that most foods from plants have been consumed by humans for centuries, long before the existence of food laws and regulations, and that the criteria used by plant breeders have generally ensured that new varieties are safe for human consumption.[101]

INTERDEPARTMENTAL MECHANISMS

In Canada, the three main regulatory agencies involved in regulating agricultural biotechnology have been AAFC / CFIA, Health Canada, and Environment Canada. Of the three, AAFC is easily the most authoritative actor through the combination of its historic regulatory duties in agriculture and its early start in the mid-1980s on regulatory development. Environment Canada

[100] United States. Food and Drug Administration (1992). The two key provisions in the FDCA the FDA is using for genetically-engineered foods have been in use for some time. The post-market enforcement provision (s 402 (a) (1) of the FDCA dates back to 1906, allowing it to take action to remove adulterated food from the marketplace. The FDA has stated that it expects this provision to be its main policy instrument. Its second policy instrument comes from an amendment passed in 1958 in order to regulate food additives, a measure FDA notes was supported by the food industry. This amendment provides authority to require premarket review and approval of new food additives. However, it is left to industry to decide whether to seek FDA approval for a new food additive.

[101] Exceptions have been made for certain plants that are more likely to pose food safety concerns, such as potatoes which have varying levels of glycoalkaloids. In high enough levels, glycoalkaloids can cause serious illness and even death in humans and animals. The FDA attempted to include new plant varieties that had been significantly altered by breeding under its GRAS scheme in the early 1970s. It passed a regulation to this effect in 1971, suggesting monitoring when nutrients decreased by 20 per cent or more, or toxicants increased by 19 per cent or more. It was realized that there was a lack of baseline information and more elaboration was needed. A FDA-USDA task force established a set of guidelines. However, a vigorous three-year campaign against this measure by plant breeders, the seed industry, and to a lesser extent the food industry, assisted by a National Academy of Sciences task force, meant that while the regulation exists, it has never been enforced. While the FDA dealt in an ad hoc manner with some inquiries about nutrient and toxicant levels in new plant varieties, it did not keep track of these inquiries and so did not generate data on the composition of new plant varieties. See Doyle (1985).

appears to be the weakest.[102] Interdepartmental committees on biotechnology have existed since 1983. The interdepartmental Subgroup on Safety and Regulations first met in 1985 and was the chief architect of the 1993 federal regulatory framework. According to participants in its creation, the framework was intended to signal agreement within the federal government to work in concert on biotechnology regulation. All departments adopted the same definition of biotechnology and agreed to implement the same guiding principles when developing biotechnology regulations. One state official argues that the framework reinforces the success of interdepartmental coordination because it "drives individual departments to look at each other's approaches". Participants in the Subgroup describe the atmosphere of meetings as collegial and the functioning of the group as productive and relatively trouble-free.

Interdepartmental debates did occur on some issues, such as the distinction between product-based and process-based regulation, how much flexibility should be built into the regulatory process, whether guidelines had enough "teeth", and what "consultation" meant. One participant noted that once the decision was taken as to which department would handle which products, the most difficult issues were settled. The most apparent tension or "turf war" was between Environment Canada and AAFC over which department should regulate the release of genetically-engineered organisms including plants. Some members of the policy community believe that there are ongoing tensions between the two departments, but that Environment Canada is no match for AAFC with its strong clientele base. It is perhaps worth noting also that the regulatory framework, since it was released in 1993, came long after AAFC had already established its guiding principles for regulation. In fact, as one former regulatory official observed: "the regulatory framework came after a lot of thinking was already done on how to approach regulation". She described the framework as simply a formalized statement needed to

[102] Environment Canada's internal weaknesses, including the conflict caused by its dual resource management and regulatory functions, have made it difficult for it to come out on top in interdepartmental battles. The department also suffers from its failure to build a stable and productive relationship with its diverse clientele of industry, environmental groups, and the public. Further, the lack of support from both top elected officials and central agencies, the declining priority placed on environmental issues, and inadequate financial and scientific resources have reduced the department's effectiveness. Doern and Conway (1994): 233-244 In regulating agricultural biotechnology, Environment Canada has played a supporting role. It has shared its expertise on environmental assessment with AAFC/ CFIA, while developing its own regulations for products derived through genetic engineering that are not regulated elsewhere. Health Canada began its involvement in regulating the products of genetic engineering early in the 1980s, but its focus has been more on biomedical applications. It has little, if any experience evaluating the food safety of new plant varieties, a task that has for the most part been left to plant breeders.

provide a "strong rationalization" for approaches already chosen and to ensure everyone was operating by the same principles. In 1998, measures were announced to strengthen ongoing interdepartmental coordination under the renewed Canadian Biotechnology Strategy.

In the US, in contrast, efforts to coordinate among agencies came largely after problems had already been encountered in clarifying roles and jurisdictions. Unlike Canada, there does not appear to be a "single window" approach to agricultural biotechnology regulation. Coordination resulting in a federal regulatory framework came as a response to the uncertainty within the biotechnology industry about commercializing biotechnology products in the early and mid-1980s, given a rash of lawsuits and public controversy. The references to agency discretion and coordination in the framework documents suggest that coordination was a troubling issue. The interdepartmental task force charged with drafting the framework proposed an institutional mechanism intended to promote consistency and consensus among the various agencies involved in regulating biotechnology. Initially, the task force proposed a second tier of review through an interdepartmental committee. This proposal was rejected as overly onerous and because it was felt that the second-tier review process would exacerbate conflicts among individual agencies and their differing mandates.[103] Instead, an advisory coordinating committee was established in 1985, called the Biotechnology Science Coordinating Committee. Its seven members included two officials from the EPA, one from the FDA, and two from the USDA.[104] More recently, state officials and other members of the policy community report that interdepartmental coordination has improved. Contact occurs generally as needed when there is some overlap in the assessment of a product rather than on a routine basis. Agencies often must align initiatives with the priorities of the executive office, which may constrain the autonomy of a specific state actor. The release of the 1992 FDA policy on the food safety of genetically-engineered plants by the President's competitiveness council was one clear example. American agencies also appear to be more constrained by horizontal executive orders and framework laws such as NEPA than Canadian departments have been.[105]

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[103] Bureau of National Affairs (1989).

[104] The BSCC was replaced in 1990 by the Biotechnology Research Subcommittee of the Committee on Health and Life Sciences, a standing interagency committee of the Federal Coordinating Council on Science, Engineering, and Technology.

[105] For example, on February 17, 1981, Executive Order No. 12291 established the formal requirement that regulatory agencies apply a cost-benefit test to all major rules and regulations.

ORGANIZATIONAL DEVELOPMENT OF SOCIETAL ACTORS

To gauge the ability of societal actors to intervene effectively in policy making, the level of organizational development of their associational systems can be examined and assessed. An associational system is simply the "collection of associations with a given domain".[106] Certain characteristics tend to contribute to the legitimacy and capacity of associations which in turn have a direct bearing on their effectiveness within a policy community. These characteristics can be grouped into four categories: coherence, representation, utility, and resources.

First, a well-organized associational system is likely to have an umbrella or peak association that coordinates the activities and interests of the more specialized associations that are its members. The existence and strength of these links contributes to coherence. A well-differentiated and strongly-developed associational system is able to represent specialized interests and can put forward a consensus from the entire sector when necessary. In contrast, coherence in articulating an interest may be lacking when there is competition among associations for the same members or links among associations are weak or non-existent.

Second, the more representative the associational system, the more legitimacy it is likely to have within a policy community, particularly in the eyes of state actors. Representativeness flows from various factors including whether a large majority of firms within an industry are members of the associational system. Further, the process used to develop policy positions may enhance or detract from representation. For example, associations may use democratic processes to establish or "vet" policy positions, or they may develop positions internally with no input from their membership. In the latter case, the ability to claim representation may be weakened.

Third, the presence of dominant actors can indicate how useful and effective these associations are in policy participation. Large firms, for example, may not need an association to be active and effective within a policy network since they often have the resources to intervene directly. The presence of these firms within associations contributes to both legitimacy and capacity.

Fourth, a key determinant of capacity is the level of in-house ability to generate relevant information, both technical and political, and to be able to distribute it to members. The

[106] See Coleman and Skogstad (1990b): 21 for a discussion of the characteristics of associational systems. See also Atkinson and Coleman (1989): 53.

involvement of large firms that lend their resources to the association may bolster in-house capacity significantly. More generally, the stability and the diversity of sources of financial resources play an important role in the level of organizational development.

Examining these characteristics of associational systems sheds light on the nature of the role associations are likely to play in policy making and how effective they may be.[107] Some associations may be limited to a policy advocacy role, if the associational system is not well-developed enough to support a more sustained and in-depth policy participation role.[108] The examination that follows does not provide an exhaustive evaluation of the associational systems relevant to plant biotechnology regulation, but focuses on some of the key indicators of organizational development that are available.

Biotechnology industry

In both countries, the biotechnology industry is represented nationally through a single organization: BIOTECanada in Canada, and the Biotechnology Industry Organization (BIO) in the US.[109] Recent mergers in each country have improved the coherence of the associational system.[110] The size and diversity of the membership of these two national biotechnology associations suggests that they can claim to be somewhat representative of the industry.[111] If there are shortfalls in representation, they likely fall into three categories. First, agricultural biotechnology issues may

[107] The relevance of these characteristics may vary according to the associational systems.

[108] Coleman and Skogstad (1990b): 20-24.

[109] BIO had its roots in the Industrial Biotechnology Association (IBA) which began with seven firms in 1981. IBA has since merged with the Association of Biotechnology Companies to form BIO. In Canada, the biotechnology industry was first represented by the Industrial Biotechnology Association of Canada (IBAC), established in 1987 by a few firms to deal with regulatory issues regarding medical applications. In 1998, IBAC merged with the Canadian Institute of Biotechnology which represented more of the public sector organizations involved in biotechnology and the Biotechnology Human Resources Council to form BIOTECanada. There are also several regional biotechnology associations in Canada which focus primarily on economic development efforts. Most of these regional associations belong to BIOTECanada, including the British Columbia Biotechnology Alliance, the Toronto Biotechnology Initiative, and the Québec Bio-Industries Association. Among the oldest and most prominent is Saskatchewan's Ag-West Biotech. There does not appear to be an organization similar to Ag-West Biotech in the US. The concentration of firms in Saskatoon working in agricultural biotechnology, grouped largely in the Innovation Place research park next to the University of Saskatchewan, is without parallel in the US.

[110] Plant biotechnology firms often belong to other national associations, such as those of the seed trade and the agrichemical industry, who have also been involved in biotechnology regulation and thus may provide indirect competition to biotechnology associations.

[111] BIOTECanada has about 100 members, out of an estimated 282 biotechnology firms in Canada (source: www.biotech.ca), BIO has about 800 members, out of 1,283 biotechnology firms in the US (source: www.bio.org). Members of both associations include biopharmaceutical firms and firms engaged in other non-agricultural applications of biotechnology.

be neglected at times given the combination of limited resources and the dominance of the biopharmaceutical sector within the associations.[112] Second, very small firms are less likely to join the associations, in part from lack of resources. If there is a difference between the interests of small and large firms, large firms are likely to carry the day within the association. Third, the biotechnology associations have generally not made an effort to represent individual researchers, especially those in the public sector, given their focus on representing the interests of organizations.[113]

Some of the large agricultural biotechnology firms have participated directly in policy making, but their presence within both associations suggests that the associations are perceived as effective.[114] In Canada, Monsanto has been actively involved in strengthening the associational system for the biotechnology industry, believing that a united, broader voice is more effective than working as an individual firm.[115] Beyond the contributions of information resources and expertise that member firms can provide, the quality of association staff is particularly critical to the capacity of the association when the issues in play are complex and technical. Both associations have staff with scientific backgrounds and have hired former state officials who have worked for some time within government on issues of agricultural biotechnology regulation. Each has a number of committees to focus on specific issues which act as a vehicle for members to share their expertise.[116] Neither association is heavily staffed, although BIO's personnel far outnumbered

[112] The CFA has noted that agricultural issues have been marginalized in various biotechnology forums and committees including the National Biotechnology Advisory Committee. BIOTECanada initially spent less time on agricultural biotechnology issues through much of the 1990s, given that only about 20 per cent of the membership was active in agricultural applications. Since the hiring of a former AAFC official in January 1997 to head up the association, attention to agricultural issues has increased. As well, the chair of BIOTECanada in 1998 was an AgrEvo official.

[113] BIOTECanada does include several universities and other public sector institutions among its members, blending private and public sector representation. Individual researchers may secure representation through alternative channels, such as scientific societies or as individual expert witnesses and advisors.

[114] Notably, four of the five major agricultural biotechnology firms (all but DuPont) belong to BIOTECanada, while BIO counts all but Dow Agrosciences among its members.

[115] Monsanto's efforts resulted in the creation of biotechnology committees within the Crop Protection Institute of Canada and the Canadian Seed Trade Association, and the creation of IBAC as a spinoff of the US IBA. Monsanto also hired a consultant to do a report that eventually resulted in the Food Biotechnology Communications Network, a joint industry-government communications office in Canada which is intended to increase dialogue and provide information to the public on biotechnology issues. Personal interview, February 1998.

[116] For example, BIOTECanada's agriculture committee has worked on issues such as the United Nations Biosafety Protocol and the activities of Codex Alimentarius on labelling of genetically-engineered foods. BIO also has a food / agriculture committee whose membership includes representatives of several of the major agricultural biotechnology firms: Pioneer Hi-Bred, American Home Products, Zeneca Plant Sciences, Monsanto, Calgene, Novartis, Mycogen, DuPont, DNAP Holding Corporation, and AgrEvo.

BIOTECanada's until the late 1990s (see Table 4-6). In January 1997, IBAC had the equivalent of half of a staff member. Its merger into BIOTECanada in 1998 brought the new organization to a total of about thirteen staff.[117]

Agri-food industry

The associational systems of the agri-food industries of Canada and the US include general farm associations, single commodity associations, and specialized associations such as those for organic producers. Other links in the agri-food industry are represented by agricultural input associations such as seed industry associations, and food processing and retailing associations. Compared to the Canadian system, the American system appears more dynamic with new groups and factions emerging more frequently. One analysis describes the American agricultural associational system as in its fifth stage of evolution.[118] This most recent stage began in the early 1970s through a "process of accommodative adjustment" as a new and more diverse set of groups became involved in agricultural policy issues, including environmentalists, animal rights groups, labour, and consumer groups. Since the late 1960s, the Canadian system has also become more diverse, in part through the arrival of public interest groups on the margins. It is, however, still less pluralist than the American system.

Agricultural producers

Since 1935, the Canadian Federation of Agriculture (CFA) has been an integrative peak association. It brings together a relatively representative mix of commodity-based and regional producer associations. In earlier decades, the agricultural associational system was well-integrated in comparison to other Canadian sectors. In recent years, however, the associational system has been weakened by disorganization and internal division serious enough to cripple policy effectiveness. New associations have emerged including the National Farmers Union, which was formed in 1969, and more specialized commodity associations. Overall, the CFA's ability to present coherent policy positions that credibly represent the broad range of Canadian producers was weak through much of the 1980s and 1990s. This lack of coherence provokes policy makers to question which associations are truly representative. For example, the CFA's weak membership

[117] BIOTECanada also maintains a well-stocked library on biotechnology issues.
[118] Browne and Cigler (1990).

in Western Canada and among producers of red meat reduces the credibility of its claims of representation.[119] As a result, single commodity associations have enjoyed a rising profile in policy making.[120] The differences among Canadian agricultural producer associations have made the agricultural policy process more political. By 1990, as a group, Canadian producer associations seemed to have few common goals and suffered from "a serious lack of unity".[121] The major divisions have been in part ideological, focused on the appropriate degree of state intervention; the agricultural economic crises of the 1980s exacerbated these divisions. In the 1980s, these divisions sometimes seemed too great for the CFA to bridge. Unable to perform its traditional broker role, the CFA often avoided divisive policy issues and its leadership role was increasingly questioned.[122] However, there are signs in the late 1990s that the CFA has become more successful at building consensus among members on critical issues such as international trade negotiating positions.

The American associational system for agricultural producers is also fragmented by specialization and ideological differences which hinder, if not prevent, the expression of comprehensive policy positions.[123] Informal short-lived coalitions have become more common as a compensating mechanism since many groups tend to operate for the most part in narrow, specialized "policy niches". More so than in Canada, American producers lack organizational mechanisms to broker their policy preferences into a coherent single voice. There is no umbrella association similar to the CFA and the array of independent government programs that associations focus on does not encourage cooperation or interdependence. The American Farm Bureau

[119] The CFA has some members in western Canada through the Saskatchewan Wheat Pool and Agricore, but there are also rival associations such as the Western Canadian Wheat Growers. Its weak western representation stems in part from the lack of strong provincial organizations in the West.

[120] The specialist oilseeds and grains groups, and red meat associations tend to differ philosophically from CFA members. They are more market-oriented and distrust government generally. They focus on narrow policy issues and place little priority on identifying and cooperating on common goals with other producers. Their approach aligns them more closely with agribusiness interests than with general farm organizations. Skogstad (1987b): 29-31

[121] Wilson (1990): 142. Wilson provides a general discussion in pp. 130-149. The declining number of producers has also reduced the strength of the associational system.

[122] Wilson places some of blame for the CFA's plight on the "self-serving attitudes" of member groups that seemed unwilling to compromise in the interests of finding common ground. Coleman observes that producers themselves have weakened the integrative organization they created to promote their common interests, leaving themselves with less ability to present a united voice. Coleman (1988): 119-122

[123] See Browne and Cigler (1990), Browne (1995), and Browne (1988) for in-depth analysis of the US agricultural associational system. The associational system is becoming increasingly crowded. Interest groups active in agricultural policy issues have increased in the last two or three decades from approximately 150 to 215.

Federation (AFBF) is the largest American general farm association, with a membership of almost five million individual producers. The AFBF does not attempt to broker interests across associations. It is overtly ideological, taking a market-based approach to agricultural policy, and tends to be dominated by larger-scale producers.

Diversity and specialization within both the Canadian and American agri-food associational systems ensures that most interests have an association that could represent them in policy making. Of course, as Browne points out, not all associations are equally active in policy making. Many specialized associations adapt their level of involvement with the rise and fall of issues.[124] This inconsistent activity may weaken their representational ability in comparison to associations that actively maintain their contacts with state officials. However, specialization is not always an obstacle to representativeness. Policy makers may prefer to consult with those associations specializing in the specific issues at hand and whose members are affected directly. However, this tactic can obscure the interests of the wider agri-food industry, which may be overlooked and result in active protest further down the road.

The relatively few staff of most producer associations, especially commodity organizations, suggests that financial resources are often inadequate to promote the broad range of policy interests. The result is a focus on priority issues. For example, the Canada Grains Council and the Canola Council of Canada do not have offices or staff in Ottawa. In the US, financial resources tend to be more ample. The National Corn Growers' Association has a Washington office and the American Soybean Association has a Washington-based consultant. Despite these resources, even agricultural associations in the US generally must restrict their focus to critical issues and few have the capacity to deal with the broader issues affecting agriculture.[125]

In summary, it appears that the Canadian associational system for agricultural producers is becoming more like its American counterpart. This development provokes concerns about its

[124] Browne (1988): 26.
[125] Browne (1988): 106.

effectiveness, although it remains much stronger organizationally than its American counterpart.[126] In both countries, fragmentation limits the extent to which associations can claim to be legitimate representatives of producers and produce coherent policy positions on major issues. Divisions among associations may allow state officials to justify action in the absence of producer community leadership or inaction because of the lack of consensus.[127] Fragmentation generally weakens policy effectiveness. Specialized associations may be able to contribute authoritatively on narrow technical issues on which producers have expertise, but they may not have the resources or capacity to deal with broader issues. On the issue of agricultural biotechnology regulation, producer associations also are restricted by their traditionally passive role in agricultural research and regulatory issues. Compared to the ongoing stream of economic challenges producers face, other issues have often paled in their perceived importance. However, associations are beginning to adapt to the new realities of agricultural policy making, including the increased focus on highly technical regulatory issues and the internationalization of policy making, by hiring scientific experts and increasing their international focus.

Seed trade and food processing industry

Both the seed trade and the food processing industry are represented by national associations in Canada and the US: the American Seed Trade Association (ASTA), the Canadian Seed Trade Association (CSTA), the Grocery Manufacturers of America (GMA), the National Food Processors Association (NFPA), and the Food and Consumer Products Manufacturers of Canada (FCPMC).[128] These associations are longstanding and have extensive experience in trade and regulatory issues. The CSTA and the ASTA can make credible claims of representation, with

[126] At least some Canadian producers are aware of the weaknesses of their associational system. A 1997 Ontario Corn Producers' Association magazine editorial called for more effective general farm organizations, and stronger links between these organizations and commodity groups. It noted the CFA's weakness in representing all producers and the growing tendency of Western Canadian organizations to develop policies independent of other farm organizations. The editorial pointed out that Canada's strongest general farm organization appears to be Quebec's Union des producteurs agricoles (UPA). UPA derives its strength from its highly representative and balanced membership along with the largest budget among Canadian general farm organizations, at about $13-million (Cdn) a year. *Ontario Corn Producer* (1997).

[127] Wilson (1990).

[128] For the most part, these associations do not have competition. There is a small amount of overlap in GMA and NFPA membership, although GMA focuses exclusively on "brand" manufacturers. In Canada, there is also the Canadian Seed Growers Association, which is much larger than the CSTA, but includes very small seed growing operations such as individual family farms. CSTA restricts its membership to the seed industry.

their diverse membership of both large and smaller firms. However, the GMA, the NFPA, and the FCPMC tend to represent the larger food firms. They do not act as peak associations for the many smaller specialized or regional food processing associations. The lengthy membership list of these associations suggests that firms recognize that these national associations do help the food industry to present a united voice in policy communities, compensating somewhat for fragmentation.[129] However, American agribusiness is unlikely to take on a broker role in agricultural policy making because interests are too diverse and most firms tend to be conservative and cautious.[130] In terms of resources, the large food industry associations dwarf the seed trade associations, and the FCPMC is a pale shadow of its American counterparts, as Table 4-6 illustrates.

Environmental groups

The Canadian and American associational system of environmental groups is characterized by great diversity in environmental philosophies, size, tactics (militant versus more conservative), levels and sources of resources, and policy preferences.[131] The diversity has increased in recent years with the growth in the numbers of groups.[132] Only a handful of these groups have been involved in issues of agricultural biotechnology regulation, and even fewer have been consistently active. Coherence has been improved through coordinating mechanisms. In Canada, the Biotechnology Caucus of the Canadian Environmental Network has brought together environmental and public interest groups to present a united front in key forums, such as multistakeholder consultations and committee hearings. In the US, the Biotechnology Working Group served a similar purpose for about a decade until its disbanding in 1998.

Representativeness is a weakness for those environmental groups which tend to have fluctuating memberships, lack members in a domain on whose behalf they profess to make claims, and confront rival groups purporting to speak for the same interests. Representativeness is also a problem when the group lacks democratic procedures for establishing policy preferences. Some organizations do not have memberships and are instead styled as policy or research institutes,

[129] Browne (1988): 109-129. Fragmentation is much more notable in the food processing and retailing industry. There are many specialized and regional food processing associations and no single unifying peak organization.
[130] Browne (1988).
[131] Wenner (1990).
[132] A 1975 study estimated that there were about 300 environmental groups in Canada, including about twenty-nine major groups. The Canadian Environmental Network now counts more than 2000 groups.

supported by donations and grants. Membership in environmental organizations is difficult to measure in total, but is not insignificant.[133] Further, members tend to have a strong commitment to the organizations they support. Support for such organizations is the clearest indicator of their perceived utility. Policy makers often find these organizations useful during consultations, in part to improve the legitimacy of the policy making process. They have sometimes provided funding to ensure that these organizations participate in consultations.

Environmental and other public interest groups vary widely in their access to resources. Most do not enjoy stable and diverse resources.[134] Canadian groups tend to suffer more from inadequate resources than American groups. For example, the Environmental Defense Fund in the US is well-resourced with a wealth of in-house expertise compared to major Canadian groups. In 1999, it had a budget of $25-million (US) and a staff of 175, which included scientists, economists, and lawyers. American groups often benefit from the many large philanthropic foundations, of which Canada has very few. Several of the American institutes and groups working on biotechnology issues, including the Union of Concerned Scientists and the Biotechnology Working Group, have been financed by foundations. However, representatives of most of these groups report that core funding for biotechnology issues has been difficult to obtain and even project funding has tended to be scarce.

Consumer organizations

Canada has a single national consumers' association, the Consumers Association of Canada (CAC). Divisions of opinion among its provincial wings and financial problems, however, have reduced its ability to put forward a coherent policy position in the case of agricultural biotechnology regulation.[135] The largest American consumer organization is Consumers Union (CU)with almost five million members; there are also many smaller specialized and regional consumer organizations. The Consumer Policy Institute, which operates within the CU, has been the most active on biotechnology issues. Like many other public interest groups, the representativeness of consumer associations can easily be challenged. In Canada, CAC is called

[133] In Canada, a recent estimate suggested that more than one million Canadians belong to environmental organizations. Wilson (1992): 111.
[134] Doern and Conway (1994): 100-123.
[135] There has been division within CAC on other, earlier food policy issues, notably between the Prairie provinces with their strong agricultural links and other provinces. Forbes (1985): 81.

on frequently by policy makers to provide the "consumer's" point of view, although the association itself has argued against the tendency to treat its viewpoint as singularly representative of the opinion of Canadian consumers.[136] Meanwhile, CU has many members, but its policy preferences are largely generated internally on behalf of the public interest as are those of CAC.

CAC suffers hugely from a lack of financial resources.[137] CAC's relatively low membership, of about 250,000 individuals, is one source of its resource woes. Another source has been cuts in federal government funding. In 1992-1993, CAC received $875,000 (Cdn) in federal grants and contributions. As of early 1997, federal funding for CAC had declined by 70 per cent. By 1998, CAC was no longer receiving core funding from the federal government; government funding was provided only for specific projects. It has a small paid staff of about five in its national office and relies heavily on its volunteers to fulfil its functions.[138] In the US, Consumers Union fares better with its 4.8 million members. Its policy advocacy staff number almost forty.

COMPARING POLICY NETWORKS

Classifying policy networks

Coleman and Skogstad have sketched a typology of ideal policy networks with six categories, based on assessments of the degree of state autonomy and coordination, and the level of organizational development of societal actors.[139] They identify three types of pluralist networks. Pluralist networks share the characteristics of fragmented state authority and low organizational development among societal actors. Pressure pluralist networks are further distinguished by state autonomy combined with a limited, policy advocacy role for societal actors. In clientele pluralist networks, state actors lack autonomy and are often dependent on the expertise of societal actors, pulling societal actors into a participatory role. Finally, in parentela pluralist networks, societal

[136] A CAC official noted that during multistakeholder consultations, there is often one consumer representative sitting down with several industry and government representatives, yet consumers are no more homogeneous, for example, than the pharmaceutical industry or the financial services industry. Consumers' Association of Canada (1997): 8.

[137] The heyday of the CAC appears to have been in the 1960s and 1970s, when it achieved a number of victories including the establishment in 1967 of a federal Department of Consumer and Corporate Affairs. Much of this Department was merged into Industry Canada in the 1993 restructuring of federal departments. Very little of it remains. The lack of resources forced the CAC to fold its consumer magazine several years ago.

[138] For example, the chair of the National Food Committee is a volunteer.

[139] Coleman and Skogstad (1990b): 25-31.

actors become incorporated into the state by holding key positions. The second broad type of policy networks are "closed", characterized by a well-coordinated set of state actors or by a single authoritative state actor, and by well-developed associational systems and prominent societal actors. In corporatist networks, there are multiple societal actors, sometimes with conflicting policy preferences and interests. In concertation networks, there is a single societal association that holds a monopoly position. Finally, state-directed networks combine a highly autonomous and well-coordinated state with very weak or non-existent associational systems. In this type of policy network, state officials may simply make policy choices without consultation. Such networks are likely to be found in certain situations, such as during a crisis, on issues surrounding an infant industry, or when the issue is horizontal and affects a wide range of societal actors that are not well-coordinated.

Environmental release

Table 4-7 summarizes the resources of state and societal actors and the policy networks that have emerged. The Canadian policy network surrounding the issue of environmental release began as a state-directed network. A capable state actor pondered how to regulate a technology that some of its own employees had already embraced. Meanwhile, a nascent plant biotechnology industry was just beginning to develop its own associational system. By the mid-1990s, the network had evolved towards a concertation network. The plant biotechnology industry was growing in economic importance and accumulating technical expertise. The state actor's capacity and potential for autonomy had been weakened through fiscal restraint and innovation in agricultural research and regulatory policy. Environmental groups have been consistently active in the policy community, but have remained at the margins. They have not succeeded yet in transforming the policy network to a more open, pluralist variation.[140] The weakening of state capacity in the mid- and late 1990s may eventually transform the network into a clientele pluralist network. In the US, the policy network surrounding environmental release appears to have been a weak variant of concertation verging toward clientele pluralism. A a semi-capable state actor struggled to respond to the demands of an increasingly organized group of researchers and developers, but also found

[140] One disillusioned representative of a Canadian environmental group commented that AAFC / CFIA invites members of environmental and organic producers' groups just for "window dressing".

itself vulnerable to the charges of environmental groups and changing political tides.[141]

Food safety assessment

The Canadian policy network surrounding the safety assessment of genetically-engineered foods is also closest to a weak form of concertation. Health Canada's capacity and potential for autonomous action has never been strong. It has been weakened in the late 1990s by fiscal restraint. The food industry is not well-organized, but some of its firms do possess expertise required by state officials. At times, it appears that much of the expertise upon which regulation is based originates from outside the country. The national consumer association remains an extremely weak member of the policy community, valued largely for its legitimacy-conferring properties. The weaknesses of key members of the policy network suggests that it could become a clientele or pressure pluralist network unless internal resources are shored up. The American policy network on food safety is best described as clientele pluralist. The FDA lacks potential for autonomous action, particularly given a highly politicized context. While it has some capacity, policy choices have left it with little authority. Political support for its mandate was very thin at times during the 1990s. It also relies heavily on outside expertise on matters of food safety of new ingredients, given that the wealth of scientific expertise lies within the food industry.

Labelling

The policy networks surrounding the labelling of genetically-engineered foods in both countries appear to have been consistently pressure pluralist. Food labelling policy in general has focused on regulating the market and protecting consumers from misrepresentation; its evolution has been largely ad hoc. State capacity is limited by policy legacies and labelling's minor status as a policy instrument. In the US, consumer organizations have a higher level of organizational development, but are no match for the food or plant biotechnology industry associational systems. In Canada, the consumer organization is very weak and defers to industry even on labelling issues.

[141] In 1985, Roger Salquist of plant biotechnology firm Calgene (subsequently acquired by Monsanto) stated that there was "unprecedented cooperation" among industry, researchers, and state officials on biotechnology issues based on the "clear recognition on the part of all concerned that commercial exploitation of our present national position of biotechnology preeminence is vital to the future health and growth of our industrial and agricultural economy". See Salquist (1985).

Conclusion

The categorization of Canadian and American policy networks surrounding the issues of environmental release, food safety, and labelling reveals differing networks across the two countries in each case except labelling. Relatively closed policy networks emerged in the cases of environmental release and food safety in Canada, and initially in environmental release in the US. In both countries, the environmental release policy networks became more diverse and less closed during the period examined for this case study. The Canadian policy network, which went from being a state-directed to a concertation network, was transformed by the relative decline of state capacity and autonomy and the increasing resources of the plant biotechnology industry. The transformation of the American policy network, which began as a concertation network but quickly became clientele pluralist, reflected the inability of the USDA to counter pressures from the growing plant biotechnology industry and public interest groups. In contrast, the nature of the policy networks surrounding food safety and labelling remained constant during the same period. As of 1998, all three American policy networks were pluralist. Canada's labelling policy network was also pluralist, but its environmental release and food safety networks remained relatively closed.

This categorization of policy networks is consistent with the degree of variation found in the discretion allocated to regulators and the scope of regulation through policy choices. The highest level of discretion and the widest scope of regulation is found in the Canadian policy response to environmental release. Canadian food safety regulators were also given a relatively high level of discretion, although the scope of regulation was somewhat more circumscribed by a more detailed definition of the regulatory trigger than in the response to environmental release. These policy choices coincide with relatively closed policy networks in which the dominant state actor enjoys some capacity and the potential for autonomous action. Not surprisingly, state capacity and autonomy appear to be necessary conditions for policy choices that continue to contribute to capacity and autonomy. In the US, the policy response to environmental release provided a relatively narrow, and somewhat illogical from a risk perspective, scope of regulation given the nature of the regulatory trigger. The discretion of regulators in conducting reviews is limited by the detailed criteria in regulations that predetermine the extent of review. However, this review is mandatory for qualifying products unlike the American policy response to food safety.

This latter response provides no discretion to regulators, since it is a voluntary regime. It leaves the scope of regulation ultimately up to industry. Industry makes its own determination of whether and to what extent a safety assessment is required and chooses whether to consult with regulatory officials. These American policy choices, which provide little or no discretion to regulators, are arguably consistent with the clientele pluralist policy networks surrounding each issue. Once again, the degree of state capacity and autonomy within a policy network appears to translate directly through to policy choices in a self-perpetuating fashion. Finally, labelling policy networks in both countries have been pressure pluralist. These networks have contributed to virtually identical policy responses in the two countries. These responses provide a narrow, albeit mandatory, regulatory regime with no discretion for regulators.

The nature of these six policy networks also is highly consistent with the policy legacies identified in Chapter One. The effect of policy legacies on state capacity and autonomy is consistent with the levels of capacity and autonomy exercised within the contemporary policy networks. Further, the contribution of institutionalized ideas to the authority and legitimacy of actors within networks, determined by the balance between market-based and science-based ideas in the case of environmental release and food safety, also appears to have carried through to the 1980s and 1990s. For example, policy legacies were most favourable for state actors for the case of environmental release in Canada. The policy network surrounding this issue has been the most closed of all six networks examined due to high state capacity and autonomy and the historic dominance of science-based ideas combined with the concentration of relevant scientific expertise in the public sector. At least initially, the network protected and privileged state actors and researchers. Its transformation into a concertation network, however, is a reminder that policy legacies can be diluted and displaced.

The transformation of networks illustrates the influence of policy boundaries. As Chapter Two demonstrated, innovation in agricultural research policy and the federal regulatory frameworks for biotechnology contributed to the ascendance and institutionalization of market-based ideas, backed by the popularity of technological neoliberalism. The challenge of these ideas diluted science-based ideas in the environmental release policy networks in both countries and reinforced the market-based ideas of policy legacies in food safety and labelling. They expanded the original science / risk focus of biotechnology regulation created through lab safety guidelines

to encompass the economic goal of competitiveness through innovation with a preference for market-based instruments. Scientific expertise remained an important resource for policy actors, particularly within the Canadian environmental release and food safety policy networks and the American food safety policy network, as Chapter Five argues. However, the popularity and institutionalization of market-based ideas in agricultural research and regulatory policies and through the federal regulatory frameworks served to enhance the authority and legitimacy of industry actors within policy networks.

TABLE 4-1
Representative societal policy community members
plant biotechnology regulation
Canada and the United States[1]

CANADA	UNITED STATES
AGRI-FOOD INDUSTRY	**AGRI-FOOD INDUSTRY**
Agricultural producer associations	**Agricultural producer associations**
General	General
Canadian Federation of Agriculture	American Farm Bureau Federation
National Farmers Union	National Family Farm Coalition
Commodity	Commodity
Canola Council of Canada	American Soybean Association
Canadian Grains Council	National Corn Growers Association
Flax Council of Canada	US Grains Council
Biotechnology associations	**Biotechnology associations**
BIOTECanada	Biotechnology Industry Organization
Food processing associations	**Food processing associations**
Food and Consumer Products Manufacturers of Canada	Grocery Manufacturers of America
	National Food Processors Association
Seed industry	**Seed industry**
Canadian Seed Trade Association	American Seed Trade Association
PUBLIC INTEREST GROUPS	**PUBLIC INTEREST GROUPS**
Consumer	**Consumer**
Consumers Association of Canada	Consumer Policy Institute, Consumers Union
Environmental groups	**Environmental groups**
Canadian Environmental Network, Biotechnology Caucus	Environmental Defense Fund
Canadian Institute for Environmental Law and Policy	Environmental Law Institute
	National Wildlife Federation
	Union of Concerned Scientists
AGRICULTURAL RESEARCH COMMUNITY	**AGRICULTURAL RESEARCH COMMUNITY**
Canadian Agri-Food Research Council	Agricultural Research Service, USDA
Plant Biotechnology Institute, NRC	Board of Agriculture, National Research Council, National Academy of Sciences
Research Branch, AAFC	Individual public and private sector scientists
Individual public and private sector scientists	National Association of State Universities and Land-Grant Colleges

[1]Given the diverse and fluctuating membership of these policy communities, this list is not exhaustive. It focuses on active members and members that are representative of their sector. Identification of members of the policy community is based on several sources including participation in relevant legislative committee hearings, media coverage, and asking actors about other prominent actors involved in the policy area.
Note that names used here are current as of 1998. Some associations have changed names during the period studied.

TABLE 4-2
Evolution of policy communities, 1973-1998

CANADA[1]	UNITED STATES
	1973 (Focus on safety of rDNA lab research) Researchers National Institutes of Health (NIH) and other research funding agencies
1975 Medical Research Council (takes lead in establishing committee to develop guidelines for rDNA research, which issues guidelines in 1977) Cooperation from the National Research Council, the Ministry of State for Science and Technology, Agriculture Canada and Health and Welfare Canada	**1974** NIH issues guidelines for lab research
	1977 Foundation on Economic Trends established (founded by Jeremy Rifkin, critic of genetic engineering)
	1979 DuPont (becomes involved in biotechnology as a line of business)
	1981 *Industrial Biotechnology Association created (now Biotechnology Industry Organization)
1983 Interdepartmental Committee on Biotechnology Science Council of Canada (publishes discussion paper: Regulation of Recombinant DNA Research: A Trinational Study) National Biotechnology Advisory Committee (established by the federal government)	**1983** *Environmental Policy Institute (Jack Doyle, publishes Altered Harvest in 1985)
1984 Canadian Institute of Environmental Law and Policy (held conference on environmental implications of biotechnology)	**1984** *Agracetus / Cetus (biotechnology firm) (now part of Monsanto)

[1] These dates are based on information from documents and interviews. The dates are sometimes approximate, according to the accuracy of personal recollections. These dates usually reflect the first time an organization took action such as issuing a document, establishing a committee, testifying at a committee hearing, or consulting with state officials. An asterix indicates that the organization is no longer active on issues emerging from plant biotechnology. This list is not exhaustive, but is intended to represent the entry of key types of policy community members.

CANADA

1985
Interdepartmental Sub-Group on Safety and Regulations

1986
Monsanto Canada

1987
Industrial Biotechnology Association of Canada (created)
Agricultural research community
(AAFC begins consultations)

1988
Canadian Seed Growers Association
Canadian Seed Trade Association
Dow Elanco Canada (now Dow AgroSciences)
DuPont Canada
Food and Consumer Product Manufacturers of Canada
Hoechst Canada (now AgrEvo) (CARC conference)

1989
Consumers Association of Canada (issued statement of principles)

1993
AGCare (Ontario)
Canadian Environmental Network
Canadian Federation of Agriculture
Canadian Horticultural Council
Canadian Organic Growers
Canadian Society of Agronomy
Ciba-Geigy (now Novartis)
Council of Canadians (focus on Codex and BST / BGH issue)

1994
Canola Council of Canada
National Federation of Consumers of Quebec

1995
Canada Grains Council

1996
Natural Law Party

UNITED STATES

1985
*Environmental Law Institute (Margaret Mellon)
*Association of Biotechnology Companies created (now merged with IBA under BIO)
American Chemical Society
Calgene
Ecological Society of America
Monsanto
Mycogen

1986
American Society for Microbiology
Committee for Responsible Genetics

1987
Environmental Defense Fund, Rebecca Goldburg,
National Wildlife Federation, Margaret Mellon

1988
Consumers Union (initial focus on BGH /BST)

1990
Northrup King
Pioneer Hi-Bred

1991
American Seed Trade Association
(formed biotechnology committee)

1992
National Food Processors Association
(formed biotechnology committee)

1993
US (Feed) Grains Council

1994
American Farm Bureau Federation

1995
American Soybean Association

1997
National Corn Growers Association

TABLE 4-3
Recent events in the global plant biotechnology industry

AgrEvo	
1994	Established as joint venture between Hoechst AG and Schering AG
1996	Acquired Plant Genetic Systems (Belgium), plant biotechnology firm for $673-million (US)
1997	Acquired Nunhems (Netherlands), fourth largest vegetable seed firm in world
1998	Acquired Cargill's North American hybrid seed business
Dow Chemical Company	
1989	DowElanco established, joint venture between Dow Chemicals (60 per cent) and Eli Lilly and Company (40 per cent)
1996	Dow takes a majority share in Mycogen Corporation, an agricultural biotechnology firm
1997	Acquired all of DowElanco ($900-million US)
1998	Renamed DowElanco to Dow AgroSciences Acquired all of Mycogen Established alliance with Performance Plants (Canada) Established Advanced AgriTraits, a plant genetic clearinghouse
DuPont	
1997	Purchased 20 per cent of Pioneer Hi-Bred[1] (world's largest seed corn firm), cost of $1.7-billion (US), creating a joint firm, Optimum Quality Grains
1998	Established research alliance focusing on wheat with John Innes Centre, The Sainsbury Laboratory, and Plant Bioscience Ltd. (England)
1999	Announced intention to buy remainder of Pioneer Hi-Bred
Monsanto	
1996	Acquired Agracetus[2] Acquired 40 per cent stake in DeKalb Genetics, large seed corn firm
1997	Acquired Holden's Foundation Seeds Inc., a family-owned Iowa seed corn firm at cost of $1-billion (US) Acquired Calgene, plant biotechnology firm
1998	Acquired rest of DeKalb Genetics for $2.3-billion (US) Acquired Delta & Pine Land Co., cotton seed firm for $1.8-billion (US) Announced, then called off merger with American Home Products, valued at $33.6-billion (US) Acquired Cargill's seed operations in Central and Latin America, Europe, Asia and Africa for $1.4-billion (US)
2000	Merger of Monsanto and Pharmacia & Upjohn is completed, creating Pharmacia Corporation. Agricultural business of the company continues under the Monsanto name, as a subsidiary.
Novartis	
1996	Created through merger of Sandoz and Ciba-Geigy[3]
1997	Novartis Seeds created through merger of Ciba Seeds and Northrup King (owned by Sandoz) Acquired Merck & Co., Inc.'s Crop Protection business
1998	Novartis Research Foundation announces plans to invest $600-million (US) for research on plant genomics, including creation of Novartis Agricultural Discovery Institute (NADI) in California, with team of 180 researchers
1999	Novartis spins off Novartis Crop Protection and Seeds Business to merge with Zeneca Agrochemicals (owned by AstraZeneca) to form Syngenta. Novartis retains approximately 60 per cent ownership.

[1] Pioneer bought the Canadian plant biotechnology firms Allelix Crop Technologies (1990) and Biotechnica (late 1980s).
[2] Agracetus was originally called Cetus Madison when founded in 1981 by Winston Brill, a university scientist. In 1984, Cetus set up a partnership with W.R. Grace and Co, renaming the firm Agracetus. In 1990, W.R. Grace bought Cetus' stake.
[3] Ciba-Geigy acquired Funk's in 1974 and Sandoz acquired Rogers Brothers in 1975 and Northrup King in 1976, giving both firms significant stakes in the US corn hybrid seed industry.

TABLE 4-4
Overview of major plant biotechnology firms

NAME	HEADQUARTERS	# COUNTRIES	EMPLOYEES
AgrEvo (1998)	Berlin, Germany	70+	8658
	GLOBAL SALES	GLOBAL R&D	EG OF PRODUCTS
	4.2-billion DM	495-million DM	HT soybeans, canola, corn
	HEADQUARTERS	# COUNTRIES	EMPLOYEES
Dow AgroSciences (1997-98)	Indianapolis, US	50+	3500
	GLOBAL SALES	GLOBAL R&D	EG OF PRODUCTS
	$2-billion (US)	$200-milllion + US	Oilseeds
	HEADQUARTERS	# COUNTRIES	EMPLOYEES
DuPont (1997-98)	Wilmington, US	70+	84000
	GLOBAL SALES	GLOBAL R&D	EG OF PRODUCTS
	$45-billion (US)	$400-million+ (US)	Wheat, oilseeds, corn
	HEADQUARTERS	# COUNTRIES	EMPLOYEES
Monsanto (1998)	St. Louis, US	100+	31800
	GLOBAL SALES	GLOBAL R&D	EG OF PRODUCTS
	$8.6-billion (US)	$1.3-billion (US) total R&D	HT and IR crops: Cotton, cano soybeans, potatoes
	HEADQUARTERS	# COUNTRIES	EMPLOYEES
Novartis (1998)	Basel, Switzerland	142+	90000
	GLOBAL SALES	GLOBAL R&D	EG OF PRODUCTS
	$21.3-billion (US)	12 per cent of sales	IR crops, corn, soybean, alfalfa

Abbreviations
HT=herbicide tolerant
IR=insect resistant

TABLE 4-5

Policy preferences of representative policy community members, Canada and the United States[1]

Regulatory Principles

A1. Regulation should be product-based.
B1. Regulation should be process-based.

A2. Existing institutional structures and statutory authorities are adequate.
B2. New institutional structures and new statutory authorities should be established.

Role of Science

A3. Regulatory decision-making must be based on science.
A4. Risk analysis is an appropriate policy instrument.
A5. The scope of regulation should be restricted to science-based issues.

B3. Regulatory decision making should include socioeconomic, environmental, and ethical concerns within its scope, along with scientific decision-making.

Competitiveness / Internationalization

A6. Regulation should not unduly hamper competitiveness or prevent products from moving in a timely way to market.
A7. Regulation should be designed to protect market access.
A8. Regulation should be based on, consistent with, or harmonized with international standards.

Labelling

A9. Label only for health and safety purposes / significant compositional changes.
B4. Mandatory labelling of all foods with genetically-engineered ingredients.

View of Agricultural Biotechnology: Benefits vs Risks

A10. Agricultural biotechnology promises significant benefits that outweigh the likely risks.
B5. Agricultural biotechnology poses potentially significant and irreversible risks; the precautionary principle should be applied.

[1] These preferences are simplified for the sake of illustrating the degree of consensus and the polarization of viewpoints within policy communities. More nuanced descriptions can be found in the text of Chapter Four.

TABLE 4-5

Policy preferences of representative policy community members, Canada and the United States

Policy community member	A1	A2	A3	A4	A5	A6	A7	A8	A9	A10	B1	B2	B3	B4	B5
CANADA															
BIOTECanada	x	x	x			x		x	x	x					
Canadian Federation of Agriculture			x	x	x	x	x	x	x						
Canada Grains Council		x	x				x	x	x						
Canola Council of Canada		x	x				x	x	x	x					
Canadian Seed Trade Association						x		x							
Consumers' Assn (Natl Food Cmte)			x			x			x				x		
Food & CPM Cda		x	x		x			x	x	x					
Cdn Envtl Network-BT Caucus / CIELAP											x	x	x	x	x
National Farmers Union													x	x	
Natural Law Party (Canada)														x	x
UNITED STATES															
American Farm Bureau Federation					x	x		x		x					
American Seed Trade Association			x						x						
American Soybean Association			x			x	x	x		x					
Biotechnology Industry Organization		x	x					x	x						
Grocery Manufacturers of America		x						x	x	x					
Natl Corn Growers Association			x			x	x	x							
Natl Food Processors Association		x	x			x	x	x	x	x					
US (Feed) Grains Council			x	x			x	x	x						
Consumers Union / Consumers Intl			x	x									x	x	x
Environmental Defense Fund	x			x								x		x	x
Union of Concerned Scientists			x	x								x		x	

TABLE 4-6

Resources of Canadian and American societal associations

ORGANIZATION	MEMBER #	MEMBERSHIP TYPE	FUNDING SOURCES (Members only=50% or more from dues)	STAFF	FOUNDED
American Seed Trade Association	800 firms	Seed industry	Members	10	1883
Canadian Seed Trade Association	180 firms	Seed industry (larger firms)	Members	2	1922
Biotechnology Industry Organization (US)	770 firms	Biotechnology industry	Members	40	1981
BIOTECanada	105 firms	Biotechnology industry	Members, projects	13	1987
American Farm Bureau Federation	4.7 million producers	Producers, rural residents	Members	85	1919
Canadian Federation of Agriculture	20 organizations	Producer organizations	Members	10	1935
American Soybean Association	24000 producers	Soybean producers	Members, govt	40	1920
National Corn Growers Assn (US)	31,000 producers	Producers, related organizations	Members, organizations	34	1957
United States Grain Council	95 members	Producers, related firms	Checkoff, members	38	1960
Canola Council of Canada	110 organizations	Canola-related organizations	Members	23	1967
Canada Grains Council	30 organizations	Organizations in grain trade	Members	4	1969
Grocery Manufacturers of America	140 firms	Processors (brands)	Members	44	1908
NFPA (US)	600 firms	Processors (all)	Members	180	1907
FCPMC (Canada)	170 firms	Processors (brands)	Members	16	1959
Consumers Union (US)	4.8 million individuals	Consumers	Members / grants	38	1936
Consumers' Association of Canada	250,000 individuals	Consumers	Members / govt	6	1947
Environmental Defense Fund (US)	100,000 individuals	Environmental	Members (57%), grants, etc	175	1967
Foundation on Economic Trends (US)	n/a	Social change organization	Foundations, royalties	6+	1977
National Wildlife Fedn (US)	4.8 million individuals	Conservation	Diverse	400+	1911
Union of Concerned Scientists (US)	70,000 individuals	Scientists and citizens	Members (70%), grants	47 FT	1969
CIELAP (Cda)	n/a	Environmental	Diverse	6	1970

TABLE 4-7

Plant biotechnology regulation policy communities and policy networks

INDICATORS OF STATE AUTONOMY AND CAPACITY

Agency	Institutions	Ideas / Mandate	Capacity	Interdepartmental	Total
AAFC / CFIA (ER)	H->M	M->L	H->M	H	H->M
AAFC / CFIA (L)	L	L	M	H	L/M
Health Canada (L)	L	L	M	L	L/M
Health Canada (FS)	M	H->M	M->L	M	M
USDA (ER)	M	M	L->M	L	L/M
FDA (FS)	L/M	L	L/M	L	L/M
FDA (L)	M	L/M	M	L	L/M

ER=environmental release, L=labelling, FS=food safety

INDICATORS OF ORGANIZATIONAL DEVELOPMENT

Interest	Coherence	Representation	Utility	Resources	Total
Cdn biotechnology assn	H	L	M	L->M	L->M
US biotechnology assn	H	M	M	M	M
Cdn producer assn	M->L	M	H	L	M
US producer assn	L	M	H	M	M
Cdn seed assn	H	H	H	L	H
US seed assn	H	H	H	L	H
Cdn food assn	L	M	M	M	M
US food assn	L	M	H	H	H/M
Cdn envtl gps	M	L	N/A	L	L
US envtl gps	M	L	N/A	M	M
Cdn consumer gps	M	L	L	L	L
US consumer gps	M	L	M	M	M

H=High, M=Medium, L=Low

TYPOLOGY OF POLICY NETWORKS

	Environmental release	Food safety	Labelling
CANADA	State-directed -> concertation	Concertation (weak)	Pressure pluralism
UNITED STATES	Concertation -> clientele pluralism	Clientele pluralism	Pressure pluralism

CHAPTER FIVE
THE ROLE OF SCIENCE IN PLANT BIOTECHNOLOGY REGULATION

Knowledge, including in the form of scientific expertise, has long been acknowledged as a potentially vast source of political power. This chapter examines the role of science in the development of the regulation of genetically-engineered plants. In North American political culture, science is a "world view" demonstrated by the widely-held and well-institutionalized treatment of the scientific method as an absolute and neutral source of knowledge.[1] Drawing on its status as a world view, policy makers often translate science into a programmatic idea during policy making. The authoritative nature of science provides legitimacy and can insulate policy choices from challenge.[2] The authority of science, used as a programmatic idea that provides the means to achieve policy goals, has the potential to exclude or marginalize "non-scientific" problem definitions, other programmatic ideas, and incompatible guiding ideas about alternative or additional policy goals. Further, invoking the authority of science can privilege actors with scientific expertise and marginalize those who lack it. This potential often makes the characterization of science a central point of contention in debate over regulatory policy. This chapter examines the characterization of science in the case of regulating genetically-engineered plants by evaluating the extent to which science has been championed or contested as a programmatic idea within policy communities and networks.

The dominant characterization of science within policy communities and networks can range from totally neutral to highly contested. Its characterization can shift advantage among actors during efforts to propose problem definitions, policy instruments, and the appropriate scope of regulation. This chapter begins by outlining the starting points for the characterization of science for the issues of environmental release and food safety.[3] These starting points emerge from societal attitudes in Canada and the United States toward science and from relevant policy legacies.

[1] Goldstein and Keohane (1993): 8-9, in classifying ideas, define world views as those all-encompassing ideas that are deeply-embedded within a culture and thus shape action and discourse. Examples include liberalism and scientific rationality.

[2] Salter (1988): 5-10 discusses how science used in policy making is often characterized as ideal science (highly rational, objective, value-free), even though this "mandated science" differs in several ways. For example, it is rarely considered to be value-free, independent, or authoritative in a final way; and is rarely peer-reviewed or otherwise scrutinized publicly. See also Jasanoff (1990) on how regulatory science differs from research science.

[3] This chapter combines food safety and labelling as an issue for the purpose of examining the role of science because labelling policy in both countries is dependent on the operation of food safety assessment. Labelling is required only for those products that pose health or safety concerns, or vary significantly from conventional counterparts, as determined by the food safety assessment process.

It then discusses how strategies based on rhetorical debates, scientific uncertainty, and patterns of exchange have responded and contributed to the characterization of science during policy making within policy communities and networks. This examination reveals both common elements and variations across the issues of environmental release and food safety and between the two countries. It concludes by examining how the characterization of science has changed over time in each case. The implications of the way in which science has been characterized are summarized according to the hypothesis that the characterization of science is related to the importance of the possession of scientific expertise in contributing to influence within a policy network.

THE INSTITUTIONALIZATION OF SCIENCE AND TECHNOLOGY AS GUIDING AND PROGRAMMATIC IDEAS

Observers of North America have argued that the pursuit of innovation and progress, specifically through the accumulation of scientific knowledge and technological development, is more of a core element of both North American political culture and the larger socioeconomic context than in many other regions. The result is a longstanding and deeply-institutionalized cultural predisposition in Canada and the US to adopt policies favouring the development of science and to endorse science-based regulation as strategies to secure public goods. George Grant, a critic of the "technological society", argued in 1969 that the US and Canada were the most advanced countries in technical achievement, so much so that:

> It moulds us in what we are...in our actions and thoughts and imaginings. Its pursuit has become our dominant activity and that dominance fashions both the public and private realms.[4]

As Grant viewed it, technology became deeply embedded in North America because the continent lacked a history of ideas that could have provided significant impediments to its pursuit. North America adopted an empirical and utilitarian approach to technology which was intertwined with the compatible arguments of Calvinist Protestantism and liberalism.[5] These latter two sets of ideas were dominant in the early settlement history of North America. Both privileged individuals and thus implicitly endorsed empiricism as a basis for knowledge. Further, the pursuit of technology has been seen as the principal means by which to emancipate humanity. Finally, the challenges of

[4] See Grant (1969) especially Chapter One, "In Defence of North America". This quote is from page 15.

[5] Grant defined liberalism in this collection of essays as based on the central belief in the individual's ability and freedom to shape the world as desired (see page 114). See also Angus (1997), Chapter Four, for a discussion of Grant's writings on technology.

settling the largely uninhabited North American territory also encouraged a practical, rather than a philosophical, approach to technology:

> [North Americans] live then in the most realised technological society which has yet been;....Yet the very substance of our existing which has made us the leaders in technique, stands as a barrier to any thinking which might be able to comprehend technique from beyond its own dynamism.[6]

In more recent times, the predominance of liberalism in North America also explains the appeal of a heavy reliance on science in regulatory policy making. Within a liberal democratic society, the limits that regulatory decisions may place on the freedoms of individuals and firms require such decisions to be backed by a "clearly articulated rationale" which either reflects a societal consensus or is neutral, and thus "not seriously biased in favour of the values of one interest group against the values of others".[7] This requirement favours the image of science as a neutral arbiter whose authority is unquestioned:

> [Neutral science] can arbitrate between competing views about social policy options by demonstrating which of these impose the greatest costs or risks upon the society and generate the greatest compensating benefits and it can do so by appealing to empirically demonstrable data and principles of science universally accepted even in pluralistic society. Even if it cannot arbitrate among the different *ends* sought by different persons, it can settle disputes about the *means* to the achievement of those ends. If it cannot in the final analysis decide which policy option is the better one, it can still establish objectively the factual implications of each choice.[8]

Canada and the US share a history of favouring science and technology, but a narrower focus on recent decades of regulatory science reveals some notable differences between them.[9] These differences are evident in procedures of regulatory science and the relationships within the policy communities surrounding regulatory policy areas. For example, in the US, there has been greater contestation of the authority of science, a greater depth of scientific expertise available for use in policy making, and a more significant attempt to open the use of scientific expertise by regulators to public scrutiny.

American enchantment with science is arguably deep-rooted: "Americans have respected science as much as they have worshipped democracy; the two, indeed, have been viewed as

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[6] Grant (1969): 40.

[7] Brunk et al. (1991): 2.

[8] Brunk et al. (1991): 2.. Italics are in the original.

[9] There has been much more written about the place of science and technology in American political life than in Canada, which makes the task of general comparison somewhat difficult. The most useful Canadian-American comparative study to date, which examines differences in the role of science across several case studies, appears to be Harrison and Hoberg (1994).

mutually reinforcing"[10]. This public admiration of science, however, has declined since World War Two and the atom bomb, and particularly since the 1970s.[11] In the latter half of the twentieth century, the American public became more skeptical about the uses of science and demanded greater accountability regarding public investments in the development of science. Further, the character of regulatory science was in flux throughout the twentieth century.

The American federal government first embraced the use of scientific expertise for regulatory purposes in the late nineteenth century. Initially, the relationship between regulators and regulated was one of opposition and hierarchy, reflecting the imbalance in the possession of expertise.[12] By the 1920s, however, industry began to equal government in its level of scientific expertise by hiring its own scientists. The relationship between the regulators and the regulated was transformed to a "progressive partnership".[13] Government began to draw on scientific experts from both public and private spheres for policy making purposes. The common pursuit of science was expected to provide a nonpartisan basis for the resolution of policy problems.

This progressive partnership came under challenge in the 1960s as the ideal image of science on which it was based was portrayed as a smokescreen by American consumer organizations and investigative journalists.[14] These challengers demonstrated that science could be used, and often was, on both sides of a regulatory dispute. This challenge questioned the idea that science could provide absolute authority and certainty as a basis for policy decisions. Regulatory science escaped from the exclusive domain of scientific journals and government documents to the media and sensational books aimed at popular audiences.[15] This contestation of science reduced deference to scientists, which had been a prerequisite for the progressive partnership and the maintenance of a relatively closed policy community in food regulation. Since the 1960s, regulatory science in the US has become an exercise in evaluating competing cost-benefit (or risk-

[10] Smith (1996): 45-55, quote from page 50. See also Price (1965), Chapter One.
[11] This decline might also be tied into evidence of a more general erosion of public confidence in, and deference to, established institutions and authorities in North America. See Inglehart et al. (1996), Chapter Four.
[12] See Marcus (1994) for a thorough analysis of the changing relationship during the twentieth century between regulators and the regulated in the US, focusing on a case of food regulation.
[13] This partnership, Marcus argues, was institutionalized, for example, in the 1938 *Food, Drug and Cosmetic Act* whose provisions were dependent on its existence. This act strengthened the scientific nature of regulation and made it necessary for firms to have access to their own scientific expertise.
[14] Marcus discusses this development, but see also Dickson (1984) and Jasanoff (1990).
[15] One such book was the 1970 critical study of the Food and Drug Administration, titled *The Chemical Feast*, written by James S. Turner.

benefit) appraisals that highlight scientific uncertainty.[16] It is characterized by antagonistic relationships in which individuals rely increasingly on rhetoric rather than science to win the day. Scientists are often viewed as one among many interest groups involved in a particular policy community, although they may still claim to be better able to interpret scientific data. In Canada, there is less evidence of this heightened contestation, stemming in part from fewer opportunities and resources for those who might fuel such contestation.

The US also differs from Canada in the strength of institutionalized scientific resources available for use in policy making. The preeminent example is the National Academy of Sciences (NAS), a non-profit group of scientists. The NAS received a mandate from the American Congress in 1863 to advise the federal government on scientific and technical issues.[17] It is described as the "most influential" scientific institution in the US and as "a premier body of eminent scientists who do the research and the learned crystal-ball gazing that often determine national policies in a range of areas".[18] There has been no equivalent to the NAS in Canada. The federal Science Council of Canada, created in 1966 and eliminated in 1992, was not able to provide the same scope and depth of policy-relevant advice. Other likely candidates, such as the Royal Society of Canada, have not embraced such a role.[19]

Finally, the US moved much earlier and more substantially to open the use of science in policy making to public scrutiny. Since 1970s, for example, congressional measures have been in place that are intended to strengthen the quality of regulatory science and make the use of science more accountable to the public.[20] These measures were a response to the decline in public confidence in American regulatory agencies, such as the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA). These agencies were struggling to fulfil their recently-increased mandates of complex social regulation. Occasional failures resulted at times in

[16] Marcus (1994) and Dickson (1984). Dickson argues that the cost-benefit approach was championed vigourously in the late 1970s and early 1980s by industry representative seeking to claw back gains made by advocates of social regulation in the 1960s and 1970s. The goal was to introduce more of a market-based approach to regulation through the appraisal of costs and benefits.

[17] The policy-relevant activities of the NAS are centered within the National Research Council, which was created in 1916.

[18] Doyle (1985): 364-367.

[19] Doern (1981): 41-47 on the inadequacy of domestic scientific advice available to Canadian policy makers.

[20] Jasanoff (1990), especially Chapter Three. These measures include the *Freedom of Information Act*, adopted in 1970, and the *Federal Advisory Committee Act*, adopted in 1972. Hoberg describes these and other changes in the realm of environmental policy as creating a new doctrine of pluralist legalism. See Hoberg (1992) and Hoberg (1997).

public scandals that eroded confidence. The increased need for science by these regulatory agencies, combined with new legislative provisions that gave the public more access to the courts on regulatory policy issues, brought regulatory science much more clearly into public view.

In Canada, there were initiatives to increase public participation in regulatory policy making in the 1990s. These initiatives were seen in environmental policy making, for example, through a move to multistakeholder consultations and increased public access to the courts through legislative provisions. However, in the case of environmental policy, there have been no institutional changes on par with those that have occurred in the US since the 1970s, leaving the public with fewer tools to demand opportunities for participation in policy making.[21]

Policy legacies and the role of science

Societal attitudes and the general character of regulatory science provide a context for the characterization of science with policy communities and networks. What may be more revealing is how policy legacies providing a starting point for that characterization as regulation on new issues begins. Both Canada and the US have historically made a strong public commitment to pursuing agricultural science which reflects a broader cultural predisposition to favour science and technology; however, the institutionalization of science as a programmatic idea varied somewhat between the two countries in agricultural research and related regulatory policy areas prior to 1973.

As Chapter One has detailed, agriculture in Canada and the US has been pursued as a science for more than a century due to the establishment of extensive public agricultural research systems. These systems resulted in the ascendance and institutionalization of a "scientific" approach to agriculture.[22] They encouraged the pursuit of the discovery of the "scientific laws" of agriculture, and the emergence of agricultural scientists and their claims to be the exclusive source of agricultural innovation. In the US, the creation of the public agricultural research system "was a tacit acknowledgement by many that the institutionalization of agricultural science was the farmers' hope for the future".[23] A new division of labour was created, in which scientists produced agricultural knowledge and producers applied it. In the US, agricultural scientists promoted this new division of labour. They argued that producers lacked the necessary expertise and should rely

[21] Hoberg (1997).
[22] See Marcus (1987) and Marcus (1985): 217-220, for an account of how this occurred in the US.
[23] Marcus (1985): 220.

on knowledge produced within the agricultural colleges and research stations.[24] Thus, historically, science was strongly institutionalized as a guiding idea which privileged agricultural scientists within agricultural research and regulation policy communities. However, its adoption as a programmatic idea varied somewhat between the two countries. As Chapter One concludes (see Table 1-5), the clearest difference between the two countries emerges in policy legacies in research policy and in the sale and use of new plant varieties.

In Canada, these policy legacies resulted in a strong institutionalization of science as a programmatic idea. These legacies provided a foundation for a science-as-neutral characterization within the policy network that formed around the issue of *environmental release* of genetically-engineered plants. As a result, science held the potential to marginalize or exclude competing programmatic ideas and incompatible guiding ideas. The concentration of scientific expertise further reduced the likelihood of legitimate contestation of the authority of science. The federal government played a dominant role and its relationship with the private sector was generally cooperative, resulting in a closed, consensual pattern of exchange. The corresponding American policy legacies provided more fertile conditions for the contestation of science within a policy community through the dilution of science with market-based programmatic ideas. The dilution of science was encouraged by decentralization and increasing privatization of relevant scientific expertise. Further, the legacy of conflict between public and private research interests set the stage for a more adversarial style of regulatory policy making.

In the area of *food safety*, market-based programmatic ideas have been more strongly institutionalized through policy legacies than science in both Canada and the US, although science has been used to legitimate decisions.[25] The weaknesses of federal regulators in both countries left the authority of science vulnerable to contestation. These weaknesses were a result of the fragmentation and shared jurisdiction between levels of government of responsibility for food safety regulation. They were exacerbated by scientific dependence on the private sector in the case

[24] Buttel (1993) also makes this argument.

[25] The primary example is the GRAS (generally recognized as safe) regime for food additives in the US, established in the late 1950s. For a food additive used after 1958 to gain GRAS status and thus be exempt from further review, its safety must be demonstrated through scientific testing. Test results must be widely disseminated within the scientific community so that they are common knowledge among food scientists. Ingredients used prior to 1958 may gain GRAS status through the former method, or through a substantial history of human consumption in the US or abroad. Legal precedent has clarified that the critical point is not whether the substance is actually safe, but whether experts would agree that the substance is safe. Korwek (1986).

of the US, and on private, international, and foreign sources of expertise in Canada. However, the long history of cooperation between public and private sectors on issues of food safety regulation, which resulted in relatively closed policy networks, helped to insulate regulators from contestation.

THE ROLE OF SCIENCE: RHETORIC, UNCERTAINTY, AND EXCHANGE PATTERNS

Rhetorical battles

When a technical regulatory issue becomes controversial, rhetorical battles are often a central component of the policy debate. As part of these battles, claims are often made about the scientific merits of arguments used to justify policy preferences and choices. Such claims lead to the common use of terms such as "junk science", "sound science", "good science", and "bad science". The development of regulatory policy responses for agricultural biotechnology, including genetically-engineered plants, has been characterized by consistent use of the "rhetoric of scientific integrity" to establish legitimacy.[26] The temptation to engage in this rhetoric is particularly strong for regulators who may hope to insulate their policy choices with the padding of authority that emerges from the ideal or neutral image of science, especially when they are under challenge from other members of a policy community:

> Faith in the power of expertise as an engine of social improvement--technical expertise which neither legislators, courts nor bureaucratic generalists presumably possess--has always been an important source of legitimisation for regulators, especially in America.[27]

The term "boundary work" captures a central goal of these rhetorical battles: the attempt by actors to draw lines between scientific and "policy" or "political" decisions by attributing certain characteristics to science that make it both an exclusive and authoritative domain of knowledge.[28] Jasanoff describes boundary work as the effort of scientists to post "keep out" signs to prevent

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[26] This rhetoric is backed by claims of scientific authority, neutrality, and rationality stemming from the use of scientific methods, including peer review, along with the credentials of scientists. Stone (1996): 217-218.

[27] Majone (1997): 152.

[28] Gieryn (1983) details how scientists have attempted to distinguish scientific activities from non-scientific activities in order to garner and then preserve scientific authority and autonomy. The discussion here widens the concept of boundary work to all participating policy community members, not only scientists. See Jasanoff (1987) for other examples of boundary work in the case of regulation of carcinogens. The Mertonian norms of ideal science (universalism, communalism, disinterestedness, organized skepticism) hold that no matter who underwrites scientific activity and for what purpose, the scientist as an individual, by holding to those norms, ensures that science remains pure and autonomous. As a result, its integrity is unscathed. Kloppenburg JR (1988): 45, Jasanoff (1990): 62.

non-scientists from challenging claims labelled as science,[29] which in turn may determine whose voices are legitimate or authoritative. When boundaries hold, assessments by scientists are treated as authoritative bases for policy choices.

Efforts to define policy issues as purely scientific problems can establish boundaries that marginalize or exclude non-scientists. Regulatory controversy is often characterized by competing problem definitions.[30] Each definition may have different implications for the extent of the authoritative and legitimate participation of policy community members. As Feldman and Milch found in their study of policy issues surrounding airports, the mere presence of technical experts in a policy community increased the likelihood that policy issues would be defined in technical terms. It transformed what might have been a political debate "over conflicting values and perspectives" to a technical debate unlikely to serve the public interest and marginalized policy community members without relevant technical expertise.[31] Attempts to define a problem so to claim ownership can provide a powerful political advantage in subsequent policy choices.[32]

Rhetoric and regulation of biotechnology

In both countries, there is much evidence of the attempt by biotechnology proponents and regulators to cast the issue of biotechnology regulation narrowly as a problem of risk analysis that could be resolved largely by science. Throughout the 1980s and 1990s, biotechnology proponents championed the idea of "science-based" regulation in public statements and regulators restricted their focus almost exclusively to technical issues. In Canada, for example, the scope of the two major multistakeholder consultation meetings sponsored by regulators was limited by organizers to scientific and technical issues.[33] Similar tactics were common in the US. The initial statement released by the Office of Science and Technology Policy (OSTP) in 1984 on its plans to coordinate

[29] Jasanoff (1990): 236.

[30] See Linder (1995) for a case study of the discourse surrounding the issue of health risks of electric and magnetic fields, in which five distinct problem definitions emerged.

[31] Feldman and Milch (1982), Chapter Five.

[32] Ozawa (1991).

[33] At the 1993 consultations on regulating agricultural biotechnology, agriculture department official Brian Morrissey (assistant deputy minister of the Research Branch) noted that the consultations intended to focus on the scientific data requirements to assess the safety of a biotechnology products. These consultations also included a "special session on non-regulatory issues" during which ethical, socioeconomic, and other issues were discussed. Canada. Agriculture and Agri-Food Canada, Health Canada, and Environment Canada (1993): 3. The 1994 consultations on labelling were similarly designated a "technical" meeting. See Canada (1994b): 2.

biotechnology regulation noted that all of the agencies involved in regulation would base their efforts on "sound science".[34] Jasanoff argues that the leadership of the OSTP in biotechnology regulation showed that American policy makers had decided that it was an issue for experts and not appropriate for broad public participation:

> The object at every turn seemed to be to demonstrate that the mainstream forces of science--not activists like Jeremy Rifkin nor the assorted nay-sayers of the environmental movement--were in the driver's seat with respect to managing the emergent technology.[35]

Another form of boundary work can often be detected in examining debates over key terms. These debates are not so much about setting lines between science and politics. Instead, they attempt to institutionalize terms that suggest appropriate measures in setting goals, methods, and the scope of regulation. The central debate in regulation of agricultural biotechnology revolves around the degree of novelty of genetically-engineered products. From a scientific perspective, there is no debate on the matter of what is new about genetic engineering in terms of its theoretical potential in agricultural applications. In particular, genetic engineering, by enabling the transfer of genes between any species, vastly expands the inventory of genetic material available to scientists. Conventional methods limited scientists in terms of the choice of species between which genetic material could be transferred. The new techniques also capitalize on the ability to identify precisely which genes are responsible for which traits. These specific genes can then be introduced into existing plant varieties or animal breeds, for example, offering the possibility of greater precision in genetic transfer than that achieved by older methods. These techniques have the potential to accelerate the pace of genetic experiments and sometimes the scope of production of novel organisms. In sum, what is both most attractive and most alarming about genetic engineering is its potential to enable the creation of organisms that could not be produced without it.

Despite agreement on the potential of genetic engineering as a technique, a rhetorical battle persists between proponents and skeptics about its degree of novelty that is so common that it is predictable. From the mid-1980s into the 1990s, this debate took place in various forms. It has been a fundamental issue despite its purely rhetorical character because the degree of novelty accepted by regulators provides the parameters for regulation. It suggests the degree of risk that may result from the use of genetic engineering and the likely level of scientific uncertainty, and

[34] United States. Executive Office of the President. Office of Science and Technology Policy (1984): 50858.
[35] Jasanoff (1995a): 315.

thus the appropriate degree of oversight. The two sides of the debate neatly mirror the polarization between biotechnology proponents and skeptics in Canada and the US.

In the novelty debate, terminology is used as ammunition. The term "biotechnology" tends to be preferred by biotechnology proponents. It is ambiguous on the question of novelty. Proponents argue that "biotechnology", a term used before the twentieth century,[36] has been in use for a very long time. The tools of the "new" or "modern" biotechnology (i.e., genetic engineering) are simply a logical extension, or evolution, of human activities in genetic manipulation that date back centuries to the earliest plant breeding efforts. Biotechnology is also as old as the fermentation techniques that allow the brewing of beer and making yeast breads, yogurt, and cheese.[37] In contrast, biotechnology skeptics who wish to underline what they see as qualitative differences in outcomes that may result from the use of the new recombinant DNA techniques tend to use the term "genetic engineering".[38] They point out that while the biotechnology industry argues that its products are not so new, they are certainly novel enough to be patented and otherwise protected through intellectual property rights.[39]

More concretely, biotechnology proponents have attempted to deemphasize the novelty of genetic engineering through the "product - process" debate. This debate was most prominent in the mid- to late 1980s in Canada and the US as regulatory responses were being developed, although it was still occurring in the late 1990s. The "product, not process" position means that it is the traits of the products that should be the focus of safety / risk assessments and not the use of a specific process that triggers regulatory review.[40] A product-based approach minimizes discrimination against a specific technique such as genetic engineering. Most proponents, especially scientists, have favoured the product-based approach, while skeptics often endorsed a process-based

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[36] Grace (1997): 2.

[37] See Canada. Agriculture and Agri-Food Canada (1995b) as an example, although this argument has become so common that one can almost predict its use by proponents seeking to reassure skeptics.

[38] There are also references, at times, to genetic modification and genetic alteration, but genetic engineering best reflects the high technology and apparent precision of rDNA techniques. Proponents occasionally refer to "genetically-enhanced" organisms.

[39] Canada. Agriculture and Agri-Food Canada, Health Canada, and Environment Canada (1993). This point was made by Brewster Kneen during a multistakeholder consultation, but can be found frequently in statements by critics.

[40] There is a fairly extensive history of product-based regulation in Canada and the US, including in the area of food safety and relatively few precedents of process-based regulation. One exception would be provisions regarding the use of irradiation on food products.

approach.[41] To bolster their arguments, particularly in the US, proponents often have claimed that genetically-engineered organisms are not fundamentally different from organisms produced through more conventional means and thus do not pose unique risks.

Scientific uncertainty

Beyond rhetorical battles, there have also been fierce debates over the actual scientific evidence underpinning regulatory policy choices and the ongoing quality of regulation.[42] As in the rhetorical aspects of the debate, there has been much more public debate in the US than in Canada. Claims about the degree of scientific uncertainty surrounding risks are at the core of this debate. The discussion here does not assess the merits of arguments about the degree of risk posed to human health and the environment by genetically-engineered plants and other organisms, but is intended to demonstrate the presence of scientific uncertainty as a central aspect of this policy area.

Virtually all regulation based on risk analysis is characterized by some degree of scientific uncertainty.[43] It requires regulators to exercise discretion because there is a lack of conclusive evidence. Further, in many cases, the techniques used in risk analysis are still under debate and the science underpinning regulation is often in flux as research efforts are pursued. Finally, when scientists from various disciplines are engaged in the debate, their differing perspectives can heighten the perception of scientific uncertainty. Such scientific pluralism is not new in agricultural sciences[44], but it has likely proliferated in recent decades as newer fields of study such as molecular biology and ecology have emerged and grown in prominence.

In the regulation of genetically-engineered plants and other organisms, the novelty of the products means that there is no historical timeframe in which to assess the products. These new products are being assessed for hypothetical risks. The lack of experience has encouraged the strategy of comparison to conventional counterparts through concepts such as "substantial equivalence" and "familiarity". For many aspects of risk assessment, there is a lack of adequate

[41] This conclusion is based on personal interviews and published statements. Not all proponents endorsed the product-based approach, because some were concerned that it would result in a wider scope of regulation than a process-based approach. Further, some biotechnology and food firms favoured a process-based approach as a method to bolster consumer confidence in genetically-engineered products.

[42] See Hileman (1995) for an overview of the debates among scientists.

[43] Jasanoff (1990).

[44] For example, even in the early days of agricultural science, there was no consensus on exactly what it was and how it should be pursued. Marcus (1987).

baseline information about conventional counterparts which complicates the task. Environmental release assessment is challenged by the complexity of ecosystems. Food safety assessment is challenged by the apparent impossibility of conducting controlled long-term experiments on human subjects and the difficulty of conducting feeding trials with animals with whole foods. Faced with significant challenges in reducing the high level of scientific uncertainty about the risks of genetically-engineered organisms, biotechnology proponents have emphasized what is already known about conventional counterparts and the growing body of knowledge about these novel organisms. For example, existing scientific data on the characteristics of plants, such as weediness, may be useful for the issue of environmental release. For the issue of food safety, there is an existing body of knowledge about major known food allergens, such as those found in wheat, milk, and peanuts; and about food toxins.

Environmental release

Since the early 1980s, the issue of the risks of widespread environmental release of genetically-engineered plants has provoked a vigourous scientific debate which has evolved slightly as new studies have become available.[45] The risks debated have included the effects of insect-resistant plants on speeding the development of insect resistance to the incorporated pesticide and on non-target organisms; gene transfer from genetically-engineered plants to wild relatives which could cause weediness; the proliferation of genetically-engineered varieties in uncultivated ecosystems which could alter the existing balance; and the impact of widespread cultivation of herbicide-resistant crops such as whether it increases levels of herbicide use and thus increases risks to the environment.[46]

In the mid-1980s as regulations were being prepared, the environmental debate in the US was particularly visible. The debate took place both in scientific journals[47] and more public venues

[45] Examples of recent studies include Crecchio and Stotzky (1998) which suggested that Bt plants may cause active Bt toxins to accumulate in soil; and Snow and Jorgensen (1998) which suggested that transgenic wild plants would be just as likely to survive in the wild as their conventional counterparts. This latter study contradicts arguments made by biotechnology proponents that genetically-engineered plants would be unlikely to survive in the wild.

[46] Much has been written about the potential environmental risks. See, for example, Forsyth (1998), Kareiva and Stark (1994), Krimsky and Wrubel (1996), Rissler and Mellon (1996), Goldburg (1990), and Hardy and Segelken (1998). See Table I-1 which notes that in 1998, herbicide-resistant crops accounted for 49.5 million acres of the total of 70 million acres grown worldwide, or about 70 per cent.

[47] Examples include Sharples (1987), Davis (1987), Tolin and Vidaver (1989), Tiedje et al. (1989), Miller (1994), and Snow and Palma (1997).

such as congressional hearings.[48] It revealed division within the scientific community and between federal regulatory agencies.[49] The Environmental Protection Agency (EPA) found itself in conflict with the Food and Drug Administration (FDA) and the US Department of Agriculture (USDA) for several years, and under heavy criticism from some members of the external scientific community.[50] The EPA's efforts to carve out an approach that focused more exclusively on the novel risks of genetic engineering (process-based approach) was heavily criticized by other agencies. One of the sources cited by opponents of the EPA's approach was a 1989 National Research Council report. This report recommended that risk assessment focus on the characteristics of an organism (product-based approach) and declared that the risks posed by genetically-engineered plants should not be any different than those posed by plants produced through traditional methods with similar traits.[51]

Concern within the executive office about the conflict among agencies and the resulting regulatory uncertainty resulted in the creation of the Biotechnology Science Coordinating Committee in 1985. This committee was intended to build scientific consensus among the agencies, but largely failed. The 1992 "scope" document released by the Office of Science and Technology Policy appeared to be yet another attempt to increase consistency across federal regulatory agencies. It was meant to bring agencies more closely into line with the executive's preference for a product-based approach to biotechnology regulation relying on risk assessment.[52]

Scientists outside regulatory agencies also took differing positions. Presentations to congressional committee hearings in the early and mid-1980s illustrated the high degree of

[48] See, for example, United States. House Committee on Science and Technology. Subcommittee on Investigations and Oversight, and Subcommittee on Science, Research and Technology (1983), U.S. Congress. House Committee on Energy and Commerce. Subcommittee on Oversight and Investigation (1985), U.S. Congress. Senate Committee on Environment and Public Works. Subcommittee on Toxic Substances and Environmental Oversight (1986), and U.S. Congress. House Committee on Science, Space, and Technology. Subcommittee on Natural Resources, Agriculture Research and Environment (1988).

[49] See United States. General Accounting Office (1986): 14 for an example of the competing scientific arguments of proponents and skeptics. Scientific uncertainty encouraged disputes over the proper definitions of key regulatory terms such as "genetic engineering", "mutagen", "pathogen", "plant pest", and "release into the environment". See United States. Department of Agriculture (1987). See Krimsky (1991) on debates among agencies.

[50] As of the late 1990s, members of the American policy community reported that relationships among the agencies were much better and generally cooperative on issues of biotechnology regulation

[51] National Research Council (1989). See Chapter Six for recommendations and conclusions.

[52] The proposed scope document noted that "federal regulatory agencies experienced unanticipated difficulty developing operational definitions for regulatory purposes". United States. Executive Office of the President. Office of Science and Technology Policy (1990): 31119. See United States. Executive Office of the President. Office of Science and Technology Policy (1992) for the final version.

uncertainty about the nature of the risks and concerns about the lack of regulatory capacity to assess them.[53] Microbiologist Martin Alexander, at the time chairman of the Recombinant DNA Study Group of the EPA Science Advisory Board, underlined the fact that supposedly scientific arguments in the debate lacked evidence to support them:

> much of the discussion has resulted in a polarization of positions, and eminent biologists have frequently expressed views that are not based on knowledge of the environmental sciences. It is surprising to listen to or read these discussions and see how little science there is to support such very strong views. Some of these individuals, who are unquestionably highly competent in their own disciplines, believe that the probability of there being an undesirable ecological effect is absolutely zero, whereas others feel that the likelihood is almost 100 percent.[54]

Further commenting on the demands that were being made of scientists in developing risk analysis for genetically-engineered organisms, Alexander commented that "we have no histories. You are asking, in effect, a scientist to predict the outcomes of a nonexistent field of speculation."[55] Another scientist at the hearing, ecologist Frances Sharples, noted that despite studies of past introductions, there was no way to know ahead of time as of 1983 whether a given exotic variety would pose a problem.[56] The perception of uncertainty was also heightened by the sharply contrasting views generally between molecular biologists and ecologists on the nature of risks.[57]

In Canada, there have been similar debates about environmental consequences, but rarely in more public arenas such as legislative hearings. At the 1993 multistakeholder workshop organized by federal regulatory agencies, a few participants commented that there was inadequate scientific expertise within the agencies. They noted, for example, that the department of agriculture did not

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[53] Further, more general concerns about the adequacy of the USDA's efforts to create a regulatory response for environmental release of genetically-engineered organisms were raised in United States. General Accounting Office, (1986). Concerns about the risk analysis efforts of the USDA, FDA, and the EPA in biotechnology regulation were noted in United States. General Accounting Office (1988).

[54] United States. House Committee on Science and Technology. Subcommittee on Investigations and Oversight, and Subcommittee on Science, Research and Technology (1983): 9.

[55] United States. House Committee on Science and Technology. Subcommittee on Investigations and Oversight, and Subcommittee on Science, Research and Technology (1983): 54.

[56] United States. House Committee on Science and Technology. Subcommittee on Investigations and Oversight, and Subcommittee on Science, Research and Technology (1983): 28.

[57] To generalize, molecular biologists focus their work at the cellular level, on genetic traits, and on single organisms, while ecologists study the complex interactions of organisms. Molecular biologists tend to describe their work as very precise while ecologists stress the complexity of ecosystems. Ecologists thus tend to be more sensitive to the possibility of environmental risks, while molecular biologists see risks as minimal. See the debate between Sharples (1987) and Davis (1987) as a prime example, which included a claim by Davis that the expertise of ecologists was less relevant to risk assessment of the release of genetically-engineered organisms than that of population genetics, bacterial physiology (his own field), epidemiology, and the study of pathogenesis.

have evolutionary ecologists on staff. It lacked a baseline of measurements of the environmental impacts of traditional crops. They argued that inadequate baseline data would make risk assessment based on comparison to conventional counterparts meaningless.[58]

In both countries, the rapid growth in the cultivation of genetically-engineered plants incorporating Bt, which began in 1996, became a central focus of the environmental release debate in the late 1990s.[59] Environmentalists and the organic agricultural industry argued that the widespread and constant use of Bt crops would result in quick development of insect resistance to Bt and thus cost organic farmers one of their most valuable pest control tools.[60] Other concerns included the effects of Bt toxins on non-target insects such as beneficial insects and on soil microorganisms and the possibility of gene transfer. In February 1999, the environmental group Greenpeace organized a petition in the US on the use of Bt crops. It called on the EPA, which is responsible for regulating pesticidal plants, to cancel all registrations for Bt plants.[61] Some scientific consensus has developed that Bt crops may well hasten the development of insect resistance. In 1999 and 2000, regulators in Canada and the US introduced requirements for refuges (planting strips of non-Bt crops around Bt crops) which are intended to reduce development of resistance.[62]

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[58] Canada. Agriculture and Agri-Food Canada, Health Canada, and Environment Canada (1993): 34-35. A Canadian plant biotechnology scientist also noted that consultation of ecologists by regulators could have been done more thoroughly. Personal interview, September 1998.

[59] Bt crops have been genetically-engineered to carry insecticidal proteins called *Bacillus thuringiensis*. In 1997, Bt crops of cotton, corn, and potatoes were being grown on more than six million acres in the US. Hardy and Segelken (1998).

[60] Organic farmers have used Bt proteins as a pest management tool for decades. They apply it occasionally during the growing season by spraying, as needed.

[61] Organizations signing on to the petition included: the International Federation of Organic Agriculture Movements, the International Center for Technology Assessment, the Sierra Club, the National Family Farm Coalition, the National Campaign Against the Misuse of Pesticides, the Organic Crop Improvement Association (Arkansas Chapter), Rural Advancement Fund International-USA, California Certified Organic Farmers, the Center for Ethics and Toxics, the Institute for Agricultural and Trade Policy, the New York Coalition for Alternatives to Pesticides, and the Texas Organic Growers Association. Details available at Greenpeace's website: http://www.greenpeace.org/~geneng/ [March 12, 1999]. The Environmental Defense Fund also submitted a petition in July 1999 calling for the EPA to require refuges to protect non-target insects until more data is available on the effects of pollen from Bt corn on those insects.

[62] The issue was still being studied into the year 2000. For example, the National Academy of Sciences (NAS) undertook a review of pesticidal crops in 1999, with the results expected in early 2000, intended to examine the risks and benefits of these plans, to recommend research needed to better assess the risks and benefits, and to examine the social and economic impacts of the US policy response. Details are available at the NAS website: www.nas.edu/.

Food safety

Compared to environmental release, food safety assessment of genetically-engineered plants received relatively little public scrutiny through much of the 1980s and 1990s in either country. American public interest groups and organizations, including the Union of Concerned Scientists, the Environmental Defense Fund, and Consumers' Union followed the development of the American policy response. FDA regulators. however. provided very few opportunities for public debate that might have highlighted scientific uncertainty. As detailed earlier in Chapter Three, the FDA appeared to make a concerted effort through much of the 1990s to keep the issue's visibility very low. It did not pass any new regulations, held very few public meetings, and accepted comments on its policies, but never summarized or responded to them. Only in 1999, with growing consumer resistance and public awareness of the arrival of genetically-engineered foods in the marketplace, did the FDA feel compelled to hold three one-day public meetings in which a broad spectrum of groups and individuals were able to comment on its food safety and labelling policies. In Canada, as in the case of environmental release, biotechnology skeptics lacked opportunities and resources to bring the issue of food safety assessment firmly into public view until the late 1990s. In the late 1990s, the growth of consumer resistance overseas prompted organizations such as the Sierra Club of Canada and the Council of Canadians to make the commercialization of genetically-engineered crops a higher priority issue. Tactics included public demonstrations outside supermarkets.

Also in contrast to environmental release, the issue of food safety was arguably more insulated from the exploitation of scientific uncertainty. The longer history of food safety regulation in both countries facilitated claims of adequate expertise by regulators. These claims were backed by the presence of a relatively large scientific community in the US and internationally that specialized in food safety issues such as toxicology and allergenicity.[63] Databases on food toxins and allergens that already existed provided a more thorough baseline for risk assessment than any data relevant to environmental risk. Further, the food safety assessment issue avoided the

[63] For example, the Institute of Food Technologists, which has 28,000 food scientists as its members, is headquartered in the US. The food regulation policy community also has a history of having ample opportunities for information exchange. Some examples during the development of more comprehensive regulation of food additives in the US included the *Food, Drug, and Cosmetic Law Quarterly*, which was first published in 1946; the creation of the Food Law Institute at New York University in 1949; and in 1950, creation of a Food Protection Committee by the National Research Council (National Academy of Sciences). See Marcus (1994).

same clash of scientific perspectives that occurred between molecular biologists and ecologists on the issue of environmental release.

Although the issue of food safety did not have the same public profile as environmental release through the 1980s and 1990s, there are concerns about the lack of knowledge regarding the long-term effects of human consumption of genetically-engineered food and the testing procedures used. For example, the Environmental Defense Fund has noted that scientific studies demonstrate that genetic engineering may cause unexpected and unpredictable effects in an organism, including changes in the levels of toxins.[64] Other concerns include the effects of using antibiotic-resistant market genes and the possible allergens that may be introduced into foods, due to the insertion of novel proteins whose allergenic potential is unknown and is difficult, if not impossible, to test.[65] The FDA's 1992 statement on the food safety of genetically-engineered plants clearly indicated the agency's own uncertainty through its terminology as in this example:

> The agency *believes* that the use of host plants with a history of safe use, coupled with a continuation of sound agricultural practice, will minimize the potential for adverse public health consequences that *may* arise from increased levels of unknown or unexpected toxicants.[66]

In 1999, the Alliance for Bio-Integrity posted on its web site FDA documents demonstrating that some FDA officials had expressed far greater uncertainty in internal policy documents than that acknowledged in the 1992 statement and subsequent policy initiatives.[67] FDA officials stated, for example, that genetically-engineered foods posed different risks than conventional counterparts, including the production of unexpected toxins and allergens--a view not reflected in the 1992 statement.

In Canada, critics of food safety assessment have raised similar concerns, although they have had few public venues. In January 2000, a group of independent scientists, academics, and

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[64] Environmental Defense Fund (1991).

[65] Concerns are also raised in National Wildlife Federation (1992). The allergy issue became one of the most prominent concerns in the 1990s. At the 1999 FDA hearings, scientists on both the proponent and skeptic sides of the debate generally agreed that the ability to test novel proteins for allergenic properties that are not similar to existing known allergens, was still quite limited. See, for example, United States. Food and Drug Administration (1999a, 1999b). A 1996 report on food safety issues by a joint FAO-WHO workshop encouraged caution on the part of researchers working with genes that could be allergenic and noted that more work was needed on the identification of allergens. See United Nations. Food and Agriculture Organization (1996).

[66] United States. Food and Drug Administration (1992): Section VII (A), italics added.

[67] These documents can be found at the Alliance for Bio-Integrity web site www.bio-integrity.org (November 1999). The Alliance for Bio-Integrity launched a lawsuit against the FDA's food safety and labelling policy in 1999.

agricultural professionals formed "GE Alert" for the purpose of sharing information with the Canadian public about the possible risks of agricultural biotechnology. One of these scientists examined all of Health Canada's food safety assessment decisions posted on its web site. She concluded that the available information did not support the department's conclusions that those genetically-engineered food sources already approved were actually safe for human consumption in terms of risks of toxicity and allergenicity.[68]

In sum, scientific uncertainty is a central characteristic of the issues of environmental release and food safety. Through the 1980s and 1990s, that uncertainty was exploited far more on the issue of environmental release. Most of the exploitation was by biotechnology skeptics, given their concerns over rapid commercialization of genetically-engineered crops Proponents also argued, however, that if society waited for solid evidence biotechnology would never be developed. Other proponents have described concerns raised on the basis of scientific uncertainty as "almost entirely bogus", a smokescreen designed to prevent the introduction of a technology, "a metaphysical objection that is not grounded in sound science or legitimate environmental objectives", "intellectually dishonest", and "extremely unreasonable".[69] A scientist who works for an American environmental interest group acknowledged that scientific uncertainty regarding the impacts of genetically-engineered crops has decreased slightly since the mid-1980s, but argues that much uncertainty remains.[70]

The exploitation of scientific uncertainty has a long history in policy making[71] and the American political system appears to encourage the strategy more than the Canadian system. Jasanoff argues that in the case of biotechnology regulation, the involvement of several agencies and scientific committees ensured that there would be differing views of risks, leading to contestation.[72] However, in the Canadian case, which has similar fragmentation of authority over

[68] Flaws in the process include feeding trials that test only the protein produced through genetic engineering, rather than the whole food; lack of longer term feeding trials; inconsistent standards across products, and a heavy reliance on assumptions and inferences rather than actual testing. Clark (2000). Clark is a professor at the University of Guelph. Health Canada responded to Clark's criticism by describing her analysis as misinformed and inaccurate. See http://www.hc-sc.gc.ca/food-aliment/english/subjects/novel_foods_and_ingredient/health_canada_response_gmo.html [February 29, 2000].

[69] Personal interviews, September and October 1998.

[70] Personal interview, November 1998.

[71] For example, during debate prior to the adoption of the first food safety legislation in the US in 1906, the lack of scientific evidence about food safety concerns allowed various groups to use scientific data to argue their preferences. Wood (1986): 190-191

[72] Jasanoff (1995a).

biotechnology regulation, differing views of risk have been less visible and there has been less contestation. This finding suggests that other factors beyond the fragmentation of authority have been more important in contributing to the varying levels of contestation between the two countries.

Increasing levels of debate over scientific uncertainty and growing consumer resistance on both issues in the 1990s prompted regulators in Canada and the US to commission special reviews of some of their policies to shore up their credibility. In late December 1999, Canadian regulators announced the creation of an independent expert panel on the safety assessment of biotechnology foods that was expected to issue a preliminary report within six months and a final report by late summer 2000. In the US, regulators announced reviews and public hearings of their environmental release, food safety, and food labelling policies in 1999. In July 1999, US Agriculture Secretary Dan Glickman announced that he would establish an independent review of the environmental release policy response.[73] In 1999, the FDA announced three public meetings to allow comment on its policies, suggesting the potential for revision.

Patterns of exchange

Resource exchange among policy community members reveals dependencies and interdependencies within a policy network.[74] If critical resources are scarce, either difficult to secure or generate, their allocation becomes that much more important in determining relative power within a network.[75] Members who control scarce resources, such as technical expertise relevant to regulation, may be able to wield power over those who do not. They can exchange expertise, for example, for the acquisition of "informational allies" and legitimacy, and thus create a broader base of support for their policy preferences. Over time, exchanges may recur frequently

[73] Glickman made several commitments at the time regarding the USDA's policy on agricultural biotechnology, including the establishment of regional sites that would evaluate biotechnology products on an ongoing basis. See press release titled "Glickman Announces Independent Review of USDA's Biotech Regulatory Process", dated September 29, 1999, available at http://www.usda.gov/news/releases/1999/09/0383 [January 27, 2000] and speech notes titled "New Crops, New Century, New Challenges: How Will Scientists, Farmers, And Consumers Learn to Love Biotechnology And What Happens If They Don't?", delivered July 13, 1999, available at http://www.usda.gov/news/releases/1999/07/0285 [January 27, 2000]. In September 1999, it was announced that the National Academy of Sciences would undertake the promised independent review and establish a standing committee on agricultural biotechnology.

[74] Knoke et al. (1996): 4, 8-9, 17-19

[75] Critical resources often include relevant technical information, political knowledge, tangible (financial) and intangible (legitimacy) resources.

which can create or reinforce inequalities within a policy network:

> Access to resources and their exchange confer unequal positional advantages, which can be represented as the actors' locations either near the centers or on the peripheries of resource networks' social spaces. Actors who are well-connected to important other actors thereby gain important advantages through their access to flows of political resources. Actors at the network margins, whose ties connect them mainly to other peripheral actors, cannot tap sufficient quantities of quality political resources to participate effectively in collective actions.[76]

Without redistribution in the allocation of valuable resources, a policy network can become a stable structure of exchange patterns in which asymmetries of power permit a consistent group of state and societal actors to dominate. Building exchange links with central actors can move a policy community member closer to the centre of influence. Without its own internal resources, however, it remains dependent.

In developing regulation for plant biotechnology, the central mechanisms of exchange have been state-societal consultations, scientific workshops and meetings of advisory expert committees, and informational coalitions intended to accumulate the highly-sought resource of legitimacy. These exchanges are intended to gather technical expertise and are used as a counterweight to the high level of scientific uncertainty.[77] For example, regulators have organized consultations and scientific workshops to reinforce policy choices with the aura of legitimacy and expertise. At times, state officials may need technical information held by societal actors; they may also solicit scientific recommendations but choose not to follow them.[78] State officials themselves may provide technical information to other societal actors lacking in expertise which may result in endorsement. Further, societal actors often exchange informational and other resources among themselves, whether through informal contact that builds tacit alliances or

[76] Knoke et al. (1996): 18.

[77] While both countries have had legislative committee hearings on the issues of biotechnology policy, these mechanisms have been a less important means of exchange, primarily because of the relatively minimal involvement of elected officials through the 1980s and 1990s in biotechnology regulation.

[78] As Browne (1988) argues in the case of American agricultural associations, the complexity of much of policy making ensures an ongoing role for societal actors, who may provide important knowledge about policy problems and solutions. Jasanoff (1990) notes that although many aspects of the use of scientific advisory committees are formalized in the US, agencies are rarely required to follow the conclusions of such committees.

through more formal coalitions.[79]

Consultations

Canadian and American regulators have differed somewhat in their consultation strategies on issues of agricultural biotechnology (see Table 5-1).[80] For the issues of environmental release and food safety issues, American regulators relied more heavily on science-focused consultations such as scientific workshops and advisory committees during the 1980s and 1990s. They often referred to these consultations in public statements and to scientific consensus generally to provide reassurance of adequate scientific capacity.[81] For example, the FDA noted in 1995 that: "*it is widely accepted in the scientific community* that a food derived from a new plant variety should be evaluated relative to other commercial varieties of the crop".[82] In 1999, FDA Biotechnology Coordinator Dr. James Maryanski stated, referring to the agency's experience in reviewing genetically-engineered food processing enzymes and pharmaceutical products, and to the experience of the Recombinant DNA Advisory Committee of National Institutes of Health in monitoring the lab safety guidelines of the late 1970s: "[the FDA] had a great deal of experience that we were able to draw on when the questions about modern biotechnology and its application to foods began to be posed to FDA."[83] USDA officials made similar claims. For example, in 1984 Dr. E.L. Kendrick, Chairman of the USDA Recombinant DNA Research Committee, in referring

[79] Formal coalitions on issues of agricultural biotechnology regulation began to emerge in the late 1990s, mores so in the US than in Canada. Browne (1988): 167-190 argues that the growing use of coalitions within the American agri-food associational system responds to increasing fragmentation of authority and influence in policy making. Coalitions reintegrate diverse groups with common interests, compensate for inadequate resources, and enhance the legitimacy of claims of representation. However, coalitions do not guarantee the achievement of desired results. For example, some organizations may find their specific interests submerged under the more general policy consensus that acts to bind the coalition.

[80] The importance placed by societal members of policy communities on consultations in legitimating policy choices can be discerned in interviews. Biotechnology proponents almost unanimously agree that there have been relatively adequate consultations, while skeptics tend to emphasize the flaws in the consultation procedures. A detailed discussion of consultations is available in Chapter Three.

[81] There is continuing evidence of the use of this tactic among American regulatory agencies. For example, in December 1998, the newly-appointed FDA Commissioner, Dr. Jane Henney, vowed to improve the science base within FDA in response to criticism that the FDA was approving new products too quickly because it could not resist industry pressure. Henney is quoted at saying "I believe that the discipline of science and a scientific approach must ground our decision-making." See Fox (1998).

[82] United States. Food and Drug Administration. Center for Food Safety and Applied Nutrition (1995): 4, italics added.

[83] United States. Food and Drug Administration (1999a).

to the American public and private agricultural research system, stated:

> We believe this vast network of scientific expertise, laboratories, and controlled environmental facilities, has indeed provided well for the nation in the past, and with our careful planning and introduction of the biotechnology initiative, including genetic engineering, we will be able to continue to so serve the nation in the future....the agricultural research community has had a long and highly successful history of developing the genetic components of plant, animal, and microbial life for the benefit of society and its environment broadly.[84]

In 1988, USDA officials were still making statements to reassure the public that adequate expertise was available to underpin regulation:

> USDA recognizes the importance of maintaining the public's confidence in the biosafety of agricultural research. USDA has established the Agricultural Biotechnology Research Advisory Committee (ABRAC) to review the biosafety aspects of USDA-funded research projects on genetically engineered organisms before the projects move from the laboratory to the field. Comprised of national experts in science, law, bioethics, and environmental policy, ABRAC's recommendations will assist senior agency officials in making science-based decisions on the safety of agricultural research involving biotechnology.[85]

In contrast, Canadian regulators were less preoccupied in the 1980s and 1990s with providing visible evidence of the bolstering of their scientific capacity through consultations. Instead, they were intent in the mid-1990s on broadening their traditional consultation patterns to a somewhat wider range of policy community members through a few selective multistakeholder meetings.[86] This strategy suggests that their priority was to increase the legitimacy of policy choices by "democratizing" the policy making process. Despite these Canadian efforts, American policy community members had more opportunities to comment on the policy responses to all three

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[84] U.S. Congress. Senate Committee on Environment and Public Works. Subcommittee on Toxic Substances and Environmental Oversight (1984): 50.

[85] This statement was made by Dr. Kenneth Gilles, Assistant Secretary for Marketing and Inspection Services, [U.S. Congress. House Committee on Science, Space, and Technology. Subcommittee on Natural Resources, Agriculture Research and Environment (1988): 86 The USDA established its mostly internal Agriculture Recombinant DNA Research Committee (ARRC) in 1976 to coordinate within USDA on biotechnology research issues. In 1988, ARRC was replaced by the Agricultural Biotechnology Research Advisory Committee (ABRAC) which was comprised of fifteen external experts who met once or twice annually to discuss scientific issues such as environmental risk. Young and Asner (1996) and Fox (1996). ABRAC was eliminated in 1996; its main contribution was to voluntary research guidelines published by the USDA in 1991.

[86] See, for example, Canada. Agriculture and Agri-Food Canada. Food Production and Inspection Branch. Plant Industry Directorate (1994b): 1, footnote 1, which summarizes some of AAFC's consultations. Not everyone was happy with the use of multistakeholder consultations. The representative of a Canadian agri-food association complained forcefully that the poor design of Health Canada's multistakeholder consultations prevented the development of consensus and allowed state officials to delay policy choices (Personal interview, July 1998). However, one could also interpret this result as providing state officials with insulation from societal pressures in a situation of weak capacity.

issues (environmental release, food safety, and labelling) in the 1980s and 1990s. There were fewer restrictions on participation, particularly because of the frequent use of the *Federal Register.*[87]

Regulators in both countries, however, have been criticized for appearing to limit consultations. Canadian regulators have been described as restricting participation through their "carefully-rigged" and "invitation-only" multistakeholder consultations. These consultations were dominated by state officials. The scope of discussion was limited largely to scientific and technical issues.[88] For example, at the 1994 multistakeholder workshop on labelling, questions to frame the debate were selected ahead of time by a technical steering committee comprised mostly of state officials, along with a few agri-food industry representatives, a consumer association representative, and two professional dietitians.

In the US, FDA regulators were also criticized for not responding to comments solicited and providing few opportunities for public debate.[89] On the issue of environmental release in the US, consultation has occurred primarily through formal procedures such as the *Federal Register* publication process. Alternative means such as public meetings[90] and scientific workshops have

[87] The *Federal Register* is used, for example, to publish regulatory proposals that invite comment and notice of public meetings or scientific workshops. The Canadian equivalent is the *Canada Gazette.*

[88] As noted in Chapter Two, Canadian regulators also received complaints about the development of the 1993 regulatory framework for biotechnology which proceeded without consultations. A former state official noted that the lack of consultation meant that officials found themselves constantly defending and explaining the framework. The framework was perceived as suspect because only government was involved in its creation and all the stakeholders were critical of the process. Personal interview, February 1998. Similar complaints about restricting participation and the scope of discussion were made by many members of the policy community about the 1998 consultations on renewing the Canadian Biotechnology Strategy, which only touched lightly on regulatory issues.

[89] The three public meetings held in late 1999 appear to be a departure from the FDA's consultation strategy, although there were complaints that the meetings restricted the number of participants that could speak. Most were restricted to two minutes of speaking time. FDA officials have noted, in their own defense, that they provided about ten opportunities to comment on their food safety and labelling policies between 1984 and 1994.

[90] Some of these public meetings have been more educational campaigns than consultations. For example, in 1987, the USDA launched a national informational awareness campaign, including four regional conferences, titled "Agricultural biotechnology and the public". These regional conferences were co-sponsored by USDA, land grant universities, state agriculture experiment stations, and the cooperative extension service. The atmosphere of the conferences was described as a "milieu of openness and helpfulness" by a USDA official. At the same time, the comment was made that officials from the USDA, the EPA, and the FDA had also met and exchanged views with industry, environmental groups, university researchers, state-level and local officials, the media and individual citizens. U.S. Congress. House Committee on Science, Space, and Technology. Subcommittee on Natural Resources, Agriculture Research and Environment (1988): 87-88.

been used occasionally.[91] The use of the *Federal Register*, while theoretically open to all, can have an adverse effect on groups with scarce resources. A representative of an American public interest group noted that it "takes a lot of energy" to constantly monitor the *Federal Register* for opportunities to participate. She described the approach to consultation as "they'll use what you produce if you can participate, and they'll go on without you if you're not there". In contrast to Canadian regulators who used mass mailings a few times, American regulators rarely have taken additional systematic steps beyond the *Federal Register* process to inform policy community members of upcoming consultations or regulatory proposals.[92] There does not appear to have been any broad multistakeholder consultations in the US akin to the two held in Canada in the mid-1990s.[93] A representative of an environmental organization argued that multistakeholder forums are not favoured in the US because they are perceived by all members of the policy community as a waste of time that uses up resources and do not force an agency to change its policy.

Informational capacity and institutionalized information networks

Possessing relevant information has always been an important resource for policy actors, but the growing complexity and technical content of many policy areas has heightened its importance.[94] Within the agricultural biotechnology policy community, a common tactic, particularly among proponents, has been to create informational coalitions and networks in the

[91] For example, in 1988, the USDA, the FDA and the EPA sponsored a conference on the scientific issues surrounding the development of transgenic plants. The purpose of the meeting was to obtain information on the types of plants being developed and to discuss environmental and health issues, prior to commercialization. U.S. Congress. House Committee on Agriculture. Subcommittee on Department Operations, Research, and Foreign Agriculture, (1991).

[92] Personal interview, November 1998. However, some members of public interest groups report good informal links with regulators that may result in the receipt of information by fax or telephone about upcoming events of interest.

[93] However, the US does have the National Agricultural Biotechnology Council, established in 1988, which is supported by non-profit agricultural research institutions, including several universities. The Council is intended to provide an open forum to discuss the issues of agricultural biotechnology. It holds major annual workshops attended by a diverse range of participants, publishes the results, and distributes them widely. One participant said that the NABC annual workshops were a very good forum for discussion in the early years, but have been avoided more by industry representatives in recent years who feel that a favourable regulatory regime has been secured. As a result, the forum has been marginalized. Personal interview, May 1998.

[94] For example, a recent study of Canadian and American environmental groups found that these groups are increasingly placing a priority on gathering, distributing, and sometimes generating information, including scientific information. The study concluded that the focus of interest group politics may increasingly lie in battles over agenda-setting, problem definition, and setting boundaries on the range of appropriate policy options, as organizations see victory in these struggles as critical components of success. Pierce et al. (1992).

hopes of creating credible allies through the persuasion of providing information in an authoritative manner.[95] One of the most visible results of this development has been the "broken-record"-like quality of the debate. Proponents and skeptics frequently repeat the same generic arguments. Proponents' efforts to build informational coalitions can be interpreted as an attempt to counter the exploitation of scientific uncertainties by biotechnology skeptics. Proponents have argued consistently that increasing educational efforts for the public would greatly reduce controversy over the introduction of genetically-engineered organisms into the environment and the food supply.[96] As a Canadian biotechnology association official stated in June 1996, the biotechnology community has:

> attempted to reach out by bringing up to speed the organizations in close contact with the consumer - medical and health care professionals, dietitian organizations, the National Institute of Nutrition, the Canadian Consumers' Association as well as FNACQ and other consumer associations across the country - in an effort to bring them up to speed to know what the contacts are, what the locations of the information are, so that they can then pass that information on to their constituents.[97]

The Food and Consumer Products Manufacturers of Canada also reports working proactively with health professionals on biotechnology issues because they "don't understand the product and business impact."[98] State officials have also included dietitians and nutritionists in their consultations.[99]

In the late 1990s, there was a proliferation of institutionalized information networks and more informal informational coalitions active on the issue of agricultural biotechnology regulation

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[95] The Consumers' Association of Canada (CAC) provides an example of a policy community member with inadequate informational resources that became dependent on other members and thus aligned itself with proponents. It is difficult for CAC to generate its own informational resources, unless one of its volunteers has the expertise. For example, the CAC produced a report on food biotechnology in 1995 for the National Round Table on the Environment and Economy, which relied heavily on government and industry sources, titled "Background Paper on Food Biotechnology in Canada".

[96] One element of this strategy is to win over public opinion, outside of the parameters of the policy community. Biotechnology firms and some agri-food associations have launched information and education campaigns periodically, particularly in the US and Europe. For both biotechnology proponents and skeptics, this strategy has often included the publication of books, reports, and other information resources.

[97] Statement made by Rick Walter of the Canadian Institute of Biotechnology, now part of BIOTECanada, at a meeting of the House of Commons Standing Committee on Environment and Sustainable Development, June 4, 1996.

[98] Personal interview, July 1998.

[99] The Canadian Dietetic Association attended the 1994 labelling conference, while representatives of Canada's National Institute of Nutrition attended three consultations.

in both Canada and the US. These networks included the International Food Information Council (IFIC) in the US, funded by agri-food firms and associations including the American Seed Trade Association and American Soybean Association; and, in Canada, the National Agriculture Environment Committee, AGCare, the Food Biotechnology Communications Network (FBCN), and most recently, a Canadian version of IFIC.[100] In the late 1990s, the American agri-food associational system came together under an informational coalition called "Ag For Biotech". later renamed the "Agricultural Biotechnology Forum" (ABF).[101] The ABF brings together many major organizations in the agri-food sector (including AFBF, NFPA, and BIO) and major biotechnology firms to develop consensus on policy preferences so to present a united voice to state officials.[102] As noted in Chapter Four, biotechnology skeptics have also used informational coalitions, creating the Biotechnology Working Group in the US and the biotechnology caucus of the Canadian Environmental Network. In Canada, there is no evidence of an effort to create a coalition similar to ABF. However, there are reports of frequent informal contact on agricultural biotechnology issues by many representatives of agri-food associations.[103]

[100] Established in 1994, NAEC brings together farm groups and began to work on biotechnology issues in the late 1990s. AGCare is an Ontario agricultural coalition that focuses on environmental issues and became involved in biotechnology issues in the mid-1990s. The FBCN, kickstarted by Monsanto Canada, was established in 1993 to improve access to information about biotechnology and contribute to accuracy in the debate. Participants state that it was established in part because members of the policy community felt that state officials were not providing enough information about biotechnology to the public. Meanwhile, the Canada Food Information Council, which was just being established in December 1998 under the leadership of Proctor and Gamble, is funded by agri-food firms. This initiative suggests the food industry in Canada believes it needs to strengthen its informational resources. The advertisement for an executive director for the council stated the council's intended goals to be "providing Canadians with science-based information about food, food safety and nutrition" and "to develop a strong network of Canadian and global partners with a shared interest in science-based decision making on food issues". Some concern has been expressed that the new council will operate as an "objectively-named propaganda machine" in competition with the National Institute of Nutrition, which was established in 1985 as a joint effort among industry, government, health professionals, and the academic community.

[101] Participants estimate that the coalition could grow to include as many as eighty to one hundred organizations.

[102] The coalition's primary focus initially was on American participation in international activities that could affect market access, such as trade negotiations and standard-setting bodies such as Codex. However, participants say that it will also monitor developments domestically. The coalition was first proposed and organized by the biotechnology industry. Discontent among some members, including commodity associations, who felt the agenda was being set by the biotechnology firms, led to its overhaul in the fall of 1998 to ensure that all links within the agri-food sector were equally represented and shared the costs to ensure equality within the coalition. The potential for differing opinions resulted in the decision that the ABF would not be a formal coalition with its own letterhead, so to ensure that the views of dissenting members were not inaccurately portrayed. Personal interviews, 1998. A much smaller coalition was formed in 1998 among commodity associations in the US, including soybean, cotton, and corn organizations, to work more intensively on issues that affect market access.

[103] Some associations, such as the Canada Grains Council, took a leadership role in the 1990s in encouraging these contacts.

CONCLUSION

The rhetorical battles that have accompanied regulatory policy making in response to the commercialization of genetically-engineered plants and other organisms have been part of strategies to institutionalize a characterization of science that suggests the proper scope of regulation within policy choices. Policy choices on the scope of regulation have implications for the legitimacy and authority of the subsequent participation of members of the policy network. Proponents have downplayed novelty, emphasized benefits, minimized risks, and championed a product-based approach. These arguments are intended to reinforce the position that existing scientific capacity in its current location is adequate enough, if not an authoritative means, to regulate the risks arising from genetically-engineered products. The goal is to ensure that development of the technology proceeds relatively unimpeded, if not enhanced, by regulation. For skeptics, the goal has been to highlight the revolutionary nature of a technology that creates novel products which may also pose novel risks and to encourage critical scrutiny of projected benefits. Arguments about the inadequacy of scientific capacity conclude that more scientific studies are needed and that the ability to source independent scientific expertise must be improved.[104] The intended policy implication has been a slow and cautious approach to commercialization or a moratorium on commercialization.

Examining policy choices suggests at first glance that proponents have emerged more victorious to date from rhetorical battles in both Canada and the US in the 1980s and 1990s, although to varying degrees across issues and countries (see Table 5-2). Much of the language and rhetoric adopted by regulators is akin to that favoured by proponents, such as the far more common use of the term "biotechnology" compared to "genetic engineering". Further, to varying degrees, policy choices in both countries seem designed to bolster claims of adequate expertise, by building on existing regulatory activities rather than creating new institutional arrangements or drafting new legislation. In all four cases (two issues, two countries), risk assessment relies in part on extrapolations from existing knowledge as well as on data requirements imposed by regulators on developers. However, there are differing acknowledgements of the degree of novelty of genetically-engineered organisms across the two countries which are reflected in policy choices.

Canadian regulators have explicitly recognized the novelty of genetic engineering in the

[104] References to "independent" scientific expertise generally imply that the scientists providing advice have no vested interests in the progress of commercialization and thus can provide an objective viewpoint.

details of their policy choices, more so than their American counterparts. They incorporate the term "novel" in the regulatory triggers of "novel trait" and "novel food". They have adopted product-based risk assessment approaches that also incorporate consideration of the method by which the product is created. In public statements, however, they have often downplayed the novelty of biotechnology. For example, the term "biotechnology" has been used much more frequently in government statements than "genetic engineering" to refer to these newer techniques and the industry they have spawned. Canada's official definition of biotechnology reflects this stance:

> the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms.[105]

This broad definition incorporates agricultural products developed both through traditional means and through techniques of genetic engineering. It provides no special treatment for genetic engineering or, put another way, does not discriminate against this new technology.[106]

American regulators at the USDA and FDA have been more forceful than their Canadian counterparts in downplaying the novelty of genetic engineering. They have characterized it as not posing greater risks than other more traditional technologies. As a supporting argument, they have taken pains to stress the relevance of existing knowledge for biotechnology regulation. The 1986 coordinated framework for biotechnology regulation and the 1992 FDA policy statement, in particular, institutionalized the preferences of proponents to see the novelty of genetic engineering for the purposes of regulation minimized.[107]

In contrast to Canada, regulatory documents issued by the OSTP, the FDA, and the USDA do not offer a single government-wide official biotechnology definition that would provide a coherent position on novelty. This discrepancy reflects the lack of successful coordination among agencies, the greater contestation of science in the American political system, and the varying vulnerability of the regulatory agencies within their respective policy networks. Agencies have

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[105] Canada. Minister of Public Works and Government Services Canada (1997): 21. The definition comes from the *Canadian Environmental Protection Act*

[106] For example, in the regulations of the *Seeds Act*, the definition that "seed includes seed from biotechnology" results in all seeds, regardless of how they are produced, being regulated the same way, and reinforces the product-based approach.

[107] Jasanoff (1995a) argues that the 1980 Supreme Court ruling *Diamond v. Chakrabarty* which found that a microorganism could be patented through existing law provided additional weight to proponents' arguments that genetic engineering did not pose sufficiently novel risks to require new legislation.

differed in the attention their policy choices draw to the novelty of genetic engineering. For example, the FDA chose in its 1992 policy statement to focus on the term "genetic modification", so to encompass all methods by which organisms might be altered genetically, including both traditional plant breeding and rDNA techniques.[108] The USDA did not use the term biotechnology in its 1987 regulations, but instead relied on the term "genetic engineering" as "the genetic modification of organisms by recombinant DNA techniques". This decision is consistent with the exclusive focus of its regulations on genetically-engineered plants.[109]

The rhetorical victories proponents have secured in minimizing the novelty of genetic engineering in some aspects of policy choices have not been sufficient, however, to paper over scientific uncertainty. They also appear to contradict other aspects of policy choices, including the fact that these policy responses were provoked by the advent of genetic engineering in the first place.[110] Further, exaggeration of risks and benefits on both sides of the debate has encouraged wider public skepticism about the ability of regulators to manage risks adequately.[111] For example, proponents wanting to attract investment in research talked about the revolutionary potential of the technology and sought intellectual property rights to protect their novel inventions, even while minimizing novelty for the purposes of regulation. The product-process debate in particular has failed to insulate genetic engineering from its inherent novelty. Of the two issues across the two countries, the American response to food safety concerns can be arguably described as the most product-based. The others all include more explicit consideration of the process in regulatory review. The USDA's response to environmental release does so most clearly through its regulatory trigger of genetic engineering. One observer described the product-process debate as "like a cat chasing its tail" rather than a clear dichotomy.[112] Despite all the rhetorical emphasis on product-based regulation, policy responses in the US have resulted generally in more stringent

[108] United States. Food and Drug Administration (1992).
[109] United States. Department of Agriculture (1987).
[110] It is somewhat ironic that some of the proponents of agricultural biotechnology, including large plant biotechnology firms like Monsanto, encouraged regulators to develop policy responses to genetically-engineered organisms because such policy responses were seen as helping to secure consumer acceptance. These responses, however, have arguably also increased public concern about genetically-engineered organisms because of their precedent-setting nature.
[111] For example, ecologists working in the areas of environmental toxicology and pest management commenting on the debate surrounding environmental risk stated that they were bewildered both by the "astounding tales" of biotechnology skeptics, and by claims by industry that it "fully understands the risk" and its "smug assurances that genetic engineering is no different than traditional plant breeding". Kareiva and Stark (1994): 55.
[112] Personal interview, November 1998.

regulation of genetically-engineered products than those produced otherwise. In Canada, these policy responses have resulted in more stringent regulation of "novel" products, whether produced through genetic engineering or by other means.

Styles of using scientific expertise

Examining two issues across two countries allows some conclusions about whether there appears to be distinct styles of scientific expertise between countries. Renn outlines an ideal typology of styles of using scientific expertise: adversarial, fiduciary, consensual, and corporatist, and a newly emerging style he calls mediative.[113] Using Renn's typology, the US environmental release case is most consistent with the adversarial style, while the relatively closed approach of the FDA verges toward a consensual style. Canada's style for environmental release appears closest to the fiduciary style and its style for food safety is closest to the consensual style. Renn describes the ideal adversarial style as open to professional and public scrutiny in an environment where scientific justification is needed for policy choices; characterized by precise procedural rules, little emphasis on personal judgments and reflection by scientists; and oriented toward producing evidence. A fiduciary style is characterized by reliance on institutional in-house expertise, a relatively closed circle of discussion, some mechanisms for public input but none for public control, and few procedural rules. It has a goal of producing faith in the system. Finally, a consensual style relies on expert judgment and scientific reputations. It is characterized by "closed-door" negotiations conducted by members of a "club" and flexible procedural rules. Its goal is to produce solidarity within the club.

These findings are somewhat consistent with the comparison of American and Canadian regulatory styles made by Harrison and Hoberg, with the exception of the American food safety case.[114] They describe the American style as pluralistic, legalistic and adversarial; characterized by open conflict, reliance on generic principles, open debate over inherent value judgments, and more reliance on formal procedures for public participation. The Canadian style, in contrast, is

[113] Renn (1995), see Table 1, p. 151.

[114] Harrison and Hoberg (1994), chapter nine. See also Ozawa (1991) and Brickman et al. (1985) on the use of science in the US during regulation. These differences also extend to the processes by which lab safety guidelines and regulatory frameworks were developed. In each case in the US, the process was visible and controversial; in Canada, the debate occurred mostly within the bureaucracy, with some consultation of the wider scientific community in the case of the lab safety guidelines. See Eddy (1983) on the style of the development of lab safety guidelines in both countries. Growing contestation of science within the American food safety policy network in the late 1990s suggests, however, that it may be moving toward a more adversarial style.

paternalistic, informal, consensual, and closed, with a preference for case-by-case review rather than reliance on general principles and more emphasis on science which permits greater flexibility. The regulation of genetically-engineered plants confirms some country-specific differences in regulatory styles, but the exception of the American food safety response underlines that the closer examination of the use of science within policy networks can reveal important sectoral differences within countries.[115]

Revisiting the hypotheses

Table 5-3 summarizes how the characterization of science has changed over time within the policy networks surrounding the issues of environmental release and food safety in Canada and the US. The potential for variation is captured in Linder's five-part classification (see Table 5-4).[116] As the degree of contestation increases, the possibility of maintaining the characterization of science as neutral diminishes within the policy network, especially when there is inadequate scientific consensus underpinning policy choices. While contestation increased in all four cases by 1998, it was a significant factor when policy choices were made only in the case of environmental release in the US. In that case, the weakness of scientific authority appears to have resulted in a compensating strategy of policy choices that institutionalized a higher degree of transparency and accountability through public notice and appeal provisions. In the other three cases, science was used successfully to marginalize and exclude other ideas. Policy choices contributed to the institutionalization of a relatively neutral characterization that protected a narrow, technical problem definition and limited policy goals, and made no provision for public participation or accountability on an ongoing basis.

For example, the Canadian policy response to environmental release, unlike the American policy response, made no provision for public comment periods or for public notification of

[115] Jasanoff (1990) concludes from case studies that there is little consistency across American regulatory agencies in how they use scientific advice. A scientist who works for an American environmental organization also noted that while the USDA appeared to be open-minded in receiving scientific advice from the external scientific community on the issue of regulating genetically-engineered plants, the FDA's use of its standing committees appeared to somewhat manipulative. Personal interview, November 1998.

[116] Linder (1995).

environmental releases.[117] In responses to arguments that it has not acknowledged or incorporated ethical aspects of the issue, AAFC has countered that it has "always been sensitive" and "recognizes its responsibility to participate in this important discussion". It also has argued that:

> ...the existence and enforcement of regulations on products such as those derived from techniques of biotechnology are founded on societal ethics that human, animal and environmental safety considerations are paramount when introducing these products into the marketplace.[118]

This statement illustrates AAFC / CFIA's definition of "ethics" which appears to be based on a procedural component of extensive consultation during policy making and equates ethics with a commitment to safety.

In the case of food safety assessment in Canada, regulators were able to characterize science as neutral as they began to examine the issue due to the issue's low public visibility and the lack of contestation within the domestic policy network. The science-as-neutral characterization was insulated by the ongoing practice of regulators to tap informally into expertise within industry and academia and to use the recommendations of international institutions to back their policy choices. Further, the separation of administrative authority for food labelling from that for food safety insulated the latter issue from more "political" debates about consumer choice, unlike the institutional arrangement in the US.

Contestation within the Canadian food safety policy network was minimal until the late 1990s, particularly given the alignment of the national consumer association with biotechnology proponents. In the late 1990s, as genetically-engineered foods entered the marketplace, controversy in Europe encouraged skeptics in Canada to debate the risks more visibly but they continued to lack opportunities and resources. The minimal contestation as of 1998 contributed to the institutionalization of a narrow, technical problem definition and the use of science as a programmatic idea, which were compatible with broader economic goals such as international

[117] Early guideline documents encouraged developers to notify immediate neighbours and communities of field trials, but this provision was withdrawn in response to concerns of developers about the costs of public notification, especially for smaller firms; the possibility of damage to test plots, as had occurred in other countries; and declining public requests for the information. AAFC has also argued that calls for a public comment period on every confined release presume that releases pose a direct risk when the regulatory process is intended to take care of these concerns. AAFC's statement also claimed there no similar procedures in other jurisdictions, although no specific examples were provided. Canada. Minister of Public Works and Government Services Canada (1997): 32-33, 36. CFIA does notify provinces about proposed releases. CFIA officials state that public consultation occurs prior to decisions about regulation, rather than being an ongoing aspect of policy making. It is also pointed out that provisions in the 1997 regulatory amendments require developers to provide regulators with any new information about risks.

[118] Canada. Minister of Public Works and Government Services Canada (1997): 31.

competitiveness. This problem definition and the reliance on science marginalized non-scientific ethical and religious concerns and the principle of consumer choice because food safety assessment underpinned labelling policy.

Canadian regulators dealing with the issue of environmental release also began with a science-as-neutral characterization. This characterization was insulated initially by relatively strong in-house expertise given federal leadership historically in agricultural research and plant breeding, and by policy legacies in the sale and use of new plant varieties which institutionalized science as a dominant programmatic idea. As in the case of food safety, Canadian skeptics had fewer opportunities and resources for contestation compared to their American counterparts.[119] The adoption of the *Canadian Environmental Protection Act* in 1988 and Canada's international commitments to environmental protection, including regulation of biotechnology, at the Rio Summit in 1992, however, provided skeptics with more of a foothold. Further, the beginning of environmental release of genetically-engineered plants through field trials in the late 1980s made skeptics' claims about hypothetical risks seem more concrete. Growing contestation encouraged AAFC regulators to use strategies to reinforce their authority through the mid-1990s. They bolstered guidelines with formal regulations and secured agreement from Environment Canada that the regulatory review in place was adequate for the purpose of environmental protection. These strategies helped regulators to maintain significant discretion and flexibility in the scope of regulation through a vague definition of the regulatory trigger of "novel trait", even when other members of the policy network tried to narrow the scope of regulation by providing rigid definitions.[120] By the late 1990s, the acreage of genetically-engineered crops began to grow rapidly in Canada. Increased scrutiny of Bt crops suggested a real likelihood of accelerated development of insect resistance and harm to non-target insects. The contestation of science increased, creating an unstable balance between neutral and contested science within the policy network by 1998.

The dominance of a neutral characterization of science in the Canadian environmental release policy network during much of the period of policy development prior to 1998 permitted

[119] Canadian skeptic Brewster Kneen has argued, for example, that science is only one way of knowing and that it should not only be the viewpoint of scientists that should be regarded as "expert". Canada. Agriculture and Agri-Food Canada, Health Canada, and Environment Canada (1993).

[120] Industry Canada, for example, proposed that regulations would specify which novel traits would fall under review. Regulators at AAFC noted in reply that they preferred to leave novel trait as a flexible definition, so that it could be applied and modified according to the accumulation of scientific information about new plant varieties. Canada. Minister of Public Works and Government Services Canada (1997): 32.

the adoption of a narrow, technical problem definition. While the goal of environmental protection is ostensibly institutionalized within the policy response, the provisions in place do not attempt to encourage or require developers to pursue products that could contribute to *increased* sustainability in agriculture or other more specific forms of social utility beyond the pursuit of competitiveness through innovation.[121] The problem definition also excluded the economic concerns of export-reliant commodity producers. They urged Canadian regulators in the late 1990s to make domestic regulatory approval of new plant varieties contingent on regulatory approvals in important export markets.[122]

Regulators at the FDA also began with a neutral characterization of science when they took on the responsibility of food safety assessment of various genetically-engineered organisms, following the release of the 1986 coordinated framework for biotechnology regulation. The FDA's initial low-key response to the food safety issue was contested almost immediately through calls to clarify its intended policy response; however, skeptics lacked opportunities to raise concerns due in part to the FDA's decision not to adopt new regulations. The FDA attempted to use science as a programmatic idea in efforts to bolster the legitimacy of its response. For example, the centrepiece of its 1992 policy statement was a section providing scientific guidance to industry on conducting risk assessment of its new plant varieties. The 1992 statement institutionalized a narrow, technical problem definition that minimized, if not denied, the possibility of increased risks from genetically-engineered foods. The reliance on science, as in the two Canadian cases, excluded concerns stemming from ethical or religious beliefs. The principle of consumer choice was also marginalized.

Contestation of the science underpinning the FDA's response increased following the 1992 policy statement on new plant varieties. FDA regulators were more vulnerable than their Canadian counterparts at Health Canada due to the general context of greater contestation of regulatory science in the American political system. They were also vulnerable because of their reliance on

[121] A representative of the Canadian Institute for Environmental Law and Policy noted that the focus of regulators on technical issues has left "significant questions" off the table. He argues that this is a result of AAFC's position as an "intellectual monolith" within the agricultural community and the "culture of scientific expertise" in Ottawa. Personal interview, July 1998. Brewster Kneen has also commented that when regulation focuses narrowly on risk assessment, larger questions such as who wins and who loses, who is in control, and whether there is there another way of proceeding that is more environmentally friendly, are pushed aside. Kneen (1992): 172.

[122] Personal interview, September 1998. This request was denied, at least initially, by regulatory officials who said that such a measure would exceed their mandate.

outside expertise--a pattern consistent with policy legacies. These legacies included giving industry discretion on how to handle safety assessments of food additives and deferring to plant breeders historically on the food safety of new plant varieties. The FDA's inability to marshal in-house scientific resources also exposed it to prevailing political winds which in the early 1990s were strongly in the direction of competitiveness and deregulation.[123] The vulnerability of scientific authority within the American food safety policy network made the FDA's 1992 effort to minimize the labelling issue somewhat unsuccessful. By 1998, it was facing a lawsuit challenging both its food safety and labelling policies as the number of foods containing genetically-engineered ingredients in the marketplace rapidly increased. The growth of consumer resistance and contestation prompted it to hold three public meetings in 1999. This initiative, which was a significant departure from previous consultation strategies, can be interpreted as a perceived need to shore up the democratic legitimacy of policy making to compensate for the weakening of the scientific legitimacy of policy choices.

Finally, the case of environmental release in the US stands apart because much of policy development took place when science was already highly contested within the policy network. Contestation emerged largely from court challenges of the lab safety guidelines for rDNA organisms in the early 1980s under the *National Environmental Policy Act.* These challenges highlighted scientific uncertainty about the effects of environmental release and created doubts that genetically-engineered organisms would be regulated adequately. Congressional hearings attracted public attention. The sheer size and wealth of scientific expertise in the US ensured that there was plenty of vigourous debate. Like the FDA, the USDA attempted to bolster its policy response with scientific authority by pointing to the extensive American network of agricultural research as a source of relevant expertise. However, the agency was clearly vulnerable to political tides. This vulnerability was illustrated most clearly by the fact that its policy response changed three times between 1986 and 1997. It first announced that no new regulations would be forthcoming and then issued detailed new regulations, only to later undertake two deregulatory initiatives. By 1998,

[123] The political pressures on FDA are evident in a May 21, 1992 memo from James B. MacRae Jr. of the Office of Management and Budget on the FDA's 1992 policy statement, eight days before the statement was released. The memo made several comments on how the statement should be revised to minimize concerns about, and references to, genetic engineering; to suggest that genetic engineering was a safer technology than older techniques because it is more precise (a point sometimes contested by skeptics), and to avoid mention of mandatory reviews. This memo is posted on the Alliance for Bio-Integrity's web site: www.bio-integrity.org.

science became even more contested within the policy network as the Bt crop issue became highly visible with warnings about dying Monarch butterflies and other adverse effects. Lawsuits and petitions against the EPA added to public visibility and increased scrutiny of the USDA's policy response.

To summarize, science was highly contested within the American environmental release policy network from the beginning, making it difficult for the USDA to rely on scientific authority to justify and insulate policy choices. Attempts to use scientific authority through claims of relevant expertise and basing new regulations on existing regulatory activities have not been successful. The USDA institutionalized a narrow, technical problem definition focused on the plant pest risk of genetically-engineered plants through its policy choices. It excluded issues such as impacts on the socioeconomic structure of the agri-food industry and on agricultural sustainability, in a similar fashion to the Canadian policy response. The design of its response, however, was not perceived by many others in the policy network as logical from a scientific point of view.[124] Its detailed procedural elements appeared to be a direct result of the USDA's vulnerability to societal pressures.

Characterizations of science and the importance of scientific expertise

This dissertation has also hypothesized that how science is characterized within a policy network determines how important the possession of relevant scientific expertise is to the influence of policy community members on policy choices. A dominant neutral characterization of science was expected to result in scientific expertise acting as a dividing line between policy community members, regardless of other resources. Further, a concentration of scientific expertise was expected to increase the likelihood of a closed policy network. Stable patterns of scientific information exchange within policy networks would reveal informational deficits and dependencies that further enhanced the power of those with scientific resources. In such a situation, those without scientific resources would leave to others the creation of scientific consensus to underpin policy making. They might choose to endorse the policy preferences of those with scientific expertise and thus expand the consensus and increase its legitimacy, or to refute it. However, they

[124] These observations are based on the lack of flexibility and discretion given to regulators to adapt to new scientific information, how the regulatory triggers exclude some genetically-engineered plants and thus may not adequately cover novel organisms as intended to reduce risks. Personal interviews with American policy community members. See also Bastian (1990) on how the USDA narrowed its problem definition.

could not contest the dominant scientific consensus legitimately or forcefully without an adequate alternative scientific consensus. Conversely, when science is strongly contested within a policy network, then scientific expertise would not be expected to be a decisive factor in determining how successful policy network members would be in securing the incorporation of their policy preferences within policy choices. Policy networks characterized by contestation should be more accessible to those without expertise and are more likely to be pluralist in nature as long as the allocation of other important resources is not highly concentrated.

Of the four cases examined in this chapter, the possession of relevant scientific capacity should be an important factor in contributing to whose policy preferences were reflected in policy choices in all except environmental release in the US if the hypothesis presented earlier is to be demonstrated. In this latter case, science was consistently highly contested.[125] Table 5-5 combines the location of scientific resources within the policy network with the nature of the policy network for each case as discussed in Chapter Four. While it is often difficult to quantify scientific resources, it is possible to identify where a notable amount of relevant scientific expertise can be found. Table 5-5 demonstrates a correlation between the allocation of scientific expertise and the nature of the policy network. The most closed policy network, found in Canada on the issue of environmental release, corresponds with the greatest concentration of scientific expertise within the federal public sector. Over time, as the plant biotechnology industry grew in resources and relevant expertise, the policy network moved toward concertation. Weak concertation policy networks are found in the case of food safety in Canada and environmental release in the US. In the former case, expertise was somewhat decentralized and the relatively small pool of domestic expertise encouraged substantial reliance on the findings of international institutions. In the latter case, expertise is also decentralized including some in the private sector. Regulators had relatively little relevant expertise beyond efforts to monitor and eliminate plant pest threats. High levels of contestation, fuelled by exploitation of scientific uncertainty, have undermined the authority of regulators and moved the policy network toward clientele pluralism. Finally, in the case of food safety in the US, expertise is found in the large and well-resourced domestic food industry and the relatively large food science community. Largely dependent on outside expertise for scientific authority, regulators have difficulty maintaining autonomy which contributes to a clientele pluralist

[125] Whether scientific expertise has indeed been influential is considered in the concluding chapter.

network. These correlations suggest that the characterization of science combined with the allocation of scientific expertise sheds light on dynamics within policy networks and thus their nature.

The findings of this chapter do not, however, confirm the hypotheses laid out regarding the strategies of policy community members. As hypothesized, those members with scientific expertise, particularly the plant biotechnology industry, were often eager to promote "science-based" regulation or regulation based on "sound science" in an effort to marginalize the "junk science" of biotechnology skeptics. However, representatives of other policy community members lacking such expertise, most notably some agricultural producer associations, also often made such arguments. This finding can perhaps best be explained as the result of dependencies of some policy network members on those with greater scientific expertise. These dependencies, evident in patterns of exchange, may be both technical and financial when the structure of the industry is examined.[126] Further, some policy community members with scientific expertise, albeit not as well-resourced as others, chose to contest science by highlighting uncertainty--notably representatives of the Union of Concerned Scientists, the Environmental Defense Fund, and Consumers' Union, all of whom held doctorates in biological sciences.[127] Thus, whether a policy community member possesses relevant scientific expertise is not sufficient to suggest what strategy will be undertaken regarding the characterization of science. This finding suggests that the use of science is highly political. In this case, it appeared that the science-as-neutral characterization was championed largely by those who preferred a narrow risk-based problem definition, while science was contested by those hoping to broaden the problem definition.

This chapter also suggests that the likelihood of the success of strategies to entrench a dominant characterization of science is dependent on several factors. These factors include policy legacies and more general patterns in the use of science in policy making which provide a starting point within a policy network; the allocation and location of scientific expertise within policy networks which creates patterns of exchange that reveal mechanisms of influence and dependencies; and the degree of scientific uncertainty combined with the opportunities and resources to be able to exploit it. Contestation appears to be easier in the US, in part due to policy

[126] The dependency of agricultural producers and their associations on other links of the agri-food industry, particularly suppliers, is evident in other areas such as agricultural research and the regulation of pesticides.
[127] This is not to say that these individuals do not believe in the authoritative nature of ideal science, but rather felt that for these issues, the scientific evidence was inadequate to justify the risk analysis regimes adopted by regulators.

legacies which have diluted the use of science as a programmatic idea and to the more fragmented and adversarial nature of the political system which both encourages and provides more opportunities for the use of science as a resource within policy networks.[128] The allocation of relevant scientific expertise in the US for food safety and environmental release issues, decentralized and largely within the private sector, fuels the perception that regulators have been captured. Finally, the greater availability and institutionalization of scientific resources in the US facilitates and promotes the prominent use of science in policy making debates. This phenomenon of the "scientification of politics", as Weingart describes it, in turn results in the politicization of science when science is used, with the ultimate potential effect of delegitimating science.[129] Greater contestation may well contribute to pluralist policy networks. This result is not necessarily to the advantage of skeptics who may no longer be able to use science that supports their policy preferences as a way to counter the other impressive resources of proponents, including economic power.

[128] See Harrison and Hoberg (1994). Jasanoff (1990): 208 notes that the regulatory process in the US also tends to be dominated by politics and law because of the practice of using political appointments to fill high-level regulatory posts.

[129] However, as Weingart (1999) acknowledges, the politicization of science has not yet led to its total delegitimation because there is no alternative to scientific expertise in terms of the continuing ability to use it to make authoritative knowledge claims.

TABLE 5-1
Domestic consultation patterns of regulators[1]

CANADA

Environmental release

Mechanisms
informal consultations, reviews, mailings
informal use of existing advisory committees
(eg., variety registration committees)
establishment of multistakeholder
Plant Biotechnology Advisory Committee
(not used extensively)
selective multistakeholder workshop (1993)
formal (*Canada Gazette*)

Scope
mostly scientific / technical issues
some discussion of economic and ethical issues in broader consultations

Composition
earlier = largely within scientific community
and government
later (1993 on) = broader spectrum including
agricultural producer organizations,
consumer organizations, and
environmental groups
Canada Gazette-open to all those able to participate

UNITED STATES

Environmental release

Mechanisms
use of existing advisory committees
(eg., National Plant Board)
establishment of internal and external advisory committees
federal-state conferences
(through plant pest regulation network)
formal (*Federal Register*)
scientific workshops
public meetings
informal meetings

Scope
mostly scientific / technical issues

Composition
largely within scientific community, public and private
some consultations with environmental organizations
Federal Register-open to all those able to participate

[1]Further details on consultations can be found in Chapter Three. This information comes from published sources and personal interviews.

Food Safety

Mechanisms
selective multistakeholder meetings
informal consultations through mailings
formal (*Canada Gazette*)
existing conferences and meetings

Scope
scientific / technical

Composition
food industry, consumer organizations, health professionals
Canada Gazette-open to all those able to participate

Food Safety

Mechanisms
closed scientific workshops
closed and open scientific advisory committee meetings
formal (*Federal Register*)
public meetings (1999)

Scope
scientific / technical[2]

Composition
scientific experts
public meetings-broad spectrum of interest groups and individuals
Federal Register-open to all those able to participate

Food Labelling

Mechanisms
selective multistakeholder (1994)
mailings

Scope
technical, although some discussion of other aspects such as the debate on the consumer's right to know versus the need to know

Composition
broad spectrum: biotechnology industry, agri-food industry, consumer groups, health professionals

Food Labelling

Mechanisms
formal (*Federal Register*)
public meetings (1999)

Scope
technical, until 1999 meetings

Composition
open to all those able to participate

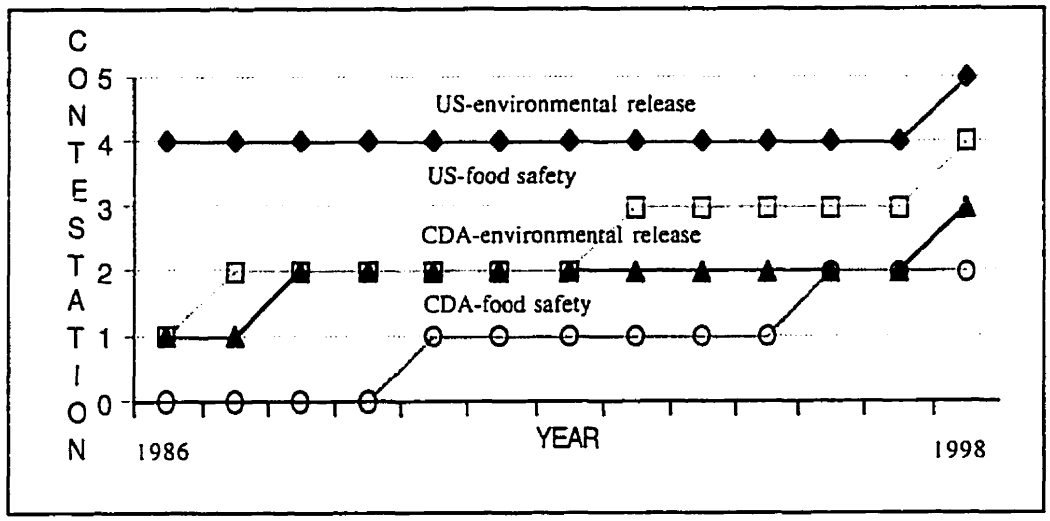
[2]The scope of the 1999 public meetings was circumscribed somewhat by a set of questions the FDA prepared to guide discussion.

TABLE 5-2
Science and policy choices[1]

CANADA	Exclusion	Novelty	Product / Process
Environmental Release	Chosen exclusive means is risk assessment.	Genetic engineering creates intrinsic novelty, but focus is on novel traits.	Product-based approach but information must be submitted on method used to incorporate the novel trait.
Food Safety	Chosen exclusive means is risk assessment.	The use of genetic engineering does not necessarily alter the degree of risk,but its novel potential may cause safety concerns.	Focus of regulation is on novel foods (product), but information must be submitted on method used to create the novel food.
UNITED STATES			
Environmental Release	Chosen exclusive means is risk assessment.	No special risks arise from the use of genetic engineering.	Regulatory trigger includes criterion of genetically-engineered.
Food Safety	Chosen exclusive means is risk assessment.	The use of genetic engineering is not expected to pose different or greater safety concerns than traditional techniques.	Scientific guidelines to industry for risk assessment focus on characteristics of host and donor organisms, newly introduced substances and the newly-created organism.

[1] This table summarizes policy choices described more fully in Tables 3-3 and 3-7.

TABLE 5-3
Characterization of science
environmental release and food safety



SCALE=DEGREE OF CONTESTATION
1=NEUTRAL
5=HIGHLY CONTESTED

ENVIRONMENTAL RELEASE

CANADA
1986=starting point
1988-1997=CEPA, Rio Summit, commercialization
1998=Bt crops issue

UNITED STATES
1986=starting point
(framework, history of NEPA challenges of NIH lab safety guidelines)
1997-98=rapid growth of commercialization, petition against Bt crops

FOOD SAFETY

CANADA
1990=starting point
1996=commercialization, labelling debate visibility grows

UNITED STATES
1986=starting point (framework)
1987=FDA receives questions about food safety
1993=responses to 1992 policy statement
1998=lawsuit against FDA, labelling debate grows

TABLE 5-4
Treatment of scientific claims[1]

Partisan

Scientific claims are viewed skeptically, as reflecting the bias of their sponsors. Their use in problem definition is assumed to be partisan.

Contributory

Scientific claims are viewed as on par with other forms of knowledge.

Compelling

Scientific claims are more compelling than non-scientific claims.

Authoritative

Non-scientific competing claims are ignored, perhaps depending on quality of scientific claims.

Decisive

Scientific claims, especially those representing a professional consensus, are viewed as decisive and appropriately used to settle empirical policy questions and thus guide policy making.

[1] Adapted from Linder (1995).

TABLE 5-5
Scientific expertise and policy networks, environmental release and food safety, Canada and the United States

CANADA

Environmental release

Scientific expertise
*Public sector scientists (federal scientists dominant historically)
*Regulators (backed by public sector)
Plant biotechnology industry (increasingly in 1990s)

Policy network
State-directed -> concertation

Food safety

Scientific expertise
*Industry (domestic, multinational)
*Academic (domestic, foreign)
*International institutions
Regulators

Policy network
Concertation (weak)

UNITED STATES

Environmental release

Scientific expertise
* Public and private sector scientists, (public decentralized, private more expertise in genetic engineering)
Regulators

Policy network
Concertation (weak) -> clientele pluralism

Food safety

Scientific expertise
*Industry (domestic)
*Academic (decentralized)
Regulators
International institutions

Policy network
Clientele pluralism

*=dominant source of scientific expertise

CHAPTER SIX:
INTERNATIONALIZATION AND THE REGULATION OF PLANT BIOTECHNOLOGY

Internationalization, defined as the "process by which various aspects of policy or policy making are influenced by factors outside national territorial boundaries",[1] is not a new facet of domestic policy making. The degree of internationalization of a policy area is the sum of several possible factors that facilitate it, including trade patterns, the economic importance of multinational firms in a sector, the constraints placed on domestic policy making by international regimes such as international trading agreements and international conventions, and the activities of transnational actors. Developments in the 1980s and 1990s captured by the concept of globalization appear to have heightened the likelihood of internationalization and an outward-looking approach to policy making in Canada and the US.

First, the vast increase in the level of capital flows across borders since the 1970s has helped to propel the rise of technological neoliberalism, a new public philosophy with programmatic elements, in Canada and the US.[2] This public philosophy portrays technological innovation as the sure route to international competitiveness and promotes market-based solutions. The gradual institutionalization of technological neoliberalism appears to be linked to the increased popularity of trade liberalization among policy makers as a disciplinary force fostering competitiveness. Second, the creation of new international regimes and the strengthening of existing ones in recent years suggests new constraints are being placed on domestic policy making.[3] Third, increased policy making activity at the international level and advances in communications technology are facilitating cross-national links among members of domestic policy communities and the emergence of transgovernmental coalitions. Finally, all of these

[1] Doern et al. (1996): 3.

[2] The image of a world in which capital is flowing across borders rapidly and with few controls is central to the view of globalization as a phenomenon which erodes state capacity and autonomy. Skeptics such as Weiss argue that while the level of these flows since the 1970s has been unprecedented, there are historical examples of temporary high points of financial openness and states vulnerable to mobile capital. Thus, history suggests that such trends are not necessarily permanent. See Weiss (1998), especially Chapter Six.

[3] Examples include the creation of the World Trade Organization in 1995 which strengthened the international trading regime established under the General Agreement on Tariffs and Trade, and the United Nations Convention on Biological Diversity (CBD), which came into force in 1993, under which member states make commitments to undertake certain environmental protection measures. The CBD is much weaker than the WTO regime given its non-binding enforcement mechanisms that consist of dispute settlement through the options of negotiation, mediation, arbitration, submission to the International Court of Justice, and establishment of a conciliation committee. There are no penalties for member states that fail to resolve disputes.

developments are easing the entry of transnational actors into domestic policy communities and legitimizing their participation.

This chapter assesses in what ways and to what extent internationalization has had the potential to shape regulation of genetically-engineered plants in Canada and the US. The conditions that facilitate internationalization also often provide incentives for domestic policy community members to become more international in their outlook. The chapter explores how internationalization has shaped the policy preferences of some members of the domestic policy communities and affected the resources they exploit. Internationalization may offer opportunities for domestic policy community members to increase their relative power within policy networks particularly when differing international venues shift to their advantage. The chapter also considers whether transnational and transgovernmental coalitions have emerged around plant biotechnology regulation. It concludes with an assessment of the constraints that internationalization has placed on policy making, consistent with the argument made earlier that we should conduct such an assessment before reaching conclusions on how much internationalization has influenced policy choices.

ASSESSING INTERNATIONALIZATION

Assessing the degree of internationalization is not simple because internationalization can occur in several different ways and to varying degrees across policy sectors and countries. The degree of internationalization may be strong or weak within a specific sector. It may also vary within that sector over time. One of the motivations for assessing the degree of internationalization is that it may explain evidence of domestic policy choices converging with those made by countries that are international leaders in the policy area and/or with standards set by international institutions. However, beyond the degree of internationalization, the nature of the conditions facilitating internationalization may determine the direction in which internationalization channels policy making.[4] Analytic distinctions can be drawn among two types of conditions that set the stage for internationalization: first, economic conditions such as the activity of multinational firms and trade patterns; and, second, political conditions such as robust international regimes that pursue broad goals like trade liberalization. Among political conditions, one distinct subset

[4] Milner and Keohane argue, for example, that differing patterns of trade and financial integration can be expected to result in differing responses by domestic policy makers. See Keohane and Milner (1996a): 254-255.

comprises international institutions that focus primarily on furthering international scientific consensus through standard-setting activities. Political and economic conditions may coexist, but can be layers which trump or reinforce each other. The following section distinguishes among the types of conditions that may encourage internationalization in an effort to isolate their effects. It first examines economic factors, including the nature of trade patterns in agri-food products and the degree of export dependence, evidence of regional economic integration in the agri-food sector, and the importance of multinational firms within the sector. It then examines political conditions, identifying those international institutions most active in plant biotechnology regulation issues, including efforts at setting scientific standards for regulation.

Trade

Global trade in agricultural products has increased rapidly during the past decade, growing from $250-billion (US) in 1988 to $462-billion in 1997. Canada and the US have seen growth in the value of their seed and agri-food exports in the 1990s. The governments of both countries have pursued liberalization in agri-food trade under various trading agreements, although there has also been an effort to protect certain sub-sectors.[5] On a global scale, both countries are major exporters in certain agricultural commodities and enjoy a trade surplus in agricultural products, including in planting seeds, field crops, and food products (see Table 6-1).[6]

Both Canada and the US have increased their economic dependence on exports since 1950, but Canada's dependence has consistently been much more significant including in the agri-food sector (see Table 6-2).[7] As a ratio of merchandise exports to gross domestic product, Canada's ratio increased from 13.0 in 1950 to 19.9 in 1973 and 36.4 in 1998. The ratio in the US also grew, from 3.3 in 1950 to 5.5 in 1973 and 8.5 in 1998, but the overall dependence on exports was

[5] In Canada and the US, the 1990s have brought changes in agricultural policy, often provoked by international trading agreements, that include moves away from commodity-specific subsidies and income supports toward direct payments that are considered to be less trade-distorting. However, there may be limits to full exposure of domestic producers to market forces and thus to liberalization in agricultural trade. Coleman and Skogstad (2000) argue that it is unlikely "that the path will be a straight one to greater internationalization, let alone globalization" in agriculture, given strong links between agriculture and deeply-rooted traditions in major agricultural-producing nations which ensure that agricultural policy remains deeply political.

[6] Unless noted otherwise, the statistics cited in this section come from the following web sites: ww.usda.gov/nass/pubs/agr98.; www.fas.usda.gov/scriptsw/bico/bico_frm.idc.; www.agr.ca/itpd-dpci/factsheete.html; http://aceis.agr.ca/food/markets/e_analysis97/titlepage.html; and http://apps.fao.org/default.htm.

[7] Keohane and Milner (1996): Table 2, p. 13.

much lower. Canadian agricultural producers have been more reliant on export sales than their American counterparts, although the American share of global trade in agricultural products is more than four times that of the Canadian share. As Table 6-1 shows, Canada exports more of its crop production in several commodities. The Canadian food processing industry is also more export dependent than the American industry. Its dependence has increased in recent decades. For example, the export share of shipments of food industry products in Canada was 9.7 per cent in 1972 and 14.6 per cent in 1986, compared to 3 per cent in 1972 and 4.1 per cent in 1986 in the US.[8] In the US, the growth in food exports from $17.8-billion (Cdn) in 1990 to $33.3-billion in 1995 has contributed to a continued increase in the ratio of exports to total shipments from 4.6 per cent in 1990 to 5.8 per cent in 1994.[9] In 1996, Canadian food exports were 16 per cent of the total shipments of $8.5-billion (Cdn). Whether in planting seeds or food products, Table 6-1 illustrates that Canada's major trading partner by far is often the US. Dependence on the American market has increased in recent years since liberalization of trade between the two countries under the free trade agreement. In contrast, the US has a much more diversified export market for agricultural products.

Multinational firms

Beyond trading patterns, the level of foreign direct investment (FDI) in the form of multinational firms (MNFs) is an important determinant of the potential for internationalization. Global booms in FDI have occurred three times in the last two decades: between 1979 and 1981, between 1987 and 1990, and between 1995 and 1998. Since 1987, global sales, a measure of the goods and services produced by foreign affiliates of MNFs, have exceeded total global exports of goods and services by a factor ranging from between 1.2 to 1.3.[10] Reflecting global growth in FDI, Canada and the US have increased steadily their FDI in each other's economies since 1973.[11]

MNFs are a dominant presence in two central links of the agri-food industry that are

[8] Coffin et al. (1993): Table 1, p. 464.
[9] Source: Industry Canada web site: http://strategis.ic.gc.ca/.
[10] United Nations Conference on Trade and Development (1997). In 1995, global sales reached $7-trillion (US), reflecting the economic activity of about 280,000 foreign affiliates of MNFs. In 1996, global FDI stock reached $3.2-trillion (US). MNFs are estimated to account for about two-thirds of total trade.
[11] Canadian FDI in the US has grown from $4-billion (US) in 1973 to $64-billion in 1997. American FDI in Canada has grown from $26-billion in 1973 to $100-billion in 1997. United States. Bureau of the Census (1998) and previous years.

involved in the development and commercialization of the products of agricultural biotechnology: the agricultural input link in agrichemicals and seed, and the food processing and retailing link. In 1997, the world's 100 largest MNFs by foreign assets included food firms Nestle and Unilever and plant biotechnology firms DuPont, Dow, and Hoescht (parent firm to AgrEvo).[12] The crop plant biotechnology industry is largely a product of the integration of the agrichemical and seed industries. In fact, in the last twenty years, the agrichemical and seed industries have become virtually synonymous due to the opportunities presented by biotechnology.[13] In 1998, global sales of genetically-engineered seeds were worth $1.6-billion (US), up 145 per cent from 1997.

MNFs dominate the agrichemical industry and are of growing economic importance in the seed industry (see Table 6-4). A 1999 study estimated that the world's ten largest agrichemical companies hold about 85 per cent, or $26.2 billion (US), of the $30.9-billion world market for agrichemicals.[14] Among seed companies, concentration is not as pronounced, likely reflecting the ongoing need for specialization given diverse growing conditions and different crops. However, the ten largest firms controlled about 32 per cent of the $23-billion (US) world seed trade in 1998. Concentration is sometimes higher for specific crops. For example, four firms (DuPont / Pioneer, Monsanto, Novartis, Dow) controlled about two-thirds of the North American market for seed corn and 47 per cent of the commercial soybean market in 1998. The global seed trade has long included a strong export orientation, but until recently there have been biological and policy-related limits on the growth of the seed industry.[15]

Within crop plant biotechnology, a handful of MNFs dominated the industry in Canada and the US as of 1998 in terms of sales and product development spending: AgrEvo, Dow

[12] United Nations Conference on Trade and Development (1997).

[13] Incentives for agri-chemical firms to move into plant biotechnology include the potential to develop plant varieties to be used in combination with their proprietary chemicals but also to protect themselves against the gains that plant biotechnology is expected to make at the expense of the market share of agri-chemicals. For more details, see, for example, Rural Advancement Foundation International (1998). See also Chapter Four.

[14] Rural Advancement Foundation International (1999).

[15] Some countries with a strong public agricultural research infrastructure, including Canada and to a lesser degree the US, have historically distributed new plant varieties at minimal or no cost to producers, making them challenging locations for seed firms to carve out market share. For many crops, it is necessary to develop varieties suited for variations in growing conditions, such as the length of growing season, average temperatures, and soil characteristics, which makes it important to have development activities in intended markets if merit is to be the basis of competition. Finally, in many countries, the tradition of producers saving their own seed to replant has made seed trade unprofitable. However, as noted in Chapter Two, many of these historical limits are now disappearing, given recent policy change and technological developments.

AgroSciences, DuPont, Monsanto, and Novartis Seeds.[16] Beyond the growing financial integration within the industry, these firms have also been drawn into a tight web of technological interdependence given proprietary products and processes. They led the commercialization of genetically-engineered plants in the late 1990s. In Canada, three MNFs (AgrEvo, Monsanto, and DuPont) accounted for 75 per cent of all environmental safety determinations between 1995 and 1998, and four (AgrEvo, DuPont, Monsanto, and Novartis) accounted for 73 per cent of all food safety assessments between 1994 and 1998.[17] In the US, four MNFs (AgrEvo, Monsanto, Novartis, and DuPont) accounted for 79 per cent of all determinations of nonregulated status between 1994 and 1998, and 81 per cent of all final consultations on food safety assessment.[18] In both categories of regulatory approval in the two countries, Monsanto dominated the field as of 1998, with its plant varieties accounting for almost half of all approvals. It was also a leader in sales. In 1998, based on the area planted with genetically-engineered plant varieties, Monsanto had 88 per cent, followed by Aventis (AgrEvo) with eight per cent, and Novartis at four per cent.[19]

The global food processing industry, which has begun to sell the products derived from genetically-engineered plants, is simply huge. The extent of its activity means that even its massive MNFs do not dominate the industry. Its vast size along with diversity in food preferences and consumption patterns worldwide helps to explain why there is less concentration in the food industry than in the seed or agrichemical industries. The ten largest firms control only about 16 per cent of global food sales.[20] Annual global food sales are currently estimated at about $2000-billion (US). The largest food firm, Nestle, had 1997 revenues of $45.3-billion (US) which is larger than the entire commercial seed industry ($23-billion) or the agrichemical industry ($31-billion), but a small percentage of total food sales. Of the ten largest food firms in 1997, six are headquartered in the US (Philip Morris, ConAgra, Cargill, PepsiCo, Coca-Cola, Mars), and four in Europe (Nestle,

[16] Some of these firms have been slower to commercialize their products, reflecting their later entry into the field of plant biotechnology and / or the pace of development. Monsanto is generally considered the pioneer, while others such as Dow AgroSciences are just beginning to sell their genetically-engineered varieties. The relative position of firms within the plant biotechnology industry has changed constantly given a steady stream of mergers, acquisitions, consolidations, and spinoffs. New entrants can be expected as the industry matures. For example, in June 1999, BASF Plant Science, which is a joint venture between the German chemical firm BASF and the Swedish seed firm Swalof Weibull, announced its plans to create a major plant biotechnology research centre in North Carolina with 150 scientists and technicians.

[17] See Tables 3-2 and 3-6.

[18] See Tables 3-4 and 3-8.

[19] Rural Advancement Foundation International (1999).

[20] Rural Advancement Foundation International (1999). See Table 6-5 for a list of the largest firms.

Unilever, Diageo/Guiness/Grand Metropolitain, Danone). In Canada, MNFs are a significant presence in the food processing industry, garnering about 40 per cent of market share as of the mid-1990s.[21] In the US, the figure is similar. An annual average of 37 per cent of total sales of food manufacturing firms between 1982 to 1993 came from foreign-owned firms.[22]

International institutions

International institutions may reinforce the degree and direction in which economic conditions encourage internationalization. They may also dilute or redirect internationalization, depending on their content and their contribution to the resources of various members of the policy network. In particular, international institutions can strengthen the capacity and increase the autonomy of state actors within their domestic policy networks. International institutions may also filter the influence of transnational actors, both economic and non-economic. Several multilateral institutions have taken an interest in biotechnology policy issues, including regulatory matters. The three institutions that have been most active on the issues of environmental safety, food safety, and labelling of genetically-engineered plants and the food products made from them are, first, the Organisation for Economic Cooperation and Development; second, the United Nations (UN) organization Codex Alimentarius Commission; and, third, the Secretariat of the Convention on Biological Diversity, which falls under the United Nations Environment Programme, in the form of negotiations on a Biosafety Protocol. The Food and Agriculture Organization (FAO) and the World Health Organization (WHO) of the UN have examined the issue of safety assessment of biotechnology foods and issued two reports with recommendations, in 1991 and 1996. Although it is more akin to a transnational coalition than an international institution, this section also includes a brief description of the efforts of the International Food Biotechnology Council toward creating consensus on food safety assessment measures. Most of the activities of these international institutions have been non-binding on member states. They have been primarily intended to build international scientific consensus and set internationally-endorsed standards for procedures such as

[21] In 1996, the Canadian food industry was comprised of about 2800 firms, with annual shipments valued at $52 billion. Eight of the twelve firms with annual sales topping $1-billion (Cdn), which together represent 35 per cent of shipments, were Canadian-owned. Of the fifty-five firms with sales between $100-million and $1-billion (Cdn), which represent 25 per cent of shipments, almost half (44 per cent) were foreign-owned.Statistical data on the Canadian food and beverage processing industry comes from Canada. Agriculture and Agri-Food Canada (1997b).
[22] Henderson et al. (1996): 71.

environmental risk assessment and food safety assessment, often with the underlying mandate to facilitate international trade. However, the Biosafety Protocol once implemented has the potential to place constraints on the domestic policy choices of member states. The standards set by Codex and the International Plant Protection Convention (housed within the FAO) do so as well.

Organisation for Economic Cooperation and Development

The Organisation for Economic Cooperation and Development (OECD) appears to have been the first international institution to have staked a claim in the debate surrounding the appropriate scope and methods for biotechnology regulation.[23] The OECD's interest dates back two decades to 1980 when its Committee for Scientific and Technological Policy commissioned a report, titled *Biotechnology: International Trends and Perspectives*.[24]

Since the early 1980s, the OECD has published several documents and reports on various aspects of biotechnology policy, including regulation, intellectual property protection, and its economic and technological potential for agriculture. For example, in 1986, the OECD released a document outlining scientific criteria for regulating the use of rDNA organisms, based on the work of its Group of National Experts on Safety and Regulations in Biotechnology which was created in 1983.[25] The document, heavily-referenced since its publication, sketched out appropriate safety considerations and a general framework for risk assessment consisting of broad principles. Subsequently, the OECD has made specific recommendations on regulation of various aspects of biotechnology, including for small-scale and large-scale field releases of genetically-engineered plants, and food safety assessment.[26] Since 1995, it has focused directly on encouraging international harmonization by distributing information on the development of domestic regulatory regimes and elaborating its guidelines through the development of "consensus documents" which provide environmental risk assessment guidelines for specific products.[27] A central goal of the

[23] The OECD's mandate is to further economic growth and development and the expansion of world trade. Its relatively small membership is comprised of the world's more developed nations, including Canada and the US.
[24] See Organisation for Economic Co-operation and Development (1995b) for a summary of the OECD's activities. For the 1982 report, see Bull et al. (1982).
[25] Organisation for Economic Co-operation and Development (1986).
[26] See Organisation for Economic Co-operation and Development (1993a), Organisation for Economic Co-operation and Development (1992b), and Organisation for Economic Co-operation and Development (1993b).
[27] See Organisation for Economic Co-operation and Development (1997b). In October 1998, a Task Force on Novel Foods and Feeds was created with the task of producing Consensus Documents on the food and feed safety of novel crop plants. Its first meeting was scheduled for September 1999.

OECD has been to establish guiding scientific principles for regulation of biotechnology that also create consensus on appropriate policy goals and policy instruments and in turn reduce obstacles to development of biotechnology and trade in its products.[28] Although the OECD does not focus its activities on creating international *scientific* consensus, it has a long history of producing reports with policy-relevant recommendations.[29]

International Food Biotechnology Council

The earliest effort at creating international consensus on safety assessment procedures for biotechnology foods came from an unusual source: the International Food Biotechnology Council (IFBC). The IFBC is a consortium of thirty agricultural input and food processing firms, many of which are multinationals.[30] Established in 1988 with the goal of providing scientific criteria for the safety assessment of biotechnology foods, the IFBC's 1990 report on safety assessment reflected the recognition of its members that "it is preferable to build a consensus on appropriate safety evaluation criteria before the widespread development of new products that may require such evaluation prior to their commercialization".[31] The IFBC saw its role in 1990 as assisting regulatory agencies in the US and abroad who had to stay on top of science "they did not develop but that underlies the products they regulate and should underlie the regulatory decisions they make."[32] The IFBC was also keenly aware that its report, to be considered legitimate, could not be viewed as an industry effort. It wanted to produce a report that would be accepted by regulators and be seen to come from "a solid consensus of acknowledged experts" both inside and outside

[28] See Table 6-6 which outlines the OECD's twin tracks of promoting development of biotechnology while outlining scientific principles for risk assessment to underpin regulation through the conclusions and principles published in the reports of its committees. At times, the OECD has warned policy makers of the consequences of restricting biotechnology development: "If plant breeding is held back by erroneously preventing the use of some sources of genes but not others, the consequences for solving major food and agriculturally-based problems of the plant like environmental pollution during the next century could be dire." Organisation for Economic Co-operation and Development (1992a): 44.

[29] Banting's (1996) characterization of the OECD's role in creating international consensus on social policy matters and how its research and recommendations can be a useful tool for state officials within their own domestic policy networks is also accurate for biotechnology policy.

[30] Members of IFBC as of 1990 included Ajinomoto, Calgene, Campbell Soup, DuPont, Frito-Lay, Kraft, General Mills, Monsanto, Nabisco, Nestle, Pioneer Hi-Bred and Procter&Gamble.

[31] International Food Biotechnology Council (1990). See Table 6-7 for some of IFBC's key recommendations.

[32] International Food Biotechnology Council (1990): S1-2

industry.[33] At the same time, the IFBC wanted to smooth the path for commercialization of biotechnology through its efforts, noting that "it is critically important to develop and apply procedures that clearly ensure safety, but that avoid an unnecessary burden that would discourage product development." The IFBC's primary target was the US FDA and its recommendations included detailed prescriptions for adapting FDA food safety regulations to biotechnology foods.

The Food and Agriculture Organization and the World Health Organization

The Food and Agriculture Organization (FAO) and the World Health Organization (WHO) have held two joint consultations on approaches to the safety assessment of biotechnology foods, in 1990 and 1996.[34] The 1990 consultation focused solely on the scientific issues of safety assessment, leaving aside issues such as ethics, consumer perceptions, and food labelling. In 1996, participants in the consultation, which included observers from Codex, were reminded that they were expected to act as independent experts and not as representatives of any government or organization. It was reiterated that the focus of the consultation "must be on science and the need was to reach consensus on the state of the science relative to the various safety issues".[35] The intent to focus solely on scientific issues appears to have been largely successful. Recommendations focused on the issues of safety assessment and did not include specific prescriptions for policy measures, unlike those of the IFBC and the OECD (see Table 6-7).

Codex Alimentarius, the International Plant Protection Convention, and the World Trade Organization

The Agreement on Sanitary and Phytosanitary Measures (the SPS Agreement), which came into force in 1995 as a product of the Uruguay Round under the General Agreement on Tariffs and Trade (GATT), strengthens and clarifies rules designed to prevent measures to protect human,

[33] Written by an expert committee, the IFBC document was peer reviewed by about 150 experts in industry, government, and academia across thirteen countries. Forty detailed comments were received and the draft was discussed during a conference attended by 120 experts.

[34] The WHO also held two workshops: one in 1993 on the health aspects of marker genes in genetically-modified plants and one in 1995 on the application of the concept of substantial equivalence to foods from plants derived through modern biotechnology. The FAO's activities on biotechnology have been primarily focused on its relationship to the conservation and use of plant genetic resources. For the reports, see United Nations. Food and Agriculture Organization (1996) and United Nations. World Health Organization (1991).

[35] United Nations. Food and Agriculture Organization (1996).

animal, plant and environmental health from being used as disguised trade barriers.[36] In the event of a trade dispute centring on such measures, the SPS Agreement requires countries to justify their use with scientific evidence.[37] The Agreement designates the standards set by the Codex Alimentarius Commission (Codex) in food safety and by the International Plant Protection Convention (IPPC) on plant health as acceptable international baselines. Codex and the IPPC predate the SPS Agreement. They were created in 1962 and 1951, respectively, to encourage international cooperation on issues of food safety and plant health, including the creation and expansion of international scientific consensus through standard-setting activities.[38] Both institutions were established with the intent that their activities would facilitate international trade. The SPS Agreement suggests that countries unable to justify scientifically measures based on standards higher than those adopted by these bodies will be required to realign those measures or compensate the challenging country. The Agreement is enforced by the World Trade Organization's dispute settlement procedures.

Codex is a joint initiative of the FAO and the WHO under the UN. Until its heightened importance since 1995 with the creation of the WTO, Codex functioned as an international scientific advisory body.[39] Its standards were guidelines and not binding on member countries. The development of standards at Codex tends to be a lengthy process because new standards must pass through as many as eight steps of approval, which can take several years, and because of the hurdle of reaching adequate consensus among its many members. As a result, Codex activities

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[36] The North American Free Trade Agreement has provisions on sanitary and phytosanitary measures that are based on the GATT SPS Agreement. However, there are several subtle differences between the two sets of provisions, including the lack of a "least trade-restrictive" requirement in NAFTA. NAFTA requires its members to use international standards, guidelines, or recommendations as long as this does not reduce protection. It requires the challenging country to prove that a measure is inconsistent, unlike the GATT SPS Agreement which places the onus on the defending country. In the event of an incompatibility between the GATT and NAFTA SPS provisions, it is expected, according to the practice under the Vienna Convention on the Law of Treaties, that the NAFTA provisions would prevail among NAFTA countries over those of GATT. Article 30(2) of the Vienna Convention states that when a treaty specifies that it is not to be considered incompatible with another treaty (whether earlier or later), the other treaty prevails. See Johnson (1994), Chapter Six.

[37] For a discussion of the SPS Agreement, see World Trade Organization (1996).

[38] As of 1998, Codex had about 150 countries as members. One hundred and five countries are parties to the IPPC.

[39] Salter (1988) describes Codex as an institution that bases its standard setting activities on both scientific and non scientific information. The non-scientific information is about trade, given Codex's mandate of trade promotion. Based on a study of Codex involvement in setting pesticide residue standards, Salter argues that at the plenary level of Codex, trade and national interests are given higher priority than health and safety issues, and science plays a minor role. At the level of the Codex technical committee examining pesticide residue standards, health and safety comes first, followed by trade and then scientific issues.

often appear to lag behind the pace of standard-setting in pioneering countries. Although the focus of Codex activities is food safety, its most visible work on the application of genetic engineering to food has been on the labelling issue.

Codex has considered some specific aspects of safety assessment for biotechnology foods such as the safety of bovine somatotrophin, the genetically-engineered hormone intended to increase milk production, but avoided attempts to establish standards for these foods throughout the 1980s and much of the 1990s. It has not been unaware of the issue. For example, in 1989, the Codex Committee on Food Additives and Contaminants discussed the issue of biotechnology foods and reviewed a paper prepared by two US state officials, one from FDA and the other from USDA.[40] In the late 1990s, Codex decided to take action. In June 1998, the Codex Executive Committee expressed its opinion that a clear statement by the Codex Commission "on the policy approach which assured the safety and nutritional aspects of food prepared from biotechnology was needed as a matter of priority".[41] In July 1999, the Codex Commission approved the creation of an intergovernmental task force to increase the pace of the development of standards for biotechnology foods. It expressed its hope that the standards would be adopted by the year 2003.

Codex's attempt to establish a standard for labelling of genetically-engineered foods has been almost fruitless to date, but not from a lack of effort. Codex's Committee on Food Labelling (CCFL), which is chaired and hosted by Canada, received a recommendation at its meeting in 1991 that it consider the issue of labelling biotechnology-derived foods. Between 1993 and 1998, the issue was on the agenda of each CCFL meeting. Discussion of the labelling issue has resulted in little progress because of a polarization in views among member countries. The cleavage is between those who support mandatory labelling of all foods derived through genetic engineering and those, including Canada and the US, who have consistently supported mandatory labelling provisions only when the genetically-engineered food differs significantly from its conventional counterpart, such as a change in nutritional content or in potential allergic reactions. By the end of the April 1999 meeting of the CCFL, observers reported that the US and Argentina were isolated in their insistence on no special labelling provisions for biotechnology foods, while Canada emerged with the responsibility of chairing a committee with the mandate of resolving the impasse. Some observers interpreted this outcome as a sign that Canada was distancing itself from its previous

[40] International Food Biotechnology Council (1990).
[41] United Nations. Codex Alimentarius Commission (1998).

close alignment to the American position, although Canadian officials denied this.[42] The meeting concluded with the decision to return to Step Three of the Codex process in order to recirculate a proposed draft standard.[43]

The SPS Agreement also references the International Plant Protection Convention (IPPC), which promotes international cooperation in plant quarantine measures to ensure the control of plant pests and diseases. The IPPC has been strengthened in recent years through the creation of a secretariat in 1989 which began work in 1993. The text of the convention was most recently revised in November 1997 to reflect IPPC's new importance as a result of the SPS Agreement. The new text includes a provision under Article XI for a Commission on Phytosanitary Measures to act as a governing body and set priorities for the secretariat's activities in standard-setting and harmonization.[44] In the past, the IPPC has had provisions for dispute settlement under Article IX, including creation of expert committees to consider the dispute. The reports of the expert committees, however, have not been binding on the parties involved. In 1998, the IPPC had just begun to consider the impact of genetically-engineered plants on its operations. Some policy community members were urging it to become active, preferring it as an alternative venue to the Biosafety Protocol discussions for international debate of the environmental risks of biotechnology.

A Biosafety Protocol and the Convention on Biological Diversity

If successful, efforts to implement a Biosafety Protocol will result in the first binding international agreement regulating trade of biotechnology products with the goal of protecting biodiversity. The Biosafety Protocol is one element of the United Nations Convention on

[42] See "Labelling and Liability", by Brewster Kneen, in *The Ram's Horn*, No. 170, June 1999.
[43] The adoption of a standard by Codex begins with a proposed draft standard, followed by a draft standard, and finally, adoption of the standard, if consensus can be reached. Step Three is when a proposed draft standard is sent to members and other international organizations for comment on all aspects.
[44] The Commission is to be composed of delegates from parties to the Convention. An Interim Commission has been established until the revised text is adopted, and first met in 1998.

Biological Diversity (CBD).[45] As of 1998, the Convention had been ratified by 174 countries including Canada, but not the US. The stated goals of the Convention are to conserve biodiversity, promote the sustainable use of biological resources, and ensure an equitable allocation of the benefits that result from the use of genetic resources.

Three provisions of the Convention are particularly relevant to the regulation of the environmental risks of biotechnology.[46] First, Article 8(g) requires parties to the Convention to take measures to protect biodiversity within national boundaries:

> to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.

Other articles are intended to govern trade in biological products so as to protect biodiversity. Article 19(3) commits the parties to consider the need for, and content of, a biosafety protocol that would ensure that importing countries are aware of and can handle any environmental risks that biotechnology products might pose. It calls for:

> setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity.

Finally, Article 19(4) requires exporting parties to provide available information about their own regulations for the safe use and handling of biotechnology products and about any potential adverse effect of these products at their destination site. The information is to be provided either directly by the state or through means that place requirements on actors under its jurisdiction.

The six negotiating sessions of the Open-Ended Ad Hoc Working Group on Biosafety regarding the content of a biosafety protocol began in 1996 and brought together the representatives of more than 170 countries. The negotiations opened up another battlefront at the

[45] The Convention emerged from the United Nations Conference on Environment and Development of 1992 and came into force in December 1993. The groundwork for the convention began with the establishment by the United Nations Environment Programme (UNEP) of the Ad Hoc Working Group of Experts on Biological Diversity in November 1988 with the mandate to examine the need for such a convention. In May 1989, the Ad Hoc Working Group of Technical and Legal Experts was set up to prepare a draft protocol. The working group became known by 1991 as the Intergovernmental Negotiating committee and it ended its work with the Nairobi Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity in May 1992. Canadian Biotechnology Strategy Task Force. Working Group on International Issues (1998)..

[46] For the text of the Convention, see United Nations Conference on Environment and Development (1992).

international level between proponents and skeptics of biotechnology. The perceived stakes for the future of the biotechnology industry were high. One representative of a Canadian environmental group described it as a "make or break" issue.[47] While the negotiations were intended to establish an environmental international regime, the effort was perceived by many as a trade issue. For example, if the protocol governed trade in bulk grains originating from genetically-engineered plants, countries whose agricultural producers were beginning to cultivate large acreages of such plants could face new paperwork requirements or even trade barriers. Concern about such a result encouraged the "Miami Group" (Canada, the US, Chile, Uruguay, Argentina, and Australia) to work together to narrow the scope of the protocol. They were supported by biotechnology, food industry and export-oriented agricultural producer associations. For biotechnology skeptics, the protocol was seen to offer a real opportunity to regulate more stringently, if not delay, the rapidly-growing commercialization of biotechnology products. These skeptics hoped the protocol would incorporate the precautionary principle and acknowledge a high degree of scientific uncertainty about the potential environmental impacts of biotechnology products.[48]

The difficulty in reaching an adequate consensus on the text of the protocol resulted from many serious disagreements about its appropriate scope and intent, but ultimately reflected the ongoing polarization of participants in the debate over the risks and use of genetic engineering.[49] Just prior to the final negotiating session in February 1999 in Cartagena, a news report noted that several veteran treaty negotiators agreed that they had never been involved in a negotiating effort where such widely-divergent views prevailed down to the last minute. According to Michael

[47] Personal interview, July 1998.

[48] The "precautionary principle" which advocates a low or zero-risk approach to regulation conflicts somewhat with the concept of risk analysis, which involves estimating risks and then determining whether and how to manage them if the decision is made to proceed.

[49] Going into the final meeting of the February 1999 negotiating session, much of the draft protocol was within square brackets, indicating lack of consensus on provisions. Weiss and Gillis (1999). The many significant areas of disagreement during discussions that made consensus elusive included whether the protocol should govern trade in only "living" products such as vaccines, seeds, and plants, or instead be extended to their products such as bulk grains, processed food, and clothing. Exporters worried that the protocol would establish onerous paperwork through documentation requirements if "advanced informed agreement" would have to be secured for each shipment and / or notification provided for each shipment, rather than only for the first shipment of a given product. Another contentious issue was whether the protocol should include explicit provisions governing the allocation of liability in the event of damage to biodiversity. Debate also raged between countries advocating the inclusion of socioeconomic considerations in the protocol as valid grounds for refusing or screening imports of biotechnology products, and those advocating a narrow environmental risk-based approach. Participants also disagreed on how to reconcile the protocol's provisions with measures under the World Trade Organization agreement, particularly the Sanitary and Phytosanitary Agreement, given the potential for conflict.

Williams of the U.N. Environmental Program, the failure of that session was the first time in more than two decades that a major international environmental negotiation concluded in disarray.[50] The result raised questions about the future of the Convention on Bological Diversity and speculation as to whether the WTO would be left to fill in the void in the absence of a biosafety protocol.[51]

Surprising many observers, subsequent extraordinary meetings overcame the significant disagreement among negotiating parties and resulted in the adoption of a protocol text by the conference parties in January 2000. The text reflected compromises made on both sides of the debate, with vague language permitting both biotechnology proponents and skeptics to claim limited victories. The text incorporates a commitment to the precautionary principle. It also states that the protocol is neither subordinate to nor alters the rights and obligations of parties under other international agreements, leaving its relationship with trade agreements somewhat unclear until interpretation occurs. The scope of the protocol is limited to genetically-engineered organisms intended for environmental release such as seeds and exempts, for example, commodities intended for food use. Many observers agreed that agreement was secured in part because participants were indeed concerned that failure to reach agreement might jeopardize the Convention on Biological Diversity. Implementation of the protocol is to occur within two or three years, once it is ratified. Until the protocol is implemented, there are no binding rules governing the trade of biotechnology products for the purpose of minimizing environmental risks. UN organizations have worked on voluntary guidelines and codes to minimize the environmental risks of biotechnology that cover both national and international measures. In particular, the 1995 UNEP International Technical Guidelines for Safety in Biotechnology were intended as an interim measure until a protocol was completed.[52]

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[50] Bajak (1999b).

[51] International Institute for Sustainable Development (1999).

[52] United Nations Environment Programme. Convention on Biological Diversity Secretariat (1997) and Canadian Biotechnology Strategy Task Force. Working Group on International Issues (1998). The FAO also worked on a proposed Code of Conduct on Biotechnology, which focused on measures to ensure the proper conservation and use of plant genetic resources and was submitted to the protocol negotiating body. The UN Industrial Development Organization (UNIDO) Voluntary Code of Conduct for the Release of Organisms into the Environment provides general principles, intended largely for countries without any regulations in place.

BILATERAL ACTIVITIES

Outside of their interaction through multilateral institutions, Canadian and American regulatory officials have a long history of informal discussions on the issue of developing regulations for the products of agricultural biotechnology. The exchange dates back at least to the late 1980s.[53] Most recently, the two countries issued a formal statement on cooperating on the risk assessment of genetically-engineered plants. In July 1998, a bilateral agreement between the USDA , the CFIA, and Health Canada produced common requirements for molecular genetic characterization data, including standard checklists.[54] The agreement includes a commitment to periodic information exchange, including quarterly telephone calls and annual meetings. The July 1998 agreement builds on previous information exchanges and may eventually allow regulators in the two countries to accept each other's assessments. The July 1998 agreement is reinforced by the December 1998 "Record of Understanding" document issued by the two countries that formalizes Canada-US cooperation on various agricultural trade issues.[55]

INTERNATIONALIZATION AND DOMESTIC POLICY COMMUNITIES

International awareness and mobilization

Members of the Canadian and American agricultural biotechnology regulation policy communities vary in sensitivity to international economic conditions, the attention paid to events in other countries, and in their level of participation in international activities. Multinational firms and

[53] For example, in August 1988, Canadian regulators held a two-day meeting with their US colleagues for the purpose of information exchange. See Hollebone (1988). Interviews with state officials from both countries also report a longstanding pattern of frequent and productive informal interaction and information exchange on biotechnology regulatory policy since the "early days", particularly on the issue of environmental release. USDA officials report that the standing joke in those early days was that Canada was closely watching the US to avoid its mistakes.

[54] Health Canada also reports routine, frequent informal interaction at working and policy levels with FDA counterparts, beyond interaction at international venues such as OECD committees.

[55] The December 1998 agreement reaffirms the commitment of both countries to reject the unjustified use of scientific measures as barriers to trade. The document includes an action plan on matters such as exchange of cattle data, veterinary drugs, horticulture, labelling, and biotechnology, with the stated intention of "facilitating and expanding" bilateral agri-food trade. It states that the Canadian agriculture minister and the American agriculture secretary will meet at least once a year to discuss agricultural trade issues and to discuss "issues of common interest" for the purpose of cooperating in other international venues. Senior officials are also to meet at least twice a year, and within thirty days on issues requiring resolution. The governments also agree in the document to establish a "comprehensive early-warning and consultation process to resolve problems at an early stage in their development." Finally, the document encourages the private sector, through its industry associations, to contribute to increased cross-border discussions, including the creation of "bilateral industry consultative mechanisms" for various sub-sectors, such as grains, livestock and meats, and horticultural products. Canada. Canadian Food Inspection Agency (1998).

state officials participating in the activities of international institutions have long included an international focus as a core aspect of their policy-related work. For others, including some environmental organizations and agricultural producer associations, an intentional effort to follow international developments is new or has become a much more important activity in recent years. Interviews with members of the plant biotechnology regulation policy communities in Canada and the US revealed an almost unanimous increased focus on international events relevant to agricultural biotechnology regulation since the mid-1990s, especially among those associations that traditionally have been less interested in international matters. The priority placed by policy community members on awareness of international developments is a function of any or all of the following factors: first, the degree of economic dependence of an industry on exports and thus the importance of market access; second, the presence of MNFs in the sector and in industry associations; third, recognition that international institutions may place or are placing constraints on domestic policy making and thus are important policy making venues; and, fourth, the perceived advantages of forging cross-national links or creating international-level associations and coalitions that allow pooling of resources and speaking with a common voice internationally.[56]

The seed industries in Canada and the US have longstanding international connections through membership of national associations in international seed trade and plant breeding organizations.[57] There is also frequent bilateral communication between national seed associations. The American Seed Trade Association (ASTA) welcomes members from Canada and Mexico, and has a vice president on its executive from each country.[58] Representatives report using these channels to discuss biotechnology regulation issues. ASTA and CSTA, as seed industry associations, do not directly represent public sector plant breeders.[59] Private and public sector scientists do rub shoulders at many venues such as meetings of scientific societies, but public sector plant breeders appear generally to be much less "plugged in" to international developments

[56] See Table 6-8 for a brief overview of the international mobilization and orientation of key policy community members.

[57] Personal interviews with ASTA and CSTA representatives in October 1998 and March 1998, respectively. ASTA and CSTA have been active in these international institutions (the International Association of Plant Breeders--ASSINSEL, and the International Seed Trade Federation--FIS) in particular since the adoption of the OECD scheme for international seed certification in the early 1960s.

[58] For 1998-1999, the Canadian vice president of ASTA is a representative of the Canadian branch of Novartis Seeds.

[59] ASTA membership is comprised of firms; CSTA membership is comprised of individuals and firms engaged in the seed industry.

on regulatory policy.[60]

Building on the long-established international orientation of the seed trade and the dominance of multinational firms in the agri-chemical industry, plant biotechnology multinational firms and the associational system of the plant biotechnology industry have had an international orientation since their beginnings in the 1980s. Linkages between the American and Canadian associations have been consistently strong through the 1990s. The Biotechnology Industry Organization (BIO), although based in the US, portrays itself as an international organization and has many members from other countries, including Canada.[61] Most recently, biotechnology industry associations from the US, Canada, Europe, and Japan have increased coordination to present a common voice at international meetings. These national associations meet a few times a year, but also have frequent informal contact on issues such as labelling. Information exchange helps to develop consensus across the industry internationally. A representative of BIOTECanada noted that developing such a consensus provides "a lot more strength" in international forums, when the biotechnology industry finds itself debating with other groups such as environmental organizations that have created international coalitions and where each international coalition is given equal time to speak.[62]

Compared to the seed trade and the plant biotechnology industry, the food industry appears, somewhat surprisingly, to be less mobilized through associations at the international level. However, exporting and multinational firms have strong incentives to be aware of international economic conditions and events and are likely to follow international developments on an individual basis. Their national associations actively follow international developments. A representative of the Food and Consumer Products Manufacturers of Canada noted that because

[60] Interviews suggest that public sector plant breeders often have a general awareness of relevant international developments, but do not take a proactive approach to monitoring them. In Canada, they report that their international awareness comes largely through informal scientific information exchange. Discussions about regulatory policy appear to be a minor aspect of such exchange, and information comes indirectly from others that are more actively internationally, such as state officials, multinational firms, and commodity associations. See also Anstey (1986): 355 for examples of international scientific exchange between public sector Canadian and foreign researchers.

[61] Canadian members include several biopharmaceutical firms and Ag-West Biotech, Ontario Agri-Food Technologies, and the Quebec Bioindustries Association. One of the predecessors of the current Canadian biotechnology industry association (BIOTECanada), called the Industrial Biotechnology Association of Canada, was created in part at the behest of Monsanto Canada as a branch plant of one of BIO's predecessors, the Industrial Biotechnology Association (US). Personal interview, February 1998.

[62] Personal interview, February 1998.

many of the association's members are multinational, the association is often briefing Canadian state officials on international developments. While state officials are aware of international issues, it is not a key focus for them in the way that it is for the food industry. The National Food Processors Association (NFPA), one of the major food industry associations in the US, reports working quite closely with its Australian counterparts on biotechnology issues, but not much with counterparts in Canada.[63] The global food industry does have at least one international-level association, currently called the International Alliance of Food Product Associations, which is based in Brussels. It has been "loosely organized" since the late 1980s and brings together the representatives of twenty-five to thirty countries. The alliance has become more formally organized since 1993 and now has annual meetings.[64] Both the NFPA and the FPCMC belong to this international alliance which provides a forum for discussion. However, the alliance has not contributed much toward establishing an international consensus on biotechnology issues across the global food industry, in part because European food firms often have different positions than their North American counterparts.[65]

For American and Canadian agricultural producers, international awareness has focused traditionally on trade and issues other than regulatory policy. It is centred within associations rather than among individual members. General farm organizations such as AFBF and the CFA do attend international meetings such as the biennial meetings of the International Federation of Agricultural Producers. They report that such meetings have included discussion of biotechnology issues. Most individual producers do not have the time or inclination to become mobilized internationally and rely on their associations to warn them of important developments. In some matters, producers rely on state officials to represent their interests. For example, a CFA representative stated that the federation's members are comfortable with the idea that Canada will adopt standards set by international institutions as long as they perceive that Canadian officials are doing an adequate job.[66] Associations that represent producers of commodities that are dependent

[63] The NFPA doesn't see much need to be involved with Canada because it perceives the Canadian system as closely aligned with the American system. Personal interview, October 1998.
[64] A FCPMC representative reported being very active in this international alliance.
[65] For example, in May 1997, a group of European food retailing firms and associations sent an open letter to American firms stating their insistence on identification of genetically-engineered food shipped to Europe. The letter was signed by associations from Denmark, Finland, France, Germany, Sweden, and the UK, and by several large European firms such as Sainsbury and Tesco in Britain.
[66] Personal interview, July 1998.

on export markets for significant portions of their sales, such as the Canola Council of Canada and the American Soybean Association, have been increasing their efforts to become aware of and active in international regulatory developments related to market access for biotechnology products. The shared dilemma of members of American and Canadian commodity associations of lost export markets is encouraging the development of cross-national links. For example, in the spring of 1998, representatives of commodity organizations in both countries met to discuss issues of common concern, with a focus on the issue of market access of biotechnology crops. More recently, in the summer of 1999, a meeting organized by the National Corn Growers Association (US) brought together more than 150 representatives of various links in the corn industry to discuss biotechnology issues.[67]

For public interest groups, including environmental and consumer organizations, the importance of being active internationally lies in the recognition of the importance of international venues for policy making and the benefits of pooling resources.[68] Such groups can be effective internationally, for example, when they can draw on informational resources and specialized expertise to provide authoritative interpretations, and make claims of popular representation.[69] While international coalitions among public interest groups appear to be an increasingly common tactic, these coalitions often are temporary, informal, and single-issue. Even within a single organization that appears to be transnational in its focus, there may be a lack of central coordination.[70] Evidence and reports of cross-national linkages and international coalitions among public interest groups on agricultural biotechnology regulatory issues suggest only a minimal level of occasional and temporary interaction for the purpose of coordinated policy activities beyond information exchange took place prior to 1998.

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[67] See NCGA website: http://www.ncga.com. The meeting was the first step in drafting a common plan of action and included representatives from Canadian, French, and Japanese firms and associations. Objectives of the effort include determining the marketability of genetically-engineered corn varieties, securing the American position as a corn supplier internationally, evaluating the regulation of genetically-engineered varieties around the world, and a discussion of technology transfer and risk allocation. The meeting concluded with agreement, among other things, to encourage regulators to increase their promotion of the American regulatory system and to work to increase consumer confidence in the safety and benefits of biotechnology.

[68] See Boardman (1992) for a discussion of the international activity of Canadian environmental policy community members.

[69] Clark (1995).

[70] For example, a recent survey of the twelve largest national environmental interest groups in the US found that seven had international affiliates, but all were only loosely aligned with their parent organizations. Information flows among the groups, but there is rarely a central control of policy activities. Jones and Smith (1995).

The Consumer Policy Institute within the Consumers Union (US) appears to be one of the most internationally-active public interest groups working on agricultural biotechnology regulation. It has worked internationally on biotechnology issues since the mid-1980s. In the 1990s, the Consumer Policy Institute worked closely on food biotechnology issues with Consumers International, an international alliance of consumer organizations based in England. The two groups have co-published reports on food biotechnology issues such as labelling.[71] In contrast to the Consumer Union's activities, the Consumers Association of Canada reports a failure to link with consumer groups in other countries and internationally on both agricultural biotechnology issues and other matters. The CAC is thus relatively isolated internationally.[72] Some American groups, like the Union of Concerned Scientists, have interacted with Canadian individuals and groups, but often cite resource constraints as limiting these linkages. Canadian groups report some linkages with American counterparts, largely for the purpose of information exchange, such as between CIELAP and UCS. Occasionally, groups work together on campaigns, as in the example of the Canadian campaign by the Council of Canadians and the Pure Food Campaign (US) on the issue of the safety of bovine somatotrophin in the mid-1990s.

Economic internationalization and policy preferences

In this case study, economic internationalization's chief apparent effect has been to shape the policy preferences of both more and less economically-powerful members of domestic policy communities. In general, Canadian policy community members are more vulnerable to the economic aspects of internationalization given their greater dependence on export markets, especially the American market, and the dominance of American and European-based multinationals in the crop plant biotechnology industry. The vulnerability that emerges from trade patterns most clearly affects export-oriented commodity producers in Canada, their American counterparts (albeit to a lesser degree), and the Canadian food industry with its increasing export intensity.

For export-oriented agricultural producers, internationalization fuels demands for tools to remain competitive in global markets. Many North American producers have embraced

[71] Halloran and Hansen (1998).

[72] In fact, the CAC reports having better links with food industry associations in the US, such as the American Meat Institute, than with consumer organization counterparts. Personal interview, February 1998.

genetically-engineered plant varieties as useful tools, apparently not aware or concerned about the issue of market access until export markets were about to be lost. Troubles in the European market no doubt accounted for the increased mobilization of agricultural producer associations in the late 1990s when faced with the argument that a biosafety protocol under the Convention on Biological Diversity could shut down or seriously hamper trade in agricultural commodities.[73] For the food industry, the commercialization of genetically-engineered plants raises the issues of food safety and labelling. National food industry associations in Canada and the US, reflecting both the presence of large MNFs and export-oriented firms within their membership, have encouraged the development of food safety assessment procedures that are internationally endorsed to protect market access and further harmonization. For many Canadian food firms, protecting access to American markets is the single most important goal of harmonization efforts.

The greater vulnerability of members of the Canadian policy community appears to provide the basis for the differing priorities of American and Canadian state officials. For American officials, the consistent priorities have been first, to maintain international technological leadership in biotechnology by quickly developing a regulatory regime allowing commercialization; and, second, to use its scientific leadership to legitimize its regulatory approach as an international model which in turn is expected to encourage harmonization in the direction of that model.[74] For Canadian officials harmonization has also been a consistent priority. For Canada, however, the focus has not been so much about providing the model although efforts have been made to do so, but ensuring that the Canadian policy response is aligned with the right international model so to avoid trade challenges and disputes.[75]

For public interest groups, economic internationalization has a more subtle effect on policy

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[73] Canada was interested in particular in how the protocol would affect trade with nonparties, such as the US. Prior to the final negotiating session, the Canadian agricultural media reported speculation that Canada might no longer be able to export biotechnology products to the US if it ratified the protocol. Others following the issue said that such a result was highly unlikely.

[74] For example, in 1990, USDA officials Terry Medley and James Glosser noted that "a very critical component" of biotechnology regulation work within USDA was to encourage international harmonization and to avoid artificial trade barriers. Glosser noted that the emphasis on harmonization has meant that "we are at the threshold of a way in which we have never conducted business heretofore" including US acceptance of data generated elsewhere, which would not have occurred in earlier decades. See U.S. Congress. House Committee on Agriculture. Subcommittee on Department Operations, Research, and Foreign Agriculture (1991): 53 and 65.

[75] Canadian leadership at international institutions in providing regulatory models is more evident in discussions about environmental risk than food safety. For example it introduced the concept of "consensus documents" to the OECD.

preferences. Market access problems for domestic producers have heightened domestic public awareness of the issues raised by genetically-engineered crop plants such as food safety and labelling. This development presents the possibility of "contagion" of public hesitation or resistance seen in other countries, particularly if public interest groups seize the opportunity. At a broader level, some public interest groups, including the Council of Canadians, the Sierra Club of Canada, and Greenpeace International, have focused on the dominant presence of multinationals in the agricultural biotechnology industry and international biotechnology policy making activities, such as those of Codex.[76] They have expressed concern that these aspects of the development of agricultural biotechnology are resulting in a loss of domestic sovereignty over important regulatory decisions.

INTERNATIONAL INSTITUTIONS AND RESOURCES

The international level presents another battleground that, depending on the specific venue, may offer advantages or disadvantages that do not exist domestically to policy community members. Policy community members do not hesitate to express their preference for certain international venues that are more likely to protect their interests and further their policy goals. These international activities also facilitate cross-national linkages between domestic policy community members, providing opportunities for information exchange. For example, at Codex and biosafety protocol negotiations, societal actors (including representatives of industry, consumer and environmental organizations) may attend as observers or non-voting participants.[77]

For domestic policy community members that are unhappy with existing policy choices, the activities of international institutions present an opportunity for policy change. For example,

[76] Some of this attention is focused on the North-South implications of biotechnology, such as concerns that firms from developed countries are engaging in "bio-piracy" by exploiting the rich biodiversity found in many less-developed countries for their own profit without permission or adequate compensation. The Council of Canadians argues that Codex standards under the WTO will act as "ceilings" for domestic standards and that the lack of funding for groups to attend the meetings of international institutions, such as Codex, excludes them from the debate.

[77] For example, the 1999 meeting of the Codex Commission brought together the representatives of ninety-eight member states, but also representatives from sixty-three non-governmental organizations. At the fifth meeting of the Biosafety Protocol negotiations, the group of non-governmental observers included representatives from Canadian organizations AgWest Biotech, BIOTECanada, the Canadian Federation of Agriculture, and the Canadian Environmental Law Association. American organizations represented included the American Seed Trade Association, the American Soybean Association, the Biotechnology Industry Organization, the National Corn Growers Association, and the US Grains Council. Multinational firms and international associations that sent observers included AgrEvo, DuPont, EUROPABIO, FIS / ASSINEL (international seed trade and plant breeders' associations), Greenpeace, Monsanto, Nestle, Novartis, and the World Wildlife Federation.

biotechnology skeptics in the US who prefer mandatory labelling hope that if the labelling debate at Codex is resolved in their favour, countries will be able to refuse imports of unlabelled biotechnology foods. Such a development might encourage rethinking of the US position on labelling.[78] Many members of the domestic American and Canadian policy communities saw the negotiations to create a biosafety protocol as having the potential to impede or reverse the rapid adoption of biotechnology in agriculture facilitated by their domestic regulatory regimes.[79] The biotechnology industry portrayed the protocol as a thinly-veiled attempt to hinder trade in biotechnology products. In 1996, for example, Richard Godown, head of BIO, argued that it appeared that the protocol would be "thoroughly restrictive in its approach and in a practical sense the necessity for complying with its provisions would most probably bring all traffic in living modified organisms to an indefinite halt."[80] The comments of a Canada-based AgrEvo representative in September 1998 were also representative of the biotechnology industry's reaction: "People in agriculture should be really scared by this. I think closing the [biotechnology] industry down is a real possibility. It is what our opponents want."[81] A biosafety protocol, if ratified, could be a key resource for those members of the Canadian policy network wishing to alter the domestic regime. This development would be especially welcome to revisionists if socioeconomic conditions were included as grounds for screening imports.

The choice of international venue may place restrictions on who is able to participate. For example, agricultural producers were initially excluded from the domestic advisory committee within Canada that discussed the Canadian position on the biosafety protocol, and had to lobby vigorously (and eventually successfully) to be included. The biotechnology industry and environmental groups were included, while agricultural associations were excluded, because the protocol was perceived as an environmental agreement rather than an agricultural trade issue. The technical content of discussions may also serve to privilege or exclude some members of policy communities. For example, one representative of an American commodity association attended a session of the biosafety protocol negotiations for a couple of days but reporting having had "a hard

[78] Personal interview, December 1998.
[79] The perceived threat of a Biosafety Protocol motivated the US government to work through its Miami Group partners to ensure that the negotiations stalled, thus avoiding adoption of a text it disliked. Although several countries withheld their approval of the final draft text, the US received much of the blame for the outcome of the negotiations, including from the European Union's Environment Commissioner Ritt Bjerregaard.
[80] Hoyle (1996).
[81] Wilson (1998a).

time making sense of the issues".[82]

Members of domestic policy communities often voice clear preferences for certain international venues. Some biotechnology skeptics have been optimistic about making gains by strengthening environmental protection through the Biosafety Protocol. Other organizations including the US Grains Council and the USDA would rather let the International Plant Protection Convention and the SPS Agreement handle the issue of environmental risks of biotechnology, under the broader aegis of the WTO. Several biotechnology proponents believe that the protocol is being used as an assault against genetic engineering across the board, rather than a genuine effort to focus on environmental risks. Both biotechnology skeptics and proponents believe that some international institutions, such as Codex and the FAO, could provide potentially favourable results. However, some domestic policy community members are frustrated at the lack of concrete results at the international level. For example, a Canadian food industry association representative suggests that Codex has been paralyzed on the issue of labelling genetically-engineered foods because of its multistakeholder approach. She argued that Codex "will have to change or die" and that it should make a decision or leave the issue of labelling alone.[83]

State officials may capitalize on the activities of international institutions to enhance their capacity and perhaps their autonomy.[84] When policy options can be presented as backed by international consensus and are then viewed as legitimate, if not desirable, within domestic policy communities, state officials may be able to establish regulatory principles that are internationally-aligned and differ from the preferences of domestic policy community members. American and Canadian state officials have been very active internationally on issues of biotechnology regulation, which suggests that they may be members of "transgovernmental coalitions".[85] The emergence of

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[82] Personal interview, October 1998.

[83] Personal interview, July 1998.

[84] Beyond sending senior officials to international meetings, the importance placed on international politics is sometimes demonstrated through internal reorganizations. For example, in October 1997, the USDA announced the creation of the "Policy-Level Group on Technical Barriers to Trade" which is a group of senior officials that works on the issue of non-tariff barriers to agricultural exports with the intent of heading off trade disputes before they reach a crisis point. *Inside US Trade* (1997).

[85] For example, during committee hearings in the mid-1980s, US state officials noted their involvement in various international activities on biotechnology regulations, including OECD deliberations. This international involvement continued US leadership in guidelines for safety in lab research involving rDNA organisms. The National Institutes of Health guidelines were used as a model by many countries, and NIH staff with involved in several international committees. See, for example, U.S. Congress. House Committee on Energy and Commerce. Subcommittee on Oversight and Investigations (1985): 99-100.

"transgovernmental coalitions" is largely a function of the activities of international regimes which provide venues that permit the establishment of networks among state officials.[86] Transgovernmental coalitions contribute to the creation of high quality information and create a political space in which actors may trade national loyalties and identities for shared collective beliefs and goals, possibly leading to the creation of an international "epistemic community".[87]

State officials in Canada and the US have demonstrated consistently their awareness of the activities of international institutions on issues surrounding agricultural biotechnology regulation and have cited their reports regularly as support for policy proposals.[88] For example, in 1983 EPA official Don Clay noted that WHO and the OECD had both examined the issues of the risks of genetically-engineered organisms.[89] In 1986, the Office of Science and Technology Policy (US) included a summary of the just-released 1986 OECD report on biotechnology regulation in its document outlining the new coordinated federal framework for biotechnology.[90] Canadian officials and the documents they wrote on agricultural biotechnology regulation also frequently referred to the activities of international institutions, including the OECD, and the value of aligning Canadian regulatory measures with international consensus.[91]

THE POTENTIAL OF INTERNATIONALIZATION: CONSTRAINTS AND OPPORTUNITIES

Four factors--trade patterns, the presence of multinational firms in the plant biotechnology industry and related agri-food industries, the activities of international institutions, and the international orientation of several key domestic policy community members--together suggest a high potential for internationalization of regulatory policy making on the issues surrounding plant

[86] Risse-Kappen (1995b), especially pp. 285-286.

[87] Haas (1992). Epistemic communities may influence domestic decision making through authoritative claims of knowledge and, for example, by framing problem definitions and assisting in the identification of state interests. Epistemic communities are more likely to be influential in times of uncertainty when policy makers turn to expert communities for guidance.

[88] While officials in both countries have frequently referenced the work of international institutions in committee hearings and documents, such references are more commonly and overtly used as a justification of policy proposals in Canada.

[89] US Congress. House Committee on Science and Technology. Subcommittee on Investigations and Oversight, and Subcommittee on Science, Research and Technology (1983): 249.

[90] United States. Executive Office of the President. Office of Science and Technology Policy (1986). The OECD report referred to is Organisation for Economic Co-operation and Development (1986).

[91] For example, see Hollebone (1988): 45 and Canada. Agriculture and Agri-Food Canada, Health Canada, and Environment Canada (1993).

biotechnology. The findings presented in Chapter Three suggest that internationalization has translated into policy choices intended to achieve the goals of competitiveness and harmonization. Often, internationalization is portrayed as an external constraint on policy making that limits the range of possible or acceptable policy choices. Before assuming that such constraints exist, it is important to examine the actual opportunities and constraints that the degree and nature of internationalization are likely to have presented for regulation of agricultural biotechnology.

Trade patterns and multinational firms

Trade patterns, including Canada's significant and growing reliance on the American market for its agri-food export products, place no obvious direct constraints on domestic regulation of the environmental risks of genetically-engineered plants.[92] However, awareness of these trade patterns is likely high among members of the Canadian policy community, particularly state officials and agricultural producers. Sensitivity to the importance of exports may translate into viewing environmental risk / safety regulatory regimes in Canada and the US as a necessary condition for ensuring access to the newest technology so that producers can maintain or increase their competitiveness in world agricultural markets. The effect of these trade patterns on food safety assessment and labelling is far more obvious. The Canadian food industry's export dependence is much higher than that of its American counterpart as is its degree of dependence on its single largest market, the US. For Canadian firms in particular then, these trade patterns translate into strong incentives for the food industry to request harmonization of domestic food safety assessment measures with either the leading international consensus and / or those of major export markets. On the issue of labelling, these economic incentives would seem less strong since manufacturers can and will adapt to differing labelling regimes rather than lose export sales, although they would prefer to avoid the extra costs. However, on the issue of genetically-engineered foods, labelling has become strongly linked to food safety and thus is relevant to market access.

As a constraint on domestic policy making, the dominant presence of multinational firms in the plant biotechnology industry has two key effects. First, policy makers are likely to be aware

[92] They do present the possible scenario of an opportunity for transnational or foreign actors to encourage boycotts of Canadian or American products in an effort to change domestic regulatory regimes. Such a scenario seems unlikely, but is not without parallel, given the example of European boycotts of British Columbian forestry products in efforts to change environmental practices.

that such firms may have the option of abandoning activities, or not beginning them at all, in a country where the regulatory regime is not to their liking. For example, agricultural biotechnology firm AgrEvo's research presence in Canada is credited largely to Canada's relatively quick creation of a regulatory regime for genetically-engineered plants and to a five-year moratorium placed on field trials of these plants in AgrEvo's home country of Germany. Further, if securing access for domestic producers to the firm's technology is a priority for policy makers, the nature of the regulatory regime becomes an issue of competitive advantage, reflecting the combined incentives of trade patterns and the presence of multinational firms.[93] The presence of multinational firms in the food industry has less obvious importance for the issues of food safety assessment and labelling. These firms are, of course, likely to demand harmonization of regulations to facilitate trade and simplify their operations. However, it seems unlikely that differences in regulatory regimes on food safety assessment and labelling would be enough to deter MNFs from potentially lucrative markets, even if these differences require extra research and paperwork.[94] In fact, since MNFs often tend to be the larger firms within an industry, they are perhaps best placed in terms of resources to deal with differing regulations across countries. Finally, food processing firms are long accustomed to adapting their products to suit local consumer tastes.[95] In May 1999, for example, the British branches of multinational food firms Unilever and Nestle announced that they would not use genetically-engineered ingredients given the adverse consumer reaction within the United Kingdom. However, these firms continued to use these ingredients in products for other markets.

International institutions

Despite all the activity within international institutions during the last two decades on agricultural biotechnology regulation, few, if any, direct and visible constraints on domestic policy choices have resulted thus far. The one notable exception, mentioned earlier, is that the Convention on Biological Diversity commits Canada to having a domestic regulatory regime in

[93] Unlike many other products, plant varieties often must be adapted to specific growing conditions to perform well. This fact makes it more important to ensure that development takes place within national boundaries.
[94] The exception might be if a firm was faced with a regulatory regime that prohibited the use of genetically-engineered ingredients or required labelling identifying such ingredients. However, even such potentially onerous measures could be overcome through domestic production using segregated ingredients.
[95] Vaughan (1995).

place to reduce environmental risks. In fact, Canadian officials described the 1993 regulatory framework as helping to fulfil Canada's obligations under the Convention. For the most part, however, it appears that American and Canadian state officials have used the activities of international institutions as opportunities to achieve policy goals.[96] The intentional exercise by the US of its scientific leadership internationally, coupled with a pale Canadian imitation, suggests that these two countries may have had more influence on the activities of international institutions than these institutions have had on their domestic regulatory regimes.[97] This conclusion seems most accurate for the issue of environmental release in both countries, but less so for Canada on food safety. It is least accurate on the labelling issue at Codex, where the two countries had failed as of 1998 to build a sufficient coalition to ensure international endorsement of their domestic labelling positions.

American policy community members generally hold that international institutions had minimal influence on their domestic agricultural biotechnology regulatory regime through the 1990s. A former US state official now working for a national biotechnology industry organization who participated in some international meetings argues that the American regulatory regime for agricultural biotechnology owes little, if any, "intellectual debt" to other countries or international institutions.[98] Rather, he argued, American participation in international activities has been more about the US shaping dialogue overseas.[99] In Canada, the activities of international institutions are described by policy community members as useful forums for discussion and the creation of

[96] Mobilization at the international level can also be important to prevent the development of international consensus or the creation of an international regime that is not perceived to be favourable to domestic interests. For state officials in Canada and the US, the negotiations surrounding creation of a biosafety protocol illustrated the importance of staying on top of such international developments.

[97] As pioneers in the development and use of genetically-engineered plants, and subsequently in regulatory regimes to govern their release, Canadian and American regimes are both regarded internationally as potential templates. Canadian officials working on both environmental release and food safety issues argue that they are at least as active as the Americans in international harmonization efforts, such as holding workshops (sometimes as a joint effort with the Americans) in regions of the world where regulatory regimes do not yet exist or are just being developed. Canada also chairs the Codex food labelling committee.

[98] Personal interview, October 1998. The only exception this source acknowledged was the use of a "decision-tree" approach in risk analysis, which apparently was first suggested in Australia, and has been used somewhat in the US and in Canada.

[99] US leadership has been exercised in several venues, but was especially evident at the OECD. For example, the development of "Good Developmental Practices" at the OECD during the early 1990s was based on a draft US document. U.S. Congress. House Committee on Science, Space, and Technology. Subcommittee on Natural Resources, Agriculture Research and Environment (1988): 48. The OECD Working Group on Food Safety of the Group of National Experts on Safety in Biotechnology, which produced the 1993 report, was chaired by Dr. Frank Young of the US, who had been the FDA Commissioner in the 1980s.

scientific consensus. They are not, however, perceived to have a direct influence on domestic regulation because of the coincident timing of domestic regulatory development.[100]

Regardless of the impressions of state officials and others within the policy communities, the fact that American and Canadian state officials have been very active in, and supportive of, the activities of international institutions, suggests a high likelihood of cross fertilization of ideas between international institutions and domestic policy networks. Further, the concurrent development of domestic regulatory regimes and international consensus on guidelines for regulation make it difficult to separate clearly the influence of one on the other and suggests the possibility of transgovernmental coalitions. A survey of participants in six major OECD and FAO/WHO international scientific conferences shows that the US sent representatives to every conference. Canada sent delegates to all but the earliest meeting in 1982 (Table 6-9).[101] The combined American and Canadian presence at these meetings contributed between approximately 20 to 30 per cent of all participants. However, there is little evidence to suggest that Canadian and American officials have become members of a transgovernmental coalition, trading in national priorities and loyalties for transnational ones. Even in the venues most conducive to such coalitions, such as the OECD and FAO/WHO expert scientific committees, coalitions have not emerged. The latter is the result of the combination of relatively infrequent meetings, the changing mix of individual representatives, and, in the case of environmental release, the variation in the issues under consideration which alters the requisite scientific expertise.[102] However, the lack of

[100] This conclusion is more convincing for the issue of environmental release. On that issue, AAFC portrays Canada as having taken a leadership role at OECD, rather than adopting OECD prescriptions. For example, the OECD has adopted the Canadian practice of developing documents outlining a detailed biology of key crop plants, to improve the database for risk assessment. On the issue of food safety assessment, Canadian state officials have carefully monitored international consensus to ensure Canadian policy is in alignment.

[101] Few of the representatives attended more than one or two meetings. American officials tend to have more multiple appearances than Canadian officials. This finding may be in part a result of the fact that the workshops and committees focused on various aspects of biotechnology policy, such as field trials of genetically-engineered plants and food safety, which tend to draw on different sets of expertise. Most of Canada's representatives have been drawn from the federal government, although a few came from industry and academic locations. The US has drawn slightly more on industry and academic representatives. Notably, Dr. Ernest George Jaworski, at the time working with Monsanto, was a member of three OECD expert groups between 1982 and 1990.

[102] An examination of the participants in key meetings reveals that American officials were more likely than Canadian officials to attend more than one meeting, providing greater continuity. For example, Sue Tolin of the Virginia Polytechnic Institute and State University attended five OECD meetings on behalf of USDA, while Frank Young of the FDA / Health and Human Services agency attended three meetings.

transgovernmental coalitions has not prevented the emergence of some scientific consensus.[103] In interviews, both state officials and regulated firms have described the science behind regulatory assessment as virtually the same across countries, including Canada, the US, and Europe, despite major differences in other aspects of regulation.

In contrast to OECD and FAO/ WHO activities, efforts within Codex and the International Plant Protection Convention and to implement a biosafety protocol appear much more likely to place real constraints on domestic policy making in the future. However, these effects will likely be visible only in the medium to long-term. As of 1999, Codex remained stymied on the labelling issue and was just beginning its effort to establish food safety standards for biotechnology foods. The IPPC was also just beginning to contemplate the implications of genetically-engineered plants for its activities, and the successful implementation of a biosafety protocol still lay ahead. The ongoing polarization of the biotechnology debate both within countries and across them suggests that it will be some time before a strong international consensus is achieved. The SPS agreement appears to be the most likely constraint that could be exercised on domestic policy making if it is applied to biotechnology products. Even so, it constitutes little challenge to the American and Canadian regulatory regimes which are unlikely to be considered protectionist.[104] It is much more likely that the two countries will use the SPS Agreement to ensure access to important export markets, possibly altering the domestic regulatory regimes of other countries. A biosafety protocol, if ratified, could be a trade barrier. Questions have been raised and not clearly answered about whether the protocol or WTO provisions would prevail in the event of a conflict.[105] Such an issue will not arise, of course, if the protocol never enters into force.

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[103] In the case of food safety assessment, following the initial report by the International Food Biotechnology Council, each subsequent report, whether by the OECD or from a joint FAO / WHO consultation, cited its predecessors, exhibiting an awareness of other efforts. Table 6-7 demonstrates the consistency among these activities on scientific principles and differences on political aspects.

[104] The provisions of the SPS Agreement could act as an external constraint on domestic environmental and food safety regimes for genetically-engineered plants, but its use would, if anything, likely serve to reduce existing regulations rather than strengthen them. Given the nature of the Canadian and American regimes compared to the level of regulatory development elsewhere, it seems unlikely that either country, especially the US, would face a challenge in this way in the near future.

[105] The wording of the finalized protocol would be an important determinant in answering this question.

CONCLUSIONS

As a prelude to the concluding chapter, several statements can now be made about the degree and nature of internationalization and its potential impact on policy making. First, in both countries, the economic sources of internationalization appear to have had more effect on policy preferences and policy choices than the activities of international institutions. Specifically, they have encouraged the establishment of efficient regulatory regimes permitting commercialization. Activities within the OECD and, to a lesser extent, the FAO / WHO joint consultations on food safety have served to enhance state capacity in the development of such regimes and reinforced the incentives of economic internationalization toward rapid commercialization. Efforts within Codex and through the Biosafety Protocol negotiations have the potential to dilute or redirect the effects of economic internationalization. In highlighting international polarization on key issues of biotechnology regulation, these forums have heightened uncertainty about biotechnology. Such uncertainty may serve ultimately to claw back some of the gains of biotechnology proponents.

Second, internationalization may differ in its potential among countries as it does in this case. In Canada, economic internationalization is much more of a clear and present reality than in the US. The export dependence of agricultural producers and the presence of multinational firms in the plant biotechnology industry combine to exert powerful incentives in Canada for a regulatory regime that is a competitive advantage by providing new tools to producers and attracting the research and development activities of the multinational firms. Representatives of these firms were quick to point out in interviews that without its relatively quick development of a regulatory regime for genetically-engineered plants, Canada would not have much of a plant biotechnology industry. As one representative said: "You take your investment to where you can get the investment back fastest".[106] In both countries but more so in Canada, state officials have been keenly aware of the potential exit of multinational firms. Further, as noted earlier, state officials in the two countries differ in their responses to economic internationalization according to its impact. In the US, the focus has been on maintaining international technological leadership, as a fundamental component of competitiveness. Goals include ensuring US-based multinational firms keep research at home,

[106] Personal interview, September 1998.

while increasing export sales of seed of genetically-engineered plant varieties and their products.[107] As a result, the US has pursued a comparatively rapid commercialization of biotechnology. Given its scientific leadership in biotechnology and its pioneering of commercialization, it has not hesitated to create indigenous regulatory regimes rather than wait for clearer international consensus. Its aggressive approach toward exporting both its regulatory approach and its genetically-engineered crops has been characterized by some observers as a "like it or lump it" attitude that has not helped its case in Europe and elsewhere.[108] The Canadian approach has been more cautious. The priority has been not so much to be the technological leader, except in specific niches. It is more to remain in the race as a way to ensure domestic competitiveness in global markets and thus maintain export markets.[109] The pursuit of harmonization is also geared toward protecting market access and is achieved through careful monitoring of developments internationally. For example, the primary reason in Canada for the delay in finalizing food safety assessment regulations was to ensure "fit" with consensus in the international community, including with FAO / WHO principles.[110] The focus has been more on monitoring international standards than those of other countries because of the desire to be efficient by aligning Canada's response in the direction of the most solid international consensus.

Third, there is little evidence that transnational or transgovernmental coalitions have had much impact on domestic regulatory regimes. The reason is perhaps that agricultural biotechnology regulation is not yet characterized by a high degree of international

[107] For example, at a 1986 US House of Representatives committee hearing, US state official David Kingsbury of the National Science Foundation noted that the American status as a world leader in biotechnology heightened its interest in cooperation across national boundaries to ensure that there is consistency in regulation for products that are developed in the US and sent overseas, and for firms that come to the US. He acknowledged concern that regulations could send firms overseas to conduct research, but was optimistic that the US framework would not have such an effect. See U.S. Congress. House Committee on Science and Technology. Subcommittee on Investigations and Oversight; and the Subcommittee on Natural Resources, Agriculture Research, and Environment; and the Subcommittee on Science, Research, and Technology, (1987): 42-43.

[108] However, USDA officials argue they have probably pursued deregulation of environmental safety assessment more slowly because of American agricultural exports, trying to keep the same pace with developments elsewhere. Personal interview, October 1998.

[109] For example, in 1987, Canada's Minister of State for Science and Technology, Frank Oberle, noted: "All of us are turning to science and technology as the means to improve our competitive position in the world's marketplace. For us in Canada, biotechnology shines as one of the most promising fields, one which offers great hope, and potential to add to our nation's economy." Organisation for Economic Co-operation and Development (1988): 78.

[110] Personal interview, August 1998. OECD activities on food safety have been far less influential than FAO / WHO activities because of their more general, less scientific, nature. Canada has "taken in" international perspectives on food safety assessment and elaborated them in developing its response.

institutionalization despite much activity.[111] Transnational actors, mainly multinational plant biotechnology firms, have been active largely through their national branches in domestic policy communities.[112] Beyond the multinational firms, Greenpeace International, based in Europe, could also be considered a transnational actor. However, its somewhat successful genetic engineering campaign was focused primarily on Europe through the 1990s. Greenpeace Canada was not directly involved in this campaign until the fall of 1999. Greenpeace activities in the US on biotechnology issues have generally been funded not by the American office, which in the 1990s saw a decline in resources, but by Greenpeace International.[113] International associations have also entered the regulation debate from time to time[114], but it is their national members that have been the active members within the Canadian and American policy communities. To date, transnational coalitions, both among industry actors and public interest groups, have been uncommon and short-lived. Further, such coalitions appear to be created almost solely for the purpose of intervention in the activities of international institutions rather than in domestic policy communities. One obvious use of coalitions came as the deadline for completion of the biosafety protocol negotiations in February 1999 approached and international coalitions of societal actors began to emerge. For example, the "Global Industry Coalition," which claimed to represent 2200 firms from 130 countries, issued a press release immediately following the failure of negotiations. The press release stated that its members supported the goals of the protocol, but that the draft text was

[111] Risse-Kappen argues that the more international institutions regulate interstate relationships (what he calls the degree of international institutionalization) in an issue-area, the more we should expect that transnational activities will flourish. Risse-Kappen (1995a) and Risse-Kappen (1995b): 299.

[112] Multinational plant biotechnology firms have varied in their activity within domestic policy communities. In the US, some of these firms, including Dow AgroSciences and Monsanto, could also be seen as domestic policy community members, given their American roots and headquarters. The major firms are central members of national biotechnology industry associations and have become increasingly visible and active with the national seed industry associations, ASTA and CSTA. Some also belong to national food industry associations.

[113] Personal interview, December 1998.

[114] For example, in April 1998, the International Agri-Food Network (IAFN) released a statement outlining its members' commitment to developing biotechnology in a transparent and responsible manner, including an action plan that stated support for "rigorous and comprehensive regulatory systems", "international harmonization of testing and control procedures, based on sound scientific principles", and support for Codex activities and decisions. Members of the IAFN at the time were: the International Association of Plant Breeders (ASSINSEL), the Confédération des Industries Agro-Alimentaires de l'UE (CIAA), the Confédération Mondiale de l'Industrie de la Santé Animale (COMISA), the International Seed Trade Federation (FIS), the Global Crop Protection Federation (GCPF), the Green Industry Biotechnology Platform (GIBiP), the International Co-operative Alliance (ICA), the International Chamber of Commerce (ICC), the International Fertilizer Industry Association (IFA), the International Federation of Agricultural Producers (IFAP), and the International Meat Secretariat (IMS). The full statement was published on the Canada Grains Council web site at: http://www.canadagrainscouncil.ca/upd98-37.htm.

unworkable, would prevent countries from benefiting from biotechnology, and "would effectively halt biotechnology-assisted plant breeding throughout the world, whether conducted by either public or private institutions". The press release concluded that, with the suspension of negotiations: "Fortunately, in Cartagena, reason prevailed over political agendas."[115] On the other side of the debate, an international coalition of environmental groups wrote to American Vice President Al Gore, stating that: "A rigorous protocol ... is absolutely necessary to protect the safety of humankind and the environment," and that "industry is arguing that its private interests take precedence over health and environmental safety."[116]

Fourth, the increasing level of activity at the international level suggests that domestic policy community members who are mobilized internationally, either directly or through international associations, will best be able to capitalize on the resources these activities offer. In this case, plant biotechnology firms and state officials have been the most internationally-mobilized in the 1990s. However, active international participation by state officials, let alone industry and public interest groups, requires significant resources. Members of the Canadian policy community complain that Canadian state officials do not seem to have the resources to participate internationally in a fully effective manner, given the growth of international activity.[117]

Fifth, the nature of the international venue appears to be important in determining the outcome of its activities and the nature of the resources available to domestic policy community members. It is on this point that the distinction between political and scientific international institutions is most useful. Of course, in reality, most international institutions are not one or the other, but sit on a spectrum between being wholly political or wholly scientific in their mandates. The FAO /WHO meetings have been closest to the wholly scientific end of the spectrum.[118] The OECD has sought to use scientific consensus to secure biotechnology's contribution toward its mandate of facilitating economic growth and world trade, while Codex's efforts on food labelling

[115] Global Industry Coalition (1999).

[116] Carter (1999).

[117] A representative of an agricultural producer association noted that Canada seems to send junior people who lack understanding to international conferences. A representative of a multinational plant biotechnology firm stated that state officials appear to be focused on multilateral institutions rather than on building bilateral links with important trading partners, citing her failure to convince Health Canada officials to visit Japan to discuss regulatory matters. Personal interviews, July and September 1998.

[118] See Table 6-8 which demonstrates that FAO / WHO recommendations have focused solely on science and have not made recommendations regarding choice of policy instruments, unlike the OECD and the International Food Biotechnology Council.

have become mired in a political debate far removed from science.[119] The biosafety protocol negotiations have been the site of a political clash, exacerbated by scientific uncertainty, between conflicting environmental and economic priorities arising from biotechnology, and between preferred methods of regulation (risk analysis versus the precautionary principle). This case suggests that the more scientific the international institution appears to be, the more likely consensus will be reached and be considered legitimate. and thus be a useful resource for domestic policy community members. However, there is also another important difference among the international venues. The FAO / WHO consultations were closed meetings, gathering a relatively small group of experts. The OECD meetings also were relatively small and closed sessions. In contrast, although membership is required for participation, attendance at Codex and Biosafety Protocol meetings involves hundreds of participants, encompassing many more countries and allowing non-governmental observers from industry and public interest groups. These relatively open meetings are those that have had the most difficulty in building consensus.

This chapter does not delve into the reasons why Codex has hesitated until quite recently to develop general standards for biotechnology foods. However, its absence has ensured that food safety evaluation efforts have taken place in relatively closed and small venues, populated by scientific experts. In contrast, efforts on environmental risk at the OECD carry the gloss of the organization's political mandate and its exclusive membership. Some biotechnology proponents have expressed disappointment that the OECD has not been been more influential to date in encouraging harmonization, particularly among European countries. This failure may well be linked to the lack of strong scientific consensus on the degree of environmental risk posed by genetically-engineered plants and the limits of using science within a political institution.[120]

Finally, this chapter has illustrated that while the evidence suggests a high potential for internationalization of policy making on agricultural biotechnology regulation, any impact of

[119] Although Codex's standard-setting activities are intended to be based on scientific analysis and evidence, the institution has also stated its intention to consider "other legitimate factors [beyond standards] relevant for the health protection of consumers and for the promotion of fair practices in food trade" such as food labelling, which clearly incorporates non-scientific considerations. This decision is outlined in the "Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process And The Extent To Which Other Factors Are Taken Into Account", contained in the Procedural Manual of the Codex Alimentarius Commission (10th edition, FAO/WHO Rome 1997).

[120] The July 1998 bilateral agreement between Canadian and American regulatory officials on environmental risk assessment data requirements and information exchange makes much more progress toward harmonization than that achieved to date through multilateral institutions such as the OECD.

internationalization has come not in the form of direct constraints on policy choices, but is instead exercised within policy communities. Economic internationalization alters perceptions of the costs and benefits of "internationalizing" policy choices. Political internationalization may provide opportunities for domestic policy community members to improve their resources and relative position within a domestic policy network, just as it may have the opposite effect. This "internationalization from within" underscores the utility of examining the impact of internationalization in combination with the concepts of policy community and policy network. By understanding the nature of domestic policy communities and policy networks, we can gauge more accurately whether, to what degree, and through what channels, the potential for internationalization translates into policy choices.

TABLE 6-1
Agricultural production and trade statistics, Canada and the United States

A. Comparative agricultural statistics

CANADA		UNITED STATES[5]	
Agriculture as a percentage of gross domestic product		**Agriculture as a percentage of gross domestic product, 1997**	
agriculture (1992)	2.1	agriculture, forest, and fishery	1.6
agri-food industry*	10.9[1]	food and kindred products	1.5
*(includes agriculture)			
Value of agricultural production, 1997		**Value of agricultural production, 1997**	
Total cash receipts, $million (Canadian)		Market value of agricultural products, $million (US)	
29, 586		196 865	
Value of agri-food exports, 1996, $billion (Cdn)[2]		**Value of agricultural exports, 1996, $billion (US)**	
19.9		60.4	
Share of world trade in agricultural products, 1997[3]		**Share of world trade in agri-food[6]**	
$15 billion (US) of total world exports of $462 billion=3.2%		$62.5-billion (US) of $462-billion of total world exports=13.5%	
$10.5 billion (US) of total world imports of $464 billion=2.3%		$41.4-billion (US) of $464-billion of total world imports=8.9%	
Major trading partners, exports and imports of the agricultural industry (crops and livestock), 1998, $million (US)[4]		**Major trading partners, exports and imports of agricultural products, 1998, $million (US)[7]**	
Total exports	6 581	Total exports	51 731
US	2 956 (45%)	Japan	9 084 (18%)
Japan	660 (10%)	Canada	6 994 (14%)
Algeria	331 (5%)	Mexico	6 152 (12%)
Total imports	3 366	Total imports	36 683
US	1 981 (59%)	Canada	7724 (21%)
Mexico	180 (5%)	Mexico	4653 (13%)
Colombia	157 (4.7%)	Italy	1 375 (4%)
Net trade 3 215 (surplus)		Net trade 15 048 (surplus)	

[1] www.agr.ca/itpd-dpci/factsheete.html
[2] www.agr.ca/policy/epad/english/pubs/chrtboook/toc.htm.
[3] http://apps.fao.org/default.htm
[4] Trade Data Online service at Industry Canada website: http://strategis.ic.gc.ca/.
[5] www.usda.gov/nass/pubs/agr98
[6] http://apps.fao.org/default.htm
[7] www.fas.usda.gov/scriptsw/bico/bico_frm.idc

CANADA

Major crops[8], (production 1996-97, thousand metric tonnes)

Wheat	29 801
Barley	15 562
Corn	7 542
Canola	5 062
Oats	4 361
Soybeans	2 170
Flax	851

Area harvested, 1996-97, 1000 acres[9]

Wheat	30 277
Barley	12 069
Corn	2 691
Canola	8 521
Oats	4 158
Soybeans	2 123
Flax	1 420

Crop production as a percentage of global production, 1996/97, thousand metric tons[10]

Wheat	29 801 / 583 007	=	5 %
Corn	7 380 / 590 091	=	1.25%
Oats	4361 / 30 553	=	14%
Barley	15 562 / 153 743	=	10%
Soybeans	2165 / 131 174	=	1.65%

Exports of major crops, 1996-97
(thousand metric tonnes and as a percentage of production)

Wheat	19366 (65%)
Barley	4002 (26%)
Corn	316 (4%)
Canola	2519 (50%)
Oats	1737 (40%)
Soybeans	478 (22%)
Flax	679 (80%)

[8] www.agr.ca/policy/winn/biweekly/English/gosd//1998/jul98e.htm

[9] These statistics have been converted from hectares to acres by the author.

[10] www.usda.gov/nass/pubs/agr98

UNITED STATES

Major crops[11], (crop yields 1997, 1000 bushels)

Corn	9 365 574
Soybeans	2 727 254
Wheat	2 526 552
Barley	374 478
Oats	176 104

Area harvested, 1996, 1000 acres

Corn	74 094
Wheat	63 118
Soybean	63 050
Barley	6 761
Oats	2 673
Canola	370

Crop production as a percentage of global production, 1996/97, thousand metric tons[12]

Wheat	62 191 / 583 007	=	11%
Corn	236 064 / 590 091	=	40%
Oats	2253 / 30 553	=	7%
Barley	8616 / 153 743	=	6%
Soybeans	64 837 / 131 174	=	49%

Exports of major crops, 1996
(million bushels and as a percentage of production)

Corn	9293 (19%)
Wheat	2285 (43%)
Soybean	2382 (37%)
Barley	31 (7%)
Oats	155 (2%)

[11] www.usda.gov/nass/pubs/agr98

[12] www.usda.gov/nass/pubs/agr98

B. Trade in planting seeds, Canada and the United States[1]

CANADA

Exports of all seeds for sowing
$million (US)

	1994	1995	1996	1997	1998
TOTAL	40.5	47.8	55.8	79.4	81.5
1. United States	30.2	37.0	41.0	59.0	63.3
2. Netherlands	1.5	1.9	2.0	2.6	3.9
3. Germany	1.2	1.1	2.2	3.3	3.9

Imports of all seeds for sowing
$million (US)

	1994	1995	1996	1997	1998
TOTAL	50.2	53.0	53.6	59.0	66.8
1. United States	40.7	43.0	42.0	46.4	50.0
2. Netherlands	3.7	3.6	4.6	4.5	5.3
3. United Kingdom	0.5	0.3	0.4	1.1	1.2

UNITED STATES
Exports of all seeds for sowing
$million (US)

	1994	1995	1996	1997	1998
TOTAL	315.4	322.2	338.7	384.3	429.8
1. Mexico	55.6	52.2	68.8	76.1	92.6
2. Canada	42.1	43.9	43.3	47.5	51.2
3. Argentina	22.0	21.0	33.1	37.2	40.4

Imports of all seeds for sowing
$million (US)

	1994	1995	1996	1997	1998
TOTAL	151.9	172.4	200.2	255.2	252.5
1. Canada	29.7	36.2	40.2	57.9	62.5
2. Chile	12.8	16.3	19.1	24.2	25.7
3. Netherlands	21.9	24.3	23.4	25.1	23.0

[1] Trade Data Online service at Industry Canada website: http://strategis.ic.gc.ca/

C. Trade and field crop farms / agricultural production crops, Canada and the United States, 1994-1998[14]

CANADA

Exports by field crop farms, $million (US)

	1994	1995	1996	1997	1998
TOTAL	5086.4	5695.6	6220.5	6787.6	4445.4
1. US	1008.2 (20%)	882.7	1050.7	1180.0	996.9 (22%)
2. Japan	790.3	989.0	968.3	1100.1	645.6
3. Algeria	269.7	346.3	251.1	418.7	330.5

Imports from field crop farms $million (US)

	1994	1995	1996	1997	1998
TOTAL	362.1	437.7	525.8	564.1	569.0
1. US	326.9 (90%)	399.1	460.6	496.0	482.6 (85%)
2. Mali	1.5	5.0	1.2	9.5	11.4
3. France	0.3	0.5	0.3	5.7	10.7

UNITED STATES

Exports of agricultural production crops, $million (US)

	1994	1995	1996	1997	1998
TOTAL	22 168	29 391	32 385	27 460	23 336
1. Japan	4 653 (21%)	5 512	6 062	5 323	4 271 (18%)
2. Mexico	2 040	1 781	3 276	2 510	3 119
3. Canada	1 687	1 850	1 864	2 032	2 015

Imports of agricultural production crops, $million (US)

	1994	1995	1996	1997	1998
TOTAL	8 745	9 815	11 099	12 284	12 194
1. Mexico	1 655 (19%)	2 204	2 394	2 472	2 749 (23%)
2. Canada	1 183	1 114	1 341	1 529	1 485
3. Colombia	941	1 013	1 011	1 299	1 199

[14] Trade Data Online service at Industry Canada website: http://strategis.ic.gc.ca/

D. Trade in food industries / food and kindred products, Canada and the United States, 1994 - 1998[15]

CANADA

Exports by food industries, $million (US)

	1994	1995	1996	1997	1998
TOTAL	5288	6019	6885	7686	7757
1. US	3447 (65%)	3699	4411	4971	5508 (71%)
2. Japan	871	1058	1062	1066	778
3. Hong Kong	42	75	120	143	174

Imports from food industries, $million (US)

	1994	1995	1996	1997	1998
TOTAL	5818	5966	6449	7056	7246
1. US	3506 (60%)	3645	3917	4402	4616 (64%)
2. Thailand	218	221	227	255	260
3. Australia	310	300	285	283	256

UNITED STATES

Exports of "food and kindred products", $million (US)

	1994	1995	1996	1997	1998
TOTAL	23 102	26 021	27 121	28 487	27 291
1. Japan	4 832 (21%)	5 607	5 570	5 114	4 843 (18%)
2. Canada	3 645	3 767	4 070	4 536	4 759
3. Mexico	2 359	1 623	1 976	2 349	2 796

Imports of "food and kindred products", $million (US)

	1994	1995	1996	1997	1998
TOTAL	17 799	18 711	21 306	23 006	24 244
1. Canada	3 619 (20%)	3 890	4 651	5 178	5 646 (23%)
2. Mexico	1 035	1 219	1 414	1 636	1 910
3. France	1 164	1 288	1 439	1 625	1 789

[15] Trade Data Online service at Industry Canada website: http://strategis.ic.gc.ca/

E. Growth in exports, 1973-1998, Canada and the United States[16]

Agricultural products

	Canada, exports of agricultural and fish products[17] $million Cdn	United States, exports of agricultural products $million US
1973	3 671	17 900
1978	6 000	29 800
1983	11 287	36 100
1988	12 326	37 100
1993	16 395	42 800
1996/7	24 437 (96)	57 100 (97)
Increase over time in exports as a ratio, dividing most recent export value by that of 1973	6.7	3.2

Food industries / products

	Canada, exports of food, feed, beverages, and tobacco,[18] $million Cdn	United States, exports of food and kindred products, $million US
1973	3108	n/a
1978	5147	9044
1983	10 146	11022
1988	10 583	15 747
1993	13 234	20 509
1996/8	19 919	27 041 (96)
Increase over time in exports as a ratio, dividing most recent export value by that of 1973 (1978 for US)	6.4	3.0

[16] Source of Canadian data is Statistics Canada's CANSIM database. Source of American data is United States. Bureau of the Census (1998) and previous years. In some cases,data for 1998 were not yet available and the most recent year for which data were available has been substituted.

[17] Canadian statistics do not separate out agricultural products from fish products.

[18] 1973 and 1978 figures are for food and beverage.

TABLE 6-2
Export intensity, Canada and the United States
1973 - 1998[1]

Overall export intensity, as a ratio of exports to gross domestic product

	CANADA			UNITED STATES		
	EXPORTS $million Cdn current dollars	GDP $million Cdn income-based market prices	RATIO %	EXPORTS $million US current dollars	GDP $million US current dollars	RATIO
1973	25 648	129 196	19.9	72 500	1 306 600*	5.5
1978	53 361	245 526	21.7	145 900	2 249 700*	6.5
1983	90 556	411 160	22.0	205 600	3 514 500	5.9
1988	143 534	611 785	23.5	322 400	5 049 600	6.4
1993	190 213	724 960	26.2	465 100	6 558 100	7.0
1998	323 400	888 390	36.4	689 200	8 079 900	8.5

[1] Source of Canadian data is Statistics Canada's CANSIM database. Source of American data is United States. Bureau of the Census (1998) and previous years. 1973 and 1978 figures for the US GDP are for GNP, since GDP figures were not available.

TABLE 6-3

Ten largest global seed firms and ten largest global agrichemical firms by 1997 revenues[1]

Seed firm	1997 revenue, $ million (US)
DuPont / Pioneer (US)	1800
Monsanto (US)	1800
Novartis (Switzerland)	928
Groupe Limagrain (France)	686
Advanta (UK / Neth)	437
AgriBiotech (US)	425
Grupo Pulsar / Seminis/ ELM (Mex)	375
Sakata (Japan)	349
KWS AG (Germany)	329
Takii (Japan)	300

Agrichemical firm	1997 revenue, $ million (US
Aventis Group* (France) (Hoescht & Rhone-Poulenc)	4554
Novartis (Switzerland)	4199
Monsanto (US)	3126
Zeneca / Astra* (UK)	2674
DuPont (US)	2518
Bayer (Germany)	2254
Dow AgroSciences (US)	2200
American Home Products (US)	2119
BASF (Germany)	1855
Sumitomo (Japan)	717

*=pending merger

TABLE 6-4

Ten largest global food and beverage firms, by 1997 revenues[2]

Food firm	1997 food and drink sales $ billion (US)	Food and drink sales as % of total sales
Nestle (Switzerland)	45.4	95
Philip Morris (US)	31.9	44
Unilever (UK / Neth)	24.2	50
ConAgra (US)	24	100
Cargill (US)	21	38
PepsiCo (US)	20.9	100
Coca-Cola (US)	18.9	100
Diageo/Guiness/ Grand Metropolitain (US)	18.8	93
Mars (US)	14	100
Danone (France)	13.97	94

[1] Rural Advancement Foundation International (1999).

[2] Rural Advancement Foundation International (1999).

TABLE 6-5

Organisation for Economic Cooperation and Development, conclusions and principles, approaches to biotechnology regulation and environmental release[1]

BIOTECHNOLOGY REGULATION

Biotechnology: International Trends and Perspectives, 1982[2]

Conclusions

- Safety matters should be examined at the international level, to reduce the potential for industrial tension between countries.
- The safety of research involving genetic engineering has ceased to be a major concern.
- Existing regulatory frameworks seem to be sufficient, with the exception of large-scale industrial biotechnology.
- Provided suitable precautions are taken, the benefits of biotechnology far outweigh any conjectural risks.
- Restrictive legislation and regulations must be avoided as these will impose major constraints on developments in technology.
- Biotechnology is fundamental to the future optimal use of the world's renewable resources.

Principles

- Definition of biotechnology: "the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services".

Recombinant DNA Safety Considerations: Safety considerations for industrial, agricultural, and environmental applications of organisms derived by recombinant DNA techniques, 1986[3]

Conclusions

- A common understanding of the safety issues raised by rDNA techniques will provide the basis for taking initial steps toward international consensus, the protection of health and the environment, the promotion of international commerce, and the reduction of national barriers to trade.
- OECD members should:

  i) share information as freely as possible to facilitate harmonization of approaches to rDNA techniques.

  ii) examine existing mechanisms to ensure adequate review and avoid undue regulatory burdens that may hamper development

  iii) take due account of work on standards at international organizations such as WHO and FAO
- While rDNA techniques may result in the production of organisms expressing a combination of traits that are not observed in nature, genetic change from rDNA techniques will often have inherently greater predictability because of the greater precision that these techniques allow.

Principles

- There is no scientific basis for specific legislation to regulate the use of rDNA organisms.

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[1] This list is not comprehensive. It highlights major conclusions and principles of relevance to this case study.

[2] Bull et al. (1982).

[3] Organisation for Economic Co-operation and Development (1986).

ENVIRONMENTAL RISK / SAFETY ASSESSMENT

Biotechnology: International Trends and Perspectives, 1982[4]

Conclusions

- An assessment of ecological consequences should precede large-scale biotechnology commercialization.

Recombinant DNA Safety Considerations: Safety considerations for industrial, agricultural, and environmental applications of organisms derived by recombinant DNA techniques, 1986[5]

Principles

- Environmental risk assessments should use and be based on information held in existing databases, gained from the extensive use of traditionally-modified organisms in agriculture and the environment.
- Experience with the evolution of "novel traits" in existing populations forms a basis for establishing parameters of potential risk.
- Risks may be assessed in generally the same way as those associated with non-rDNA organisms.
- Risk assessment should be conducted through an independent review of potential risks on a case-by-case basis.
- Applications should be developed on a step-by-step basis, for example from lab to greenhouse, to field test to large-scale cultivation.

Safety Considerations for Biotechnology, 1992[6]

(includes scientific criteria for design of small-scale field research with plants)

Principles

- The key safety factors are: 1) the characteristic of the organism(s) used, including introduced genetic material; 2) the characteristics of the research site and environment; and 3) the use of appropriate experimental conditions.
- Characteristics of plants that should be considered: 1) biology of the reproductive potential of the plant and an extended history of controllable reproduction with lack of dissemination and establishment in an environment comparable to the research site; 2) the mode of action, persistence, and degradation of any newly acquired toxic compound; 3) the nature of the biological vectors used in transferring DNA to plants; and 4) interactions with other species and/or biological systems.
- Experiments should be designed so that: 1) the genetically-engineered plants are reproductively isolated and 2) the genes or genetically-engineered organisms will not be released into the environment beyond the site, or 3) plants are used which, without reproductive isolation, will not cause unintended, uncontrolled adverse effects.
- Other scientific considerations for small-scale field trials of plants: 1) These experiments with genetically-engineered plants are conceptually analogous to the small-scale field research already conducted by plant breeders in evaluating new varieties; 2) these experiments should not be considered analogous to the uncontrolled introduction of foreign plants into entirely new environments, which involve the release of a complete genome rather than the controlled transfer of one or a few genes, but experience from such introductions may provide relevant information; and 3) various methods can be used to achieve reproductive isolation: spatial separation, removal of reproductive structures, incorporation of a male sterility trait, altering period of flowering in relation to other compatible crops / wild relatives, prevention of pollen dissemination by physical means, and harvesting of plants prior to flowering.

Safety Considerations for Biotechnology, Scale-Up of Crop Plants, 1993[7]

Principles

- Safety is achieved by appropriate application of risk / safety analysis and risk management.
- Risk / safety analysis is a) hazard identification and b) if a hazard is identified, risk assessment.
- Familiarity plays an important role in risk / safety analysis. Familiarity means having enough information to be able to judge the safety of the introduction or to indicate ways of handling the risks. Familiarity can be increased as a result of a trial or experiment.
- Risk / safety analysis is conducted prior to an intended action and can range from a routine ad hoc judgment by the researcher to adherence to a formal assessment.
- Risk / safety analysis is a scientific procedure which does not imply or exclude regulatory oversight or imply that every case will necessarily be reviewed by a national or other authority.
- Risk management to ensure safety is employed during development and evaluation of an organism in a systematic and stepwise fashion (from lab to field tests to commercialization).

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[4] Bull et al. (1982).

[5] Organisation for Economic Co-operation and Development (1986).

[6] Organisation for Economic Co-operation and Development (1992b).

[7] Organisation for Economic Co-operation and Development (1993a).

TABLE 6-6[1]

International institutions, comparing conclusions and recommendations, assessment of food safety of biotechnology foods / plants

CONSISTENCY

- Suggested components of safety assessment, such as characteristics of the donor and host organisms, composition of the novel food, toxicological tests, and nutritional value.
- Safety assessment, when possible, should be based on a comparison with a traditional (conventional) counterpart. Sometimes referred to as "substantial equivalence".
- A flexible, case-by-case approach.
- The use of rDNA techniques does not make food inherently less safe than food produced otherwise; in fact, these techniques, through greater precision, may provide more certain outcomes.

DIFFERENCES

- Importance of the implications of the process used for safety considerations:
  IFBC: process is relevant only to ensure proper questions are asked about the product
  FAO/WHO: when changes are made in the process, the implication for safety should be examined
  OECD: transformation techniques are relevant to assessment in terms of how they contribute to understanding the characteristics of the products
- Importance of establishing databases to underpin assessment, and making them accessible. (FAO/WHO 1991 and 1996)
  [although all acknowledge more needs to be known)
- Only the IFBC makes detailed recommendations for the US Food and Drug Administration's policy response.
- Specific recommendation of a "decision tree" approach. (IFBC)
- Importance of international coordination (FAO/WHO 1991 and 1996, implicit in OECD mandate]
- Consumer protection through provision of information. (FAO/WHO 1991 and 1996)
- Existing regulations should be sufficient as a basis for regulation; no fundamental change is required in legislative framework to regulate biotechnology products. (IFBC, OECD)
- A new paradigm of safety evaluation and a new framework of assessment is required for novel foods. (FAO/WHO 1991)
- Biotechnology is important to developing countries to help provide adequate and nutritious food. (FAO/WHO 1996)
- Globalization of food trade makes it imperative that proper safety assessments take place for biotechnology foods world wide. (FAO/WHO 1996)
- Discourage transfer of genes from commonly allergenic foods unless it can be documented that gene does not code for an allergen. (FAO/WHO 1996)
- Foods found to contain an allergen transferred from the donor organisms should not be marketed unless they can be clearly identified, and labelling may not be sufficient to accomplish this. (FAO/WHO 1996)
- Careful consideration of use of new proteins that have the characteristics of an allergen even if no known allergic reaction exists. (FAO/WHO 1996)
- More work to do on identification of food allergens. (FAO/WHO 1996)
- Convene workshop on issue of excluded antibiotic resistant marker genes from commercial food crops. (FAO/WHO 1996)

[1] This chart compares the recommendations and conclusions of four major studies on safety assessment of biotechnology food: International Food Biotechnology Council (1990), United Nations. World Health Organization (1991), Organisation for Economic Co-operation and Development (1993b), Chapter Two, and United Nations. Food and Agriculture Organization (1996).

TABLE 6-7
Policy community members, evidence and reports of international mobilization

ORGANIZATION	MNF MEMBERS	CDA-US CROSS-NATIONAL LINKS	ACTIVE RE: INTL INSTNS
American Seed Trade Association	Y	Y (bilateral, multilateral)	Y
Canadian Seed Trade Association	Y	Y (bilateral, multilateral)	Y
Biotechnology Industry Organization (US)	Y	Y (bilateral, multilateral)	Y
BIOTECanada	Y	Y (bilateral, multilateral)	Y
Natl Food Processors Association (US)	Y	Y (bilateral, multilateral)	Y
FCPMC (Canada)	Y	Y (bilateral, multilateral)	Y
American Farm Bureau Fedn	N	Y (multilateral)	Y
Canadian Fedn of Agriculture	N	Y (multilateral)	Y
American Soybean Association	N	Y (bilateral)	Y
National Corn Growers Association (US)	N	Y (bilateral)	Y
Canola Council of Canada	Y	Y (bilateral)	N
US Grains Council	Y	N	Y
Canada Grains Council	Y	N	Y
Consumers Union (Policy Institute) (US)	N/A	Y	Y
Consumers Association of Canada	N/A	N	Y
CIELAP (Canada)	N/A	Y (bilateral)	Y
Union of Concerned Scientists (US)	N/A	Y (minimal, bilateral)	N

TABLE 6-8
Canadian and American participation
at international expert conferences / workshops[1]

		CANADA	UNITED STATES
	of total		
OECD			
1982[2]	/14	0	2 (14%)
1986[3]	/88	4 (5%)	17 (19%)
1993[4]	/59	3 (5%)	9 (15%)
(FOOD SAFETY)			
1993[5]	/76	2 (3%)	11 (14%)
(SCALE-UP OF PLANTS)			
WHO / FAO[6]			
1991	/ 26	2 (8%)	4 (15%)
1996	/ 29	3 (10%)	6 (21%)

[1] Some participants attended as representatives of various international associations and committees, but are categorized here based on their employment location.
[2] Recommendations of group of experts published in Bull et al. (1982).
[3] Members of Ad Hoc Group of Government Experts on Safety and Regulations in Biotechnology who contributed to Organisation for Economic Co-operation and Development (1986).
[4] Organisation for Economic Co-operation and Development (1993b).
[5] Organisation for Economic Co-operation and Development (1993a).
[6] United Nations. World Health Organization (1991), United Nations. Food and Agriculture Organization (1996).

CONCLUSION: LESSONS FROM A (PRE)-CAUTIONARY TALE

The early history of the commercialization of genetically-engineered plants in Canada and the United States stands as a cautionary tale for policy makers. It is a harbinger of the changing hurdles for regulatory policy choices in post-industrial societies. When social and economic regulation intersect, multiple and sometimes conflicting policy goals are sought by state and society. For example, regulation should withstand the scrutiny of skeptical citizens *and* contribute to international competitiveness; it is expected to secure export market access *and* be resilient to trade barrier challenges from other countries. The failure to surmount these hurdles can carry a heavy price: the loss of important export markets or, at even higher stakes, the loss of domestic public confidence in the regulatory system. The lessons from this case study underline the importance of adequate policy capacity within government. Adequate policy capacity ensures that policy makers are able to engage in a more deliberative and strategic approach to policy making that incorporates a wider and longer term view of the implications of policy choices.

From a theoretical perspective, this case study has examined hypotheses about the roles of science and internationalization in influencing policy choices, using the concepts of policy community and policy network to organize analysis. It confirms that identifying and investigating key factors shaping the nature of policy communities and networks is a fruitful approach. It deepens understanding of the process and outcomes of policy making. This chapter summarizes and analyzes the findings of earlier chapters. It begins with a brief comparison of Canadian and American policy choices and outlines the degree of policy convergence in the initial phase of regulation of genetically-engineered plants from the early 1980s until 1998. While there is broad similarity across countries and evidence of convergence in some aspects of policy choices, there is also variation across issues and countries. There are intriguing differences in elements of policy choices related to state capacity and potential autonomy. The chapter next contrasts policy choices with the policy preferences of key groups of actors to gauge whose preferences have been incorporated. This analysis also reveals the potential of these policy choices to affect the resources of actors in ways that may alter position within a policy network during future policy development. The general comparison in Table 7-1 shows that large plant biotechnology developers and the food industry were most successful through the 1980s and 1990s in having their preferences incorporated within policy choices. They were followed closely by agricultural producers and state

officials. Small plant biotechnology developers, such as researchers within public sector institutions, and biotechnology skeptics were less successful. Perhaps more interesting, however, is the finding that both state officials and biotechnology skeptics may find that policy choices may increase the resources they can exercise during subsequent policy making more so than for other policy network members. Further, agricultural producers are the only major group who receive no potential resources from policy choices.

The domestic variables examined in this dissertation explain much of the substance of policy choices in both countries. This conclusion may be somewhat surprising given the relatively high potential for internationalization to shape policy making, especially in Canada. Most notably, the categorization of the policy networks surrounding the issues of environmental release, food safety, and labelling is consistent with findings of variation in the level of discretion given to regulators and the scope of regulation across issues and countries. *Key differences and evidence of divergence in policy choices correlate with differing policy networks*. Investigating the internal workings of policy networks through an exploration of the role of science provides a deeper understanding of how *the effect of ideas on relationships within policy networks* may influence policy choices. The examination of internationalization reveals the almost complete absence of direct constraints *external to policy networks*. It instead demonstrates how internationalization can shape preferences and contribute to resources exploited *within policy networks*. This result suggests that it is difficult to gauge fully the impact of internationalization on domestic policy making without exploring its interaction with domestic institutions.

The dissertation also illustrates how an assessment of the inertia of policy legacies and the constraints imposed by policy boundaries contributes to a fuller understanding of policy making. *Policy legacies supply insight into the starting points for policy making*, including levels of state capacity and autonomy and the contribution of institutionalized ideas to the nature of policy networks. During policy making, key moments of intersection of ideas, interests, and institutions--in this case study policy innovation in agricultural research, the development of lab safety guidelines for recombinant DNA research, and horizontal federal regulatory frameworks for biotechnology regulation--create *policy boundaries that shift advantage within policy networks*.

The chapter concludes with the broader lessons for policy making that emerge from this case study, focusing on the concept of policy capacity. The strengths and weaknesses of

regulators and their policy choices assist in identifying what may be necessary conditions for policy capacity. Policy capacity permits adaptive and innovative policy making, even in a context of high internationalization. Important components of policy capacity appear to include "scientific legitimacy" and "democratic legitimacy". Finally, policy capacity is integral to providing sufficient conditions for regulation in the public interest and increasing the potential for regulatory policy choices to incorporate criteria of social utility.

COMPARING POLICY CHOICES

The design of this case study provides fertile conditions for policy convergence. First, Canada and the United States are both major agricultural producers and exporters and thus face similar policy issues. Second, the central role of science in regulation suggests a consistent basis for policy choices. Third, the two countries share the likelihood of exposure to international economic trends and the activities of international institutions, transnational actors, and transgovernmental coalitions. Finally, the 1990s brought a deepening of the already substantial integration of the two countries' economies through increased trade and investment. In particular, given Canada's heavy reliance on the American market for its agri-food products and the leadership in plant biotechnology of American multinationals such as Monsanto, policy in Canada might well be expected to converge on the American model.

Using broad measures, Chapter Three shows that convergence between Canadian and American policy choices varies across issues.[1] The least convergence was found in the policy response to environmental release. There is more evidence of convergence in food safety and the highest level of convergence in labelling.[2] These findings are accompanied by consistent broad similarities between the policy responses of the two countries, most often in the choice of guiding ideas that set policy goals. The most interesting finding that emerges from the comparison is found in the details of policy choices. Differing choices in policy instruments in the cases of environmental release and food safety have resulted in important variations in the *degree of discretion* given to regulators and in the *scope of regulation*, with subsequent implications for state capacity and the potential for state autonomy. The degree of discretion is of interest because it can

[1] Further variation in the degree, or lack of, policy convergence between Canada and the US in responses to genetically-engineered organisms comes from the issue of the use of the genetically-engineered growth hormone for dairy cattle, bovine somatotrophin (BST). As of 1999, Canada had refused to approve the use of BST while the US had allowed its use since 1994.

[2] Tables 3-11 to 3-16 summarize the findings on convergence. A full discussion can be found in Chapter Three.

be an important ingredient in state autonomy when combined with adequate capacity. The coexistence of sufficient discretion for regulators, state capacity including adequate expertise, *and* rigorous accountability measures may provide the most conducive conditions for social regulation in the public interest. These may be necessary conditions for consistent and transparent regulatory policy responses. These responses in turn should contribute to public confidence in regulation and hopefully avoid regulatory disasters. The experience of European food safety regulators, in the wake of the "mad cow" and dioxin-contaminated food scares of the 1990s, serves as a sobering reminder of the difficulty of regaining public confidence in a regulatory system, once lost.

Table 7-2 summarizes how discretion varies across the six cases.[3] In the case of environmental release, the Canadian regulatory trigger of "novel trait" rests on the vague and subjective scientific concepts of familiarity and substantial equivalence, thus providing regulators with a great deal of discretion.[4] It results in a scope of regulation that is theoretically quite wide. It covers any new plant variety that regulators judge as carrying a novel trait, not just those produced by genetic engineering. American regulators have much less discretion. The scope of regulation is limited by detailed criteria that determine the degree of required oversight, including whether simple notification of environmental release is sufficient or whether a permit which requires regulatory review and approval will be necessary. Further, the scope is also narrowed by the regulatory trigger, which does not cover all genetically-engineered plants and excludes plants with novel traits not produced through genetic engineering.

In the case of food safety, Canadian regulators also have more discretion than their American counterparts. This discretion stems from the regulatory trigger of "novel food". With the finalization of regulations in fall 1999, industry was required to notify Health Canada prior to the introduction of a novel food into the marketplace. Upon notification, regulators exercise discretion in determining whether a safety assessment is necessary. In comparison to the Canadian policy response to environmental release, however, this discretion is circumscribed because novel

[3] In the case of labelling, there is no discernible difference in the degree of discretion which American and Canadian regulators possess. While labelling is mandatory in both countries, it is mandatory only when certain criteria are met (health and safety concerns or substantial difference in characteristics compared to conventional counterparts). These criteria leave little, if any, discretion with regulators particularly since the identification of these criteria is dependent on the food safety assessment process.

[4] In the regulations, novel trait is defined as, first, a trait has been intentionally introduced into a variety through a genetic change and, second, a trait not substantially equivalent to existing varieties in terms of its weediness potential, gene flow, plant pest potential, impact on non-target organisms, and impact on biodiversity. Canada. Minister of Public Works and Government Services Canada (1997).

food is defined more narrowly in the regulations than novel trait.[5] However, Canadian regulators still have much more discretion than their American counterparts. The American policy response leaves all discretion with industry through its voluntary regime. If requested, the FDA provides guidance to industry to help firms decide whether their products pose a safety risk and whether to have products assessed in-house and/or engage in consultations with the FDA.

Preferences

Table 7-1 matches the broad policy preferences of key groups within the policy communities to the broad principles of policy choices. It also indicates how some policy choices may subsequently provide additional resources to policy community members within policy networks. The table shows that large plant biotechnology developers such as Monsanto and the food industry, whose associations include large multinational firms, were the most successful in securing the highest number of policy preferences within policy choices. Further, the choice of science-based risk assessment as a programmatic idea suggests that their scientific expertise may be a valuable resource during subsequent policy making. The table also indicates that agricultural producers have secured several of their preferences within policy networks.[6] Major producer associations have aligned themselves with their partners in the supplier and processing links of the agri-food industry in their policy preferences. Their presence within the camp of biotechnology proponents illustrates their technical and financial dependency on these members of the policy network. None of the policy preferences secured within policy choices as of the late 1990s provided agricultural producer associations with potential additional resources. In fact, these policy choices may serve instead to deepen the dependence of producers on the rest of the agri-

[5] Debate over the definition of novel food was said by participants to be the major reason why it took Health Canada seven years to finalize its regulatory response to genetically-engineered foods. The definition was revised at least twice and narrowed in scope, reflecting the preferences of the food industry. In particular, the final definition includes the provision that a novel food is one that does not have a history of safe use. This provision suggests that a history of safe use in another country would have to be taken into account by regulators, potentially limiting their discretion. Previous drafts referred to a history of safe use *within Canada*. Canada. Minister of Supply and Services Canada (1999).

[6] Whether the relatively rapid commercialization of genetically-engineered crops has truly been in the best interests of agricultural producers was not clear as of the late 1990s. A USDA study released in 1999 found that in 12 of 18 cases, genetically-engineered crops did not result in higher yields than conventional varieties. In seven out of twelve cases, producers used the same amount of pesticides for genetically-engineered crops as for conventional crops. Studies such as these contribute to skepticism about the benefits of genetically-engineered crops for producers and whether the premium paid for the seed of genetically-engineered crops may outweigh other financial benefits. The benefits of genetically-engineered varieties appear to vary significantly according to individual cultivation conditions.

food industry because commercialization of genetically-engineered plants has been controlled largely by a handful of firms.

Smaller developers of plant biotechnology, such as public sector researchers, have been pleased that policy choices have allowed commercialization to proceed given that other countries have delayed commercialization. Many of them would have preferred, however, not to have an additional and onerous (in terms of time and financial cost) layer of regulation. This new layer of regulation is less of an obstacle for the large firms. These smaller developers were accustomed to the long-established tradition of plant breeders practicing self-regulation during much of the development phase on issues of plant quality such as food safety, even though they may have had to meet some regulatory requirements prior to commercialization. However, these developers also benefit from the choice of science-based risk assessment since they have relevant scientific expertise which may provide influence within the policy network.

State officials have designed policy choices to secure their broad policy goals of competitiveness and public confidence (although whether they succeeded in securing public confidence by the late 1990s is debatable). Harmonization has been a more pressing policy goal in Canada than in the US. More interestingly, of all the groups within the policy community, state officials have the most potential to increase their resources of expertise and legitimacy through policy choices. Harmonization to internationally-endorsed models may enhance state capacity and autonomy, for example, by adding to legitimacy and supplying additional expertise to back policy choices. Further, the use of existing institutional arrangements and legislative authorities also provides the appearance, if not the reality, of tapping into a reservoir of relevant expertise. Finally, science-based risk assessment may enhance state capacity and state autonomy, depending on the location of scientific expertise and the degree of contestation of scientific authority.

Biotechnology skeptics have been the least successful in securing broad policy preferences within policy choices. Several of their preferences have been excluded from policy choices including a more precautionary approach to environmental safety and food safety assessments, broad mandatory labelling provisions, and a more critical scrutiny of the socioeconomic benefits and costs of biotechnology compared to other technologies. However, these skeptics can take some comfort in the fact that policy choices may well provide them with a stronger foothold in policy networks during subsequent policy development. The institutionalization of formal

environmental risk assessments and food safety assessments for new plant varieties is precedent-setting in both countries and thus increases the legitimacy of these issues. Further, harmonization efforts may also provide skeptics with greater legitimacy for their arguments. For example, the Biosafety Protocol drafted in early 2000 arguably may help skeptics to promote the precautionary principle.[7] The challenge of reaching consensus during negotiations over the Biosafety Protocol and within the Codex Alimentarius forum on the issue of labelling has heightened public awareness of scientific uncertainty and arguably furthered the case of skeptics. Other efforts toward harmonization like those pursued within the OECD forum, however, may instead marginalize the preferences of skeptics.

EXPLAINING AND UNDERSTANDING POLICY CHOICES

Policy networks

The correlation between the nature of policy networks and the degree to which policy choices enhance state capacity and the potential for autonomy illustrates the utility of analyzing policy making at the sectoral level. Variations in the policy networks surrounding the issues of environmental release, food safety, and labelling correspond with variations in policy choices in the degree of discretion and the scope of regulation discussed earlier (see Table 7-2).

On the issue of environmental release, Canada initially had a state-directed policy network. This network was the result of the combination of an authoritative and capable state actor, an emerging plant biotechnology industry with minimal organizational development, and the marginal influence of biotechnology skeptics. During the 1990s, the network shifted toward concertation as the plant biotechnology industry accumulated expertise. The state actor remained relatively capable, if less autonomous. The nature of the policy network is consistent with the success of state officials in carving out a significant degree of discretion. This ample discretion provides the potential for action relatively autonomous of the regulated industry and other societal pressures such as public interest groups.

In contrast, the American policy network surrounding the issue of environmental release began as a weak concertation style in the early 1980s that quickly verged toward clientele

[7] The protocol will not come into force until it is ratified by fifty countries. The text incorporates the precautionary principle explicitly although somewhat vaguely. The strength of the protocol will be unknown, however, until it is tested, for example, by a international trade challenge under the World Trade Organization and the Sanitary and Phytosanitary Agreement. Such a challenge may clarify how the potentially conflicting provisions of the WTO agreement and the Biosafety Protocol will be reconciled.

pluralism. As the key state actor, the United States Department of Agriculture (USDA) was semi-capable, but not very autonomous. Its policy response reveals its vulnerability to the challenges of environmental groups and the demands of biotechnology industry. Policy choices, designed to appease its critics on both sides of the debate by offering transparency and certainty, are based on detailed criteria establishing the degree of regulatory oversight according to categories. These criteria have greatly limited the discretion regulators have been able to exercise. Further, the vulnerability of USDA to societal pressures has been well-illustrated by the agency's revision of its policy three times between 1984 and 1997.[8] In 1999, the USDA's announcement of an independent review of its policy, under a barrage of criticism, once again demonstrated the agency's vulnerability.

On the issue of food safety, state officials in Canada operated within a weak concertation policy network. Their policy response provided them with more discretion than their American counterparts who worked within a clientele pluralist policy network. In particular, in the fall of 1999, premarket notification became mandatory in Canada with the finalization of regulations. Meanwhile, American regulators designed a policy response that made premarket notification and consultations voluntary, leaving discretion to industry. Compared with policy responses to environmental release, the policy responses to food safety reflect the relative lack of state capacity and autonomy of Health Canada and the Food and Drug Administration (FDA) within their respective policy networks. The FDA appears to be even more vulnerable to political tides than the USDA, given the atmosphere of constant scrutiny from industry and public interest groups in which it operates. Both food safety agencies felt the need to shore up capacity or at least the legitimacy of policy choices by launching consultations in late 1999. In Health Canada, this initiative was to take the form of an independent expert advisory committee on food biotechnology. The FDA, in contrast, decided to hold three public meetings in late 1999 on both its food safety and labelling policies. In May 2000, responding to increasing public pressure, the FDA announced that it would propose a rule that would require industry to notify it at least 120 days before introducing a new genetically-engineered food or animal feed product and to provide information about the product. If passed, this new rule will replace the voluntary system with a mandatory system.

[8] It first declared there was no need for special regulations for genetically-engineered plants. It then implemented such regulations in 1987, and subsequently reduced regulatory oversight twice, in 1993 and 1997.

Finally, in the case of labelling, similar pressure pluralist policy networks in both countries resulted in minimal discretion. As Table 4-7 illustrates, Canadian and American regulatory agencies lacked capacity and potential for autonomy on the issue of labelling. Perhaps to compensate, the decision was made to link labelling policy to the food safety assessment process. Further, consumer organizations lacked sufficient resources to counteract the relatively well-organized food industry which worried that labelling would alarm consumers. In Canada, the major national consumer association was heavily dependent on the relevant scientific expertise of biotechnology proponents. It aligned its policy preferences with those of biotechnology proponents to favour a narrow scope for mandatory labelling tied to the food safety assessment process. In the US, the major national consumer association favoured a broad basis for mandatory labelling, but was no match for well-organized and well-resourced biotechnology proponents. Ultimately, these weak policy networks contributed to a lack of scientific, informational, and democratic legitimacy to bolster policy choices. They created an unstable foundation for policy responses, which attempted to break partially with policy legacies by incorporating a science-based programmatic idea in a policy area long characterized by a reliance on market-based ideas.

The role of science: ideas and policy networks

Studying how ideas work within policy networks provides a deeper understanding of how the allocation of critical resources within a network results in dependencies and interdependencies that create patterns of exchange. Patterns of exchange are underpinned by ideas in the form of norms and conventions that justify and reinforce them,[9] such as the authority of science and its proper role in policy making. The ideas that drive patterns of exchange may serve to privilege some actors and marginalize others through their effects on the range of ideas seriously considered during policy debate, on the modes of discourse, and the authority and legitimacy of policy network members.

Categorizing dominant programmatic ideas identifies the nature of authority that is likely to be exercised within the policy network and which resources are most critical to influence. For example, science as a programmatic idea suggests the exercise of an exclusive type of authority based on the legitimacy of science. Scientific expertise would likely be the most important resource within the policy network. Market-based programmatic ideas suggest that no authority is

[9] March and Olsen (1989).

needed beyond the discipline of the efficiency of market forces. Such ideas privilege industry actors within policy networks, especially those with economic power. Democracy as a programmatic idea suggests that authority broadly based on a plurality of interests and legitimate representation will be a requisite aspect of policy making. Legitimacy based on democratic representation is a critical resource in this situation. Those policy network members lacking critical resources will find themselves in a position of dependency or interdependency if they have resources to exchange for others.[10]

The identification of ideas institutionalized in policy legacies provides insight into the factors behind starting points for the nature of policy networks. Ideas affect the importance of resources and thus patterns of exchange. During policy making, the use of ideas to challenge the nature of authority and legitimacy creates dynamics within the policy network with the potential to transform that network. Ideas within policy boundaries may have a similar effect. Finally, policy choices may perpetuate, dilute, or transform previously institutionalized ideas, once again with potential effects on the nature of the policy network by designating which resources are most critical.

Ideas that persist may lock in patterns of exchange within policy networks. The likely durability of ideas can be gauged by assessing the degree of institutionalization. Krasner outlines two dimensions of institutionalization that contribute to the persistence of an institution including the ideas embedded within it: depth and breadth.[11] Depth can be assessed as the extent to which an actor relies on the institution for self-identification, including the elements of policy preferences and capabilities (resources). Breadth refers to the extent to which the institution is linked to other institutions: the greater the number of linkages, the more resistant it is likely to be in the face of change.

Chapter Five has detailed the role of science as a programmatic idea and its likely impact on the importance of scientific resources to the influence of a policy network member. From a broader perspective, science is well-institutionalized as a guiding and programmatic idea in North America and not easily displaced. Its depth is profound, reflected in a secular society in which the fundamental system of knowledge is based on scientific rationality and reduces the potency of

[10] For example, interdependency can occur when scientific expertise is exchanged for democratic legitimacy. The actor with scientific expertise desires to broaden support for policy preferences; the actor that can make claims of representation desires to bolster its internal knowledge-based resources so as to maintain its utility for its members.
[11] Krasner (1988).

alternative systems such as religion and traditional cultural practices. Actors possessing scientific expertise are privileged by the institutionalization of science throughout public and private organizational structures because they are able to tap into the resource of scientific authority. The application of the scientific method to policy making, whether in the form of experimental data or economic projections, is pervasive in North America and shapes organizational structures of policy making. This technocratic approach permits the exercise of an exclusive type of authority. It requires state and societal policy actors who seek to be influential to reorganize themselves to be well-versed in the requisite expertise. Thus, a technocratic approach is self-perpetuating and expansionary unless challenged.

The most forceful challenge to science comes from the concept of democratic legitimacy since technocratic approaches may exclude aspects of policy making they cannot capture through the scientific method. Market-based ideas may also challenge science by diluting or replacing policy prescriptions stemming from expertise with those based on market forces. The market-based programmatic prescriptions of technological neoliberalism and the participatory elements of democratic legitimacy hold the same potential for influence as the role of science, given the broad and deep institutionalization of capitalism and democracy in North American society. However, the dominant ideas institutionalized *within policy networks* may differ somewhat and be insulated from the dominant ideas entrenched in broader institutional structures. The resilience of the policy network to the challenge of external ideas determines the degree of insulation. A resilient policy network may protect ideas of democracy or science, for example, from dilution by market-based ideas, even if those latter ideas are dominant in the wider context.

Chapter Five examined the degree of contestation of scientific authority and the allocation of scientific resources as a key aspect of dynamics within the policy networks. It concluded that scientific resources should have been an important resource within policy networks in three cases according to the hypotheses laid out in the introduction: environmental release in Canada, and food safety in Canada and the US.[12] In fact, in these three cases where science was institutionalized at the moment of policy choices as a relatively neutral programmatic idea, the location of scientific expertise does correlate with resulting policy choices (see Table 7-3). The greater the degree of *independent* scientific expertise available to and used by regulators, the higher the degree of

[12] For the purposes of examining the role of science, the issue of food labelling was not examined separately, given its link to and dependence on the food safety assessment process.

discretion and the wider the scope of regulation that resulted from policy choices.

In the case of environmental release in Canada, scientific resources were concentrated in the public sector and particularly in the federal government. Policy legacies in agricultural research and regulation of the sale and use of new plant varieties provided regulators with a strong scientific backing that translated into both autonomy and capacity. In the case of food safety in Canada, expertise resided in domestic and multinational food firms, academic settings, and in international institutions. Regulators engaged in frequent consultation with these sources to bolster capacity with a mixed effect on autonomy. The reliance on expertise in public sector settings and the work of international institutions arguably could protect autonomy, but reliance on industry could jeopardize it. Finally, in the case of food safety in the US, relevant scientific expertise has been ample, but resides in domestic and multinational food firms and to some extent in academia.[13] As in Canada, American regulators often consult with outside experts to bolster capacity. Reliance on experts in the private sector encourages the perception, if not the result, of capture of regulators by the regulated. There is less evidence of intentional alignment with international institutions in the US than in Canada, at least in this case study. The massive size of the food industry in the US, including several multinational firms, suggests that American regulators are likely to be less able than Canadian regulators to balance the influence of the food industry with other sources of expertise, such as recommendations by international institutions.

In the case of environmental release in the US, scientific authority was weakened within the policy network as a result of high levels of contestation and inadequate state capacity in terms of relevant scientific expertise. Other ideas and their corresponding resources were influential, again confirming the hypotheses regarding the role of science. Court challenges in the early 1980s under the *National Environmental Policy Act* heightened the importance of democratic legitimacy. Further, the ascendance of technological neoliberalism during policy development and its incorporation in the horizontal regulatory framework, with its preference for market-based policy instruments, reinforced the importance of the economic and technical resources of large plant biotechnology firm and increased the legitimacy of their participation within policy networks.

[13] The extent to which food science expertise located in academic institutions can be considered independent is a matter for further scrutiny. In the plant biotechnology field, the increasingly close links between academia and industry documented in Chapter Two suggest that it might be difficult to find independent expertise. Similar trends may be occurring more broadly in food science. There is plenty of anecdotal evidence of food scientists located in academic institutions collaborating in research with the food industry.

Technological neoliberalism is not incompatible with science as a guiding idea, but tends to dilute science as a programmatic idea through its preference for market-based policy instruments. The vulnerability of the USDA to pressures from public interest groups and industry left it hemmed in on both sides of the debate. Its policy response appeared fashioned as a compromise to appease both biotechnology proponents and skeptics. It offered a formal environmental assessment process focused solely on genetically-engineered plants in an effort to respond to demands for certainty and transparency. Its detailed procedural commitments, including public comment periods and appeal provisions, appeared to be intended to bolster the democratic legitimacy of policy choices.

Finally, the labelling case demonstrates the difficulties that may arise for policy makers when policy choices attempt to incorporate a new idea that conflicts with existing ideas in a context of inadequate legitimacy. Policy legacies in food labelling in Canada and the US are characterized by a reliance on market-based programmatic ideas. The intent has been to ensure consumer protection largely through the effective functioning of the food marketplace. Departing somewhat from these policy legacies, policy choices on the labelling of genetically-engineered food attempted to incorporate science as the dominant programmatic idea through a reliance on the food safety assessment policy response. As a result of these policy choices, special labelling of genetically-engineered foods is to be triggered solely when the results of the food safety assessment process indicate significant differences in the characteristics of a product, such as those that might cause health or safety concerns, or be an unfair basis for competition.

The narrow scope of food labelling policy in the past has tended to restrict the grounds on which consumers may exercise choice in the food marketplace. However, it has encouraged the perception of consumer choice through its reliance on measures intended to give consumers information on which to select their purchases (such as net quantity and ingredient lists). In contrast, the labelling policy for genetically-engineered foods in both countries clearly ignores the principle of consumer choice by making it impossible for consumers to know consistently whether their food purchases contain genetically-engineered ingredients. The weakening of the scientific legitimacy of the food safety assessment policy responses through contestation and the lack of democratic legitimacy behind policy choices, especially in the US, has made consumers skeptical about the lack of choice, resulting in a policy responses that are very difficult for Canadian and

American policy makers to defend.

Internationalization and policy networks

Chapter Six assessed the potential for internationalization through trade patterns, the dominant presence of multinational firms, the array of international institutions active on the issues of biotechnology regulation, and the general international orientation of key domestic policy community members. In this case, internationalization during the 1980s and 1990s was found not to constrain policy making directly, but rather to affect the preferences, opportunities, and resources of domestic policy community members. This dissertation has investigated the hypothesis that the degree and nature of internationalization shapes domestic policy preferences and alters the resources available to policy community members. Its findings confirm that a high degree of internationalization can encourage policy convergence and, when convergence occurs, the nature of internationalization is likely to indicate the direction in which convergence will travel.

In this case study, trade patterns appear to have influenced the preferences of policy community members in Canada in ways that contributed to policy convergence. For example, the high export dependence of the Canadian agri-food sector on the American market for food products and on several export markets for crops translated into broad policy preferences of competitiveness and harmonization for both state officials and the agri-food industry with the goal of securing market access. The greater degree of convergence in the Canadian responses to the food safety and labelling issues toward the American model, compared to environmental release, tends to confirm the hypothesis that external economic dependence encourages convergence toward the policy response of major trading partners.[14] External economic dependence in the agri-food sector in the US is lower than that in Canada, although it grew in the 1990s. American state officials have also pursued competitiveness and harmonization, but without the goal of aligning their policy responses toward another model. The American approach has instead been to exercise its domestic scientific resources in international institutions, such as the OECD, with the intent of securing harmonization

[14] Environmental release is arguably more of a domestically-focused issue than food safety or labelling since the risks examined are largely expected to occur within territorial boundaries. However, developments such as the Biosafety Protocol, which is intended to govern trade in biotechnology products in order to minimize environmental risks, encourage policy makers to view environmental release policy responses as an international issue as well.

by other countries with the existing American regulatory regime.[15] The agri-food industry has generally supported this strategy, although troubles with export market access in the late 1990s have raised doubts about the adequacy of the American policy response.

The dominance of multinational firms in the plant biotechnology industry also shaped preferences within policy networks in the 1980s and 1990s, but resulted in relatively low pressure toward convergence. Their contribution to convergence is most evident in the response of Canadian state officials who have sought to attract research investment from these firms to bolster Canada's relatively small plant biotechnology industry.[16] From the point of view of these firms, American policy responses to the commercialization of genetically-engineered plants were undoubtedly the pioneering regime in terms of timing and perhaps the most competitive in terms of facilitating relatively rapid commercialization. Canadian officials strove to develop a regulatory regime permitting environmental release relatively quickly. Their goal was also to ensure that Canadian agricultural producers had early access to genetically-engineered plant varieties just as their American counterparts undoubtedly would.[17] The preferences of multinational plant biotechnology firms such as Monsanto for certainty and transparency in the regulatory response arguably were a key factor in encouraging greater formality in the Canadian policy response to environmental release. This formality was achieved in the move from guideline documents to regulations. Canadian policy responses did, however, differ significantly from American responses in ways that provided Canadian regulators with more discretion and potentially more autonomy and which has resulted in a relatively low degree of policy convergence.

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[15] It is generally believed that American policy makers feel less obliged to align their activities with the recommendations of international institutions than do Canadian policy makers. Another example is described by Salter (1988: 86-87). She shows that, as of 1984, the US was much less eager to align its pesticide residue standards with those endorsed by the United Nations food safety organization Codex Alimentarius, compared to Canada. Canada fully accepted 436 standards, while not accepting sixteen. The US fully accepted 158, while not accepting 405. Countries can also take a position of ignoring the standard rather than full or non-acceptance. At the time of Salter's study, Canada was a far more active participant in aligning its domestic standards with those of Codex, even though it independently assesses the data before accepting a Codex standard.

[16] Canada had a strong history of public sector plant breeding up until the 1980s and into the 1990s, and some public sector researchers have worked on genetically-engineered plant varieties since at least the early 1980s. However, policy innovation in agricultural research policy in the 1980s and 1990s (detailed in Chapter Two), spurred in part by fiscal restraint, encouraged state officials to look to the private sector to secure a higher level of plant biotechnology research and development.

[17] There was less concern about developing food safety and labelling responses quickly to please multinational firms. These firms are in fact best positioned among developers to absorb the costs of conforming to differing food safety and labelling domestic regimes, although they are likely to prefer harmonization for the sake of efficiency.

Finally, the activities of international institutions through the 1980s and 1990s did not place direct constraints on Canadian and American policy choices that would have encouraged policy convergence.[18] The influence of international institutions and thus any contribution to policy convergence has instead occurred in two related ways. First, state officials and other members of the domestic policy community have attempted to use the activities and recommendations of these institutions to enhance their position within domestic policy networks. Second, as a result, there may have been transmission of ideas from the international level to the domestic level. Chapter Six has noted that Canadian and American state officials were a dominant presence at many of the international forums in which biotechnology regulation was discussed during the 1980s and 1990s. Further, state officials often cited the reports and recommendations of international institutions in the 1980s and 1990s to justify domestic policy choices, particularly the scientific aspects.

There were signs in late 1990s that internationalization will place increasing pressures on North American policy makers into the new century. The growing contestation of the science underpinning Canadian and American policy choices in environmental release and food safety has been propelled largely by the growth of consumer resistance elsewhere, in Europe and Asia. Public interest groups have developed international links, aided by new communication technologies, to garner public attention and raise concern in North America with some success in the late 1990s. This development combined with the significant reliance on export markets of Canadian and American agricultural producers and agri-food industries are part of the contribution of internationalization to the changing hurdles for regulatory policy choices.

[18] The one exception, noted in Chapter Six, is that the United Nations Convention on Biological Diversity required Canada, as a member, to implement a domestic regulatory regime for biotechnology products. The US is not a member of the Convention. This constraint contributed to the Canadian decision to adopt a more formal regulatory regime including a horizontal regulatory framework, which can be interpreted as broad evidence of convergence toward the American regime. Looking toward the future, those institutions which are most likely to impose limits on policy choices in the medium-term are Codex and the International Plant Protection Convention, given their enhanced status as reference bodies under the Sanitary and Phytosanitary Agreement of the WTO; and the Biosafety Protocol of the United Nations Convention on Biological Diversity, if and when it is ratified.

Science and internationalization

In this case study, in the three policy networks where science enjoyed a dominant neutral characterization at the time of policy choices, policy choices were generally consistent with the scientific consensus produced by the most scientifically-credible international institutions: the FAO-WHO workshops and the OECD reports. However, it is not clear that this result can be considered as evidence of policy convergence encouraged by international institutions.

These findings do confirm the hypothesis that policy networks in which the dominant characterization of science is neutral will produce policy choices that are consistent with the consensus produced by credible scientific international institutions. In a science-as-neutral policy network, science should be treated as authoritative. There should not be discrepancies between the international and domestic levels in terms of the scientific conclusions that underpin policy choices. In such a situation, domestic policy community members with scientific resources can be expected to use the scientific activities of international institutions to reinforce the legitimacy of their policy preferences and consolidate the institutionalization of science as neutral within the domestic arena. However, this strategy did not sufficiently counter the scientific uncertainty characterizing the issues of environmental release and food safety. This uncertainty was highlighted in other international forums in the 1990s: the Codex discussions on food labelling and the negotiations to create a Biosafety Protocol. The case study also confirms that if science is contested within a domestic policy network and therefore displaced as the primary basis for policy making, as has been the case in the American response to environmental release, the activities of international scientific institutions might well be less influential than economic or less scientific versions of political internationalization, or domestic factors.

In this case study, science was institutionalized as neutral in policy choices responding to the issues of environmental release and food safety in Canada, and in food safety in the US. Of all the international institutions examined in Chapter Six, the two FAO-WHO conferences on food safety during the 1990s had the highest scientific credibility, followed by the several OECD workshops and reports.[19] Credibility was enhanced because the small group of participants in the

[19] In contrast to the FAO-WHO workshops and the OECD reports, the Codex discussions on food labelling policy and negotiations leading to the Biosafety Protocol did not create or put forward a scientific consensus prior to 1998. The debates instead amplified the scientific uncertainty surrounding issues of environmental release and food safety, providing resources to biotechnology skeptics within domestic policy networks who were consequently better able to challenge scientific authority. These results reduced scientific credibility.

FAO-WHO conferences were food science experts. Further, their recommendations put forward a scientific consensus through a series of scientific guidelines. Unlike their OECD counterparts, the participants avoided making broad "political" recommendations about how to accomplish regulation or to what ends it should be directed.[20]

Confirming the hypothesis, Canadian and American policy responses to the issue of food safety are generally consistent with the recommendations that resulted from the two FAO-WHO conferences, particularly in terms of the components of the safety assessment.[21] The 1996 FAO-WHO workshop, however, did issue recommendations that sounded a greater level of caution than that expressed generally in the policy responses of Canadian or American regulators.[22] The OECD's scientific guidance on food safety assessment is highly consistent with the FAO-WHO recommendations, and thus also with Canadian and American policy responses. The OECD recommendations, however, lack the detailed caution of the 1996 FAO-WHO workshop on the issue of food allergens and include the policy-oriented recommendation that existing regulatory regimes should be an adequate basis for regulating the products of biotechnology.

On the issue of environmental release, the OECD was the only international institution to issue relevant recommendations.[23] A 1982 report endorsed the policy initiative of conducting environmental risk assessments prior to large-scale commercialization. A subsequent report in 1986 outlined general scientific principles that could be used in regulatory efforts. For example, it recommended using existing information on traditional counterparts including the evolution of "novel traits" in non-genetically engineered plants as a basis for assessing the risk of genetically-engineered plants, and treating genetically-engineered plants in the same manner as plants produced through other means from the perspective of risk assessment. In 1992, yet another OECD report provided detailed criteria for designing field trials of genetically-engineered plants.

[20] The 1996 workshop did state that it considered biotechnology a potentially important tool in providing developing countries with an adequate and nutritious food supply.

[21] For example, the domestic policy responses prescribe consideration of changes in levels of toxins, allergens, and nutritional value, and the comparison of novel foods to a traditional counterpart as part of the food safety assessment process. All of these measures were recommended by the FAO-WHO workshops.

[22] For example, it recommended that foods found to contain an allergen as a result of genetic engineering should not be sold unless they can be clearly identified. Venturing onto the ground of policy recommendations, it also suggested that labelling might not be adequate to protect consumers from such allergens.

[23] In the 1990s, the UN Industrial Development Organization Voluntary Code of Conduct for the Release of Organisms into the Environment also provided guidance to regulators. However, its general nature was intended largely for countries without any regulations in place. Compared to OECD recommendations, it was rarely, if ever, cited by Canadian and American officials to justify policy choices.

Both Canadian and American policy responses to environmental release are largely consistent with the OECD's recommendations. The consistency of Canadian regulations tends to confirm the hypothesis that science-as-neutral domestic policy networks are likely to reflect the scientific consensus put forward by international institutions. The OECD, however, is a hybrid scientific and political international institution. Its mandate is not to produce scientific consensus, but rather to encourage economic growth and the expansion of world trade. Its biotechnology regulation activities have been conducted with the intent that such coordinating activity would contribute to fulfilling its mandate. The OECD workshops and reports did produce scientific guidelines. They also delved into how regulation would best be accomplished and underlined the importance of ensuring that regulation contributed to economic growth and did not impede international trade. As a result, the OECD is arguably as much, if not more, of a "political" international institution than a scientific institution. Thus, it is not surprising that American policy responses to environmental release have also been compatible with OECD recommendations. The OECD's mandate has been compatible with American policy goals of ensuring competitiveness in the emerging domestic biotechnology industry. However, American officials dealing with the issue of environmental release made fewer prominent references to international institutions such as the OECD, suggesting that these international recommendations were not expected to provide significant utility within the domestic policy network.[24]

It is difficult, however, to conclude with certainty that the consistency observed in broad policy principles and scientific guidelines between international institutions and domestic policy choices was a result of domestic regulatory regimes converging toward internationally-endorsed models. It may instead have been a function of the scientific leadership role of American and Canadian officials.[25] In fact, the coincident timing of the activities of international institutions and the development of key elements of the domestic regulatory regimes suggests that it is less often

[24] For example, the 1987 USDA regulations made no reference to international activities such as those already undertaken by the OECD on environmental release issues. The 1992 FDA policy statement, in contrast, noted that its scientific concepts were consistent both with OECD and FAO-WHO recommendations. USDA officials may have felt that domestic studies, such as the 1989 National Research Council report on field testing, provided sufficient backing, although they did not refer to this study either in the 1987 regulations

[25] In interviews, American policy community members uniformly dismissed any influence on domestic policy responses from international institutions and instead claimed a leadership role. Canadian officials working on environmental release also suggested that they exercised leadership in international forums such as the OECD. Canadian officials working on food safety were most explicit in acknowledging the goal of alignment with international institutions.

convergence and more often congruence that has occurred. Exceptions may perhaps be found in the initial OECD report, published in 1982, which predated the publication of policy responses in both countries, but made very general policy prescriptions. The first FAO-WHO conference on food safety issues which occurred in 1990 was also prior to the first official policy statements on food safety assessment in both countries.

Evidence of possible convergence of scientific aspects of domestic responses to international or foreign recommendations is easier to find in Canadian than American policy responses. For example, it appears that the concept of familiarity first emerged as an appropriate risk assessment tool for biotechnology regulation in a 1989 study by the US National Research Council of the National Academy of Sciences.[26] It was subsequently endorsed by the OECD in its 1993 report on larger-scale field testing and adopted by Canada in the mid-1990s.[27] Canada also explicitly uses the concept of substantial equivalence for environmental and food safety assessments. This concept complements the principle of familiarity. It appears to have been first endorsed by the OECD for biotechnology food safety assessment.[28] In contrast, American regulators do not use the term of substantial equivalence for environmental release, but their scientific approach is very similar.[29] Efforts within international institutions to create scientific consensus on biotechnology regulation raise the question of whether there have been epistemic communities attempting to influence policy choices through authoritative knowledge claims. However, there is not much evidence that epistemic communities were active and influential in international institutions or domestic policy networks in the 1980s and 1990s.[30]

[26] National Research Council (1989).
[27] Organisation for Economic Co-operation and Development (1993b).
[28] See Canada. Agriculture and Agri-Food Canada (1995a)
[29] United States. Department of Agriculture. Office of the Secretary (1991).
[30] It is outside the scope of this dissertation to thoroughly investigate whether epistemic communities have existed for the issue of biotechnology regulation. The evidence indicates that certain ideas about regulation have persisted over time. However, the apparent lack of consistent and coherent epistemic communities relevant to this case study, probably in part a function of the relatively high degree of scientific uncertainty which characterizes the issues of environmental release and food safety in biotechnology regulation, suggests that the persistence and influence of ideas is more a result of factors other than the existence of epistemic communities.

Policy legacies and boundaries

Identifying relevant policy legacies and boundaries provides an extra dimension to efforts to understand policy choices. The depth of understanding achieved through the identification of policy legacies illustrates the importance of inertia through which institutions carry forward ideas. Even in new policy areas, such as biotechnology, policy making rarely starts from scratch. Policy legacies can provide information about the starting point of the timeframe of study from the examination of institutional arrangements, embedded ideas, and choices of policy instruments. The analysis of policy legacies provides a historical perspective. It permits conclusions as to whether policy making is travelling in a consistent direction over time and thus perpetuating patterns of interaction and protecting institutionalized ideas, or whether key moments of intersection among ideas, interests, and ideas have altered the trajectory. In this case study, the examination of policy legacies has provided insight into the sources of variations in state capacity and autonomy found within the newly emerging policy networks surrounding the issues of environmental release, food safety, and labelling (see Table 7-4). The decision to use existing institutional arrangements and legislative authorities to implement biotechnology regulation, reinforced by the horizontal regulatory frameworks in each country, further ensured that policy legacies would provide the foundation for the new policy networks.

Policy legacies are not immune to disruption, however. The dynamics within policy networks and the influence of external factors during policy making may result in policy choices that mark a departure from policy legacies. This case study does reveal strong elements of continuity between policy legacies and policy choices. In three cases (environmental release in Canada and the US, and food safety in Canada), however, policy choices were also precedent-setting in their establishment of formal and systematic evaluations of new plant varieties to assess risks to the environment and food safety. In the case of food safety assessment in the US, the scientific guidance provided by the FDA to industry on assessing new plant varieties for food safety was also a departure from the previous practice of general deference to the judgment of plant breeders, even though policy choices did not result in a mandatory assessment system.[31] In the two labelling cases, in contrast, there was little divergence from the inertia of underlying policy

[31] In 1999-2000, some representatives of the American food industry began to express a preference for mandatory consultations, in response to rising consumer skepticism and resistance regarding genetically-engineered foods. In May 2000, as noted earlier, the FDA indicated it would propose such a change to its policy.

legacies except in the effort to introduce science as a programmatic idea.[32]

Depending on the limits they place on policy choices, policy boundaries can explain departures from policy legacies or reinforce their inertia. They capture how the intersection of ideas, interests, and institutions at a given moment can limit future policy choices.[33] Chapter Two identified the two key events that established important policy boundaries for choices about regulating the commercialization of genetically-engineered crops. These events shaped policy making by encouraging the choice of certain problem definitions, policy goals, and policy instruments; and ensured that some aspects of policy legacies were brought forward into the new policy networks. Together with the nature of innovation in agricultural research policy, these boundaries established and shifted advantage within policy communities and policy networks. They did not, however, totally determine policy choices.

The first key event that established a significant policy boundary was the establishment of lab safety guidelines for working with recombinant DNA organisms in the mid-1970s in both countries. This event was the initial decision by policy makers about whether and how to regulate the use of genetic engineering and its products. These guidelines set precedents by providing an original problem definition and selecting appropriate methods for regulation. Researchers provided both the problem definition, which focused exclusively on risks to the environment and human health, and the policy response of risk assessment. The choice of risk assessment institutionalized science as a dominant programmatic idea, which privileged those with scientific expertise in the nascent biotechnology regulatory policy communities. While the guidelines resulted in a situation largely of self-regulation for researchers, it also set the precedent that genetic engineering required its own distinct regulatory measures.

The second key event that created policy boundaries was the development of horizontal regulatory frameworks for biotechnology, in the US during 1984 to 1992, and in Canada in 1993. These frameworks were intended to ensure a consistent approach to regulation across federal agencies and departments. Prior to and during the development of these frameworks, the underlying public philosophy in both countries was shifting increasingly toward technological

[32] While food labelling generally expanded in scope in the 1980s and 1990s in both countries to provide more nutritional information and to allow some health claims, even these measures arguably are a response intended to regulate competition on the basis of claims about the qualities of products rather than a measure intended primarily in the public interest.

[33] Weir (1992a, 1992b).

neoliberalism. The ascent of technological neoliberalism was also evident in the nature of innovation in agricutural research policy in both countries. In the US, the executive branch favoured a strategy of minimal regulation, if not deregulation. It saw regulation as a policy tool to achieve competitiveness. In Canada, regulators were also under pressure to reduce the regulatory burden in ways that would facilitate competitiveness. In the case of biotechnology regulation, they sought ways to balance the goals of social regulation with the demands of competitiveness.

These regulatory frameworks created significant and identical policy boundaries in both countries. First, they endorsed the use of existing institutional arrangements and legislative authorities as an appropriate foundation for the new issue of regulating biotechnology. This measure ensured that policy legacies from agricultural research and regulation would be carried forward into the new policy communities and reinforce existing asymmetries of power within policy networks. Second, the initial problem definition from the development of lab safety guidelines which focused on risks to human health and the environment was broadened. The new problem definition focused on how to ensure regulation enhanced rather than detracted from competitiveness while providing adequate risk management. Regulatory science became a programmatic idea intended to achieve the guiding idea, or policy goal, of international competitiveness. This problem definition privileged the policy preferences of industry and increased the legitimacy of its involvement in policy making. Finally, the regulatory frameworks of both countries firmly excluded a number of issues from the scope and intent of biotechnology regulation. These issues included ethical concerns extending beyond safety about the development and use of genetic engineering; the incorporation of criteria of social utility (beyond economic growth and innovation) within regulations such as improving agricultural sustainability, food quality or food safety; and an evaluation of the socioeconomic costs and benefits of biotechnology. The exclusion of these issues reinforced the focus of regulation on anticipated risks. It continued to position the possession of scientific expertise as a potential prerequisite for authoritative participation in the policy network and marginalized policy network members who could speak authoritatively only on other aspects of the impact of commercialization.

THE RELATIVE WEIGHT OF DOMESTIC AND INTERNATIONAL FACTORS

The workings of the role of science *and* internationalization within policy networks both help to explain policy choices. The identification of policy legacies and policy boundaries provides an understanding of how they may direct policy making and place limits on policy choices. This section summarizes the degree to which policy choices across the six cases are adequately explained by domestic factors compared to explanations stemming from the nature and degree of internationalization.

Domestic factors

The dissertation has confirmed that domestic factors, including policy networks, the role of science within those networks, policy legacies and policy boundaries provide much of the explanation of policy choices including observed similarities, differences, and divergence. Across all three issues, the two countries exhibit a relatively high degree of similarity in *broad aspects* of policy choices, especially policy goals (see Tables 3-11, 3-13, and 3-15). These similarities are largely the result of parallel domestic factors in the two countries including the similar composition of policy networks, similar policy boundaries, and some similarities in policy legacies. They include the fundamental choice of proceeding with relatively rapid commercialization of genetically-engineered plants. This choice can be easily explained by the similar domestic histories of strong public support of innovation in agriculture in both countries, reinforced by the more recent imperative of technological neoliberalism. On the issue of environmental release, the two countries have pursued similar goals of environmental safety, protection of the agricultural sector, harmonization, and competitiveness; and similar means of science-based assessment and reliance on existing institutional arrangements and legislative authorities. On the issue of food safety, there have been similar goals of safety, public confidence, harmonization, and competitiveness; and similar means of substantial equivalence, science-based flexibility, and risk assessment. Finally, on the issue of labelling, there have been similar goals of safety and truth in labelling; a similar scope for regulation that excludes consideration of the process used to create a product; and a similar regulatory trigger of health and safety concerns.

Differences and divergence across countries can be explained largely by differing policy networks, including variations in the role of science within the networks. These differences appear

to result in the potential for a more cautious and rigorous approach to assessing the risks of genetically-engineered plants in Canada than in the US.[34] For example, as of 1998, there was evidence of divergence between the two countries on the degree of regulation in environmental release. Canada had formalized its regulations to make them mandatory and maintained a wide scope of regulation. Meanwhile, the US had reduced the scope of review twice through deregulatory initiatives. On the issue of food safety, the eventual finalization of Canadian regulations in 1999 resulted in both a more formal response than that to the south and a mandatory regulatory regime, beginning a trend of divergence which reversed the initial appearance of convergence. Further, the two countries differed in their assessment of the degree of novelty inherent in genetically-engineered plants from the perspective of the issues of environmental release and food safety.[35] This difference is consistent with variations in the degree of discretion and the scope of regulation given to regulators in responses to these two issues.[36] Further, disparities between the two countries in the institutional arrangements on all three issues maintained persistent historic differences between the two countries. This outcome was a result of parallel decisions to adopt regulatory frameworks mandating the use of existing institutional arrangements for biotechnology regulation.[37]

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[34] This dissertation does not evaluate the qualitative outcomes of regulation to date, in part because the number of decisions was still relatively low as of 1998. Interviewees observed that the science behind regulation was similar in both countries, but that Canada demanded significantly more information from developers seeking regulatory approval. Policy community members interviewed did not know of a genetically-engineered plant variety that had been approved in one country and refused in the other, although the US had approved both more and a broader range of plant varieties as of 1998. Qualitative differences would be more evident if the transparency of decision making was increased.

[35] From their case studies of the regulation of carcinogens, Harrison and Hoberg (1994) conclude that when scientific uncertainty was high enough, regulators in different countries were able to adopt differing assessments of the degree of risk. This reduced the possibility that science might contribute to policy convergence--a conclusion that appears to hold true in this case as well.

[36] There are also minor differences in labelling policy, but these differences do not alter the narrow scope of labelling policy nor its dependence on the food safety assessment process. Canada's labelling policy is consistent for all novel foods, while the FDA's statement focuses on new plant varieties. In the US, the FDA has stated that the "consumer's desire to know" is not a relevant basis for labelling requirements, while Canadian policy makers have decided that religious dietary restrictions would be dealt with adequately without changes to federal labelling policy.

[37] Some might argue that the parallel decision to adopt regulatory frameworks, which the US first began in 1984 and Canada did in 1993, is really another example of policy convergence, perhaps through the mechanism of emulation. Bennett (1991). However, in interviews, Canadian state officials who participated in the development of the Canadian framework denied being influenced or inspired at all by the American framework. While both countries have frameworks and their intent and broad principles are similar, the style in which they were developed and their details differ significantly. See Chapter Two for more details.

Internationalization

Domestic factors do explain many of the similarities, differences, and much of the divergence revealed in comparing the policy choices of the two countries. Internationalization, however, does help to explain evidence of convergence. As Chapter Three has documented (see Tables 3-12, 3-14, and 3-16), convergence can be observed in the food safety and labelling cases, and to a lesser extent, in the case of environmental release. For example, the decision to create a formal regulatory regime for environmental release in Canada, moving from guidelines to regulations, appeared to echo the American policy response. This decision was arguably as much a reaction to internationalization pressures as domestic demands from environmental groups. Multinational firms and environmental groups both demanded certainty and transparency. Canada was also obliged by its international commitment at the Rio Summit to create a domestic regulatory regime for biotechnology and encouraged by the larger competitiveness agenda to attract the research activities of multinational firms by providing regulatory certainty.

On the issue of food safety, consistency and convergence can be observed initially on the measures of degree of regulation and flexibility / formality. The Canadian decision to issue guidelines in 1994, following a similar move in the US in 1992, resulted in the appearance of convergence. This convergence appears to be a result of the sensitivity of Canadian state officials and the food industry to trade patterns. It is also consistent with the traditional reliance of Canadian regulators on the findings of international institutions to assist in developing regulatory regimes. Details of the Canadian policy response emerged publicly only in 1994, after both the OECD and the FAO-WHO had issued their first reports on food safety assessment, and were consistent with these reports.

The case of labelling provides the clearest indication of convergence of the Canadian response to the American response on both the degree of regulation and the flexibility / formality of the policy response, given the similar narrow scope for the mandatory aspect of labelling. This result is consistent with a weak Canadian policy network vulnerable to the preferences created by internationalization, including trade dependence on the American market and a strong export orientation, generally.[38] It demonstrates that the impact of internationalization can be much stronger

[38] Within the Canadian policy network, regulators did make a more concerted effort to create democratic legitimacy through consultations on the labelling policy response than their American counterparts. At the same time, however, they consistently kept an eye on policy developments elsewhere, including Codex discussions on labelling.

in the absence of policy capacity, which is higher in the Canadian policy networks surrounding environmental release and food safety.

Although it provides some insight on the forces behind policy convergence, an exclusive reliance on internationalization variables to explain policy choices would leave much unexplained. As argued earlier, much of the impact of internationalization in this case study can be gauged only by investigating its effects on preferences and resources within a policy network. Thus, the ways in which domestic institutions mediate internationalization are an integral part of any explanation of domestic policy making. Otherwise, it is difficult to explain how countries react differently to similar internationalization pressures and to extract relevant lessons from those varying reactions.

ALTERNATIVE EXPLANATIONS

The utility of the theoretical framework applied in this dissertation can be assessed by a consideration of the less persuasive and partial accounts that contending explanations could provide. For example, a macro-level approach that focuses exclusively on variables at the national level might explain those findings which are relatively consistent between countries and across issues. However, this approach fails to explain sufficiently the variations observed across policy responses within a country. Variables that differ at the national level such as the adversarial nature of American politics compared to the consensual nature of Canadian politics, the differing international positions of the two countries, institutional structures, and the resources of key actors could help to explain differing aspects of policy making and policy choices. These differing aspects include the much lower level of discretion given to American regulators than Canadian regulators for the issues of environmental release and food safety; the greater reliance on international institutions by Canadian regulators which is consistent with the country's traditional investment in multilateralism, its greater integration into the international economy, and its status internationally as a middle power; the more adversarial use of science in the US; and finally, the greater strength of American plant biotechnology and food industries and the better-resourced American public interest groups which contribute to relatively more vulnerable state actors within pluralist policy networks. Macro-level analyses do not, however, help us understand differing responses *across issues within the same country*. A sectoral approach focusing on policy networks can.

The argument could also be made that policy responses in Canada and the US in the 1980s and 1990s to the commercialization of genetically-engineered plants were shaped primarily by the allocation of economic power. Large plant biotechnology and food processing firms often appeared to have substantial influence during policy making. This argument has some accuracy, but a more interesting and policy-relevant approach is to investigate how ideas and institutions facilitate or impede the exercise of economic power. As the dissertation has demonstrated, market-based ideas favour the involvement of the private sector in policy making by enhancing its authority and legitimacy and potentially weakening the influence of other actors. Contending ideas such as science and democracy and their programmatic variants may dilute economic power by increasing the authority and legitimacy of other actors, ultimately resulting in different policy choices. For example, science and democracy could both be used to promote the improvement of social regulation while mediating the effects of economic power.[39] Further, a reliance solely on economic explanations might obscure important ideational aspects of explanation such as the longstanding commitment of the state to technological innovation in agriculture, long before there were powerful economic interests in the agricultural industry that could demand such an investment. At the same time, an exclusive reliance on ideas for explanation would provide a partial account. Ideas can be powerful, but their influence is dependent on context. To understand how ideas can shape policy making, it is fruitful to examine how they work within policy networks to designate critical resources which in turn establish patterns of exchange.

Another contending explanation could be based on a rational choice model that focuses on actors pursuing self-interest. In this case, members of policy networks did pursue policy preferences they perceived as in their self-interest. However, a rational actor approach may ignore how environmental factors such as policy networks, policy legacies, and policy boundaries can shape policy preferences. For example, as Chapter Four demonstrated, the preferences of the consumer association in Canada are much easier to understand with a knowledge of dynamics within the policy network. The financial and technical dependency of the consumer association on better-resourced actors combined with the socializing effects of dominant ideas such as technological neoliberalism provides some insight into the basis for the preferences of key Canadian consumer representatives who appeared to be more biotechnology proponents than

[39] Social regulation may, of course, also be in the best interest of industry as when it provides a powerful competitive advantage.

skeptics, in contrast to their American counterparts. Further, the socialization of agricultural producer organizations within longstanding agricultural research policy networks contributed to a general enthusiasm for new agricultural technologies. This result helps to explain their relatively passive participation in biotechnology regulation policy making in both countries into the late 1990s, despite the high stakes for their members. A rational actor approach may also be weak in explaining policy choices when it fails to explore how environmental factors can place a premium on certain resources within policy networks which in turn can affect the success of actors in securing their preferences.

LESSONS AND FUTURE DIRECTIONS

In the late 1990s, the loss of export markets and growing consumer resistance at home suggested that Canadian and American policy makers had failed to anticipate fully the possible implications of the commercialization of genetically-engineered plants. They had developed regulatory responses that were precedent-setting in terms of establishing far more formal and systematic evaluations of environmental and food safety risks of new plant varieties. Those responses were not foolproof, however, when it came to guaranteeing consumer acceptance both at home and abroad. Policy choices have come under heavy public scrutiny and have been criticized as lacking scientific and democratic legitimacy.[40] These developments illustrate how hurdles may

[40] In the late twentieth century, many citizens developed greater interest in the manner in which commodities were produced and in the qualities of those products. This interest increased pressures for social regulation in the agri-food sector, based on a longer-term view of safety, a relatively low tolerance for risk, and a growing ethical component to food purchases. A prime example of the impact of this development is the rapidly growing organic food industry in the US and Canada. The industry grew about 20 per cent a year in the US through the 1990s, reaching annual sales of about $6-billion (US) by 1999. Further, genetic engineering appears to have played a key role in encouraging greater public scrutiny of agricultural research, resulting in the first serious and unexpected threat to the well-entrenched idea of "freedom to research". Over decades, the techniques of plant breeding had been continually improved, with wide crosses and mutagenesis among the latest additions, but never before had a new technique aroused public suspicion and been the specific focus of regulatory policy making. The resistance of researchers (as opposed to developer firms) to regulation can be seen in the responses to the USDA's initial proposals on regulation of the release of genetically-engineered plants. Following its 1986 proposal, the USDA received 68 comments from researchers and their institutions opposed to what they perceived as the regulation of their research. The USDA disagreed, stating that its regulations were not intended to regulate research because they did not interfere with what researchers did within confined laboratory facilities, but instead focused on environmental release and were intended to reduce the risk of plant pest problems. United States. Department of Agriculture (1987). Somewhat ironically, this new level of regulation was largely guaranteed by those researchers who initially drew public attention to the risks of working with rDNA organisms, during the lab safety debate. Krimsky argues that scientists expressed these concerns publicly because they felt it was important for scientists to regain the public's confidence and demonstrate that science could be conducted in a responsible fashion, in the context of rising skepticism in the early 1970s about the social utility of science and technology. Krimsky (1982), Chapter 24.

change over time for regulators, requiring adaptation and innovation rather than reliance on the status quo. In early 2000, the future of these crops was unclear with increasing numbers of proponents and skeptics lining up on both sides of the debate. The vigorous debate raises the issue of whether the massive investment already made in agricultural biotechnology has been premature or misdirected, thus wasting considerable financial and human resources. The subsequent question is whether policy makers have foreseen such a result and if so, why didn't they?

Policy capacity

Some American and Canadian policy makers may have anticipated that the road to commercialization would be rocky, but their ability to prepare for that possibility appears to have been constrained by inadequate policy capacity. As a result, this case study highlights the importance of adequate policy capacity to meet domestic *and* international policy hurdles. It sheds light on what may be necessary institutional conditions and resources for policy capacity in a context of internationalization. There is no simple recipe for policy capacity[41], but conclusions from this case study suggest that it rests substantially on three interrelated factors: first, *state capacity and autonomy*; second, *scientific legitimacy* which is achieved by the way in which science is used during policy making and is contingent on access to independent expertise that legitimizes the use of science;[42] and third, *democratic legitimacy* which is the capacity to conduct policy making in a manner that will be widely perceived as legitimate in a democratic sense should it come under public scrutiny. These last two procedural aspects of policy making contribute to policy capacity during policy development and to public confidence in the regulatory system. When science is highly contested and scientific legitimacy is jeopardized, a premium may be placed on democratic legitimacy instead. Ideally, however, these two forms of legitimacy should coexist, serving to complement and balance each other in terms of the authority they bestow. Democratic legitimacy provides a broad foundation for policy making, but scientific (or informational) legitimacy ensures that the best possible information base is available when political leadership must be exercised.

[41] Peters (1996) suggests that policy capacity exists when a government is able to make longer-term strategic policy choices that depart from the status quo if necessary, are proactive, and are well-coordinated with related policy activities. His discussion focuses on factors which constrain or contribute to policy capacity.

[42] A similar prescription can be made for cases that require additional or other types of expertise, when science is not a central element of policy making and policy choices.

Developments in the 1980s and 1990s, including fiscal restraint and a changing philosophy of regulation, have constrained state capacity and autonomy in Canada and the US.[43] Enthusiasm for the new public management, which has included shrinking the role of the state and increasing that of the private sector, may also be reducing the ability of state officials to provide effective and democratic political forums for debate of controversial issues.[44] The lack of an effective political forum can encourage marginalized interests to turn to the economic forum of the marketplace. For example, in the late 1990s, biotechnology skeptics appealed directly to consumer self-interest on issues such as food safety and encouraged boycotts. The increasing demands for labelling of genetically-engineered foods can be interpreted as a form of economic democracy, given the failings of the political forum to respond to societal concerns. Such tactics, if successful, hold the potential for serious economic damage should public confidence in the regulatory system be shaken. Trust in regulation is the foundation of social regulation; without it, regulatory efforts do not instil public confidence. The level of contestation of scientific authority and growing resistance to genetically-engineered food crops in North American in the 1990s suggests that Canadian and American regulators have achieved limited success in securing scientific and democratic legitimacy to bolster policy capacity. Their experiences suggest ways in which policy capacity can be strengthened.

STRENGTHENING POLICY CAPACITY

Scientific legitimacy

The success of policy makers in achieving scientific legitimacy depends on how science is used during policy making. Success occurs when the use of science maintains the authority of science. However, science should not be relied on exclusively during policy making because it may marginalize "non-scientific" aspects of a policy issue. Securing scientific legitimacy may be an increasingly difficult but more necessary objective for policy makers. In industrialized countries, the growth of scientific literacy and constant public exposure to the most recent scientific findings contribute to what some scholars term a "risk society" in which "we increasingly live on a

[43] For example, the tighter links drawn between regulation and competitiveness place new constraints on state capacity and autonomy. Hill (1998) argues that the focus on the links between regulation and competitiveness in the 1990s encouraged regulators to consider an "international division of labour" and to work toward mutual recognition and harmonization. Such achievements could help to meet the requirements of trade agreements and could result in administrative savings, although with the potential loss of some domestic sovereignty.

[44] Graham and Phillips (1997).

high technological frontier which absolutely no one completely understands and which generates a diversity of possible futures".[45] Skeptical and more scientifically-aware citizens contribute to the new hurdles for policy makers. Knowing that scientific "truths" can and often do change frequently, citizens expect regulators to access the fullest possible range of relevant scientific knowledge and to seek expertise from independent sources. Attempts to use scientific authority to sidestep the "political" aspects of regulatory issues are less likely to withstand scrutiny than in the past, depending on the nature of the policy network and the level of contestation during policy making. These challenges suggest possible strategies for regulators.

First, regulators should ensure they have access to what is and appears to be adequate independent scientific expertise and other requisite forms of expertise. Regulators may have to supplement in-house expertise with consultations of outside experts because those experts have more relevant expertise. Such consultations can be made more transparent. Regulators should provide thorough and accessible information on the sources of scientific expertise they rely on for policy choices and ongoing implementation. For example, when naming advisory committees, regulators should specify which individuals are on the committee; what personal interests they have in the issue(s) under consideration, if any; and on what basis they have been named to the committee (ie, what is their specific expertise or experience that makes them a valuable committee member). The rationale behind the composition of advisory committees should leave nothing to public speculation.

Further, regulators must strive to demonstrate that they have adequate in-house expertise and discretion to examine critically data provided from outside sources. This effort should avoid patterns of dependency that may restrict the ability to develop regulation in the public interest.[46] When the expertise on which regulation is based is largely within the private sector among firms that have an interest in regulatory outcomes, scientific legitimacy may be jeopardized since regulators are perceived to be, and may well be, dependent on the expertise of those they regulate. In this case study, the threat to scientific legitimacy from such a situation looms larger in the US than in Canada, because of the varying scientific strengths of the public and private sectors. Fiscal restraint and policy innovation in the 1990s in Canada, however, has led to declining scientific

[45] Giddens (1998).

[46] As Doern (1998): 42 suggests, when regulators have less relevant expertise available to them than those they regulate, the regulated have "an enormous political advantage". He suggests that the capacity for discretion is one counterweight that regulators could exercise.

resources within the AAFC Research Branch and within the Food Directorate of Health Canada. Scarce resources at the CFIA also threaten scientific legitimacy as regulators are forced to rely on outside expertise (although it will depend on where that expertise is located).

Scientific legitimacy can also be jeopardized, as it has been in the case studied here, when efforts are made to portray the policy making process as neutral because it has a scientific component for the purpose of avoiding discussion of political aspects. It has been observed before that attempts to use science to end a policy controversy are doomed to fail if conflicting political viewpoints are not also considered.[47] The growth of social regulation and the constant reference to cost-benefit, or risk-benefit, analyses makes it impossible for policy makers to convincingly deny that these regulatory decisions contain fundamental political elements.[48] Ironically, the more vociferous the claims of the neutrality of science in attempts to exclude or marginalize "political" elements of the debate, the more likely the authority of science is likely to be challenged because it becomes the focal point of debate. This development delegitimizes science as a source of authority. Canadian biotechnology skeptic Brewster Kneen's comment on the rhetorical uses of science illustrates how it becomes delegitimized:

> By making their distinction between "science" and "sound science", ... the users of the term "sound science" are, in effect, admitting the arbitrary, or culturally determined, character of scientific knowledge, and thereby destroying its claimed facticity. If there can be science and sound science, then there can also be blue science or green science. The social character of science is unavoidable.[49]

Reinforcing this argument, a representative of an American public interest group argues that the term "science-based" has become a "coded political football" in American politics that indicates the likely presence of differing political viewpoints.[50] She notes that she has never been challenged on the merits of her scientific arguments, but instead on her risk-benefit analyses; in other words, it is the political rather than the scientific aspects of her policy preferences that are scrutinized.

Science should not be used to exclude the economic, social, and ethical dimensions of a policy issue. Its use to sidestep other issues during policy making can be seen as an abdication of political leadership. Instead, before and during efforts to build a credible and adequate scientific

[47] Jasanoff (1990) 250 and Ozawa (1991). Salter argues that the effort is often made to separate scientific and economic aspects of policy making because of the difficulties of acknowledging the allocation of costs and benefits. Salter (1988): 168-169.
[48] Jasanoff (1990): 3, Brunk (1991), and Leiss (1994).
[49] Kneen (1992): 201.
[50] Personal interview, November 1998.

basis for regulation, the full range of political debate must be engaged. This debate should encompass varying interpretations of the potential costs and benefits of policy options and an acknowledgement of the degree of scientific uncertainty that exists and its implications for policy options. At the same time, regulators should create mechanisms that permit the effective use of science. This may mean establishing forums in which science can be negotiated and compromises can be reached.[51] Salter recommends that regulators use "scientific focus groups" with a limited mandate that includes commenting on what certainty scientific data does and does not provide.[52] This mandate would provide a credible scientific foundation for policy debate.

Democratic legitimacy

The changing hurdles for regulators seen in this case study include a component of democratic legitimacy.[53] Among citizens, there is increased risk aversion, more interest in how products are produced and their qualities, and more skepticism about whether policy making of recent decades is truly in the public interest. Policy choices are considered more legitimate when regulators can convincingly demonstrate that a broad debate has occurred that has included the participation of credible, representative organizations. Democratic legitimacy does not necessarily require massive public consultation, but makes narrow and closed consultative mechanisms inadequate.

Technology and democracy are sometimes treated as incompatible: it is impossible or difficult to make sound technical decisions in a democratic forum because expertise can not hold sway just as it is impossible or difficult to make technical decisions democratic because of the narrow nature of expertise.[54] Arguments have been made, however, about how the two can be reconciled.[55] Further, there are more general strategies that can be applied. Carroll and Carroll list criteria that provide legitimacy during policy making.[56] These criteria include repeated and

[51] Jasanoff (1990).
[52] Salter (1995).
[53] The growing importance of democratic legitimacy has been evident, for example, in reforms in environmental policy making, such as the use of multistakeholder consultations in Canada.
[54] Some argue that leaving decision making solely to technical or scientific experts will inevitably result in narrow decisions reflecting the interests and beliefs of those involved. There is some validity to this argument. For example, a survey of rDNA researchers found that two-thirds (65 per cent) opposed applying a socioeconomic criterion for regulation of genetic engineering and 59 per cent opposed the idea of incorporating socioeconomic criteria or values into research funding decisions. Rabino (1996).
[55] Sclove (1995).
[56] Carroll and Carroll (1999).

sustained interaction within a policy community; incorporating substantive expertise *and* the views of the general population; ensuring participants in policy making are perceived as representative and accountable; and that these participants are independent from the government.[57]

One strategy that policy makers could consider is the more productive use of legislatures on regulatory issues likely to generate controversy. In the case studied here, the Canadian and American legislatures did not provide a forum for a sustained debate on the commercialization of genetically-engineered products. During the 1980s and 1990s, there were a few ad hoc committee meetings in Canada. There were many more committee hearings in the US, but these hearings tended to be adversarial in nature. Witnesses were grilled by legislators on the latest controversial issue or carefully selected to make arguments backing preferred policy options on research funding, intellectual property rights, or other matters. As quickly as the interest developed in specific issues, it often disappeared.[58] Properly designed, legislative committee hearings could provide a transparent forum in which the full range of competing problem definitions of an issue could be aired from the earliest stages of policy making. They should not be restricted purely to a role of oversight after policy choices are made, as they often are now. These committees could periodically revisit policy responses to issues to evaluate the effectiveness and to continue to provide a forum for diverse viewpoints. The effective use of legislative committees would also complement or replace consultations conducted by state officials. These latter consultations have often been criticized as intentionally restrictive in the scope of participation and discussion.

Democratic legitimacy will not guarantee democratic outcomes, nor should it necessarily. In the form discussed here, it is a procedural characteristic of policy making and is not a substitute for accountable political leadership exercised when policy choices are made. That leadership should, however, be prefaced and surrounded by an ongoing democratic public discussion. The policy making process itself should be backed by rigorous measures that make both policy makers and other participants accountable for their contribution. These measures should include clear information on who was consulted during policy making, whom they represented, and what they

[57] The discussion of policy making in this case study has illustrated how it has fallen short in these areas including the lack of an effort to develop ongoing dialogue within the policy community. There have also been some problems with the independence of groups, in part because of the importance of scientific expertise as a resource within some policy networks and its uneven allocation.

[58] The late 1990s brought another surge of interest resulting in committee hearings.

said. The basis on which policy options were selected or discarded should be readily available.[59]

Innovative policy making: providing competitive advantage

Despite all the factors that would lead us to expect Canadian policy choices to be closely aligned with American policy choices, the case study has revealed some important and perhaps surprising differences and divergence in the details of regulation. In the cases of environmental release and food safety, Canadian regulators benefit from policy choices that provide much more capacity and potential autonomy than those enjoyed by American regulators. These policy choices, by providing greater discretion to regulators and thus the potential for greater rigour, may prove more robust over time in the arena of international trade than comparative American policy choices. They may provide a more secure route to market access and be better able to withstand scrutiny imposed by international trading rules and new international regimes such as that which may be created under the Biosafety Protocol. Properly exercised, the discretion given to Canadian regulators could also be more easily used to instil domestic public confidence in the regulatory regime.

This finding results in the conclusion that the country more exposed to the pressures of economic internationalization was able to provide more capacity to its regulators. It counters the impression that internationalization necessarily constrains the state. As Weiss has argued, the level of integration of a country into the world economy does not necessarily correlate inversely with the degree of state strength or capacity.[60] In fact, internationalization and state strength may be mutually reinforcing. Internationalization may allow state officials to exercise greater autonomy from domestic pressures; however, the ability to do so may well be contingent on the nature of the domestic institutions that mediate the effects of internationalization.

Differences in domestic institutions across countries may result in varying abilities to provide competitive advantage in the context of a global market. The findings of this case study suggest that *differences in the nature of policy networks* can be an important ingredient in allowing states to design policy choices that can withstand both domestic and international scrutiny and

[59] Regulatory documents sometimes do discuss briefly alternative policy options and why they were or were not selected, but more detailed explanations should be consistently provided

[60] Weiss (1998).

contribute to competitiveness.[61] In Canada, these differences in the cases of environmental release and food safety stemmed in part from a wealth of in-house and public sector expertise in agricultural research and regulation and the tradition of food safety regulators of supplementing their expertise with the recommendations of relatively credible scientific international institutions. These differences were largely the result of policy legacies. Developments in the 1980s and 1990s, however, appear to have eroded expertise within Canadian regulatory agencies with the ultimate effect of making Canadian policy networks more similar to their American counterparts.[62] Canadian policy makers allow these distinctive differences in the allocation of scientific expertise to slip away at the cost of state capacity and autonomy, policy capacity, and ultimately the ability to make policy choices in the public interest.

Pursuing innovation in the public interest

This case study has demonstrated how varying levels of policy capacity within the policy networks surrounding the commercialization of genetically-engineered crops have resulted in differing policy choices. Both scientific and democratic legitimacy may be important in allowing policy makers to create innovative and adaptive policies that will provide competitive advantage and meet domestic expectations. Scientific legitimacy can contribute to state capacity and autonomy. Properly implemented, democratic legitimacy can contribute to autonomy in an accountable manner. Their importance in this policy area was highlighted by developments in the late 1990s. For example, the Canadian federal government established a new advisory committee on biotechnology designed to increase scientific legitimacy and democratic legitimacy through its expert membership and its wide mandate. Health Canada also established an expert food biotechnology committee to bolster scientific legitimacy.[63] However, in both of these cases, state officials could have provided a more thorough justification of the composition of these advisory committees. In the US, the USDA is attempting to bolster scientific legitimacy with an

[61] This dissertation takes a broad view of competitiveness, considering that it can be a result of, for example, the long-term sustainability of an industry, the quality or safety of its products, as well as the selling price.
[62] However, the February 2000 federal budget allocated $90-million (Cdn) in new spending for biotechnology regulation over three years, with $46-million going to Health Canada.
[63] The Canadian Food Inspection Agency (CFIA) has also bolstered its scientific resources indirectly through its co-sponsorship of the creation in January 2000 of a Canadian Institute for Food Inspection and Regulation at the University of Guelph through a three-year agreement. The new institute will have a regulatory research program and CFIA president Ron Doering was quoted in press release saying that institute will "help [the CFIA] keep pace with new technological and scientific advancements."

independent scientific review of its policy and democratic legitimacy through the creation of a broad-based advisory committee (much broader than the Canadian counterpart) to enhance democratic legitimacy.[64] The FDA turned instead to a set of three public meetings in 1999 to increase democratic legitimacy.

In Canada, policy makers fared better than their American counterparts in preserving elements of scientific legitimacy during policy development in the 1980s and 1990s. This success came largely as a result of the location of the dominant sources of available scientific expertise (whether in-house, public or from international institutions) and because of the lack of resources and opportunities among those who might contest scientific authority. However, there is no guarantee that these conditions will continue; the absence of intentional efforts by Canadian policy makers to maintain and improve scientific legitimacy may result in a more adversarial context for the use of science. Scientific legitimacy has been much more vulnerable in the American context. Higher levels of contestation have correlated with more formal responses and, as a result, less potential for scientific flexibility. For example, the issue with the highest contestation, the American response to environmental release, resulted in the most formal response.[65] This vulnerability is also reflected in the extent to which policy choices vary in being "science-based".[66]

The responses for environmental release and food safety varied in the degree of scientific flexibility (through discretion) given to regulators. The degree of flexibility affects the ability to adapt the policy response to accommodate the accumulation of scientific knowledge and to deal appropriately with the level of risk. Specifically, the Canadian response to environmental release has been the most science-based due to the wide discretion given to regulators. It is followed by the Canadian response to food safety, which has given some discretion to regulators although in a more circumscribed manner than in the case of environmental release. The American food safety response was relatively science-based in that its scientific guidance component was intended to be risk-based. Its scientific legitimacy, however, was weakened by the FDA's declaration that genetic

[64] The USDA's Advisory Committee on Agricultural Biotechnology, created in 1999, consists of twenty-five members that include representatives of government, academia, production agriculture, agribusiness, ethicists, environmental and consumer groups and has the mandate to explore a broad range of issues.

[65] One exception might be the American response to food safety which was relatively informal throughout the 1990s; however, increased contestation in the late 1990s led some representatives of the food industry to call on the FDA to switch from voluntary to mandatory consultations.

[66] This argument is based in part on the evaluations of members of the policy community, gathered during personal interviews.

engineering did not pose different risks than conventionally-produced counterparts. Finally, the American response to environmental release is widely considered among members of the policy communities as the least science-based because the ability of regulators to apply science is greatly limited by the detailed criteria governing the depth of oversight. Regulators lack flexibility to adjust quickly to new scientific data. The policy response is illogical in its scope from a scientific perspective in terms of its risk assessment mandate; the scope of regulation covers only those plants which are genetically-engineered *and* are believed to pose a plant pest risk. It exempts some genetically-engineered plants (such as those produced without the use of a vector and instead through mechanical means) and plants with novel traits similar to those being reviewed but not produced through genetic engineering. The regulatory regime thus may exclude from review new plant varieties that pose worrisome risks. It is the most process-based of the four cases, which counters the endorsement of an exclusively product-based approach by a plurality of scientists.[67]

The failure to incorporate adequate scientific and democratic legitimacy during policy making can carry high costs. In this case study, both countries have had mixed results on democratic legitimacy. Consultations have occurred, but often with limits on the scope of discussion and on the range of participants, and never in a sustained fashion. The appropriate use of new communication technologies should make it easier for policy makers to create conditions for early and ongoing democratic debates. If the procedural elements of policy making fail to stand up under scrutiny, the credibility of the regulatory system as well as that of specific policy choices can be damaged or destroyed. Less dramatically, but also important, the adversarial use of science (which in turn delegitimizes scientific authority) can impose significant costs that affect credibility, including long-running political battles which swallow up time and resources, and may result in inconsistent policy making.[68]

If challenges for policy makers are increasing, is it realistic to hope for regulation in the public interest? At least one observer of regulatory politics is pessimistic that policy making can pursue and create a consensual public interest in an American context heavily imbued with individualism:

> Faith, belief, confidence, even authority, the basis for persisting societal

[67] A 1995 American survey of 1257 researchers working with rDNA organisms found that 11 per cent supported process-based regulation, 42 per cent favoured product-based regulation, and 38 per cent favoured regulation that incorporates both approaches. Rabino (1996).

[68] Ozawa (1991).

> agreements, seem no longer to exist. Quaint ideas of the past, these ideas have become relics locked in past times. In late twentieth-century regulatory questions, only individuals have the right to decide. And in every case, each individual as purchaser and modern citizen, each interest group as advocate, and each governmental unit as regulator always knows for certain the correct action that must be taken.[69]

Such pessimism is not, however, sufficient grounds for not making an effort. Ensuring that policy makers are able to engage in a more deliberative form of policy making yet remain accountable is in the long-term interest of every citizen. Early and periodic democratic forums for debate to fully air issues will provide policy makers with a more complete perspective on the scope of an issue.[70] The goal should be to establish the range of questions that should be asked and answered on the public's behalf during policy making, such as which criteria of social utility regulation should be incorporated. These questions will help what types of expertise will be needed during policy making. Policy makers should evaluate the contributions of policy legacies and boundaries for both strengths and weaknesses in a conscious manner rather than a default mode, particular in situations where more challenging hurdles for policy makers are likely to arise. In the absence of a clear consensual definition of the public interest within a policy community or network, policy makers must take responsibility and exercise political leadership. Adequate policy capacity should allow policy makers to balance the short-term orientation of democratic government with a longer-term perspective. It should produce sustainable policy responses that can achieve multiple policy goals such as competitiveness, food safety, and environmental protection. These high standards for policy making also require that citizens and their representatives (elected and interest groups) take on more responsibility.

The policy prescriptions that emerge from the findings of this case study echo arguments made by Coote about planning for uncertainty in a risk society:

> ...public policy requires long-term planning for uncertainty, within a clear framework of principles and evidence to support devolved and flexible decision-making. This in turn requires the involvement of informed and active citizens, enjoying a mature, adult-to-adult relationship both with experts and with politicians. A high-trust democracy: the only way to face a risky future.[71]

[69] Marcus (1994): 159.

[70] This point was made by a representative of the Consumers' Association of Canada in reference to the constant tendency of policy makers to consult late in the policy development process: "We are, quite frankly, getting tired of being asked to provide 'the consumer view' after the report has been drafted. More importantly, if consumers weren't involved from the beginning, how do you know you asked all the questions that needed to be asked." Consumers' Association of Canada (1997): 7.

[71] Coote (1998): 131.

For Coote, this "adult-to-adult" relationship among citizens, policy makers, experts is founded on mutual respect for each other's knowledge and experience, interaction and acknowledgement of interdependence. It builds trust on a foundation of "informed understanding".

The future of agricultural biotechnology

Returning to the case of agricultural biotechnology, weak policy capacity has contributed to uncertainty in the late 1990s and into the new century about its future.[72] In the years ahead, will the pursuit of genetic engineering in agriculture be seen as another example of human predilection for tunnel vision in the form of the fervent embrace of a single technology as a magic bullet? Will we regret having invested so much as a society in this technology at the expense of other lower-cost, more effective technologies?[73] What contribution will genetic engineering make to sustainable economic activity growth? Will it contribute to the reduction of world hunger, less environmentally-damaging agricultural practices, or increased food safety? Will advocates of biotechnology argue that the failure to innovate more boldly resulted in its own risks of lost opportunities? That a precautionary approach has stalled the pursuit of the innovation necessary to maintain the status quo in agriculture in terms of yields in the face of challenges such as disease resistance?

Questions of this nature should be debated openly *before* policy choices are made and periodically afterwards. Benefits should be scrutinized as extensively as risks and costs to assess the potential for pursuing social utility. Why shouldn't policy makers raise the bar for genetic engineering? Why should its products only have to be as safe as, or as productive as, conventional

[72] In 1999 and 2000, Canadian and American agri-food firms and agricultural producers were adopting defensive strategies toward genetically-engineered crops. In the fall of 1999, the Canadian Wheat Board declared that no genetically-engineered varieties of wheat should be registered for commercial production in Canada until they have achieved full commercial acceptance in all of their potential markets, or until there were cost-effective segregation technologies. In early 2000, there were signs that sales of genetically-engineered seed would be lower than in 1999. Further, new rules announced in 1999 and 2000 for the cultivation of Bt crops created additional concern about the wisdom of planting these crops. For example, rules created by the US Environmental Protection Agency require producers to plant refuges of non-Bt corn of 20 to 50 per cent of total corn acreage and, forbid them from spraying these refuges with insecticides unless it is demonstrated that pests exceed a set level. See http://www.epa.gov/pesticides/biopesticides. Ideally, policy choices should help to avoid these types of developments that can result in losses for developers and users and encourage the growth of consumer skepticism.

[73] Buttel (1993), for example, suggests that the hype surrounding biotechnology has been excessive. He suggests that rather than a revolutionary technology, genetic engineering will instead have the status of a "substitution technology", used to fix the problems created by chemical agriculture.

varieties? If the technology is so promising in terms of new benefits, why do regulations only require that genetically-engineered plants be equivalent to conventional counterparts in characteristics such as environmental impact and food safety? It is not unprecedented to incorporate criteria of social utility in regulation. The rigorous standards of plant variety registration in Canada, for example, resulted in high quality varieties for cultivation in the Canadian climate and contributed to Canada's excellent reputation overseas as a commodity producer.[74] Benefits accrued to producers, consumers, and the larger agri-food industry.

There is no obvious need to speed commercialization of the products of genetic engineering chiefly to allow industry to recoup its investment and please its shareholders or to provide innovative products.[75] If the development and application of genetic engineering indeed holds the promise its proponents proclaim, there will be solid reasons for public investment for the most socially useful applications even in the absence of private investment. Such public investments should be designed to ensure that this potentially powerful technology will be harnessed in the service of the public interest and with the consent of society, rather than despite its ignorance. Democratic debate about the costs, benefits, and risks may provide an adequate consensus for the manner in which genetic engineering should be pursued, and deliberative policy making could provide a solid and purposeful foundation for commercialization.

[74] The rigorous standards of variety registration have been diluted somewhat in the 1980s and 1990s, consistent with the general direction of policy innovation in agricultural research in Canada at the federal level.

[75] Conventional breeding practices continue to produce improved varieties of plants and animals, without the use of genetic engineering, and will as long as they are adequately funded.

TABLE 7-1
Policy choices compared with stated and objective preferences, assessment of potential resources from policy choices

	PROPONENTS			
	Developers (large)	Developer (small)	Users	Users
	(eg., Monsanto)	(eg., public sector plant breeders)	(producers)	(food industry)
GOALS	P-ERA			
	P-HMZN (ER, FS)		P-HMZN (ER, FS)	P-HMZN (FS, L)
			P-CMP	P-CMP
	P-FSA		P-FSA	P-FSA
	P-PC	P-PC	P-PC	P-PC
	P-MML	P-MML	P-MML	P-MML
MEANS	P/R-SBRISK	P/R-SBRISK	P-SBRISK	P/R-SBRISK
	P-SQ	P-SQ		P-SQ
TOTAL	7P, 1R	4P, 1R	6P	7P, 1R
	STATE OFFICIALS	**STATE OFFICIALS**	**SKEPTICS**	
GOALS			P/R-ERA	
	P/R-HMZN (ER, FS, L)	P/R-HMZN (ER, FS, L)	R-HMZN (depends on content)	
	P-CMP			
			P/R-FSA	
	P-PC			
MEANS	P/R-SBRISK			
	P/R-SQ			
TOTAL	5P, 3R		2P, 2-3R	
	ABBREVIATIONS			
	CMP=COMPETITIVENESS			
	ERA=ENVIRONMENTAL RISK ASSESSMENT			
	FSA=FOOD SAFETY ASSESSMENT			
	HMZN=HARMONIZATION			
	MML=MINIMAL MANDATORY LABELLING			
	PC=PUBLIC CONFIDENCE			
	SBRISK=SCIENCE-BASED RISK ASSESSMENT			
	SQ=STATUS QUO INSTITUTIONAL AND LEGISLATIVE ARRANGEMENTS			
	P=PREFERENCE			
	R=RESOURCE			

TABLE 7-2
Policy choices, state capacity, and policy networks
Canada and the United States

CANADA

	Policy choices	Policy network
ENVIRONMENTAL RELEASE	High discretion Mandatory	State-directed ->Concertation
FOOD SAFETY	Moderate discretion Mandatory (since Oct. 99)	Weak concertation
LABELLING	Low discretion Mandatory	Pressure pluralist

UNITED STATES

	Policy choices	Policy network
ENVIRONMENTAL RELEASE	Low discretion Mandatory	Concertation ->Clientele pluralist
FOOD SAFETY	No discretion (discretion with industry) Voluntary	Clientele pluralist
LABELLING	Low discretion Mandatory	Pressure pluralist

TABLE 7-3
Science and policy networks, environmental release and food safety Canada and the United States

	SCIENCE		
	CONTESTATION*	LOCATION OF EXPERTISE	POLICY NETWORK
ENVIRONMENTAL RELEASE			
CANADA	neutral (1) -> neutral / contested (3)	centralized, public (federal)	state-directed -> concertation
US	moderately contested (4) -> highly contested (5)	decentralized, public-private	concertation -> clientele pluralist
FOOD SAFETY			
CANADA	neutral (1) -> neutral / contested (2)	decentralized, industry, academia (domestic and foreign)	weak concertation
US	neutral (1) -> moderately contested (4)	decentralized, industry, academia (domestic)	clientele pluralist

*Characterization of science ranges from neutral (1) to highly contested (5), see Table 5-5

TABLE 7-4
Policy legacies and policy networks

	POLICY LEGACIES: EFFECT ON CAPACITY AND AUTONOMY		
	CAPACITY	POTENTIAL AUTONOMY	POLICY NETWORKS
ENVIRONMENTAL RELEASE			
CANADA	high	high	state-directed -> concertation
US	low-moderate	low	concertation -> clientele pluralism
FOOD SAFETY			
CANADA	low	low-moderate	concertation (weak)
US	low	low	clientele pluralism
LABELLING			
CANADA	low	low	pressure pluralism
US	low	low	pressure pluralism

TABLE 7-5
Ideas and policy networks

ENVIRONMENTAL RELEASE

	CANADA	UNITED STATES
POLICY LEGACIES		
Ideas	Science	Market / science
Resources	Scientific expertise	Private, economic power / scientific expertise
Patterns	Independent state officials	Semi-dependent state officials
	Dependent producers	Dependent producers
	Cooperative developers	Semi-cooperative developers
Policy network	State-directed	Concertation
POLICY BOUNDARIES		
Lab safety guidelines		
Ideas	Science	Science
Resources	Scientific expertise	Scientific expertise
Patterns	Independent researchers	Independent researchers
	Independent regulators	Semi-dependent regulators
	Minimal industry	Growing industry
Policy network	State-directed	Concertation
Regulatory frameworks (technological neoliberalism)		
Ideas	Market	Market
Resources	Private, economic power	Private, economic power
Patterns	More influence to developers	More influence to developers
	Semi-dependent regulators	Dependent regulators
Policy network	-> Concertation	-> Clientele pluralist
SCIENCE		
Contestation	Low -> Moderate	Moderate -> High
Allocation	Centralized	Decentralized
	Public (decline), private (growth)	Private (growth), public
Resources	Scientific expertise -> democratic legitimacy	Private economic power and democratic legitimacy, importance of scientific expertise minimal
Patterns	Relatively independent regulators	Dependent regulators
	Cooperative developers	Powerful developers (economic, technical)
	Moderate challenge from public interest groups	Significant challenge from public interest groups (NEPA)
Policy network	-> Concertation	-> Clientele pluralist
INTERNATIONALIZATION		
Resources	OECD -> state, proponents	OECD -> state, proponents
	Biosafety Protocol -> skeptics	Biosafety Protocol -> skeptics
Constraints	Rio Summit	None
Policy network	-> Concertation	-> Clientele pluralist

CORRELATIONS FOR TRANSFORMATION OF NETWORKS

Policy boundary of regulatory framework and contestation of science transform policy networks in both countries.

FOOD SAFETY

	CANADA	UNITED STATES
POLICY LEGACIES		
Ideas	Market / science	Market / science
Resources	Private, economic power scientific expertise	Private, economic power scientific expertise
Patterns	Dependent regulators (on mix of international, foreign domestic sources of expertise)	Dependent regulators (on domestic expertise)
	Cooperative industry	Cooperative industry
	Marginal public interest groups	History of challenge from public interest groups
Policy network	Weak concertation	Clientele pluralist
POLICY BOUNDARIES		
Lab safety guidelines		
Ideas	Science	Science
Resources	Scientific expertise	Scientific expertise
Patterns	Independent researchers	Independent researchers
	Dependent regulators	Dependent regulators
	Minimal industry	Growing industry
Policy network	Weak concertation	Clientele pluralist
Regulatory frameworks (technological neoliberalism)		
Ideas	Market	Market
Resources	Private, economic power	Private, economic power
Patterns	More influence to developers	More influence to developers
	Dependent regulators	Dependent regulators
Policy network	Weak concertation	Clientele pluralist
SCIENCE		
Contestation	Low	Low -> Moderate
Allocation	Decentralized	Decentralized
	Private, international, public	Private, public
Resources	Scientific expertise	Scientific expertise -> democratic legitimacy
Patterns	Dependent regulators	Dependent regulators
	Independent industry	Independent industry
	Minimal challenge from public interest groups	Moderate challenge from public interest groups
Policy network	Weak concertation	Clientele pluralist
INTERNATIONALIZATION		
Resources	OECD, FAO-WHO relied on by state for guidance, capacity ->proponents	OECD, FAO-WHO used by state to justify policy choices ->proponents
	Codex -> skeptics	Codex -> skeptics
Constraints	None	None
Policy network	Weak concertation	Clientele pluralist

CORRELATIONS FOR TRANSFORMATION OF NETWORKS

None

LABELLING

	CANADA	UNITED STATES
POLICY LEGACIES		
Ideas	Market	Market
Resources	Private, economic power	Private, economic power
Patterns	Dependent regulators	Dependent regulators
	Independent industry	Independent industry
	Episodic consumer challenge	Episodic consumer challenge
Policy network	Pressure pluralist	Pressure pluralist
POLICY BOUNDARIES		
Lab safety guidelines		
Ideas	Science	Science
Resources	Scientific expertise	Scientific expertise
Patterns	Independent researchers	Independent researchers
	Dependent regulators	Dependent regulators
Policy network	Pressure pluralist	Pressure pluralist
Regulatory frameworks (technological neoliberalism)		
Ideas	Market	Market
Resources	Private, economic power	Private, economic power
Patterns	More influence to industry	More influence to industry
	Dependent regulators	Dependent regulators
Policy network	Pressure pluralist	Pressure pluralist
SCIENCE (not applicable beyond links to food safety assessment)		
INTERNATIONALIZATION		
Resources	Codex -> skeptics (polarization)	Codex -> skeptics (polarization)
	OECD, FAO-WHO (food safety) -> state, proponents	OECD, FAO-WHO (food safety) -> state, proponents
Constraints	None	None
Policy network	Pressure pluralist	Pressure pluralist

CORRELATIONS FOR TRANSFORMATION OF NETWORKS

None

BIBLIOGRAPHY

Adler, Emanuel and Peter M. Haas (1992). "Conclusion: Epistemic Communities, World Order, and the Creation of a Reflective Research Program." *International Organization* 46: 367-390.

Ahearn, Mary, Jet Yee, et al. (1998). *Agricultural Productivity in the United States*. Washington: United States Department of Agriculture. Economic Research Service.

Alexander, Martin (1985). "Spread of Organisms with Novel Genotypes", *Biotechnology and the Environment: Risk & Regulation*. A. H. Teich, M. A. Levin and J. H. Pace, Eds. Washington, American Association for the Advancement of Science: 115-136.

Allaby, Michael, Ed. (1992). *The Concise Oxford Dictionary of Botany*. New York: Oxford University Press.

Althouse, Vic (No date). Briefing Notes on C-107, An Act respecting plant breeders' rights.

Angus, Ian (1997). *A Border Within: National Identity, Cultural Plurality, and Wilderness*. Montreal & Kingston: McGill-Queen's University Press.

Anstey, T.H. (1986). *One Hundred Harvests: Research Branch, Agriculture Canada, 1886-1986*. Ottawa: Minister of Supply and Services Canada.

Ashford, Douglas E., Ed. (1992). *History and Context in Comparative Public Policy*. Pittsburgh: University of Pittsburgh Press.

Atkinson, Michael and William Coleman (1989). "Strong States and Weak States: Sectoral Policy Networks in Advanced Capitalist Economies." *British Journal of Political Science* 19: 47-67.

Atkinson, Michael M. and William D. Coleman (1996). "Policy Networks, Policy Communities, and the Problems of Governance", *Policy Studies in Canada: The State of the Art*. L. Dobuzinskis, M. Howlett and D. Laycock, Eds. Toronto, University of Toronto Press: 193-218.

Auer, L (1971). *Measuring the Social and Economic Benefits of Publicly Supported Agricultural Research*. 1971 Symposia on Agricultural Research, Sponsored by the Department of Agricultural Economics, University of Manitoba with the support and co-operation of the Canada Department of Agriculture.

Bajak, Frank (1999a, February 22). *Gene-Modified Food Talks Stalled*. [America Online news service: The Associated Press].

Bajak, Frank (1999b, February 24). *Biogenetic Treaty Plan Scuttled*. [America Online news service: The Associated Press].

Baker, Beth (1994). "Streamlining of biotech regulations pleases industry". *BioScience*. 44: 527.

Banting, Keith G. (1996). "Social Policy", *Border Crossings: The Internationalization of Canadian Public Policy*. G. B. Doern, L. A. Pal and B. W. Tomlin, Eds. Toronto, Oxford University Press: 27-54.

Banting, Keith, George Hoberg, et al., Eds. (1997). *Degrees of Freedom: Canada and the United States in a Changing World*. Montreal & Kingston: McGill-Queen's University Press.

Bastian, Kevin (1990). "Biotechnology and the United States Department of Agriculture: Problems of Regulation in a Promotional Agency." *Ecology Law Quarterly* 17: 413-446.

Bauer, Martin, Ed. (1995). *Resistance to new technology*. Cambridge: Cambridge University Press.

Baumgartner, Frank R. and Bryan D. Jones (1991). "Agenda Dynamics and Policy Subsystems." *Journal of Politics* 53 (4): 1044-1074.

Bennett, Colin J. (1991). "Review Article: What is Policy Convergence and What Causes it?" *British Journal of Political Science* 21: 215-233.

Bennett, Colin (1992). *Regulating Privacy: Data Protection and Public Policy in Europe and the United States*. Ithaca: Cornell University Press.

Benson, Susan, Mark Arax, et al. (1997). "A Growing Concern". *Mother Jones*, January - February: 36-68.

Berger, Suzanne (1996). "Introduction", *National Diversity and Global Capitalism*. S. Berger and R. Dore, Eds. Ithaca, Cornell University Press: 1-25.

BIOTECanada (1998). *Formal Submission to the Canadian Biotechnology Strategy Sectoral Consultation for Agriculture*. [Online]. Available at: http://www.biotech.ca/ [1998, December 14].

Black, Debra (1998). "Frankenfoods?". *The Toronto Star*, September 2: F1.

Bloch, Carolyn (1986). *Plant Agriculture: Federal Biotechnology Activities*. Park Ridge: Noyes Publications.

Boardman, Robert (1992). "The Multilateral Dimension: Canada in the International System", *Canadian Environmental Policy: Ecosystems, Politics, and Process*. R. Boardman, Ed. Toronto, Oxford University Press: 224-245.

Boyce Thompson Institute for Plant Research (1987). *Regulatory Considerations: Genetically-Engineered Plants, Summary of a Workshop Held at Boyce Thompson Institute for Plant Research at Cornell University*, Center for Science Information.

Bradford, Neil (1998). *Commissioning Ideas: Canadian National Policy Innovation in Comparative Perspective*. Toronto: Oxford University Press.

Brickman, Ronald, Sheila Jasanoff, et al. (1985). *Controlling Chemicals: The Politics of Regulation in Europe and the United States*. Ithaca: Cornell University Press.

Briere, Karen (1998). "North Americans not riled by modified food". *The Western Producer*. (Saskatoon), November 26: 17.

Brooks, H.G. and W.H. Furtan (1984). "An Analysis of Public Agricultural Research in the Canadian Prairie Provinces." *Canadian Journal of Agricultural Economics* 32: 355-375.

Browne, William P. (1987). "An Emerging Opposition? Agricultural Interests and Federal Research Policy", *Public Policy and Agricultural Technology: Adversity Despite Achievement*. D. F. Hadwiger and W. P. Browne, Eds. Hong Kong, Policy Studies Organization: 81-90.

Browne, William P. (1988). *Private Interests, Public Policy, and American Agriculture*. Lawrence: University Press of Kansas.

Browne, William P. (1995). *Cultivating Congress: Constituents, Issues, and Interests in Agricultural*

Policymaking. Lawrence: University Press of Kansas.

Browne, William P. and Allan J. Cigler, Eds. (1990). *U.S. Agricultural Groups: Institutional Profiles*. New York: Greenwood Press.

Brunk, Conrad G., Lawrence Haworth, et al. (1991). *Value Assumptions in Risk Assessment: A Case Study of the Alachlor Controversy*. Waterloo: Wilfrid Laurier University Press.

Bull, Alan T., Geoffrey Holt, et al. (1982). *Biotechnology: International Trends and Perspectives*. Paris: Organisation for Economic Co-operation and Development.

Bureau of National Affairs (1989). *U.S. Biotechnology: A Legislative and Regulatory Roadmap*. Washington, D.C.: Bureau of National Affairs, Inc.

Burkholz, Herbert (1994). *The FDA Follies*. New York: BasicBooks.

Busch, Lawrence and William B. Lacy (1983). *Science, Agriculture, and the Politics of Research*. Boulder: Westview Press.

Busch, Lawrence, William B. Lacy, et al. (1991). *Plants, Power, and Profit: Social, Economic, and Ethical Consequences of the New Biotechnologies*. Cambridge: Basil Blackwell.

Buttel, Frederick H. (1993). "Ideology and Agricultural Technology in the Late Twentieth Century: Biotechnology as Symbol and Substance." *Agriculture and Human Values* 10 (2): 5-15.

Button, Tom (1998). "Mixed messages on Bt planting protocols". *Farm & Country*, October 19: 18-20.

Campbell, Ken (1998). *Current R&D Organization and Funding Levels*. Winnipeg: Canada Grains Council Conference: Research & Development, Proceedings.

Canada (1993). *News Release: Federal Government Agrees on New Regulatory Framework for Biotechnology*. Ottawa.

Canada (1994a). *Technical Workshop on the Labelling of Novel Foods Derived Through Genetic Engineering: Background Paper*. Ottawa.

Canada (1994b). *Technical Workshop on the Labelling of Novel Foods Derived Through Genetic Engineering: Proceedings*. Ottawa.

Canada (1996). *Science and Technology for the New Century: Summary*. Ottawa: Minister of Supply and Services Canada.

Canada. Agriculture and Agri-Food Canada (1995a). *BioInfo: Biofertilizers*. Ottawa.

Canada. Agriculture and Agri-Food Canada (1995b). *BioInfo: Biotechnology, Agriculture and Regulation*. Ottawa.

Canada. Agriculture and Agri-Food Canada (1995c). *BioInfo: Food Derived From Biotechnology*. Ottawa.

Canada. Agriculture and Agri-Food Canada (1995d). *BioInfo: Legislation and Agricultural Products*. Ottawa.

Canada. Agriculture and Agri-Food Canada (1995e). *BioInfo: Livestock Feeds*. Ottawa.

Canada. Agriculture and Agri-Food Canada (1995f). *BioInfo: Plants With Novel Traits.* Ottawa.

Canada. Agriculture and Agri-Food Canada (1995g). *BioInfo: The Safety-Based Approach to Regulation of Agricultural Products.* Ottawa.

Canada. Agriculture and Agri-Food Canada (1995h). *BioInfo: Veterinary Biologics.* Ottawa.

Canada. Agriculture and Agri-Food Canada (1995i). *Branching Out: Special Matching Investment Initiative Issue.* Ottawa.

Canada. Agriculture and Agri-Food Canada (1995j). *Research Branch, Business Plan 1995-2000.* Ottawa: Minister of Supply and Services Canada.

Canada. Agriculture and Agri-Food Canada (1995k). *Securing our future in agriculture and agri-food.* Ottawa.

Canada. Agriculture and Agri-Food Canada (1996a). *Agriculture and Agri-Food Canada's Action Plan: Science & Technology for the New Century.* [Online]. Available at: http://www.agr.ca/research/scitech/s%26t=e.html [1998, January 23].

Canada. Agriculture and Agri-Food Canada (1996b). *The History of Plant Biotechnology Regulation in AAFC.* Ottawa.

Canada. Agriculture and Agri-Food Canada (1997a). *News Release: Agri-Food Research Pays Big Dividends For Canadians, Canadian Economy.* [Online]. Available at: http://www.agr.ca/cb/news/n71217ae.html [1998, January 1].

Canada. Agriculture and Agri-Food Canada (1997b). *The Canadian Food and Beverage Processing Sector.* [Online]. Available at: http://aceis.agr.ca/food/markets/e_analysis97/titlepage.html [1999, April 8].

Canada. Agriculture and Agri-Food Canada (undated). *Biotechnology in Agriculture and Agri-Food Canada.* Ottawa.

Canada. Agriculture Canada (undated). *Biotechnology in Agriculture: Science For Better Living.* Ottawa.

Canada. Agriculture and Agri-Food Canada (undated). *Field Trials and Registered Products of Biotechnology Under Agriculture and Agri-Food Canada's Acts.* Ottawa.

Canada. Agriculture and Agri-Food Canada (undated). *General Questions and Answers on Biotechnology.* Ottawa.

Canada. Agriculture and Agri-Food Canada (undated). *Glossary of Terms.* Ottawa.

Canada. Agriculture and Agri-Food Canada (undated). *Make it happen with the Matching Investment Initiative.* Ottawa.

Canada. Agriculture and Agri-Food Canada (undated). *Questions and Answers on Agriculture and Agri-Food Canada's Acts and Regulations.* Ottawa.

Canada. Agriculture and Agri-Food Canada, Health Canada, and Environment Canada, (1993). *Workshop on Regulating Agricultural Products of Biotechnology,* Ottawa.

Canada. Agriculture and Agri-Food Canada. Biotechnology Strategies and Coordination Office (1995, December 1). *Labelling of Novel Foods Derived Through Genetic Engineering.* [Online]. Available at: http://www.agr.ca/fpi/agbiotec/commarea/foodinsp/engcomm.html [1997, September 10].

Canada. Agriculture and Agri-Food Canada. Committee on Biotechnology Regulation (1993). *Regulation of Agricultural Products of Biotechnology.* Ottawa: Agriculture and Agri-Food Canada. Biotechnology Strategies and Coordination Office.

Canada. Agriculture and Agri-Food Canada. Food Production and Inspection Branch. Plant Industry Directorate (1994a). *Field Testing Genetically Modified Plants in Canada.* Ottawa.

Canada. Agriculture and Agri-Food Canada. Food Production and Inspection Branch. Plant Industry Directorate (1994b). *Regulatory Proposal: Assessment Criteria for Determining Environmental Safety of Genetically Modified Plants.* Nepean.

Canada. Agriculture Canada (1993). *Workshop on Food Biotechnology: An information session to increase awareness of food biotechnology within Agriculture Canada.* Ottawa.

Canada. Agriculture Canada (undated). *Biotechnology in Agriculture: Science For Better Living.* Ottawa.

Canada. Agriculture Canada. Research Branch (1985). *Plant breeders' rights: workshop on the proposed legislation and its implications on Canadian agriculture.* Ottawa.

Canada. Agriculture Canada. Research Branch (1988). *Canadian Agricultural Research and Technology Transfer, Planning For the Future, Part 5: Research Branch, Proposal for Action.* Ottawa.

Canada. Agriculture Canada. Research Branch (1989). *Research Branch Report, 1988.* Ottawa: Minister of Supply and Services Canada.

Canada. Agriculture Canada. Research Branch (1991). *Canadian Agricultural Research and Technology Transfer, Planning For the Future, Part 9: Agriculture Canada, Research Branch, Strategic Directions.* Ottawa.

Canada. Auditor General of Canada (1994). "Federal Management of the Food Safety System." *Report of the Auditor General of Canada* 8 (Chapter 13): 3-41.

Canada. Canadian Food Inspection Agency (1997). *A Guide to Plant Breeders' Rights.* Ottawa.

Canada. Canadian Food Inspection Agency (1998, December 2). *Record of Understanding Between the Governments of Canada and the United States of America Regarding Areas of Agricultural Trade.* [Online]. Available at: http://www.cfia-acia.agr.ca/english/corpaffr/international/recorde.html [1999, February 4].

Canada. Canadian Food Inspection Agency. Plant Biotechnology Office (1994). *Regulatory Directive Dir94-08: Assessment Criteria for Determining Enviornmental Safety of Plants with Novel Traits.* [Online]. Available at: http://www.cfia/acia.agr.ca/english/plant/pbo/dir9408e.html [1998, August 31].

Canada. Canadian Food Inspection Agency. Plant Biotechnology Office (1995). *Regulatory Directive Dir95-01: Field Testing Plants with Novel Traits in Canada.* [Online]. Available at: http:www.cfia-acia.agr.ca/ english/plant/pbo/dir9501e.html [1998, August 31].

Canada. Canadian Food Inspection Agency. Plant Biotechnology Office (1999). *Insect Resistance Management of Bt Corn in Canada.* [Online]. Available at: http://www/cfia-acia.agr.ca/english/plant/pbo/btweb1_e.html [1999, March 19].

Canada. Department of Agriculture (1972). *Agricultural Research Pays.* Ottawa: Information Canada.

Canada. Department of Agriculture (1977). *Orientation of Canadian Agriculture: A Task Force Report, A Review of the Canadian Agriculture and Food Complex--The System.* Ottawa.

Canada. Department of National Health and Welfare (1948). *Pure Food, Safe Drugs: Services of the Food and Drug Divisions.* Ottawa.

Canada. Department of National Health and Welfare. Food and Drug Directorate (1966). *Food, Drug, Cosmetic Protection for Canadians.* Ottawa: Queen's Printer.

Canada. Department of National Health and Welfare. Food and Drug Directorate (1970). *Health Protection and Food Laws.* Ottawa: Minister of National Health and Welfare.

Canada. Department of National Health and Welfare. Health Protection Branch (1981). *Health Protection and Food Laws.* Ottawa: Minister of Supply and Services Canada.

Canada. Federal/Provincial Committee on Research and Technology Transfer (1990). *Growing Together: Report to Ministers of Agriculture, Canadian Agricultural Research and Technology Transfer.*

Canada. Health and Welfare Canada. Health Protection Branch (1992). *Information Letter, No. 806.* Ottawa.

Canada. Health Canada (1995). *Information: Proposed Regulations for Novel Foods Published.* Ottawa.

Canada. Health Canada. Health Protection Branch (1993). *A Strategic Direction for Change: A Review of the Regulations under the Food and Drugs Act.* Ottawa: Supply and Services Canada.

Canada. Health Canada. Health Protection Branch. Food Directorate (1994). *Guidelines for the Safety Assessment of Novel Foods.* Ottawa.

Canada. Health Canada. Health Protection Branch. Food Program (1997a). *Information: Safety Assessment of Genetically Altered Soybean.* [Online]. Available at: http://www.hc-sc.gc.ca/main/hc/web/datahpb/datafood/english/publications/ofb/soybeane.htm [1997, September 11].

Canada. Health Canada. Health Protection Branch. Food Program (1997b). *Information: Safety Assessment of Genetically Modified Corn.* [Online]. Available at: http://www.hc-sc.gc.ca/main/hc/web/datahpb/datafood/english/publications/ofb/corne.htm [1997, September 11].

Canada. Health Canada. Health Protection Branch. Food Program (1997c). *Information: Safety Assessment of Potatoes Resistant to the Colorado Potato Beetle.* [Online]. Available at: http://www.hc-sc.gc.ca/main/hc/web/datahpb/datafood/english/publications/ofb/potatoe.htm [1997, September 11].

Canada. Health Canada. Health Protection Branch. Food Program (1997d). *Information: Safety Assessment of the Flavr Savr Tomato.* [Online]. Available at: http://www.hc-sc.gc.ca/main/ hc/web/datahpb/datafood/english/publications/ofb/tomatoe.htm [1997, September 11].

Canada. Health Canada. Health Protection Branch. Food Program (1997e). *Novel Food - Decisions, 1994-1996.* [Online]. Available at: http://www.hc-sc.gc.ca/main/hc/web/datahpb/datafood/english/

Canada. Health Canada. Health Protection Branch. Food Program (1997f). *Novel Food - Decisions, 1997.* [Online]. Available at: http://www.hc-sc.gc.ca/main/hc/web/datahpb/datafood/english/publications/ofb/decis97e.htm [1997, September 11].

Canada. House of Commons. Standing Committee on Agriculture and Agri-Food (1996a, October 10). *Evidence: Meeting No. 38.* [Online]. Available at: http://www.parl.gc.ca/committees352/agfo/evidence/38_96-10-10/agfo38_blk101.html [1997, August 12].

Canada. House of Commons. Standing Committee on Agriculture and Agri-Food (1996b, October 30). *Evidence: Meeting No. 42.* [Online]. Available at: http://www.parl.gc.ca/committees352/agfo/evidence/42_96-10-30/agfo42_blk101.html [1997, October 6].

Canada. House of Commons. Standing Committee on Agriculture and Agri-Food (1996c, November 20). *Evidence: Meeting No. 48.* [Online]. Available at: http://www.parl.gc.ca/committees352/agfo/evidence/48_96-11-20/agfo48_blk101.html [1997, October 6].

Canada. House of Commons. Standing Committee on Agriculture and Agri-Food (1998, May). *Capturing the Advantage: Agricultural Biotechnology in the New Millennium.* Available at: http://interparl.parl.gc.ca/InfocomDoc/AGRI/Studies/Reports/agrirp03-e.htm [1998, June 12].

Canada. House of Commons. Standing Committee on Environment and Sustainable Development (1996). *Biotechnology Regulation in Canada: A Matter of Public Confidence.*

Canada. Industry Canada (1994). *News Release: Industry Canada Releases Biotech Survey Results.* Ottawa

Canada. Industry Canada. Bio-Industries Branch (1998, August 6). *Factsheet: Key Elements of the Renewed Canadian Biotechnology Strategy.* [Online]. Available at: http://strategis.ic.gc.ca/SSG/bh00229e.html [1998, August 12].

Canada. Industry Canada. Canadian Biotechnology Strategy Taskforce (1998, April 17). *Sector Consultation Document: Health.* Available at: http://strategis.ic.gc.ca/SSG/bh00157e.html [1998, August 24].

Canada. Industry, Science and Technology Canada. National Biotechnology Advisory Committee (1989). *Annual Report, 1987-88, The Regulation of Biotechnology: A Critical Issue for Canadian Research and Industrial Development.* Ottawa.

Canada. Minister of Public Works and Government Services Canada (1997). *Canada Gazette, Part II: Regulatory Impact Analysis Statement and Seeds Regulations, amendment,* January 8. Ottawa.

Canada. Minister of Supply and Services Canada (1994). *Canada Gazette, Part I: Feeds Regulations, 1983--Amendment,* September 24: 4095-4098. Ottawa: Queen's Printer For Canada.

Canada. Minister of Supply and Services Canada (1995). *Canada Gazette, Part I: Food and Drug Regulations-Amendment,* August 26. Ottawa: Queen's Printer For Canada.

Canada. Minister of Supply and Services Canada (1996). *Canada Gazette, Part I: Seeds Regulations-Amendment,* August 17: 2384-2388. Ottawa: Queen's Printer For Canada.

Canada. Minister of Supply and Services Canada (1999). *Canada Gazette, Part II: Food and Drug Regulations-Amendment.* Ottawa: Queen's Printer For Canada.

Canada. Ministry of State Science and Technology Canada (1987). *InnovAction: The Canadian Strategy for Science and Technology.* Ottawa: Minister of Supply and Services Canada.

Canada. National Advisory Board on Science and Technology (1991a). *Science and Technology, Innovation and National Prosperity: The Need for Canada to Change Course.* Ottawa.

Canada. National Advisory Board on Science and Technology (1991b). *Statement on Competitiveness Report of the National Advisory Board on Science and Technology.* Ottawa.

Canada. National Advisory Board on Science and Technology (1993). *Committee on Federal Science and Technology Priorities.* Ottawa.

Canada. National Biotechnology Advisory Committee (1985). *Annual Report, 1984.* Ottawa: Ministry of State, Science, and Technology.

Canada. National Biotechnology Advisory Committee (1986). *Annual Report: Moving Biotechnology From the Laboratory to the Market.* Ottawa: Ministry of State, Science, and Technology.

Canada. National Research Council (1990). *Plant Biotechnology Institute, Annual Report, 1989-90.* Ottawa: National Research Council.

Canada. Office of the Auditor General (1993). *Agri-Food Policy Review, Chapter 13, Report of the Auditor General (1993).* [Online]. Available at: http://www.oag-bvg.gc.ca/oag-bvg/rep93/1993e/html/9313e/ch9313e.html [1998, March 18].

Canada. Prosperity Secretariat (1991a). *Canada's Prosperity: Challenges and Prospects.* Ottawa: Minister of Supply and Services Canada.

Canada. Prosperity Secretariat (1991b). *Prosperity Through Competitiveness.* Ottawa: Minister of Supply and Services Canada.

Canada. Prosperity Secretariat (1993). *The Prosperity Action Plan: A Progress Report.* Ottawa: Minister of Supply and Services Canada.

Canada. Science Council of Canada (1970). *Agricultural Science in Canada.* Ottawa: Science Council of Canada.

Canada. Science Council of Canada (1971). *Two Blades of Grass: The Challenge Facing Agriculture, Report No. 12.* Ottawa: Information Canada.

Canada. Science Council of Canada (1982). *Regulating the Regulators: Science, Values, and Decisions.* Ottawa: Minister of Supply and Services.

Canada. Science Council of Canada (1985). *Seeds of Renewal: Biotechnology and Canada's Resource Industries.* Ottawa: Minister of Supply and Services.

Canada. Science Council of Canada (1991). *Sustainable Agriculture: Economic Perspectives and Challenges.* Winnipeg.

Canada. Science Council of Canada (1992). *Sustainable agriculture: the research challenge.* Ottawa: Minister of Supply and Services.

Canada. Statistics Canada (1983). *Science Statistics: Federal Government Personnel Engaged in Scientific Activities, 1975-76 to 1983-84.* Ottawa.

Canada. Statistics Canada (1984). *Science Statistics: Federal Government Activities in the Natural Sciences, 1984-85.* Ottawa.

Canada. Statistics Canada (1985). *Canada Yearbook.* Ottawa: Minister of Supply and Services Canada.

Canada. Statistics Canada (1988). *Science Statistics: Federal Government Personnel Engaged in Science and Technology Activities, 1980-81 to 1988-89.* Ottawa.

Canada. Statistics Canada (1994). *Science Statistics: Federal Government Expenditures on Scientific Activities, 1994-95.* Ottawa.

Canada. Statistics Canada (1996). *Science Statistics: Federal Government Personnel Engaged in Science and Technological Activities, 1987-88 to 1996-97.* Ottawa.

Canada. Statistics Canada (1997a). *Science Statistics: Biotechnology Research and Development (R&D) in Canadian Industry, 1995.* Ottawa.

Canada. Statistics Canada (1997b). *Science Statistics: Federal Government Expenditures on Scientific Activities, 1997-98.* Ottawa.

Canada. Statistics Canada (1997c). *Science Statistics: Total Spending on Research and Development in Canada 1986-1997, and Provinces, 1986-1995.* Ottawa.

Canadian Agri-Food Research Council (1996). *Agri-Food Research and Technology Transfer Capacity in Canada.* [Online]. Available at: http://WWW.CARC-CRAC.ca/english/weave.htm [1998, January 29].

Canadian Agri-Food Research Council (1997). *Canada's national strategy for agri-food research and technology transfer, 1997-2002.* Ottawa.

Canadian Agricultural Research Council (1983). *Biotechnology: research and development for Canada's agriculture and food system.* Ottawa.

Canadian Agricultural Research Council (1991). *Proceedings of the Partnerships: a Focus on technology Conference.* Ottawa.

Canadian Agricultural Research Council (1992). *A National Strategy for Agri-Food Research and Technology Transfer.* Ottawa: Canadian Agricultural Research Council.

Canadian Biotechnology Strategy Task Force. Working Group on International Issues (1998). *International Issues Report.* Ottawa: Industry Canada.

Canadian Institute for Environmental Law and Policy (1988). *Biotechnology Policy Development.* Toronto.

Canadian Seed Trade Association (1995). *The Merchants of Seed: A history of the Canadian seed industry.* Nepean.

Carew, Richard, Peter Chen, et al. (1992). "Evaluating Publicly-Funded Research in Canadian Agriculture: A Profit Function Approach." *Canadian Journal of Agricultural Economics* 40: 547-560.

Carey, John (1999). "'Incredibly Stressed' at the FDA: Can it meet new challenges on a 10-year-old budget?". *Business Week [Online]*, October 11.

Carroll, Barbara Wake and Terrance Carroll (1999). "Civic Networks, Legitimacy and the Policy Process." *Governance* 12(1): 1-28.

Carter, Janelle (1999, February 6). *Biosafety Pact Could Hit US Trade.* [America Online news service: The Associated Press].

Clark, Ann Marie (1995). "Non-Governmental Organizations and their Influence on International Society." *Journal of International Affairs* 48(2): 507-525.

Clark, E. Ann (2000). *Food Safety of GM Crops in Canada: toxicity and allergenicity.*

Clayton, O. (1995). "The Canadian Seed Growers' Association", *Harvest of Gold: The History of Field Crop Breeding.* A. E. Slinkard and D. R. Knott, Eds. Saskatoon, University Extension Press, University of Saskatchewan: 335-343.

Coffin, Garth, Bruno Larue, et al. (1993). "Competitiveness in the Canadian Food Industry." *Canadian Journal of Agricultural Economics* 41: 459-473.

Coghlan, Andy (1994). "Arguing Till the Cows Come Home". *New Scientist.* 144: 14-15.

Colapinto, Robert (1998). "Frankenfoods or wonder foods?". *Canadian Living*, June: 51-54.

Coleman, William D. (1988). *Business and Politics: A Study of Collective Action.* Kingston: McGill-Queen's University Press.

Coleman, William (1990). "State Traditions and Comprehensive Business Associations: A Comparative Structural Analysis." *Political Studies* 38: 231-252.

Coleman, William (1991). "Fencing Off: Central Banks and Networks in Canada and the United States", *Policy Networks: Empirical Evidence and Theoretical Considerations.* B. Marin and R. Mayntz, Eds. Boulder, Westview Press: 209-234.

Coleman, William (1994). "Policy Convergence in Banking: A Comparative Study." *Political Studies* 42: 274-292.

Coleman, William and Grace Skogstad (1995). "Neo-Liberalism, Policy Networks, and Policy Change: Agricultural Policy Reform in Australia and Canada." *Australian Journal of Political Science* 30: 242-263.

Coleman, William D. and Tony Porter (1996). "Banking and Securities Policy", *Border Crossings: The Internationalization of Canadian Public Policy.* G. B. Doern, L. A. Pal and B. W. Tomlin, Eds. Toronto, Oxford University Press: 55-81.

Coleman, William D. and Grace Skogstad (1990a). "Introduction", *Policy Communities and Public Policy in Canada: A Structural Approach.* W. D. Coleman and G. Skogstad, Eds. Mississauga, Copp Clark Pitman Ltd.: 1-13.

Coleman, William D. and Grace Skogstad (1990b). "Policy Communities and Policy Networks: A Structural Approach", *Policy Communities and Public Policy in Canada: A Structural Approach.* W. D. Coleman and G. Skogstad, Eds. Mississauga, Copp Clark Pitman Ltd.: 14-33.

Coleman, William D. and Grace Skogstad (2000). "Agricultural Policy: Regionalization and Internationalization", *Political Economy and the Changing Global Order*. R. Stubbs and G. R. D. Underhill, Eds. Toronto Oxford University Press: 310-319.

Coleman, William D., Grace D. Skogstad, et al. (1997). "Paradigm Shifts and Policy Networks: Cumulative Change in Agriculture." *Journal of Public Policy* 16 (3): 273-301.

Commins, Patricia (1996, August 14). *Reuter Newswire*. [Online].

Consumers Union (1993). *Consumers Union's Comments on Docket No. 92-0139, Food Labeling; Foods Derived From New Plant Varieties*.

Consumers' Association of Canada (1994). *Statement of Policy: Regulating Agricultural Products of Biotechnology*. Ottawa.

Consumers' Association of Canada (1995). *CAC and the Public Interest*. Ottawa.

Consumers' Association of Canada (1996). *Presentation to the House of Commons, Standing Committee on the Environment and Sustainable Agriculture (sic) on Labelling of Novel Food Products Derived From Genetic Engineering*. Ottawa.

Consumers' Association of Canada (1997). *The Role of Consumer Organizations in Public Policy Development*. Ottawa.

Coote, Anna (1998). "Risk and Public Policy: Towards a High-Trust Democracy", *The Politics of Risk Society*. J. Franklin, Ed. Cambridge, Polity Press: 124-131.

Crawford, Mark (1986). "Regulatory Tangle Snarls Agricultural Research in the Biotechnology Arena". *Science*: 275-277.

Crecchio, C. and G. Stotzky (1998). "Insecticidal activity and biodegradation of the toxin from Bacillus thuringiensis subsp. kurstaki bound to humic acids from soil." *Soil Biology and Biochemistry* 30: 463-470.

Davidson, A. Linton (1949). *Canada Pioneers in Food and Drug Control: The Story of the Food and Drug Directorate*. Ottawa: Department of National Health and Welfare.

Davidson, A. Linton (1950). *The Genesis and Growth of Food and Drug Administration in Canada*. Ottawa: Minister of National Health and Welfare.

Davis, Bernard D. (1987). "Bacterial Domestication: Underlying Assumptions." *Science* 235: 1329-1335.

Davis, Bernard, Ed. (1991). *The Genetic Revolution: Scientific Prospects and Public Perceptions*. Baltimore: John Hopkins University Press.

Davison, Aidan, Ian Barns, et al. (1997). "Problematic Publics: A Critical Review of Surveys of Public Attitudes to Biotechnology." *Science, Technology & Human Values* 22(3): 317-348.

De Marchi, Bruna (1995). "Environmental problems, policy decisions and risk communication: what is the role for the social sciences?" *Science and Public Policy* 22(3): 157-161.

Dickson, David (1984). *The New Politics of Science*. New York: Pantheon Books.

Doern, G. Bruce (1981). *The Peripheral Nature of Scientific and Technological Controversy in Federal Policy Formation*. Ottawa: Science Council of Canada (Minister of Supply and Services).

Doern, G. Bruce and Thomas Conway (1994). *The Greening of Canada: Federal Institutions and Decisions*. Toronto: University of Toronto Press.

Doern, G. Bruce, Leslie A. Pal, et al. (1996). "The Internationalization of Canadian Public Policy", *Border Crossings: The Internationalization of Canadian Public Policy*. G. B. Doern, L. A. Pal and B. W. Tomlin, Eds. Toronto, Oxford University Press: 1-26.

Doern, G. Bruce and Brian W. Tomlin (1996). "Trade-Industrial Policy", *Border Crossings: The Internationalization of Canadian Public Policy*. G. B. Doern, L. A. Pal and B. W. Tomlin, Eds. Toronto, Oxford University Press: 167-187.

Dohler, Marian (1991). "Policy Networks, Opportunity Structures and Neo-Conservative Reform Strategies in Health Policy", *Policy Networks: Empirical Evidence and Theoretical Considerations*. B. Marin and R. Mayntz, Eds. Boulder, Westview Press: 235-296.

Doyle, Jack (1985). *Altered Harvest: Agriculture, Genetics, and the Fate of the World's Food Supply*. New York: Penguin Books.

Duckworth, Barbara (1991). "Research stations need new funding". *Western Producer* (Saskatoon), April 18: 20.

Dunn, James A., Jr. and Anthony Perl (1994). "Policy Networks and Industrial Revitalization: High Speed Rail Initiatives in France and Germany." *Journal of Public Policy* 14: 311-343.

Dyer, Gwynne (1999). "Frankenstein Foods". *The Globe and Mail* (Toronto), February 20: D1.

Eddy, Howard (1983). *Regulation of Recombinant DNA Research*. Ottawa: Science Council of Canada.

Eggertson, Laura (1997a). "Scientists warn Rock about cuts to Food Directorate". *The Globe and Mail* (Toronto), July 12: A4.

Eggertson, Laura (1997b). "Rock to investigate laboratory cutbacks". *The Globe and Mail* (Toronto), July 16: A4.

Einsiedel, Edna F. (1997). *Biotechnology and the Canadian Public: Report on a 1997 National Survey and Some International Comparisons*. Calgary: University of Calgary.

Environmental Defense Fund (United States) (1991). *A Mutable Feast: Assuring Food Safety in the Era of Genetic Engineering*. New York.

Environmental Defense Fund (1992). *Written Comments on Notice of "Statement of Policy: Foods Derived From New Plant Varieties"*. New York.

Evenson, Brad (1998). "What's in your food?". *The Ottawa Citizen*, May 26: A1.

Ewins, Adrian (1997). "Sask. Wheat Pool, Calgene co-operate on canola". *The Western Producer* (Saskatoon), January 2: 5.

Ewins, Adrian (1998). "Canada's grasp on canola starting to slip". *The Western Producer* (Saskatoon), March 19: 4.

Fairbairn, Garry (1997). "United Nations targets biosafety". *The Western Producer* (Saskatoon), July 17: 6.

Feldman, Elliot J. and Jerome Milch (1982). *Technocracy versus Democracy: The Comparative Politics of International Airports*. Boston: Auburn House Publishing Company.

Fitzgerald, Deborah (1990). *The Business of Breeding: Hybrid Corn in Illinois, 1890-1940*. Ithaca: Cornell University Press.

Forbes, J.D. (1985). *Institutions and Influence Groups in Canadian Farm and Food Policy*. Toronto: Institute of Public Administration of Canada.

Forsyth, Sheila (1998). *Pest Resistance and Gene Escape: Hazards of Biotechnology*. Toronto: AGCare Update.

Fowler, Cary and Pat Mooney (1990). *Shattering: Food, Politics and the Loss of Genetic Diversity*. Tucson: University of Arizona Press.

Fox, Michael W. (1992). *Superpigs and Wondercorn: The Brave New World of Biotechnology...and Where It All May Lead*. New York: Lyons & Burford.

Fox, Jeffrey L. (1996). "USDA downplays closing of biotech advisory programs". *Nature Biotechnology* 14: 261.

Fox, Jeffrey L. (1997). "EPA seeks refuge from Bt resistance". *Nature Biotechnology* 15: 409.

Fox, Maggie (1998, December 8). "New U.S. FDA head promises more science at agency". *Reuters Online*.

Franklin, Jane, Ed. (1998). *The Politics of Risk Society*. Cambridge: Polity Press.

Frieden, Jeffry A. and Ronald Rogowski (1996). "The Impact of the International Economy on National Policies: An Analytical Overview", *Internationalization and Domestic Politics*. R. O. Keohane and H. V. Milner, Eds. New York, Cambridge University Press: 25-47.

Fuglie, Keith, Nicole Ballenger, et al. (1996). *Agricultural Research and Development: Public and Private Investments Under Alternative Markets and Institutions*. Washington: United States Department of Agriculture. Economic Research Service.

Garland, S.W. and S.C. Hudson (1969). *Government Involvement in Agriculture: A Report Prepared for the Federal Task Force on Agriculture*. Ottawa: Queen's Printer.

Garrett, Geoffrey and Peter Lange (1996). "Internationalization, Institutions, and Political Change", *Internationalization and Domestic Politics*. R. O. Keohane and H. V. Milner, Eds. New York, Cambridge University Press: 48-75.

Garvin, Theresa and John Eyles (1997). "The sun safety metanarrative: Translating science into public health discourse." *Policy Sciences* 30: 47-70.

Giddens, Anthony (1998). "Risk Society: the Context of British Politics", *The Politics of Risk Society*. J. Franklin, Eds. Cambridge, Polity Press: 23-34.

Gieryn, Thomas F. (1983). "Boundary-Work and the Demarcation of Science from Non-Science: Strains and Interests in Professional Ideologies of Scientists." *American Sociological Review* 48: 781-795.

Global Industry Coalition (1999, February 25). *Industry Reaffirms CBD Goals.* [America Online news service: PRNewswire].

Goldburg, Rebecca J. (1987). *Testimony of Rebecca J. Goldburg of the Environmental Defense Fund on Federal Regulation of Biotechnology Before the Subcommittee on Hazardous Wastes and Toxic Substances of the Senate Environment and Public Works Committee.*

Goldburg, Rebecca (1990). *Biotechnology's Bitter Harvest: Herbicide-Tolerant Crops and the Threat to Sustainable Agriculture*: Biotechnology Working Group.

Goldstein, Judith and Robert Keohane, Eds. (1993). *Ideas and Foreign Policy: Beliefs, Institutions and Political Change.* Ithaca, NY: Cornell University Press.

Goncalves, Maria Eduarda (1995). "Scientific expertise and European Community regulatory processes." *Science and Public Policy* 22(3): 183-187.

Gooderham, Mary (1998). "Long-awaited biotech strategy arrives with issues unresolved". *The Globe and Mail.* Toronto, October 20: C6.

Grace, Eric S. (1997). *Biotechnology Unzipped: Promises & Realities.* Toronto: Trifolium Books Inc.

Graham, Katherine A. and Susan D. Phillips (1997). "Citizen engagement: beyond the customer revolution." *Canadian Public Administration* 40 (2): 255-273.

Grant, George (1969). *Technology and Empire.* Toronto: House of Anansi.

Griffiths, Angela (1996). *Implementation of Biotechnology Research and Development Policy: Implications for Agricultural Sustainability.* PhD Dissertation, Resource Management and Environmental Studies Program, University of British Columbia (Vancouver).

Guitard, A.A. (1985). "The Canadian Agricultural Research Institution", *Economics of Agricultural Research in Canada.* K. K. Klein and W. H. Furtan, Eds. Calgary, University of Calgary Press: 21-49.

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

Hadwiger, Don F. and William P. Browne, Eds. (1987). *Public Policy and Agricultural Technology: Adversity Despite Achievement.* Hong Kong: Policy Studies Organization.

Hall, Peter (1989). "Conclusion: the Politics of Keynesian Ideas", *The Political Power of Economic Ideas: Keynesianism Across Nations.* P. Hall, Eds. Princeton, NJ, Princeton University Press: 361-391.

Hall, Peter A. (1993). "Policy Paradigms, Social Learning, and the State: The Case of Economic Policymaking in Britain." *Comparative Politics* 25(3): 275-296.

Hall, Peter A. and Rosemary C.R. Taylor (1996). "Political Science and the Three New Institutionalisms." *Political Studies* 44(5): 936-957.

Hall, Peter (1997). "Letter to the Editor: Ag research". *The Western Producer* (Saskatoon), January 16: 7.

Halloran, Jean and Michael Hansen (1998, April). *Why We Need Labeling of Genetically Engineered Food.* [Online]. Available at: http://www.consunion.org/food/whywenny798.htm [1998, December 1].

Halstead, R.L. and D.F. Kirkland (1991). *Partnerships: a focus on technology. A discussion paper on research and technology transfer in the agri-food industry.* Ottawa: Canadian Agricultural Research Council.

Hardy, Ralph W.F. and Jane Baker Segelken (1998). *NABC Report 10: Agricultural Biotechnology and Environmental Quality: Gene Escape and Pest Resistance.* Ithaca: National Agricultural Biotechnology Council.

Harrison, Kathryn and George Hoberg (1991). "Setting the Environmental Agenda in Canada and the United States: The Cases of Dioxin and Radon." *Canadian Journal of Political Science* 24(1): 3-27.

Harrison, Kathryn and George Hoberg (1994). *Risk, Science, and Politics.* Montreal & Kingston: McGill-Queen's University Press.

Harvey, B.L. (1995). "The Western Grain Registration Recommending Committees and Their Role in Cultivar Development", *Harvest of Gold: The History of Field Crop Breeding.* A. E. Slinkard and D. R. Knott, Eds. Saskatoon, University Extension Press, University of Saskatchewan: 326-334.

Hatch, Upton and Fred Kuchler (1989). "Regulation of Agricultural Biotechnology: Historical Perspectives", *Biotechnology and the New Agricultural Revolution.* J. J. Molnar and H. Kinnucan, Eds. Boulder, Westview Press: 51-71.

Haynes, Fred (1997). *Canadian Biotechnology 1998.* Georgetown: Contact Canada.

Heclo, Hugh (1994). "Ideas, Interests, and Institutions", *The Dynamics of American Politics.* L. C. Dodd and C. Jillson, Eds. Boulder, Westview Press: 366-392.

Heffernan, William (1999). *Consolidation in the Food and Agriculture System.* [Online]. Available at: http://www.nfu.org [1999, July 19].

Heinz, John P., Edward O. Laumann, et al. (1993). *The Hollow Core: Private Interests in National Policy Making.* Cambridge: Harvard University Press.

Hellström, Tomas (1996). "The science-policy dialogue in transformation: model-uncertainty and environmental policy." *Science and Public Policy* 23(2): 91-97.

Henderson, Dennis R., Charles R. Handy, et al. (1996). *Globalization of the Processed Foods Market.* Washington, D.C.: United States Department of Agriculture. Economic Research Service.

Herriott, Eva (1998). "Counterfeit crops". *Yoga Journal*, July / August: 30-35.

Hightower, Jim (1973). *Hard Tomatoes, Hard Times: A Report of the Agribusiness Accountability Project on the Failure of America's Land Grant College Complex.* Cambridge: Schenkman Publishing Company.

Hileman, Bette (1995). "Views Differ Sharply over Benefits, Risks of Agricultural Biotechnology". *Chemical and Engineering News.* 73: 8-17.

Hill, Margaret M. (1998). "The Theory and Pratice of Regulation in Canada and the United States: Opportunities for Regulatory Learning in the United Kingdom", *Changing Regulatory Institutions in Britain and North America.* G. B. Doern and S. Wilks, Eds. Toronto, University of Toronto Press: 187-217.

Hinich, Melvin J. and Richard Staelin (1980). *Consumer Protection Legislation and the U.S. Food Industry.* New York: Pergamon Press.

Hiss, Tony (1994). "How Now, Drugged Cow? Biotechnology comes to rural Vermont". *Harper's Magazine,* October: 80-90.

Hoban, Thomas, Eric Woodrum, et al. (1992). "Public Opposition to Genetic Engineering." *Rural Sociology* 57(4): 476-493.

Hoberg, George (1992). *Pluralism By Design: Environmental Policy and the American Regulatory State.* New York: Praeger.

Hoberg, George (1996). "Putting Ideas in Their Place: A Response to 'Learning and Change in the British Columbia Forest Policy Sector' "." *Canadian Journal of Political Science* 29: 135-144.

Hoberg, George (1997). "Governing the Environment", *Degrees of Freedom: Canada and the United States in a Changing World.* K. Banting, G. Hoberg and R. Simeon, Eds. Montreal & Kingston, McGill-Queen's University Press: 341-385.

Hollebone, Jean (1988). *An Overview of the Canadian Federal and Agricultural Regulatory Frameworks for Biotechnology.* Workshop: Regulation of Agricultural Products of Biotechnology. Ottawa: Canadian Agricultural Research Council.

Hollebone, Jean (1993). *Biotechnology: A Federal Framework For Regulation.* Agri-Food Safety Workshop on Food Biotechnology. Ottawa: Agriculture Canada.

Hollingsworth, J. Rogers and Robert Boyer, Eds. (1997). *Contemporary Capitalism: The Embeddedness of Institutions.* New York: Cambridge University Press.

Holm, W.R. (1992). *Prosperity Initiative, Agri-Food Sectoral Response: Final Report.* Guelph: Agri-Food Competitiveness Council.

Horlick-Jones, Tom and Bruna De Marchi (1995). "The crisis of scientific expertise in *fin de siècle* Europe." *Science and Public Policy* 22(3): 139-145.

Howlett, Michael and M. Ramesh (1995). *Studying Public Policy: Policy Cycles and Policy Subsystems.* Toronto: Oxford University Press.

Hoyle, Russ (1996). "Biosafety protocol draft spooks US biotechnology officials". *Nature Biotechnology* 14: 803.

Hoyle, Russ (1997). "Food and Drug Administration: Commissioner Kessler's agbio legacy". *Nature Biotechnology* 15: 2.

Ikenberry, G. John (1993). "Creating Yesterday's New World Order: Keynesian 'New Thinking' and the Anglo-American Postwar Settlement", *Ideas and Foreign Policy: Beliefs, Institutions, and Political Chnage.* J. Goldstein and R. O. Keohane, Eds. Ithaca, Cornell University Press: 57-86.

Industrial Biotechnology Association of Canada (1997). *Vector: The Canadian Biotechnology Newsletter.* Saskatoon: The Signature Group Inc.

Inglehart, Ronald F., Neil Nevitte, et al. (1996). *The North American Trajectory: Cultural, Economic and Political Ties Among the United States, Canada, and Mexico.* Hawthorne: Aldine de Gruyter.

Inside US Trade. (1997). "New USDA group to focus on non-tariff barriers to agriculture trade", Volume 15, October 31.

International Food Biotechnology Council (1990). "Biotechnologies and Food: Assuring the Safety of Foods Produced by Genetic Modification." *Regulatory Toxicology and Pharmacology* 12 (3): S1-196.

International Institute for Sustainable Development (1999, February). *Earth Negotiations Bulletin.* [Online]. Available at: http://www.canadagrainscouncil.ca/ [1999, April 13].

Jackson, Charles O. (1970). *Food and Drug Legislation in the New Deal.* Princeton: Princeton University Press.

James, Clive (1997). *Global Status of Transgenic Crops in 1997.* Ithaca: International Service for the Acquisition of Agri-biotech.

Jansen, Dorothea (1991). "Policy Networks and Change: The Case of High-Tc Superconductors", *Policy Networks: Empirical Evidence and Theoretical Considerations.* B. Marin and R. Mayntz, Eds. Boulder, Westview Press: 137-174.

Jasanoff, Sheila (1986). *Risk Management and Political Culture.* New York: Russell Sage Foundation.

Jasanoff, Sheila (1987). "Contested Boundaries in Policy-Relevant Science." *Social Studies of Science* 17: 195-230.

Jasanoff, Sheila (1990). *The Fifth Branch: Science Advisers as Policymakers.* Cambridge: Harvard University Press.

Jasanoff, Sheila (1995a). "Product, process, or programme: three cultures and the regulation of biotechnology", *Resistance to new technology: nuclear power, information technology, and biotechnology.* M. Bauer, Ed. Cambridge, Cambridge University Press: 311-331.

Jasanoff, Sheila (1995b). *Science at the Bar: Law, Science, and Technology in America.* Cambridge: Harvard University Press.

Johnson, Jon R. (1994). *The North American Free Trade Agreement: A Comprehensive Guide.* Aurora: Canada Law Book Inc.

Jones, Robert L. and Zachary A. Smith (1995). "Rethinking the internationalization of environment interest groups: A regime approach to behaviour." *Resources Policy* 21(1): 5-12.

Kadvany, John (1996). "Taming chance: Risk and the quantification of uncertainty." *Policy Sciences* 29: 1-27.

Kareiva, Peter and John Stark (1994). "Environmental Risks in Agricultural Biotechnology." *Chemistry & Industry,* January 17: 52-55.

Kasanmoentalib, Soemini (1996). "Science and Values in Risk Assessment: The Case of Deliberate Release of Genetically-Engineered Organisms." *Journal of Agricultural and Environmental Ethics* 9(1): 42-60.

Kenis, Patrick and Volker Schneider (1991). "Policy Networks and Policy Analysis: Scrutinizing a New Analytical Toolbox", *Policy Networks: Empirical Evidence and Theoretical Considerations.* B. Marin and R. Mayntz, Eds. Boulder, Westview Press: 25-59.

Kenney, Martin (1989). "The Debate over the Deliberate Release of Genetically Engineered Organisms: A Study of State Environmental Policy Making", *Biotechnology and the New Agricultural Revolution.* J. J. Molnar and H. Kinnucan, Eds. Boulder, Westview Press: 73-99.

Keohane, Robert O. and Helen V. Milner (1996a). "Internationalization and Domestic Politics: A Conclusion", *Internationalization and Domestic Politics.* R. O. Keohane and H. V. Milner, Eds. New York, Cambridge University Press: 243-258.

Keohane, Robert O. and Helen V. Milner (1996b). "Internationalization and Domestic Politics: An Introduction", *Internationalization and Domestic Politics.* R. O. Keohane and H. V. Milner, Eds. New York, Cambridge University Press: 3-24.

Kerr, Clark (1983). *The Future of Industrial Societies: Convergence or Continuing Diversity?* Cambridge: Harvard University Press.

Kingdon, John W. (1984). *Agendas, Alternatives, and Public Policies.* Boston: Little, Brown and Company.

Kirk, Bruce D. (1997). *Some Role-of-Government Issues in Agri-Food and Western Grains R&D Policy.* Winnipeg: Canada Grains Council.

Kitschelt, Herbert, Peter Lange, et al., Eds. (1999). *Continuity and Change in Contemporary Capitalism.* New York: Cambridge University Press.

Klein, K.K. (1985). "Economics, Research and Agriculture", *Economics of Agricultural Research in Canada.* K. K. Klein and W. H. Furtan, Eds. Calgary, University of Calgary Press: 4-10.

Klein, K.K. (1997). *Grains and Oilseeds Research in Canada: Regulations, Committees and Decision Making Processes.* Winnipeg: Canada Grains Council.

Klein, K.K., B. Freeze, et al. (1996). "Economic Returns to Yield-Increasing Research on Wheat in Western Canada." *Canadian Journal of Agricultural Economics* 44: 207-218.

Kleiner, Kurt (1994). "Milk hormone dispute boils over into court". *New Scientist.* 142: 6-7.

Kloppenburg JR, Jack Ralph (1988). *First the Seed: The Political Economy of Plant Biotechnology.* Cambridge: Cambridge University Press.

Kneen, Brewster (1992). *The Rape of Canola.* Toronto: NC Press.

Knoke, David, Franz Urban Pappi, et al. (1996). *Comparing Policy Networks: Labor Politics in the U.S., Germany, and Japan.* New York: Cambridge University Press.

Korwek, Edward L. (1986). "FDA Regulation of Food Ingredient Produced By Biotechnology." *Food Technology*, October: 70-74.

Krasner, Stephen D. (1988). "Sovereignty: An Institutional Perspective." *Comparative Political Studies* 21 (1): 66-94.

Krasner, Stephen D. (1995). "Power politics, institutions, and transnational relations", *Bringing transnational relations back in: Non-state actors, domestic structures and international institutions.* T. Risse-Kappen, Ed. New York, Cambridge University Press: 257-279.

Krimsky, Sheldon (1985). "Regulation of Biotechnologies: State and Local Roles and Initiatives", *Biotechnology and the Environment: Risk & Regulation*. A. H. Teich, M. A. Levin and J. H. Pace, Eds. Washington, American Association for the Advancement of Science: 159-177.

Krimsky, Sheldon (1991). *Biotechnics and Society: The Rise of Industrial Genetics*. New York: Praeger.

Krimsky, Sheldon and Roger P. Wrubel (1996). *Agricultural Biotechnology and the Environment: Science, Policy, and Social Issues*. Urbana: University of Illinois Press.

Lacy, William B. and Lawrence Busch (1989). "The Changing Division of Labor Between the University and Industry: The Case of Agricultural Biotechnology", *Biotechnology and the New Agricultural Revolution*. J. J. Molnar and H. Kinnucan, Eds. Boulder, Westview Press: 21-50.

Lee, Kai (1993). *Compass and Gyroscope: Integrating Science and Politics for the Environment*. Washington: Island Press.

Le Gras, Gilbert (1998, June 22). *Monsanto seeks world policy on gene-altered food*. [Online]. Available at: America Online news service, Reuters [1998, June 23].

Leiss, William and Christina Chociolko (1994). *Risk and Responsibility*. Montreal & Kingston: McGill-Queen's University Press.

Lertzman, Ken, Jeremy Rayner, et al. (1996). "Learning and Change in the British Columbia Forest Policy Sector: A Consideration of Sabatier's Advocacy Coalition Framework." *Canadian Journal of Political Science* 29(1): 111-133.

Lesser, W. (1988). "Canadian Seeds Act: Does It Mimic Plant Breeders' Rights Legislation?" *Canadian Journal of Agricultural Economics* 36: 519-529.

Lesser, W. (1995, March). *Patenting of Plants and Animals: The Impacts on the Canadian Agri-Food Sector*. Available at: http://www.agr.ca/policy/patent/elesser.html [1997, October 15].

Levidow, Les, Susan Carr, et al. (1997). "European Biotechnology Regulation: Framing the Risk Assessment of a Herbicide-Tolerant Crop." *Science, Technology, & Human Values* 22 (4): 472-505.

Lewis, Robert (1996). "BST use in the U.S. short of expectations". *The Western Producer (* Saskatoon), September 5: 56.

Lindemann, Julianne (1990). "Biotechnologies and Food: A Summary of Major Issues Regarding Safety Assurance." *Regulatory Toxicology and Pharmacology* 12: 94-104.

Linder, Stephen H. (1995). "Contending discourses in the electric and magnetic fields controversy: The social construction of EMF risk as a public problem." *Policy Sciences* 28: 209-230.

Lindquist, Evert A. (1996). "New Agendas for Research on Policy Communities: Policy Analysis, Administration, and Governance", *Policy Studies in Canada: The State of the Art*. L. Dobuzinskis, M. Howlett and D. Laycock, Eds. Toronto, University of Toronto Press: 219-241.

Locke, Michelle (1998, November 23). *Novartis Academic Grant Questioned*. [Online]. Available at: America Online news service, The Associated Press.

Lyons-Johnson, Dawn (1998, March). *Public-Private Partnership Boosts Public Benefits*. [Online]. Available at: http://www.ars.usda.gov/is/cgi-bin/ffp.pl/is/AR/archive/mar98 [1999, February 14].

MacArthur, Mary (1998). "Canola crossbreeds create tough weed problem". *The Western Producer* (Saskatoon), October 15: 1, 3.

MacMillan, J.A. (1971). *Feasibility of Cost-Benefit Analysis for the Evaluation of Agricultural Research Projects*. 1971 Symposia on Agricultural Research, Sponsored by the Department of Agricultural Economics, University of Manitoba with the support and co-operation of the Canada Department of Agriculture.

Madden, J. Patrick (1987). "Toward a New Covenant for Agricultural Academe", *Public Policy and Agricultural Technology: Adversity Despite Achievement*. D. F. Hadwiger and W. P. Browne, Eds. Hong Kong, Policy Studies Organization: 93-108.

Majone, Giandomenico (1989). *Evidence, Argument and Persuasion in the Policy Process*. New Haven: Yale University Press.

Majone, Giandomenico (1997). "From the Positive to the Regulatory State: Causes and Consequences of Changes in the Mode of Governance." *Journal of Public Policy* 17 (2): 139-167.

Manzer, Ronald (1985). *Public Policies and Political Development in Canada*. Toronto: University of Toronto Press.

Manzer, Ronald (1994). *Public Schools and Political Ideas: Canadian Educational Policy in Historical Perspective*. Toronto: University of Toronto Press.

March, James G. and Johan P. Olsen (1989). *Rediscovering Institutions: The Organizational Basis of Politics*. New York: The Free Press.

Marcus, Alan I. (1985). *Agricultural Science and the Quest for Legitimacy: Farmers, Agricultural Colleges, and Experiment Stations, 1870-1890*. Ames: Iowa State University Press.

Marcus, Alan I. (1987). "Constituents and Constituencies: An Overview of the History of Public Agricultural Research Institutions in America", *Public Policy and Agricultural Technology: Adversity Despite Achievement*. D. F. Hadwiger and W. P. Browne, Eds. Hong Kong, Policy Studies Organization: 15-30.

Marcus, Alan I. (1994). *Cancer from Beef: DES, Federal Food Regulation, and Consumer Confidence*. Baltimore: John Hopkins University Press.

Marin, Bernd and Renate Mayntz (1991). "Introduction: Studying Policy Networks", *Policy Networks: Empirical Evidence and Theoretical Considerations*. B. Marin and R. Mayntz, Eds. Boulder, Westview Press: 11-24.

Marsh, David and R.A.W. Rhodes (1992). "Policy Networks in British Politics: A Critique of Existing Approaches", *Policy Networks in British Government*. D. Marsh and R. A. W. Rhodes, Eds. New York, Oxford University Press: 1-26.

Mather, Robin (1995). *A Garden of Unearthly Delights: Bioengineering and the Future of Food*. New York: Penguin Books.

Marx, Karl (1932). "The German Ideology: Part I", *The Marx-Engels Reader*. R. Tucker, Ed. New York, WW. Norton and Company Inc.: 110-164.

McBane, Michael (1998). "'A very nasty business'". *The Ottawa Citizen*, November 21: B7.

McDonald, M.B. Jr and W.D. Pardel, Eds. (1985). *The Role of Seed Certification in the Seed Industry*. Madison: Crop Science Society of America.

McIlroy, Anne (1998). "Safety's tarnished stamp of approval". *The Globe and Mail* (Toronto), November 18: A1.

McIntyre, T.C. (1990). *Asleep at the Switch. The Federal Government, Environment, and Planning for High Technology, The National Biotechnology Strategy, 1983-1993*. PhD Dissertation, Regional Planning and Resource Development, University of Waterloo.

Medley, Terry L. (1988). *Regulation of Biotechnology in the United States*. Proceedings: Workshop on the Regulation of Agricultural Products of Biotechnology. Ottawa: Canadian Agricultural Research Council.

Mellon, Margaret (1994). *Comments to the US Food and Drug Administration Advisory Committee on Genetically Engineered Food*. Washington: Union of Concerned Scientists.

Mestel, Rosie (1994). "Bean patent sweeps the field". *New Scientist* 142: 7.

Miller, Henry I. (1994). "A Need To Reinvent Biotechnology Regulation at the EPA." *Science* 266: 1815-1818.

Miller, Henry I. (1997). *Policy Controversy in Biotechnology: An Insider's View*. Austin: R.G. Landes Company.

Mittelstaedt, Martin (1999). "Genetic experiments on Canadian crops top 4,200 in decade". *The Globe and Mail* (Toronto), March 19: A6.

Molnar, Joseph J. and Henry Kinnucan (1989). "Introduction: The Biotechnology Revolution", *Biotechnology and the New Agricultural Revolution*. J. J. Molnar and H. Kinnucan, Eds. Boulder, Westview Press: 1-18.

Monsanto Company (1997). *Speech by Hendrik Verfaillie, President of Monsanto, to The Forum On Nature and Human Society, National Academy of Sciences*. [Online]. Available at: http://www.monsanto.com/MonPub/InTheNews/Speeches/97-10-30Verfaillie_Hendrik.html [1997, November 26].

Morrissey, Brian (1998). *The Challenges Ahead--Setting Priorities*. Presentation at the Conference: Research & Development: Developing Tomorrow's Products Today. Winnipeg: Canada Grains Council.

Munson, Abby (1995). "Risk associated with and liability arising from, releases of genetically manipulated organisms into the environment." *Science and Public Policy* 22 (1): 51-63.

National Academy of Sciences (1996, November 5). *Intellectual Property Rights and Plant Biotechnology*. [Online]. Available at: http://www.nap.edu/readingroom/books/intellectual/index.html [1999, February 16].

National Food Processors Association (no date). *Policy on Food Biotechnology*.

National Research Council (United States) (1989). *Field Testing Genetically Modified Organisms: Framework For Decisions*. Washington: National Academy Press.

National Research Council (1996). *Colleges of Agriculture at the Land Grant Universities: A Profile*. [Online]. Available at: http://www.nap.edu [1999, February 17].

National Research Council. Board on Agriculture (1989). *Investing In Research: A Proposal to Strengthen the Agricultural, Food, and Environmental System.* Washington: National Academy Press.

National Research Council. Board on Agriculture (1994). *Investing in the National Research Initiative: An Update of the Competitive Grants Program of the U.S. Department of Agriculture.* Washington: National Academy Press.

National Research Council. Committee on a National Strategy for Biotechnology in Agriculture (1987). *Agricultural Biotechnology: Strategies for National Competitiveness.* Washington: National Research Council.

National Wildlife Federation (1992, October 15). *Comments to the Food and Drug Administration on the Statement of Policy: Foods Derived From New Plant Varieties.* [Online]. Available at: ftp://ftp.ucsusa.org/pub/FDA92.TXT [1998, October 8].

Olempska-Beer, Zofia S., Paul M. Kuznesof, et al. (1993). "Plant Biotechnology and Food Safety." *Food Technology* 47 (12): 64-72.

Ontario Corn Producer (1997, November / December). *Editorial.* [Online]. Available at: http://www.ontariocorn.org/edit1197.html [1998, February 3].

Optima Consultants (1994). *Study Findings: Understanding the Consumer Interest in the New Biotechnology Industry.* Ottawa: Optima Consultants in Applied Social Research Inc.

Organisation for Economic Co-operation and Development (1986). *Recombinant DNA Safety Considerations: Safety considerations for industrial, agricultural, and environmental applications of organisms derived by recombinant DNA techniques.* Paris.

Organisation for Economic Co-operation and Development (1988). *Biotechnology and the Changing Role of Government.* Paris.

Organisation for Economic Co-operation and Development (1992a). *Biotechnology, Agriculture and Food.* Paris.

Organisation for Economic Co-operation and Development (1992b). *Safety Considerations for Biotechnology.* Paris.

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

Organisation for Economic Co-operation and Development (1993b). *Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles.* Paris.

Organisation for Economic Co-operation and Development (1995a, August 18). *Biotechnology, Agriculture and Food.* [Online]. Available at: http://www.oecd.org/dsti/biotech/agr.html [1997, December 3].

Organisation for Economic Co-operation and Development (1995b, September 4). *Safety-related work of the DSTI Biotechnology Unit.* [Online]. Available at: http://www.oecd.org/dsti/biotech/safety.html [1997, December 3].

Organisation for Economic Co-operation and Development (1996, June 14). *Mandate of the OECD Working Party on Biotechnology.* [Online]. Available at: http://www.oecd.org/dsti/biotech/moreb.html [1997, December 3].

Organisation for Economic Co-operation and Development (1997a, February 6). *Biotechnology.* [Online]. Available at: http://www.oecd.org/dsti/biotech/ [1997, December 3].

Organisation for Economic Co-operation and Development (1997b, February 10). *OECD's Programme of Work on the Harmonization of Regulatory Oversight in Biotechnology.* [Online]. Available at: http://www.oecd.org/ehs/projects.htm [1997, December 3].

Ozawa, Connie P. (1991). *Recasting Science: Consensual Procedures.* Boulder: Westview Press.

Packer, Kathryn and Andrew Webster (1996). "Patenting Culture in Science: Reinventing the Scientific Wheel of Credibility." *Science, Technology, & Human Values* 21 (4): 427-453.

Pal, Leslie A. (1995). "Competing paradigms in policy discourse: The case of international human rights." *Policy Sciences* 28: 185-207.

Persley, Gabrielle J. (1990). *Beyond Mendel's Garden: Biotechnology in the Service of World Agriculture.* Wallingford: CAB International.

Peters, B. Guy (1996). *The Policy Capacity of Government.* Ottawa: Canadian Centre for Management Development.

Peters, B. Guy (1998). "Institutionalization and Deinstitutionalization: Regulatory Institutions in American Government", *Changing Regulatory Institutions in Britain and North America.* G. B. Doern and S. Wilks, Eds. Toronto, University of Toronto Press: 51-79.

Pierce, John C., Mary Ann E. Steger, et al. (1992). *Citizens, Political Communication, and Interest Groups.* Westport: Praeger.

Plein, Christopher L. (1990). "Biotechnology: Issue Development and Evolution", *Biotechnology: Assessing Social Impacts and Policy Implications.* D. J. Webber, Ed. New York, Greenwood Press: 147-165.

Pontusson, Jonas (1995). "From Comparative Public Policy to Political Economy: Putting Political Institutions in Their Place and Taking Interests Seriously." *Comparative Political Studies* 28 (1): 117-147.

Portz, John (1996). "Problem Definitions and Policy Agendas: Shaping the Educational Agenda in Boston." *Policy Studies Journal* 24 (3): 371-386.

Powell, Douglas and William Leiss (1997). *Mad Cows and Mother's Milk: The Perils of Poor Risk Communication.* Montreal & Kingston: McGill-Queen's University Press.

Price, Don K. (1965). *The Scientific Estate.* New York: Oxford University Press.

Przeworski, Adam and Henry Teune (1970). *The Logic of Comparative Social Inquiry.* New York: John Wiley & Sons.

Rabino, Isaac (1996). "What U.S. Researchers Think of Regulations and Regulators." *Bio/technology* 14: 147-150.

Rabino, Isaac (1998). "Ethical Debates in Genetic Engineering: U.S. Scientists' Attitudes on Patenting, Germ-Line Research, Food Labeling, and Agri-Biotech Issues." *Politics and the Life Sciences* 17 (2): 147-163.

Raeburn, Paul (1995). *The Last Harvest: The Genetic Gamble That Threatens To Destroy American Agriculture.* New York: Simon & Schuster.

Rampton, Roberta (1997). "Countries work on biotech standards". *The Western Producer* (Saskatoon), October 16: 16.

Rampton, Roberta (1999). "Seed breeding limited by rules". *The Western Producer* (Saskatoon), February 18: 19.

Rappert, Brian (1995). "The US extension of plant variety protection: a critical evaluation." *Science and Public Policy* 22 (2): 95-105.

Renn, Ortwin (1995). "Style of using scientific expertise: a comparative framework." *Science and Public Policy* 22(3): 147-156.

Reuters Newswire (1999, February 25). *EU blames U.S. for collapse of gene-food talks.* [America Online news service, Reuters].

Rifkin, Jeremy (1983). *Algeny: A New Word--A New World.* New York: Penguin Books.

Rifkin, Jeremy (1998). *The Biotech Century.* New York: Peguin Putnam.

Risse-Kappen, Thomas (1995a). "Bringing transnational relations back in: introduction", *Bringing transnational relations back in: Non-state actors, domestic structures and international institutions.* T. Risse-Kappen, Ed. New York, Cambridge University Press: 3-33.

Risse-Kappen, Thomas (1995b). "Structures of governance and transnational relations: what have we learned?", *Bringing transnational relations back in: Non-state actors, domestic structures and international institutions.* T. Risse-Kappen, Ed. New York, Cambridge University Press: 280-313.

Rissler, Jane and Margaret Mellon (1996). *The Ecological Risks of Engineered Crops.* Cambridge: MIT Press.

Rochefort, David A. and Roger W. Cobb (1993). "Problem Definition, Agenda Access, and Policy Choice." *Policy Studies Journal* 21 (1): 56-71.

Rogers, Karen Keeler (1996). *Fields of Promise: Monsanto and the Development of Agricultural Biotechnology.* [Online]. Available at: http://www.monsanto.com/MonPub/InTheNews/MonsantoMagazine/FieldsOfPromise/monmag.html [1997, November 26].

Rogers, Karen Keeler (1997). *Monsanto and the Development of Agricultural Biotechnology: Creating the Future.* [Online]. Available at: http://www.monsanto.com/MonPub/InTheNews/MonsantoMagazine/FieldsOfPromise2/Monmag.html [1997, November 26].

Rogul, Marvin (1985). "Risk and Regulation in Biotechnology: Context for the Seminar Series", *Biotechnology and the Environment: Risk & Regulation.* A. H. Teich, M. A. Levin and J. H. Pace, Eds. Washington, American Association for the Advancement of Science: 1-13.

Ronk, Richard J., James H. Maryanksi, et al. (1990). "Governmental Regulatory Issues--Reducing Uncertainties in Food Safety." *HortScience* 25 (12): 1482-1484.

Roqueplo (1995). "Scientific expertise among political powers, administrations and public opinion." *Science and Public Policy* 22 (3): 175-182.

Rose, Richard (1993). *Lesson-Drawing in Public Policy*. Chatham: Chatham House Publishers, Inc.

Rural Advancement Foundation International (1998, July / August). *RAFI Communique: Seed Industry Consolidation: Who Owns Whom?* [Online]. Available at: http://www.rafi.org/communique/19983.html [1999, April 11].

Rural Advancement Foundation International (1999, March / April). *RAFI Communique: The Gene Giants, Masters of the Universe?* [Online]. Available at: http://www.rafi.org/communique/fltxt/19992.html [1999, April 11].

Sabatier, Paul A. and Hank C. Jenkins-Smith (1993). "The Advocacy Coalition Framework: Assessment, Revisions, and Implications for Scholars and Practitioners", *Policy Change and Learning: An Advocacy Coalition Approach*. P. A. Sabatier and H. C. Jenkins-Smith, Eds. Boulder, Westview Press: 211-236.

Salquist, Roger (1985). "Issues in Regulation of Plant Biotechnology". *Food Technology*, October: 121-123.

Salter, Liora (1988). *Mandated Science: Science and Scientists in the Making of Standards*. Dordrecht: Kluwer Academic Publishers.

Salter, Liora (1995). *Mechanisms and Practices for the Assessment of the Social and Cultural Implications of Science and Technology*. Ottawa: Industry Canada.

Saunderson, Hugh (1971). *Agricultural Research--Retrospect and Prospect*. 1971 Symposia on Agricultural Research, Sponsored by the Department of Agricultural Economics, University of Manitoba with the support and co-operation of the Canada Department of Agriculture.

Scholte, Jan Aart (1997). "Global capitalism and the state." *International Affairs* 73 (3): 427-452.

Schultz, Theodore W. (1985). "Agricultural Research: Canada and Beyond", *Economics of Agricultural Research in Canada*. K. K. Klein and W. H. Furtan, Eds. Calgary, University of Calgary Press: 12-19.

Schwartz, Rosie (1998). "Nutritional heroes, demons". *The Ottawa Citizen*, April 8: C4.

Sclove, Richard E. (1995). *Democracy and Technology*. New York: The Guilford Press.

Seeliger, Robert (1996). "Conceptualizing and Researching Policy Convergence." *Policy Studies Journal* 24 (2): 287-306.

Sharples, Frances E. (1987). "Regulation of Products From Biotechnology." *Science* 235: 1329-1335.

Shohet, Simon (1996). "Biotechnology in Europe: contentions in the risk-regulation debate." *Science and Public Policy* 23 (2): 117-122.

Silber, Norman Isaac (1983). *Test and Protest: The Influence of Consumers Union*. New York: Holmes & Meier.

Simeon, Richard, George Hoberg, et al. (1997). "Globalization, Fragmentation, and the Social Contract", *Degrees of Freedom: Canada and the United States in a Changing World*. K. Banting, G. Hoberg and R. Simeon, Eds. Montreal & Kingston, McGill-Queen's University Press: 389-416.

Skogstad, Grace (1987). "Agriculture: Sharing the Responsibility", *How Ottawa Spends, 1987-88: Restraining the State*. M. J. Prince, Ed. Ottawa, Methuen Publishers: 268-292.

Skogstad, Grace (1987). *The Politics of Agricultural Policy-Making in Canada.* Toronto: University of Toronto Press.

Skogstad, Grace (1996). "Agricultural Policy", *Border Crossings: The Internationalization of Canadian Public Policy.* G. B. Doern, L. A. Pal and B. W. Tomlin, Eds. Toronto, Oxford University Press: 145-166.

Slinkard, A.E. and Douglas R. Knott (1995). *Harvest of gold: the history of field crop breeding in Canada.* Saskatoon: University Extension Press, University of Saskatchwan.

Smardon, Bruce (1995). *Promoting Science and Technology in a Free Trade Environment: The Mulroney Tories and Industrial R&D.* Paper presented at the Annual Meeting of the Canadian Political Science Association, Montreal, Quebec.

Smith, Bruce L. (1996). "The Accountability of Science." *Minerva* 34: 45-56.

Smith, Martin J. (1992). "The Agricultural Policy Community: Maintaining a Closed Relationship", *Policy Networks in British Government.* D. Marsh and R. A. W. Rhodes, Eds. New York, Oxford University Press: 27-50.

Smith, Martin J. (1993). *Pressure, Power and Policy: State Autonomy and Policy Networks in Britain and the United States.* Pittsburg: University of Pittsburg Press.

Smith, Martin J., David Marsh, et al. (1993). "Central Government Departments and the Policy Process." *Public Administration* 71: 567-594.

Snow, Allison A. and Pedro Moran Palma (1997). "Commercialization of Transgenic Plants: Potential Ecological Risks." *BioScience* 47: 86-96.

Snow, A. and R. Jorgensen (1998). *Costs of transgenic glufosinate resistance introgressed from Brassica napus into weedy Brassica rapa.* paper presented at the annual meeting of the Ecological Society of America, Baltimore, Maryland.

Soule, Judith D. and Jon K. Piper (1992). *Farming in Nature's Image: An Ecological Approach to Agriculture.* Washington, DC: Island Press.

Stevens, Candice (1993). "Harmonization, Trade, and the Environment." *International Environmental Affairs* 5: 42-49.

Stevenson, Ian L., Ed. (1988). *Proceedings: Workshop on the Regulation of Agricultural Products of Biotechnology.* Ottawa: Canadian Agricultural Research Council.

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

Stone, Diane (1996). *Capturing the Political Imagination: Think Tanks and the Policy Process.* Portland: Frank Cass.

Sudduth, Mary Alice (1993). "Genetically Engineered Foods, Fears and Facts: An Interview with FDA's Jim Maryanski". *FDA Consumer*, January / February.

Swaffield, Simon (1998). "Contextual meanings in policy discourse: A case study of language use concerning resource policy in the New Zealand high country." *Policy Sciences* 31: 199-224.

Szego, T. (1995). "The Canadian Seed Trade Association", *Harvest of Gold: The History of Field Crop Breeding.* A. E. Slinkard and D. R. Knott, Eds. Saskatoon, University Extension Press, University of Saskatchewan: 344-352.

Teich, Albert H., Morris A. Levin, et al., Eds. (1985). *Biotechnology and the Environment: Risk & Regulation.* Washington: American Association for the Advancement of Science.

The Globe and Mail (Toronto) (1998). "Health group renews calls for inquiry into cutbacks", September 10: A8.

The New York Times Magazine (1993). "Tomatogate". *The New York Times Magazine*, November 21: 24.

The Toronto Star (1998). "Food firms lobby against labels", May 27: A7.

The Western Producer (Saskatoon) (1991). "Editorial: Budget for research is a useful expenditure", May 23: 6.

The Western Producer (Saskatoon) (1997). "Government, industry researching together", January 9: 10.

The Western Producer (Saskatoon) (1998). "Prince Charles opposes gene-modified food", June 18: 10.

The Western Producer (Saskatoon) (1999). "Seed committee asks Ottawa to clarify 'harm'", March 4: 94.

Thelen, Kathleen and Sven Steinmo (1992). "Historical institutionalism in comparative politics", *Structuring Politics: Historical Institutionalism in Comparative Analysis.* S. Steinmo, K. Thelen and F. Longstreth, Eds. Cambridge, Cambridge University Press: 1-32.

Thompson, Michael and Steve Rayner (1998). "Risk and Governance Part I: The Discourses of Climate Change." *Government and Opposition* 33 (2): 139-166.

Thompson, Paul B. (1997). *Food Biotechnology in Ethical Perspective.* London: Blackie Academic & Professional.

Tiedje, James M., Robert K. Colwell, et al. (1989). "The Planned Introduction of Genetically Engineered Organisms: Ecological Considerations and Recommendations." *Ecology* 70 (2): 297-315.

Tolin, Sue A. and Anne K. Vidaver (1989). "Guidelines and Regulations For Research with Genetically Modified Organisms: A View From Academe." *Annual Review of Phytopathology* 27: 551-581.

Toner, Glen and Tom Conway (1996). "Environmental Policy", *Border Crossings: The Internationalization of Canadian Public Policy.* G. B. Doern, L. A. Pal and B. W. Tomlin, Eds. Toronto, Oxford University Press: 108-144.

Tosterud, R.J. et al. (1971). *Benefit-Cost Evaluation of Research Relating to the Development of Selkirk Wheat and Target Rapeseed.* 1971 Symposia on Agricultural Research, Sponsored by the Department of Agricultural Economics, University of Manitoba with the support and co-operation of the Canada Department of Agriculture.

Tower, Courtney (1997). "Agriculture Canada enters new era of research". *The Western Producer*, January 9: 10.

Tudge, Colin (1993). *The Engineer in the Garden.* London: Jonathan Cape.

Union of Concerned Scientists (1998). "A Surge in Commercial Transgenic Crops". *The Gene Exchange: A Public Voice on Biotechnology and Agriculture*. Fall/Winter 1998.

United Nations Conference on Environment and Development (1992). *Convention on Biological Diversity*. [Online]. Available at: http://www.biodiv.org/chm/conv/cbd_text_e.htm [1999, April 12].

United Nations Conference on Trade and Development (1997). *World Investment Report*. New York: United Nations.

United Nations Environment Programme. Convention on Biological Diversity Secretariat (1997, March 18). *Background Document on Existing International Agreements Related to Biosafety*. [Online]. Available at: http://www.biodiv.org/biosafe/bswg2-3.html [1999, April 13].

United Nations. Codex Alimentarius Commission (1998). *Report of the Forty-Fifth Session of the Executive Committee of the Codex Alimentarius Commission*. Rome: Codex Alimentarius Commission.

United Nations. Food and Agriculture Organization (1996). *Biotechnology and Food Safety: Report of a Joint FAO/WHO Consultation*. [Online]. Available at: http://www.fao.org/waicent/faoinfo/economic/esn/biotech/tabconts.htm [1999, May 31].

United Nations. Food and Agriculture Organization. Committee on Agriculture (1999, January). *Biotechnology*. [Online]. Available at: http://www.fao.org/unfao/bodies/COAG/COAG15/x0074e.htm [1999, July 19].

United Nations. World Health Organization (1991). *Strategies for assessing the safety of foods produced by biotechnology: Report of a Joint FAO / WHO Consultation*. Geneva: World Health Organization.

United States Congress. House Committee on Agriculture. Subcommittee on Department Operations, Research, and Foreign Agriculture, (1991). *Review of Current and Proposed Agricultural Biotechnology Regulatory Authority and the Omnibus Biotechnology Act; October 2, 1990*. Washington, DC: Government Printing Office.

United States Congress. House Committee on Energy and Commerce. Subcommittee on Oversight and Investigations (1985). *Biotechnology Regulation*. Washington, DC: Government Printing Office.

United States Congress. House Committee on Energy and Commerce. Subcommittee on Oversight and Investigations (1986). *Biotechnology Development*. Washington, DC: Government Printing Office.

United States Congress. House Committee on Science and Technology. Subcommittee on Investigations and Oversight, and Subcommittee on Science, Research and Technology (1983). *Environmental Implications of Genetic Engineering*. Washington: Government Printing Office.

United States Congress. House Committee on Science and Technology, Subcommittee on Investigations and Oversight (1986). *Issues in the Federal Regulation of Biotechnology: From Research to Release*. Washington, DC: Government Printing Office.

United States Congress. House Committee on Science and Technology. Subcommittee on Investigations and Oversight; Subcommittee on Natural Resources, Agriculture Research, and Environment; and the Subcommittee on Science, Research, and Technology (1987). *Coordinated Framework For Regulation of Biotechnology; July 23, 1986*. Washington, DC: Government Printing Office.

United States Congress. House Committee on Science, Space, and Technology. Subcommittee on Environment (1992). *Biotechnology in a Global Economy*. Washington: Government Printing Office.

United States Congress. House Committee on Science, Space, and Technology. Subcommittee on Natural Resources, Agriculture Research and Environment (1988). *Field Testing Genetically-Engineered Organisms; May 5, 1988.* Washington, DC: Government Printing Office.

United States Congress. House Committee on Science, Space, and Technology. Subcommittee on Technology, Environment and Aviation (1994). *Biotechnology, November 8, 1993.* Washington, DC: Government Printing Office.

United States Congress. House Committee on the Judiciary. Subcommittee on Intellectual Property and Judicial Administration (1993a). *Biotechnology Development and Patent Law: Hearing Before the Subcommittee on Intellectual Property and Judicial Administration of the Committee on the Judiciary, November 20, 1991.* Washington, DC: Government Printing Office.

United States Congress. House Committee on the Judiciary. Subcommittee on Intellectual Property and Judicial Administration (1993b). *Biotechnology Patent Protection Act of 1991: Hearing Before the Subcommittee on Intellectual Property and Judicial Administration of the Committee on the Judiciary, November 21, 1991.* Washington, DC: Government Printing Office.

United States Congress. Joint Hearing of the House Committee on Agriculture, Nutrition, and Forestry; and the House Committee on the Judiciary, Subcommittee on Technology and the Law (1988). *The Use and Regulation of Biotechnology in Agriculture.* Washington, DC: Government Printing Office.

United States Congress. Senate Committee on Commerce, Science, and Transportation. Subcommittee on Science, Technology, and Space (1994). *Competitiveness of the U.S. Biotechnology Industry: Hearing Before the Subcommittee on Science, Technology, and Space of the Committee on Commerce, Science, and Transportation, March 23, 1994.* Washington, DC: Government Printing Office.

United States Congress. Senate Committee on Environment and Public Works. Subcommittee on Toxic Substances and Environmental Oversight (1984). *The Potential Environmental Consequences of Genetic Engineering.* Washington, DC: Government Printing Office.

United States Congress. Senate Committee on Environment and Public Works. Subcommittee on Toxic Substances and Environmental Oversight (1986). *Releasing Genetically Engineered Organisms into the Environment; May 16, 1986.* Washington, DC: Government Printing Office.

United States (1997). *Biotechnology Permits: 7 Code of Federal Regulations part 340.* [Online]. Available at: http://www.aphis.usda.gov/bbep/bp/7cfr340.html [1998, January 20].

United States. Bureau of the Census (1998). *Statistical Abstract of the United States.* Washington.

United States. Department of Agriculture (1986). *Final Policy Statement for Research and Regulation of Biotechnology Processes and Products. Federal Register* 51: 23336, June 26, 1986.

United States. Department of Agriculture (1987). *Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There is Reason To Believe Are Plant Pests. Federal Register* 52: 22892, May 16, 1987.

United States. Department of Agriculture (1995). *Genetically Engineered Organisms and Products; Simplification of Requirements and Procedures for Genetically Engineered Organisms. Federal Register* 60: 43567, August 22, 1995.

United States. Department of Agriculture (undateda). *1995 Farm Bill--Guidance of the Administration: Section 6. Research, Education and Economics*. [Online]. Available at: http://www.reeusda.gov/new/legis/dir2.htm [1998, October 22].

United States. Department of Agriculture (undatedb). *Background, Federal Science Policy and Agriculture: A Brief History*. [Online]. Available at: http://www.reeusda.gov/new/legis/concept.htm [1998, October 22].

United States. Department of Agriculture. Animal and Plant Health Inspection Service (1991). *Questions and Answers on Biotechnology Permits for Genetically Engineered Plants and Microorganisms.*

United States. Department of Agriculture. Animal and Plant Health Inspection Service (1997). *Genetically Engineered Organisms and Products; Simplification of Requirements and Procedures for Genetically Engineered Organisms.* Federal Register 62: 23945, May 2, 1997.

United States. Department of Agriculture. Economic Research Service (1993). *Agriculture Information Bulletin: Regulating Bio-Engineered Foods.*

United States. Department of Agriculture. Office of the Secretary (1991). *Proposed USDA Guidelines for Research Involving the Planned Introduction Into the Environment of Organisms with Deliberately Modified Hereditary Traits. Federal Register* 56: 4134, February 1, 1991.

United States. Department of Agriculture. Office of the Secretary (1993). *Genetically Engineered Organisms and Products: Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status. Federal Register* 58: 17044, March 31, 1993.

United States. Executive Office of the President. Office of Science and Technology Policy (1984). *Proposal for a Coordinated Framework for Regulation of Biotechnology. Federal Register* 49: 50856, December 31, 1984.

United States. Executive Office of the President. Office of Science and Technology Policy (1985). *Coordinated Framework for Regulation of Biotechnology: Establishment of the Biotechnology Science Coordinating Committee. Federal Register* 50: 47174, November 14, 1985.

United States. Executive Office of the President. Office of Science and Technology Policy (1986). *Coordinated Framework for Regulation of Biotechnology. Federal Register* 51: 23302, June 26, 1986.

United States. Executive Office of the President. Office of Science and Technology Policy (1990). *Principles for Federal Oversight of Biotechnology: Planned Introduction into the Environment of Organisms With Modified Hereditary Traits. Federal Register* 55: 31118, July 31, 1990.

United States. Executive Office of the President. Office of Science and Technology Policy (1992). *Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment. Federal Register* 57: 6753, February 27, 1992.

United States. Food and Drug Administration (1986). *Statement of Policy for Regulating Biotechnology Products. Federal Register* 51: 23309, June 26, 1986.

United States. Food and Drug Administration (1992). *Statement of Policy: Foods Derived From New Plant Varieties. Federal Register* 57: 22984, May 29, 1992.

United States. Food and Drug Administration (1995, August). *Milestones in U.S. Food and Drug Law History*. [Online]. Available at: http://vm.cfsan.fda.gov/mileston.html [1999, February 24].

for Foods Developed by Biotechnology. [Online]. Available at: http://vm/cfsan.fda.gov/~lrd/biopolcy.html [1998, January 20].

United States. Food and Drug Administration. Center for Food Safety and Applied Nutrition (1996, July). *Safety Assurance of Foods Derived by Modern Biotechnology in the United States*. [Online]. Available at: http://vm.cfsan.fda.gov/~lrd/biojap96.html [1998, August 7].

United States. Food and Drug Administration. Center for Food Safety and Applied Nutrition (1997, October). *Guidance on Consultation Procedures, Foods Derived From New Plant Varieties*. [Online]. Available at: http://vm.cfsan.fda.gov/~lrd/consulpr.html [1998, July 8].

United States. Food and Drug Administration. Center for Food Safety and Applied Nutrition (1998, September 4). *Guidance for Industry: Use of Antibiotic Resistance Marker Genes in Transgenic Plants*. [Online]. Available at: http://vm.cfsan.fda.gov/~dms/opa-armg.html [1998, September 12].

United States. Food and Drug Administration (1999a). *Transcript from Public Meeting: Biotechnology in the Year 2000 and Beyond*, Chicago.

United States. Food and Drug Administration (1999b). *Transcript from Public Meeting: Biotechnology in the Year 2000 and Beyond*, Oakland, California.

United States. General Accounting Office (1985). *Biotechnology: The United States Department of Agriculture's Biotechnology Research Effort*. Washington.

United States. General Accounting Office (1986). *Biotechnology: Agriculture's Regulatory System Needs Clarification*. Washington.

United States. General Accounting Office (1988). *Biotechnology: Managing the Risks of Field Testing Genetically Engineered Organisms*. Washington.

United States. General Accounting Office (1996a). *Food Safety: New Initiatives Would Fundamentally Alter the Existing System*. Washington.

United States. General Accounting Office (1996b, March). *Agricultural Research - Information on Research System and USDA's Priority Setting*. [Online]. Available at: http://www.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=gao&docid=f:rc96092.txt [1999, February 16].

United States. General Accounting Office (1997a, March 13). *Agricultural Research: More Efficient and Accountable System Could Better Respond to New Challenges*. [Online]. Available at: http://www.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=gao&docid=f:rc97101t.txt [1999, February 16].

United States. General Accounting Office (1997b). *Food Safety: Fundamental Changes Needed to Improve the Nation's Food Safety System*. [Online]. Available at: http://www.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=gao&docid=f:rc98024t.txt [1999, February 24].

University of Manitoba. Department of Agricultural Economics (1971). *Proceedings of 1971 Symposia on Agricultural Research*, Sponsored by the Department of Agricultural Economics, University of Manitoba with the support and co-operation of the Canada Department of Agriculture.

Van Dijck, José (1998). *Imagenation: Popular Images of Genetic*. New York: New York University Press.

Van Wagner, Lisa R. (1995). "The return of the Republican". *Food Processing*, March: 78-81.

Vaughan, Odette S. (1995). *Implications of Foreign Direct Investment for the Canadian Food and Beverage Manufacturing Industry*. Ottawa: Agriculture and Agri-Food Canada.

Vogel, David (1986). *National Styles of Regulation: Environmental Policy in Great Britain and the United States*. Ithaca: Cornell University Press.

Vogel, David (1995). *Trading Up: Consumer and Environmental Regulation in a Global Economy*. Cambridge: Harvard University Press.

Vogel, Steven K. (1997). "International Games With National Rules: How Regulation Shapes Competition in 'Global' Markets." *Journal of Public Policy* 17 (2): 169-193.

Vorman, Julie (1998). "Lawsuit challenges U.S. agency on gene-altered foods". *The Western Producer* (Saskatoon), June 18: 19.

Webber, David J. (1995). "The Emerging Federalism of U.S. Biotechnology Policy." *Politics and the Life Sciences* 14 (1): 65-72.

Weingart, Peter (1999). "Scientific expertise and political accountability: paradoxes of science in politics." *Science and Public Policy* 26: 151-162.

Weir, Margaret (1992a). *Politics and Jobs: The Boundaries of Employment Policy in the United States*. Princeton: Princeton University Press.

Weir, Margaret (1992b). "Ideas and the Politics of Bounded Innovation", *Structuring Politics: Historical Institutionalism in Comparative Analysis*. S. Steinmo, K. Thelen and F. Longstreth, Eds. New York, Cambridge University Press: 188-211.

Weiss, Linda (1998). *The Myth of the Powerless State*. Ithaca: Cornell University Press.

Weiss, Rick and Justin Gillis (1999). "U.S. 'Observers' Lobby Against Trade Curbs on Biotechnology: Accord Would Be First to Target Genetically Engineered Products". *The Washington Post*, February 13: A4.

Wenner, Lettie McSpadden (1990). *U.S. Energy and Environmental Interest Groups*. New York: Greenwood Press.

Wheale, Peter and Ruth McNally, Eds. (1988). *Genetic Engineering: Catastrophe or Utopia?* New York: St. Martin's Press.

Wheale, Peter and Ruth McNally, Eds. (1990). *The Bio-Revolution: Cornucopia or Pandora's Box*. London: Pluto Press.

Widmer, Lorne, Glenn Fox, et al. (1988). "The Rate of Return to Agricultural Research in a Small Country: The Case of Beef Cattle Research in Canada." *Canadian Journal of Agricultural Economics* 36: 23-35.

Wilson, Barry K. (1990). *Farming the System: How Politicians and Producers Shape Canadian Agricultural Policy*. Saskatoon: Western Producer Prairie Books.

Wilson, Barry (1991a). "Agricultural research a closed circuit, says scientific paper". *The Western Producer* (Saskatoon), August 1: 55.

Wilson, Barry (1991b). "Agriculture research makes a correction in its course". *The Western Producer* (Saskatoon),

May 23: 14.

Wilson, Barry (1992a). "Ag research not commercial enough, says competitiveness group". *The Western Producer* (Saskatoon), October 15: 41.

Wilson, Barry (1992b). "Canadian agricultural research under pressure". *The Western Producer* (Saskatoon), July 16: 6.

Wilson, Barry (1998a). "Ag company official decries possible biotech restrictions". *The Western Producer* (Saskatoon), October 1: 65.

Wilson, Barry (1998b). "Modified food: right to know issue heats up". *The Western Producer* (Saskatoon), Ocotober 29: 70.

Wilson, Barry (1998c). "Whelan outlines agricultural fears". *The Western Producer* (Saskatoon), March 19: 25.

Wilson, Jeremy (1992). "Green Lobbies: Pressure Groups and Environmental Policy", *Canadian Environmental Policy: Ecosystems, Politics, and Process*. R. Boardman, Ed. Toronto, Oxford University Press: 109-125.

Winsor, Hugh (1998). "Health branch in 'transition' sparks question: To where?". *The Globe and Mail* (Toronto), September 9: A7.

Winsor, Hugh (1999). "Who should test new drugs for safety? Health Canada is a house divided". *The Globe and Mail* (Toronto), November 12: A4.

Wodicka, Virgil O. (1996). "Regulation of Food: Where Have We Been?". *Food Technology*, March: 106-109.

Wood, Donna J. (1986). *Strategic Uses of Public Policy: Business and Government in the Progressive Era.* Marshfield: Pitman Publishing.

World Trade Organization (1996, July). *Understanding the World Trade Organization Agreement on Sanitary and Phytosanitary Measures*. [Online]. Available at: http://www.wto.org/goods/spsund.htm [1999, May 31].

Yee, Albert (1996). "The Causal Effects of Ideas on Policies." *International Organization* 50: 69-108.

Yoxen, Edward (1983). *The Gene Business: Who Should Control Biotechnology?* New York: Oxford University Press.

Young, Alvin L. and Marti R. Asner (1996). "A Government Agency's Responsibility to the Consumer." *Journal of Nutrition* 126: 1010S-1012S.

Zahariadis, Nikolaos and Christopher S. Allen (1995). "Ideas, Networks, and Policy Streams: Privatization in Britain and Germany." *Policy Studies Review* 14 (1/2): 72-93.

Zentner, R.P. (1985). "Returns to Public Investment in Canadian Wheat and Rapeseed Research", *Economics of Agricultural Research in Canada*. K. K. Klein and W. H. Furtan, Eds. Calgary, University of Calgary Press: 169-188.

WHAT IS GENETIC ENGINEERING? A PRIMER[1]

One of the frequent problems encountered in developing regulatory policy for biotechnology has been the fundamental issue of defining biotechnology. Some define biotechnology as any technique that uses living things to produce items, such as the yeast in bread and the bacterial culture in yogurt. Such a definition implies that genetic engineering is a logical extension of such techniques, which is why it is sometimes referred to as "modern" biotechnology. Few scientists disagree, however, with the view that genetic engineering is a significant departure from previous techniques in that it allows theoretically for genetic material to be taken from one organism and combined with the DNA of any other. It removes barriers that previously existed to combining disparate sources of genetic material.

Many plant breeders view the arrival of rDNA techniques, or genetic engineering, as the latest addition to their toolbox which has consistently been updated. Prior to genetic engineering, plant breeders introduced techniques such as random mutagenesis resulting from chemical treatment and physical mutagens; somoclonal variation through tissue culture techniques; and wide crosses using techniques such as hybridization and protoplast fusion to overcome physical or genetic barriers that otherwise restrict the crossing of distant relatives.

Genetic engineering involves identifying genetic material that expresses a desired trait, isolating that material, and reinserting it into the target organism. Various techniques are used to accomplish this task including the use of biological vectors such as plasmids and viruses that transplant foreign genetic material into the cells of the target organisms. Other techniques that are mechanical rather than biological such as electro- and chemical poration, microinjection, and bioballistics. Electro- and chemical poration involves using chemicals or electricity to create holes in cell membranes to allow the entry of foreign genetic material. Microinjection simply involves injecting the foreign genetic material into the target organism's cell. Finally, bioballistics uses metal slivers to deliver the genetic material to the cell.

[1] For further details, see United States. Food and Drug Administration (1992), Grace (1997), and the web site of the Union of Concerned Scientists at http://www.ucsusa.org.

PUBLIC OPINION ON GENETIC ENGINEERING / BIOTECHNOLOGY[1]

Many surveys have been conducted in various countries to assess public opinion toward aspects of biotechnology, including regulatory policy. The examples below present the highlights of a few of these surveys.

CANADA

1) Optima Study for federal departments, November 1994[2]

sample size=2000

Impact of biotechnology

- Thirty-three per cent felt biotechnology would make the world a riskier place.
- Twenty-eight per cent felt Canadians should accept some risks from biotechnology if it benefits the economy.
- Twenty-six per cent agreed that only biotechnology companies would benefit from biotechnology.
- Twenty-four per cent agreed that the risks from biotechnology have been greatly exaggerated.

Government response

- Fifty-one per cent agreed that decisions about the safety of biotechnology should be left to the experts.
- Sixty-two per cent felt that the government should increase its regulation of biotechnology.
- Twenty-three per cent felt that biotechnology was adequately regulated by the government.
- Eighty-one per cent felt the public should be consulted on regulation of biotechnology products and uses.
- Seventy-seven per cent felt that the government should conduct a public information campaign about biotechnology.

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[1] Davison (1997) provides an overview of some of the major public opinion surveys conducted in various countries since the mid-1980s and discusses their weaknesses.

[2] Optima Consultants (1994).

- Seventy-five per cent felt the government should be involved in the ethical aspects of biotechnology
- Thirty-seven per cent agreed that the government should financially support biotech research in the private sector.

Awareness and consumer response

- Seventy-seven per cent said they had heard of genetically-engineered crops designed to be more resistant to insects.
- Ninety per cent wanted labelling of genetically-engineered foods to indicate the process used.
- Forty-three per cent said they would pay more for non-biotechnology foods.
- Forty-nine per cent said they would buy biotechnology foods if they were proven to be nutritious.
- Forty-four per cent said they would buy a genetically-modified tomato that had a longer shelf life.
- Nineteen per cent said they would buy a tomato made frost resistant through the insertion of a fish gene.
- Forty-five per cent accepted the use of genetically-engineered bacteria as a pesticide. Acceptance dropped to twenty-eight per cent when told that insects could develop a resistance to the bacteria and further to twenty-five per cent when told that the food chain would be affected.

2) Einsiedel, *Biotechnology and the Canadian Public*, February 1997[3]

sample size=1002

Impact of biotechnology

- Fifty-four per cent felt genetic engineering would improve our way of life; twenty-six per cent felt it would worsen our way of life.
- Sixty-two per cent felt that some degree of risk from biotechnology had to be accepted if it contributes to Canadian competitiveness.

Government response

- Thirty-six per cent felt current regulations were adequate to protect the public from the risks of biotechnology. Fifty per cent disagreed.
- Sixty-eight per cent disagreed that regulation of modern biotechnology should be left mainly to the industry.
- Sixty-seven disagreed with the argument that modern biotechnology is so complex that public consultation is a waste of time.
- Seventy-two per cent disagreed with the statement that it is not worthwhile to put special labels on genetically-modified foods.

Awareness and consumer response

- Thirty per cent thought it was impossible to transfer animal genes into plants; thirty-eight per cent knew that it is possible.
- Sixty-four per cent had heard of genetically-engineered plants made them more resistant to pests. Eighty-three per cent agreed that this was useful for society, thirty-eight per cent felt it was risky for society, seventy-nine per cent felt it was morally acceptable, and seventy-seven per cent felt it should be encouraged.
- Forty-two per cent felt only traditional breeding methods should be used, rather than modern biotechnology.

[3] Einsiedel (1997). This survey also found that the use of the term "biotechnology" is still nebulous for most Canadians who make only vague statements about what it is or may do when asked. The comparative aspect of the study found that Canadians tend to be "cautiously predisposed toward biotechnology" but support varies according to application. However, Canadians also expressed distrust of current regulatory efforts.

- Fifty-three per cent would buy genetically modified foods if they tasted better.
- Fifty-four per cent reported hearing something in the three months prior to the survey about biotechnology either through the media or personal contact.
- Fifty-three per cent characterized biotechnology issues as "very important", scoring it at eight or higher on a scale of one to ten.

UNITED STATES

1) Office of Technology Assessment, 1986

sample size=1273

Impact and response to biotechnology

- Two-thirds believed that genetic engineering "will make life better for all people".
- One-quarter felt that "humans should not meddle with nature".
- One quarter felt it was morally wrong to use genetic engineering on plants and animals, but one quarter also thought that classical breeding techniques were morally wrong.
- Opposition to genetic engineering was greatest in the area of human genetic engineering; but three-quarters supported application to specific human diseases.

2) Hoban, *Public Opposition to Genetic Engineering*, 1992[4]

sample size=552

Degree and explanation of public opposition

- Twenty-three per cent oppose plant genetic engineering, twenty-three per cent are neutral.
- Fifty-three per cent oppose animal genetic engineering; twenty-one per cent are neutral.

[4] Hoban et al. (1992).

- Women are more likely to be morally opposed to genetic engineering than men and more likely to be concerned about environmental and food safety risks. Individuals with more formal education or income are less likely to be opposed. Higher awareness of the technology is more likely to lead to acceptance.

3) International Food Information Council, March 1997[5]

sample size=1004 (Americans)

Awareness and government response

- Seventy-nine per cent say they are aware of biotechnology.
- Fifty-four per cent say biotechnology has already provided benefits to them.
- Almost half realize biotechnology foods are already in the marketplace.
- Seventy-eight per cent support the current FDA labelling policy on biotechnology foods, when it is described to them.
- Fifty-seven per cent still support the policy when criticisms of the policy are provided to them.

[5] From IFIC web site: http://ificinfo.health.org/.

GLOSSARY

AAFC	Agriculture and Agri-Food Canada name changed in 1993 from Agriculture Canada and regulatory responsibilities transferred in 1997 to CFIA
AFBF	American Farm Bureau Federation
APHIS	Animal and Plant Health Inspection Service (USDA)
ASA	American Soybean Association
ASTA	American Seed Trade Association
BIO	Biotechnology Industry Organization
BSCC	Biotechnology Science Coordinating Committee (US))
CAC	Consumers Association of Canada
CARC	Canadian Agri-Food Research Council
CEN	Canadian Environmental Network
CEPA	*Canadian Environmental Protection Act*
CFA	Canadian Federation of Agriculture
CFIA	Canadian Food Inspection Agency
CIELAP	Canadian Institute of Environmental Law and Policy
CSTA	Canadian Seed Trade Association
EDF	Environmental Defense Fund
EPA	Environmental Protection Agency (US)
FAO	Food and Agriculture Organization (United Nations)
FCPMC	Food and Consumer Products Manufacturers of Canada
FDA	Food and Drug Administration (US)
FDCA	*Food, Drug and Cosmetic Act* (US)
GAO	General Accounting Office (US)
HPB	Health Protection Branch, Health Canada
HWC	Health and Welfare Canada name changed to Health Canada in 1993

ICB	Interdepartmental Committee on Biotechnology (Canada)
IFBC	International Food Biotechnology Council (headquartered in US)
ISTC	Industry, Science and Technology Canada name changed to Industry Canada in 1993
MOSST	Ministry of State (Science and Technology) (Canada)
NAS	National Academy of Sciences (US)
NBAC	National Biotechnology Advisory Committee (Canada)
NBS	National Biotechnology Strategy, 1983 (Canada)
NCGA	National Corn Growers Association (US)
NEPA	*National Environmental Policy Act* (US)
NFPA	National Food Processors Association (US)
NIH	National Institutes of Health (US)
OECD	Organisation for Economic Cooperation and Development
OSTP	Office of Science and Technology Policy (US)
PBR	plant breeders' rights
PVPA	*Plant Variety Protection Act* (US)
PNT	plants with novel traits (Canada)
RAC	Recombinant DNA Advisory Committee, NIH (US)
rDNA	recombinant DNA
SAES	State Agriculture Experiment Stations (US)
UCS	Union of Concerned Scientists (US)
USDA	United States Department of Agriculture
WHO	World Health Organization (United Nations)

INTERVIEWS

Canada

- AGCare (Agricultural Groups Concerned about Resources and the Environment), Ontario farm alliance of horticultural and field crop producers' associations that represents members' views on environmental issues including biotechnology; February 26, 1998 (Guelph, Ontario, by telephone).
- AgrEvo Canada; September 29, 1998 (Regina).
- Agriculture and Agri-Food Canada, Research Branch administrators and scientists; February 18, 1998 (Ottawa); March 16, 1998 (Ottawa); July 20, 1998; September 25, 1998 (Saskatoon).
- Ag-West Biotech Inc.; September 25, 1998 (Saskatoon).
- BIOTECanada / Industrial Biotechnology Association of Canada; February 17, 1998 (Ottawa).
- Canadian Agri-Food Research Council; February 27, 1998 (Ottawa).
- Canada Grains Council; September 24, 1998 (Winnipeg).
- Canadian Federation of Agriculture; July 3, 1998 (Ottawa).
- Canadian Food Inspection Agency, chair of Canadian delegation to Codex Food Labelling Committee meetings; September 2, 1998 (Ottawa).
- Canadian Food Inspection Agency, Plant Breeders' Rights Office; February 23, 1998 (Ottawa).
- Canadian Food Inspection Agency, Office of Biotechnology; August 19, 1998 (Ottawa); August 27, 1998 (Ottawa).
- Canadian Institute for Environmental Law and Policy; July 9, 1998 (Toronto).
- Canadian Seed Trade Association; March 10, 1998 (Ottawa).
- Canola Council of Canada; September 23, 1998 (Winnipeg).
- Consumers' Association of Canada, National Food Committee; February 19, 1998 (Ottawa); February 23, 1998 (Winnipeg, by telephone).
- Council of Canadians; July 21, 1998 (Ottawa, by telephone).
- Dow AgroSciences Canada, development scientists; September 24, 1998 (Saskatoon).
- Flax Council of Canada; September 23, 1998 (Winnipeg).
- Food Biotechnology Communications Network; February 24, 1998 (Guelph, Ontario, by telephone).

- Food and Consumer Products Manufacturers of Canada; July 7, 1998 (Toronto, by telephone).

- Health Canada, Office of Food Biotechnology; August 25, 1998 (Ottawa).

- Kneen, Brewster; farmer, writer, biotechnology skeptic and editor of *The Ram's Horn* which examines developments in the agri-food industry; May 28, 1998 (Ottawa).

- Monsanto Canada; February 24, 1998 (Ottawa).

- National Farmers Union; September 25 and 27, 1998 (Saskatoon).

- Ontario Agri-Food Technologies, a consortium of government, agri-food industry, and university groups with goal of coordinating research and commercialization efforts in agri-food technologies; March 6, 1998 (Guelph).

- Plant Biotechnology Institute, National Research Council, senior researcher /administrator; September 25, 1998 (Saskatoon).

- Saskatchewan Ag-biotech Regulatory Affairs Service, Ag-West Biotech Inc.; September 25, 1998 (Saskatoon).

- Saskatchewan Wheat Pool; September 24, 1998 (Saskatoon).

- SubGroup on Safety and Regulations of the Interdepartmental Committee on Biotechnology, Canadian federal government, a longtime member; August 27, 1998 (Hull, Quebec).

- University of British Columbia, agri-food research scientist; February 19, 1998 (Vancouver, by telephone).

- University of Saskatchewan, Crop Development Centre, senior researcher/administrator; September 15, 1998 (Saskatoon, by telephone).

- University of Saskatchewan, Department of Plant Sciences, senior researchers/administrators; September 24, 1998 (Saskatoon); September 28, 1998.

United States

- American Seed Trade Association; October 13, 1998 (Washington, DC).
- American Soybean Association; October 19, 1998 (Washington, DC, by telephone).
- Biotechnology Industry Organization; October 13, 1998 (Washington, DC).
- Consumer Policy Institute, Consumers Union; December 10, 1998 (Yonkers, NY, by telephone).
- Environmental Defense Fund; October 22, 1999 (New York, NY).
- National Corn Growers Association; October 14, 1998 (Washington, DC).
- National Food Processors Association; October 13, 1998 (Washington, DC).
- Union of Concerned Scientists; November 9, 1998 (Washington, by telephone).
- United States Department of Agriculture officials (5); October 15, 1998 (Washington, DC).
- United States Grains Council; October 13, 1998 (Washington, DC).