

**Food Safety, Labelling, and the Role of Science:
Regulating Genetically-Engineered Food Crops in Canada and the United States**

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Food Safety, Labelling, and the Role of Science: Regulating Genetically-Engineered Food Crops in Canada and the United States¹

Many of the new plant varieties of the first generation of crops produced through genetic engineering are intended ultimately for human consumption. Canada and the United States (US) are among the pioneers globally in the commercialization of these genetically-engineered crops.² The novelty of these new varieties has created policy issues including whether they pose different food safety risks and whether foods made from them should be labelled so to allow consumer choice. Canadian and American policy makers have facilitated commercialization by developing regulatory policy responses to these issues.

A comparison of Canadian and American policy responses to food safety and labelling issues reveals similar narrow problem definitions and policy choices that privilege market-based policy goals and rely primarily on science as the means to achieve those goals. These policy responses have excluded or marginalized additional or alternative ideas about what policy goals should be pursued through regulation and through what means. The comparison also highlights interesting differences in the policy responses to food safety that provide Canadian regulators with more capacity and discretion than their American counterparts, even while labelling policy responses are virtually identical. These differences in the policy responses to food safety assessment may provide Canadian regulators with more policy capacity to design regulation in the public interest and in a manner that contributes to a longer term, sustainable competitive advantage even in a context of high economic internationalization. Further, because both countries have linked their labelling policy responses to food safety assessment, the success of labelling policy is somewhat dependent on the operation of the food safety assessment process.

The paper examines the nature of the policy networks in both countries surrounding the issue of food safety risks in an effort to determine why there are differing policy responses, given the implications for policy capacity. This analysis suggests that there is a correlation between the nature of the policy networks and policy choices. To investigate the internal dynamics of the food safety policy networks, the role of science is examined as a programmatic idea that can designate scientific expertise as a critical resource and thus underpin patterns of exchange that shape a policy network.³ To establish the starting points for the food safety policy networks, the North American context for the role of science in regulatory policy making is briefly described, as are the ideational components of relevant policy legacies. During development of policy responses to the commercialization of genetically-engineered food crops, the role of science has been more politicized in the US than in Canada. This characteristic of policy making has been evident, for example, in the position of regulators in the debate over how novel genetically-engineered organisms truly are and in the types of resources sought during consultations. Within both food

¹ The author gratefully acknowledges financial support from the Social Sciences and Humanities Research Council of Canada.

² In 1998, of total acreage of genetically-engineered crops at 70 million acres, Canada grew 7 and the US grew 51.3. Argentina is another pioneer, at 10.8 million acres in 1998. Source: www.isaaa.cornell.edu.

³ The term “programmatic ideas” refers to ideas used to achieve policy goals; in other words, the means to the end.

safety policy networks, however, science as an idea still enjoyed a predominantly neutral characterization at the moment of policy choices, thus privileging policy network members with relevant scientific expertise. A comparison of the nature of the policy networks with the allocation and location of relevant scientific expertise in the two countries suggests that investigating the role of science does shed light on the internal dynamics of policy networks.

The paper concludes by noting that Canadian and American regulators have been constrained by inadequate policy capacity in developing their policy responses to the commercialization of genetically-engineered plants. In particular, the lack of scientific and democratic legitimacy during policy making, which has made these policy responses vulnerable to challenge and thus potentially jeopardizes public confidence in the regulatory system, provides lessons for similar regulatory policy issues.

CANADIAN AND AMERICAN POLICY RESPONSES

There are many reasons to expect similar policy responses in Canada and the US to issues arising from the commercialization of genetically-engineered plants. For example, both countries are major agricultural producers and exporters of crops such as wheat, corn, and soybeans. The central role of science in risk assessment suggests a common basis for policy choices. Further, the 1990s brought a deepening of the already substantial integration of the two countries' economies through increased trade and investment. Finally, Canada's heavy reliance on the American market for the export of Canadian agri-food products and the leadership in the global plant biotechnology industry of American multinationals such as Monsanto also encourage predictions of highly similar policy responses.

Comparing policy responses to the issues of food safety and labelling reveals that policy makers in both countries selected identical narrow official problem definitions.⁴ In the case of food safety, the problem definition focused exclusively on whether it is safe to eat products containing genetically-engineered plants or other organisms. This definition excluded, for example, a consideration of the socioeconomic costs and benefits of these products or other explicit criteria of social utility. Policy makers did not take the opportunity to require genetically-engineered foods to be superior to conventional counterparts in characteristics such as food safety or quality, relying instead on a measure of equivalence. For the labelling problem definition, policy makers focused on the consumer's "need to know", rather than the right or desire to know. This focus excluded the principle of consumer choice, including on grounds such as religious or ethical beliefs.

A detailed comparative analysis of policy choices finds that Canadian and American responses to food safety vary more than their labelling policy choices. In their responses to both issues there is a high degree of similarity, especially in policy goals. Unlike the American response, however, the Canadian policy response to food safety is based on mandatory premarket notification, provides discretion to regulators in deciding whether to conduct a food safety assessment, and explicitly acknowledges the novelty of genetically-engineered products. In contrast, policy responses to the labelling issue were almost identical in the two countries. Both countries require

⁴ The term "official" problem definition refers to the problem definition selected by policy makers.

special labelling provisions for genetically-engineered foods only in very specific circumstances (such as health and safety concerns, or significant changes in composition), have tied the operation of the labelling regime to the food safety assessment process, and as a result, have provided minimal discretion to regulators in implementing these provisions.

Food safety assessment

As Table 1 shows, the two countries share policy goals of safety, public confidence, harmonization, and competitiveness. Their programmatic ideas are also similar, including a risk-based approach and the use of informal industry consultations. Examining the details of policy instruments reveals the notable differences in the policy responses of the two countries.⁵ Since finalizing its new regulations for novel foods in the fall of 1999 (which were first published in 1995), Canada has had a mandatory premarket notification system in place.⁶ The US, in contrast, continues to rely on existing legislative and regulatory authorities, and the system of voluntary consultations with industry that it established in 1992 through its policy statement on food safety assessment of new plant varieties.⁷ Canada's response contributes to the capacity and autonomy of regulators by providing them with a mandatory system with some discretion for regulators; the American response instead leaves discretion with industry and makes no contribution to state capacity or autonomy.

In Canada, the choice of the "novel food" definition as a regulatory trigger extends the scope of the regulatory response beyond genetically-engineered products, although virtually all of the novel foods approved as of 1998 involved the use of genetic engineering.⁸ It establishes a built-in flexibility that reduces regulatory oversight of similar products as scientific evidence accumulates. This approach does not discriminate overtly between novel foods produced through genetic engineering techniques and those produced through other means, although Health Canada has stated that genetic engineering causes safety concerns because of its potential for novelty.

In the US, food safety assessment is guided by product characteristics. Since the safety assessment of the first genetically-engineered food plant in 1994, developers have had the option of providing summaries of their own safety assessments to the Food and Drug Administration (FDA) for the purpose of notification or as the basis for consultations to discuss safety or regulatory issues. The FDA publishes a list of new plant varieties for which it has completed "final

⁵ The two countries have, however, both adopted the scientific concept of "substantial equivalence" to guide the scope of the food safety assessment process. This concept is based on the comparison of the novel food to its conventional counterpart, which usually has a long history of safe use in humans. Points of comparison include 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 a case-by-case approach and is intended to allow for variation of assessment according to the potential risk.

⁶ Canada. Minister of Supply and Services Canada (1999).

⁷ United States. Food and Drug Administration (1992).

⁸ Personal interview with Health Canada official, September 1998.

consultations” with the developers, meaning that there are no scientific or regulatory issues outstanding. While consultations are voluntary, developers consistently have consulted with the FDA since 1994. For legal authority, the FDA uses existing provisions under the *Food, Drug, and Cosmetic Act* that give it authority to remove adulterated foods from the marketplace and to require pre-market approval of foods falling under the category of “food additives”.⁹ The scientific policy instrument is the “guidance” section of its 1992 policy statement which sets out a voluntary process for developers.¹⁰ The guidance section, based on criteria used in traditional plant breeding, includes flow charts to assist developers in determining when it would be advisable to consult with the FDA. Regulation does not vary with the method of production: although the 1992 policy statement was provoked by questions about the food safety of new plant varieties derived through genetic engineering, the policy extends to new plant varieties produced through any means.

Labelling

Canadian and American policy responses to the labelling of foods containing genetically-engineered ingredients, including those from plants, are highly similar in policy goals and policy instruments (see Table 2).¹¹ The American policy response was briefly laid out in the FDA’s 1992 policy statement on new plant varieties and has not been revised since, while Canada’s response has been developed through a consultation process, resulting in “interim” guidelines last revised in 1997.¹² In both countries, additional labelling requirements are triggered only when the food safety assessment process reveals health and safety concerns, and/or significant changes in composition. With the exception of these additional requirements, labelling policy for foods from genetically-engineered plants is akin to that for all other food products.

The two countries share the policy goals of safety and truthful labelling. They also agree that the process behind the product is irrelevant information for labelling, thus limiting the scope of labelling to product characteristics. The American declaration that the consumer’s desire to know is not an adequate basis for labelling requirements is arguably similar to Canada’s conclusion that religious dietary restrictions are outside the scope of its labelling policy and are adequately

⁹ The FDA has stated that it does not expect to use its pre-market approval authority frequently to regulate new plant varieties. 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.

¹⁰ 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).

¹¹ Institutional frameworks differ and reflect the continuation of policy legacies because both countries rely on existing legislative and regulatory authorities. In the US, the FDA holds primary responsibility for food labelling and has subsumed labelling within its food safety assessment policy. Responsibility in Canada is divided between Health Canada and the Canadian Food Inspection Agency; the latter agency plays the lead role. Health Canada sets health and safety standards, while CFIA administers economic regulations and enforces all labelling requirements.

¹² Canada. Canadian Food Inspection Agency. Biotechnology Strategies and Coordination Office (1997). A private sector advisory board is now developing more specific guidelines for *voluntary* labelling of foods with genetically-engineered ingredients.

addressed elsewhere. However, Canada alone has made an explicit commitment to harmonize its policy with regimes developed in major markets elsewhere and its labelling guidelines provide clearer parameters of its policy response.

Why the differences in food safety assessment policy responses are interesting

The differences revealed between the Canadian and American responses to the issue of food safety assessment are interesting because they have implications for state capacity and autonomy. They affect the potential for regulation in the public interest and for policy choices that can provide competitive advantage in the context of internationalization. The degree of discretion given to regulators can be an important ingredient in state autonomy when combined with adequate capacity. The coexistence of sufficient discretion for regulators, state capacity including adequate independent expertise, and thorough accountability measures may be necessary conditions for social regulation in the public interest. These conditions should allow consistent, rigorous, and transparent regulatory policy responses that 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 priceless possession of public confidence in a regulatory system and the difficulty of regaining it, once lost.

Further, policy choices that provide greater discretion to regulators and thus the potential for greater rigour, may prove more robust over time in the arena of international trade. They may provide a more secure route to market access by being better able to withstand scrutiny imposed by international trading rules and new international regimes such as that which may be created under the draft United Nations Biosafety Protocol, intended to govern trade in biotechnology products to manage environmental risks.¹³ The realization of this potential, however, is dependent on the details of implementation. It is also important not to overstate the strength of Canadian food safety regulators compared to their American counterparts. Both are, in fact, relatively vulnerable state actors within their respective policy communities and networks.

COMPARING POLICY COMMUNITIES AND POLICY NETWORKS

The concepts of policy community and policy network organize analysis that focuses on variables at the sectoral level. These concepts are applied here in the effort to determine why there are distinctive differences between the Canadian and American policy responses to food safety, and not in their responses to labelling. Policy communities surrounding the regulation of plant biotechnology emerged in both countries in the early to mid-1980s (see Table 3).¹⁴ Researchers, regulators, and a handful of biotechnology skeptics (including environmentalists) formed the original core. As new issues arose in the 1990s, including consumer resistance overseas that

¹³ These conditions may, for example, permit a more “science-based” approach that could better withstand a trade challenge under the Sanitary and Phytosanitary Agreement of the World Trade Organization.

¹⁴ 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”. Coleman and Skogstad (1990): 25-26.

translated into lost exports and demands for mandatory labelling of foods with genetically-engineered ingredients, the policy communities expanded somewhat dramatically in both countries. The newer members included a more diverse mix of public interest groups, agricultural producer associations, and agri-food industry associations.

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.¹⁵ The nature of a policy network reflects “the properties that characterize the relationships among the particular set of actors that forms around an issue of importance to the policy community”.¹⁶ 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, and by the nature of exchange relationships within the policy network.

Coleman and Skogstad have sketched an ideal typology of 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.¹⁷ The three types of 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 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.

Examining the characteristics of policy community members according to this typology (see Table 4), the Canadian policy network surrounding the safety assessment of genetically-engineered foods is closest to a weak form of concertation. To summarize, Health Canada’s capacity and potential for autonomous action has been limited by the fragmentation of responsibility across federal agencies and by shared jurisdiction between levels of government for food safety regulation. This fragmentation reduces its ability to fulfil its public interest mandate in food safety. The agency

¹⁵ Knoke et al. (1996), Smith (1993).

¹⁶ Coleman and Skogstad (1990): 26.

¹⁷ Coleman and Skogstad (1990): 25-31.

has been further weakened since the mid-1990s by fiscal restraint.¹⁸ The Canadian food industry is the dominant societal member of the policy network. It is not highly-organized, but it does have a national association, is a relatively large industry with some large firms, and some of its firms possess expertise required by state officials.¹⁹ In contrast, the national consumer association is an extremely weak member of the policy community, lacking financial and technical resources.²⁰ Its influence comes only from its legitimacy-conferring properties. The weaknesses of key members of the policy network suggests that the network could become either clientele or pressure pluralist unless internal resources are shored up.

The American policy network on food safety can be best described as clientele pluralist. The capacity of the FDA is also weakened by the fragmentation of responsibility for food safety both within the federal government and across levels of government. Further, the agency lacks potential for autonomous action, particularly given the highly politicized context it works within. Aggressive oversight by congressional committees, industry associations, and public interest groups places the FDA under near constant scrutiny. Political and financial support for its mandate has been very thin at times during the 1980s and 1990s, in the context of deregulatory pressures.²¹ Policy choices on genetically-engineered foods have not provided any reinforcement. FDA regulators face a well-organized and massive domestic food industry.²² The resources of the major national consumer association, Consumers Union, are much higher than those of its Canadian counterpart and there is scientific expertise on staff.²³ However, these resources are dwarfed by those of the food industry.

In both countries, the fragmentation of authority over food safety regulation has been blamed for reducing the effectiveness of federal food safety efforts.²⁴ Food safety assessment measures appear to have developed generally in an ad hoc and reactive manner, in response to the latest food safety concerns and scandals, rather than in a proactive manner. Overall, regulators in

¹⁸ Between 1993-94 and 1999-2000, the Canadian federal government announced a total reduction in the Health Protection Branch's budget, within Health Canada, from \$237-million (Cdn) to \$118-million. This branch is responsible for the safety assessment of biotechnology foods. However, the 1999 and 2000 federal Budgets promised some restoration of funding to Health Canada. The 1999 Budget allocated \$65-million over three years for food safety regulation; the 2000 Budget allocated \$46-million over three years for biotechnology regulation within Health Canada.

¹⁹ The Food and Consumer Products Manufacturers' Association of Canada, which is the major national food processors' association, has 170 member firms and 16 staff members.

²⁰ The Consumers' Association of Canada has about 250,000 individual members and six staff members.

²¹ For example, the Center for Food Safety and Applied Nutrition (CFSAN), within the FDA, has lost 20 per cent of its staff over the last two decades. Responsibility for the safety assessment of biotechnology foods lies within CFSAN. See Carey (1999).

²² There are two major food industry associations in the US. The Grocery Manufacturers of America, which represents only processors of branded foods, has 140 member firms and 44 staff members. The National Food Processors Association, which represents all types of processors, has 600 member firms and 180 staff members.

²³ The Consumers Union has 4.8 million individual members and about 38 staff members.

²⁴ 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 (1997) and United States. General Accounting Office (1996). 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.

both countries appear vulnerable within their policy networks to societal pressures. However, Canadian regulators are somewhat more insulated because of the relatively fewer resources of societal network members, particularly public interest groups, which in turn contributes to a less politicized context for food safety regulation.

The policy networks surrounding the *labelling* of genetically-engineered foods in both countries appear to have been pressure pluralist. This type of policy network is consistent with the policy choices which have established a mandatory labelling regime, but provided regulators with minimal discretion. State capacity within policy networks is limited by policy legacies, including labelling's minor status as a policy instrument.²⁵ State autonomy is a function almost solely of the weakness of policy network members, especially that of consumer organizations. As the comparison of food safety policy networks revealed, the major American consumer organization has a higher level of organizational development than its Canadian counterpart. Neither consumer organization, however, can match the resources of the food industry and its associations, which have been consistently in the biotechnology proponent camp on the issues arising from commercialization of genetically-engineered food crops. In Canada, the weakness of the consumer organization has been evident in the deference of its national food committee to the food industry's policy preferences on the labelling issue.

The differing Canadian and American policy networks surrounding the issue of food safety assessment highlight the higher state capacity and autonomy of the Canadian state actor, and the higher levels of organizational development of both industry and public interest groups in the US. The nature of the policy networks suggests that the FDA is likely to be more vulnerable to societal pressures than Health Canada. To take a deeper look at the internal dynamics shaping the two policy networks, the next section examines the role of science. Science is a central characteristic of the food safety assessment issue, frequently invoked and challenged by participants in their debates over the wisdom of policy choices.

THE ROLE OF SCIENCE

Science can be treated as an idea operating within policy networks to examine how it contributes to the dynamics of policy making and, ultimately, policy choices. Science is a "world view" in North American political culture, demonstrated by the well-institutionalized acknowledgement of the scientific method as an absolute and neutral source of knowledge.²⁶ Drawing on its status as a world view, policy makers often translate science into a programmatic idea during policy making because the authoritative nature of science provides legitimacy and can

²⁵ In Canada and the US, food labelling policy in general has focused on regulating the market and protecting consumers from misrepresentation; like food safety regulation, its evolution has been largely ad hoc and its content has done little to enhance state capacity or autonomy in labelling policy.

²⁶ 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.

insulate policy choices from challenge.²⁷ The authority of science 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. Members within a policy network may compete to have their preferred characterization of science institutionalized in policy choices. Some will prefer a “neutral” characterization of science drawn from the authority of science and others will contest the apparent objectivity of science. Depending on the outcome of such debates, the institutionalized characterization of science within policy choices will vary between the extremes of absolutely neutral and highly contested. A neutral characterization reinforces the authority of science as a programmatic idea, while contestation challenges this authority.

Studying how ideas such as science 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 and propelled by ideas in the form of norms and conventions that justify and reinforce them²⁸, such as the authority of science and its proper role in policy making. Categorizing dominant programmatic ideas identifies the nature of authority that is likely to be exercised within the policy network and therefore, which resources are most critical to influence. For example, science as a dominant 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.²⁹ Those policy network members lacking critical resources will find themselves in a position of dependency, or, if they have resources to exchange for others, of interdependency.³⁰ Ideas that persist may lock in patterns of exchange within policy networks.³¹ Science as a world view, and through its adoption in a wide variety of policy choices as a guiding and/or programmatic

²⁷ 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.

²⁸ March and Olsen (1989).

²⁹ In comparison, market-based programmatic ideas suggest that no authority is 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 must be broadly based on the participation of 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.

³⁰ 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 to maintain its utility for its members.

³¹ The durability of institutionalized ideas can be gauged by assessing the degree of institutionalization. Krasner (1988) outlines two dimensions of institutionalization that contribute to the persistence of an institution, including the ideas embedded within it: depth and breadth. Depth can be assessed as the extent to which an actor relies on the institution for self-identification. 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.

idea, is deeply-institutionalized in North America.

The North American context of the role of science

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 to design 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.³²

As Grant viewed it, technology became deeply embedded 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.³³ 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 in North America as the principal means by which to emancipate humanity. The challenges of 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.³⁴

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”.³⁵ 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

³² See Grant (1969), especially Chapter One, “In Defence of North America”. This quote is from page 15.

³³ Grant (1969): 114 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 also Angus (1997), Chapter Four, for a discussion of Grant’s writings on technology.

³⁴ Grant (1969): 40.

³⁵ Brunk et al. (1991): 2.

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.³⁶

Canada and the US share a history of favouring science and technology, but there have been notable differences in the nature of regulatory science between the two countries in recent decades.³⁷ 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.

Throughout the twentieth century, the character of regulatory science was in flux in the US. Initially, in the late nineteenth century, the relationship between regulators and regulated was one of opposition and hierarchy, reflecting the imbalance in the possession of expertise.³⁸ 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”. Government began to draw on scientific experts from various spheres, public and private, 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.³⁹ These challengers demonstrated that science could be used, and often was, on both sides of a regulatory dispute, bringing into question the idea that science could provide absolute authority and certainty as a basis for policy decisions. 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

³⁶ Brunk et al. (1991): 2. Italics are in the original.

³⁷ 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).

³⁸ 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.

³⁹ Marcus discusses this development, but see also Dickson (1984) and Jasanoff (1990).

competing cost-benefit (or risk-benefit) appraisals, which tends to highlight scientific uncertainty.⁴⁰ 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 it.

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), which is 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.⁴¹ 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”.⁴² 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 and other likely candidates, such as the Royal Society of Canada, have not embraced such a role.⁴³

Finally, the US moved much earlier and more substantially to open up 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.⁴⁴ 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.⁴⁵

⁴⁰ Marcus (1994) and Dickson (1984). Dickson argues that the cost-benefit approach was championed vigorously 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.

⁴¹ The policy-relevant activities of the NAS are centered within the National Research Council, which was created in 1916.

⁴² Doyle (1985): 364-367.

⁴³ See Doern (1981): 41-47 on the inadequacy of domestic scientific advice available to Canadian policy makers.

⁴⁴ 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 American environmental policy as creating a new doctrine of pluralist legalism. See Hoberg (1992).

⁴⁵ Hoberg (1997).

Policy legacies and the role of science

Beyond the North American context that promotes the role of science in policy making, the identification of ideas institutionalized in food safety policy legacies in Canada and the US provides further insight. These policy legacies provide starting points for policy networks. 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 historically to have been episodic and reactive.⁴⁶ The scope of regulation has been determined largely by developments in the food marketplace rather than by proactive state intervention. The primary goals have been to ensure effective functioning of the marketplace and to encourage development of a reputable food industry. As a result, market-based programmatic and guiding ideas have been more strongly institutionalized than science, although science has been used as a programmatic idea to legitimate decisions.⁴⁷ These ideas have privileged industry actors within food safety policy networks, while also making the possession of scientific expertise an important resource.

The importance of scientific expertise combined with the nature of its allocation has resulted in somewhat different patterns of exchange within food safety policy networks historically in Canada and the US. Health Canada food safety regulators have a long tradition of turning to external scientific expertise and relying on industry cooperation to bolster capacity. The jeopardy to state autonomy through dependency on the scientific expertise of the domestic food industry has been countered somewhat by balancing its scientific input with that from international institutions and policy makers in other countries. Throughout the history of food safety regulation, Canadian regulators have consistently looked outside the country at scientific consensus developed in other countries and especially by international scientific bodies for guidance and reinforcement. This practice is encouraged by the relatively small food science community within Canada and by an increasing priority of securing access to export markets through harmonization of food safety regulations. Further, for the issue of food safety of new plant varieties, it appears that regulators generally deferred historically to the expertise of plant breeders, which was concentrated within the federal government.⁴⁸

In the US, American food safety regulators have also long been dependent on external sources of expertise. However, these sources appear to have been primarily within the large domestic food industry and, to some extent, within academic institutions. There is less evidence of the same degree of consistent monitoring of, or reliance on, scientific consensus developed

⁴⁶ See, for example, Davidson (1949), Davidson (1950), Wood (1986), and Wodicka (1996).

⁴⁷ A primary example is the “GRAS” (generally recognized as safe) regime for food additives in the US, established in the late 1950s to respond to consumer concerns. The GRAS system is based on the operation of the scientific method. 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. See Korwek (1986).

⁴⁸ Until the 1980s, Canadian plant breeders were almost all located within public sector institutions and primarily at the federal level.

elsewhere, as in Canada, in the history of food safety regulation. Further, in the last several decades, the private sector has taken on a dominant role in plant breeding. In summary, American food safety regulators appear to have been more dependent on private sector sources of expertise than their Canadian counterparts and less willing, or able, to balance them with international and public sector sources.

The role of science during policy making

The nature of these policy legacies, particularly the patterns of exchange of scientific expertise, suggest that the FDA may be more vulnerable to the contestation of science and scientific authority than Health Canada. This result would be consistent with the greater politicization of science seen in regulatory policy making in the US in recent decades. Ironically, at the same time that a more politicized use of science makes scientific legitimacy more vulnerable during policy making, there is often a greater effort to invoke the authority of science. This phenomenon is evident in this case study. During development of the policy response to the food safety issue, American policy makers and biotechnology proponents made stronger efforts to counter the scientific uncertainty surrounding food safety risks than their Canadian counterparts. The strategies of American policy makers included arguing that genetically-engineered foods were not that novel and thus didn't require a substantially new regulatory regime, and highlighting the use of scientific consultations to justify the scientific underpinnings of policy choices.

The issue of food safety assessment of genetically-engineered plants is characterized by a relatively high degree of scientific uncertainty. The novelty of the products means that they are being assessed for hypothetical risks prior to widespread and longstanding use. The lack of experience has encouraged the strategy of comparison to conventional counterparts, seen in the use of the concepts of "substantial equivalence" and "familiarity". For many aspects of risk assessment, there is a lack of adequate baseline information about conventional counterparts, which complicates the task. Food safety assessment is also 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, biotechnology proponents and regulators have emphasized what is already known about conventional counterparts and the growing body of knowledge about these novel organisms. For the issue of food safety, for example, there is an existing body of knowledge about common food allergens, such as those found in wheat, milk, and peanuts; and about food toxins.

In contrast to the issue of environmental release of genetically-engineered plants, the issue of food safety has been arguably more insulated from the exploitation of scientific uncertainty. The longer history of food safety regulation legitimizes claims of adequate expertise by regulators, backed by the presence of a relatively large scientific community in the US and internationally that specializes in food safety issues, such as toxicology and allergenicity.⁴⁹ The history of cooperation

⁴⁹ For example, the Institute of Food Technologists, which has 28,000 food scientists as its members, is headquartered in the US.

between public and private sectors on issues of food safety regulation, which contributed in the past to relatively closed policy networks, also helped to insulate regulators from the contestation of scientific authority until the late 1990s.

Increased contestation in the late 1990s was fuelled by serious concerns about the lack of knowledge regarding the long-term effects of human consumption of genetically-engineered food. For example, an American public interest group, 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, which may pose food safety concerns.⁵⁰ 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 difficult, if not impossible to test.⁵¹ The FDA's 1992 statement on the food safety of new plant varieties clearly indicated the agency's own uncertainty about food safety risks 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.⁵²

Further, in 1999, the American-based Alliance for Bio-Integrity posted on its web site 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.⁵³

The novelty debate

When a technical regulatory issue becomes controversial, rhetorical battles are often a central component of the policy debate. The term “boundary work” captures the goal of actors to draw lines between scientific and “policy” or “political” decisions by attributing certain

⁵⁰ Environmental Defense Fund (1991).

⁵¹ Such concerns are raised in National Wildlife Federation (1992). The allergy issue became one of the most prominent concerns in the 1990s. At 1999 FDA hearings, scientists on both the proponent and skeptic sides of the debate generally agreed that the ability to test novel proteins that are not similar to existing known allergens for allergenic properties, is 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).

⁵² United States. Food and Drug Administration (1992), Section VII (A), italics added.

⁵³ In these documents, for example, FDA officials stated 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. These documents can be found at the Alliance for Bio-Integrity web site www.bio-integrity.org (November 1999). The Alliance launched a lawsuit against the FDA's food safety and labelling policy in 1998.

characteristics to science that make it both an exclusive and authoritative domain of knowledge.⁵⁴ 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, but rather about institutionalizing scientific consensus through terms that suggest appropriate measures in setting goals, methods, and the scope of regulation.

The central rhetorical 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. 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, the rhetorical battle that persists between proponent and skeptics about its degree of novelty is so common that it is predictable. From the mid-1980s through the 1990s, the novelty debate has continued because consensus on the degree of novelty provides the parameters for regulation by suggesting the degree of risk that may result from the use of genetic engineering and the likely level of scientific uncertainty, and thus the appropriate degree of oversight.

Biotechnology 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 biotechnology 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.⁵⁵ The intended policy implication is the adoption of a slow and cautious approach to commercialization or a moratorium on commercialization.

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.

⁵⁴ 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. See Kloppenborg JR (1988): 45 and Jasanoff (1990): 62. Gieryn (1983) details how scientists have attempted to distinguish scientific activities from non-scientific activities in order to garner and 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 regulation of carcinogens.

⁵⁵ 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.

Proponents argue that “biotechnology”, a term used before the twentieth century,⁵⁶ 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.⁵⁷ 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. 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”.⁵⁸ 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.⁵⁹

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 in this debate argues that the traits of the products should be the focus of safety / risk assessments and not the use of a specific technique.⁶⁰ 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, particularly in the 1980s, often endorsed a process-based approach.⁶¹

Arguments used in the novelty debate have been similar in Canada and the US, but regulators in the two countries have adopted differing acknowledgements of the degree of novelty of genetically-engineered organisms which are reflected in policy choices. Canadian regulators have explicitly recognized the novelty of genetic engineering in the details of their policy choices, more so than their American counterparts. For example, they have incorporated the term “novel” in the regulatory trigger of “novel food”. The information requirements placed on developers

⁵⁶ Grace (1997): 2.

⁵⁷ See Canada. Agriculture and Agri-Food Canada (1995) as an example.

⁵⁸ 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.

⁵⁹ 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.

⁶⁰ 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.

⁶¹ 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.

explicitly incorporate consideration of the method by which the product is created. American regulators have been more forceful in downplaying the novelty of genetic engineering and its potential risks. In its 1992 policy statement, the FDA characterized genetic engineering as providing safety advantages over older techniques by being more precise and thus increasing the potential for more predictable foods. At the same time, it stated that:

The agency is not aware of any information showing that foods derived by these new methods [of genetic engineering] differ from other foods in any meaningful or uniform way, or that, as a class, foods developed by the new techniques present any different or greater safety concern than foods developed by traditional breeding.⁶²

The FDA also chose in its 1992 policy statement to use the term “genetic modification”, so to encompass all methods by which plants might be altered genetically, including traditional plant breeding.⁶³

Patterns of exchange: consultations

Resource exchange reveals dependencies and interdependencies within a policy network.⁶⁴ If critical resources are scarce, either difficult to secure or generate, their allocation becomes that much more important in determining relative power within a policy network.⁶⁵ Members who control critical scarce resources, such as technical expertise relevant to regulation, may be able to wield power over those who do not. They can exchange this expertise, for example, for the acquisition of “informational allies” and legitimacy, and thus create a broader base of support for their policy preferences. 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.

In developing regulations for genetically-engineered plants, central mechanisms of exchange within Canadian and American policy networks have been state-societal consultations, scientific workshops, and meetings of advisory expert committees, intended to accumulate the highly-sought resource of legitimacy, often through the appearance of gathering technical expertise and often as a counterweight to scientific uncertainty.⁶⁶ Canadian and American regulators have differed somewhat in their consultation strategies (see Table 5). American regulators relied more heavily on science-focused consultations during the 1980s and 1990s, such as scientific workshops and expert advisory committees. They often referred to these consultations in public statements, to scientific consensus generally, and to in-house expertise to provide reassurance of adequate scientific

⁶² United States. Food and Drug Administration (1992), Section VI.

⁶³ United States. Food and Drug Administration (1992).

⁶⁴ Knoke et al. (1996): 4, 8-9, 17-19

⁶⁵ Critical resources often include relevant technical information, political knowledge, tangible (financial) and intangible (legitimacy) resources.

⁶⁶ Both countries have had legislative committee hearings on biotechnology regulation, but 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 making policy choices.

capacity.⁶⁷ 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*”.⁶⁸ 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.”⁶⁹ In contrast, Canadian regulators were less preoccupied in the 1980s and 1990s with providing public statements and visible evidence of the bolstering of their scientific capacity through consultations. Instead, they chose, from the mid-1990s on, to broaden their traditional consultation patterns to a somewhat wider range of policy community members through a few selective multistakeholder meetings.⁷⁰ This strategy suggests that their priority was to increase the legitimacy of policy choices by “democratizing” the process. When reference was made to scientific consensus, it was usually to assert that Canadian policy choices were consistent with the recommendations made by international institutions, notably those from joint Food and Agriculture Organization / World Health Organization workshops and Organisation for Economic Cooperation and Development meetings.⁷¹ Regulators in both countries, however, have been criticized for appearing to limit broader consultations. Canadian regulators have been described as restricting participation during their “carefully-rigged” and “invitation-only” multistakeholder consultations, which were dominated by state officials, and for attempting to limit the scope of discussion largely to scientific and technical issues.⁷² In the US, FDA regulators were also criticized for not responding to comments solicited and providing few opportunities for public debate.⁷³

⁶⁷ There is continuing evidence of the use of this tactic. 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 as saying “I believe that the discipline of science and a scientific approach must ground our decision-making.” See Fox (1998).

⁶⁸ United States. Food and Drug Administration. Center for Food Safety and Applied Nutrition (1995): 4, italics added.

⁶⁹ United States. Food and Drug Administration (1999a).

⁷⁰ For proceedings of these workshops, see Canada. Agriculture and Agri-Food Canada, Health Canada, and Environment Canada (1993); and Canada (1994a and 1994b).

⁷¹ United Nations. Food and Agriculture Organization (1996), United Nations. World Health Organization (1991), Organisation for Economic Co-operation and Development (1986); Organisation for Economic Co-operation and Development (1993).

⁷² For example, at the 1994 multistakeholder workshop on labelling in Canada, 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.

⁷³ The three public meetings held in late 1999 on food safety and labelling 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, although they never responded officially to those comments.

Characterization and contestation of science

The characterization of science, on a scale between absolutely neutral and highly contested, can change over time within policy networks. The potential for variation is captured in Linder's five-part classification (see Table 6).⁷⁴ As the degree of contestation increases, the possibility of maintaining a neutral characterization diminishes, especially when there is inadequate scientific consensus underpinning policy choices. Contestation did increase in Canadian and American food safety policy networks in the late 1990s; however, at the time of policy choices it was still largely neutral in both networks (Table 7).

Canadian regulators were able to characterize science as neutral within the food safety policy network as they began to examine the issue in the late 1980s due to the issue's low public visibility and the lack of contestation. They were aided by the alignment of the national consumer association with biotechnology proponents. The neutral science characterization was also 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 also insulated the latter issue from more "political" debates about consumer choice, unlike the institutional arrangement in the US.

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 result, combined with the current labelling policy, likely reduced consumer awareness that more and more products containing genetically-engineered food ingredients were entering the marketplace in the late 1990s. In fact, the issue of food safety assessment did not attract much public attention in Canada until the late 1990s. Biotechnology skeptics lacked both opportunities and resources to bring the issue firmly into public view. Beginning in 1998-99, European and other international developments prompted public interest groups such as the Sierra Club of Canada and the Council of Canadians to make genetically-engineered foods a higher priority issue through tactics such as public demonstrations outside supermarkets.⁷⁵ In January 2000, a group of independent scientists, academics, and agricultural professionals formed the organization "GE Alert" to share information

⁷⁴ Linder (1995).

⁷⁵ These developments resulted in a flurry of mainstream media coverage. See, for example, Colapinto (1998), Dyer (1999) and Black (1998). At the same time, 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).

with the Canadian public about the possible risks of agricultural biotechnology.⁷⁶

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 federal coordinated framework for biotechnology regulation. As in Canada, food safety assessment received relatively little public scrutiny through much of the 1980s and 1990s. 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, but FDA regulators provided very few opportunities for public debate that might have highlighted scientific uncertainty. In fact, the FDA appeared to make a concerted effort through much of the 1990s to minimize the issue's visibility. 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. When public controversy did surface, it was focused more on the labelling issue than on the process of food safety assessment. Further, the food safety risks of genetically-engineered plants received relatively little mainstream press until the late 1990s compared to the significant media attention in the mid-1990s surrounding the issue of the use of genetically-engineered bovine somatotrophin (BST), a bovine growth hormone, to increase milk production in cows.⁷⁷

Within the policy network, largely sheltered from public view, there was some contestation of the science during development of the FDA's policy response. Initially, in the mid-1980s, the FDA asserted that genetically-engineered foods could be regulated in the same way as other foods and were generally a "non-issue" in terms of requiring special regulatory provisions. In response to demands from industry, government agencies, academia, and the public for more details, the FDA issued its 1992 policy statement on foods from new plant varieties. Contestation of the science underlying policy responses increased following the 1992 statement. During this period, the FDA's lack of capacity and autonomy exposed it to prevailing political winds which, in the early 1990s, were strongly in the direction of competitiveness and deregulation.⁷⁸ Representatives of public interest groups are quick to point out that the FDA's 1992 policy was actually announced by

⁷⁶ One of these scientists examined all of Health Canada's food safety assessment decisions that were 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. 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. See 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].

⁷⁷ On the issue of BST/BGH, see, for example, Hiss (1994), Kleiner (1994), Coghlan (1994).

⁷⁸ These political pressures 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.

the executive office's 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.⁷⁹ 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.⁸⁰ 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 premarket notification system was planned.

The 1992 policy statement was still the FDA's working policy through to 1999, although there had been some unsuccessful attempts to refine it.⁸¹ The agency continued to explore some of the scientific issues arising from genetically-engineered foods through the 1990s.⁸² Developments in Europe and at home toward the end of the decade suggested that the FDA's policy may come under more intense public scrutiny into the new century.⁸³ In fact, increasing levels of debate over scientific uncertainty and growing consumer resistance in the late 1990s prompted regulators in both Canada and the US to commission special reviews to shore up the credibility of policy responses.⁸⁴

⁷⁹ Kneen (1992): 179.

⁸⁰ Mellon (1994).

⁸¹ As the FDA began its first review of a safety assessment of a genetically-engineered plant food product, Calgene's Flavr Savr tomato, public interest groups urged the agency to finalize its 1992 policy, assuming that it would respond to the critical and widespread reaction. In 1994, the FDA did contemplate moving to premarket notification. Observers believe that the agency was seriously committed to the idea of premarket notification, but withdrew from it when the Republican landslide in 1994 produced a renewed deregulatory fever. 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. 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).

⁸² For example, in April 1994, it held a workshop on the issue of allergenicity and in September 1998, it issued a draft guidance document on the use of antibiotic resistance marker genes in plants to solicit comments. See United States. Food and Drug Administration. Center for Food Safety and Applied Nutrition (1998). Margaret Mellon of the American public interest group, the National Wildlife Federation, (and 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).

⁸³ These developments include the May 1998 lawsuit launched against the FDA by the "Alliance for Bio-Integrity". 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. See the Alliance's web site (<http://www.bio-integrity.org/>) and Vorman (1998).

⁸⁴ 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 1999, the FDA held three public meetings on its food safety and labelling policies, allowing a broad spectrum of groups and individuals to comment and suggesting the potential for revision of its policy.

Characterizations of science and the importance of scientific expertise

A dominant neutral science characterization within a policy network is expected to place a premium on scientific resources. In such a situation, the possession of scientific expertise would act as a dividing line between influential and marginal policy community members, regardless of other resources. Those without scientific resources leave to others the creation of the scientific consensus that is to underpin policy making. They may choose to endorse the policy preferences of those with scientific expertise, which expands the consensus and increases its legitimacy, or to refute it. They can contest the dominant scientific consensus forcefully only with an adequate alternative scientific consensus or with the opportunity and resources to exploit high levels of scientific uncertainty.⁸⁵

Within the food safety assessment policy networks examined here, the possession of relevant scientific capacity should be an important factor in contributing to influence within the policy network because science still enjoyed a predominantly neutral characterization at the time of policy choices. The allocation of scientific expertise would shape patterns of exchange that reveal the nature of dependencies. Table 8 compares the location of scientific resources within the policy network with the nature of the policy network. 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. The table demonstrates a correlation between the allocation of scientific expertise and the nature of the food safety policy networks.

The weak concertation policy network found in the case of food safety in Canada exists in a situation where relevant scientific expertise is somewhat decentralized. The relatively small pool of domestic expertise encourages substantial reliance on the findings of international institutions and actions of other countries, which appears to bolster state capacity *and* autonomy from domestic actors. In the US, expertise is located in the large and well-resourced domestic food industry and the relatively large food science community.⁸⁶ While there is some consideration of recommendations and decisions taken elsewhere, it appears that domestic sources of food science

⁸⁵ When science is strongly contested within a policy network, scientific expertise is not expected to be a decisive factor in determining the influence of policy network members. 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.

⁸⁶ The extent to which food science expertise located in academic institutions in Canada and the US can be considered independent is a matter for further scrutiny. In the plant biotechnology field, the increasingly close links between academia and industry suggest that it might be difficult to find independent expertise. Similar trends may be occurring more broadly in food science. There is certainly plenty of anecdotal evidence of food scientists located in academic institutions collaborating in research with the food industry, possibly jeopardizing independence from commercial interests.

expertise hold more influence.⁸⁷ Largely dependent on outside expertise for scientific authority located in domestic industry and academic institutions, regulators have difficulty maintaining autonomy from societal pressures, which contributes to a clientele pluralist network. These correlations suggest that the characterization of science combined with the allocation of scientific expertise can be an important aspect of the dynamics within policy networks and thus their nature.

THE ROLE OF SCIENCE AND POLICY CAPACITY

This paper has examined the role of science in food safety policy networks in part to determine the extent to which science has marginalized or excluded other ideas during policy making. Official problem definitions and policy choices suggest that science has had the effect of excluding additional guiding ideas, or policy goals, that cannot be achieved through science because they are unavoidably political in nature. Such “political” policy goals include, for example, policy choices that affect the allocation of the socioeconomic costs and benefits of genetically-engineered plants.⁸⁸ The dominance of science, by creating an exclusive type of authority within policy networks, has also marginalized the importance of democratic legitimacy during policy making. It has not, however, impeded the simultaneous pursuit of market-based guiding ideas. Science-based and market-based ideas are not incompatible in certain combinations as, for example, when science is used to pursue economic goals.⁸⁹

These effects of science are a result of its consistent dominance as a programmatic idea within Canadian and American food safety policy networks up to the point of policy choices, reinforced by the neutral characterization of science. Initially, the neutrality of science was protected by North American political culture which favours reliance on science in policy making. Policy legacies provided starting points for the policy networks that emerged around the issue of food safety risks of genetically-engineered plants. They set a precedent of the use of science as a programmatic idea to achieve market-based policy goals and patterns of scientific exchange that resulted in varying levels of state autonomy. The reliance of Canadian regulators on international sources of expertise to supplement domestic sources appears to have provided some autonomy from domestic pressures. American regulators, working in a more politicized context and more

⁸⁷ One example comes from scientific consultations by the FDA between November 1996 and February 1997 on the issue of the use of antibiotic resistant marker genes in genetically-engineered crops. Five experts were called on to provide guidance; all were from American academic institutions. The experts were given documents on actions and recommendations of other countries and international institutions. The scope of discussion, however, focused solely on scientific questions. United States. Food and Drug Administration. Center for Food Safety and Applied Nutrition (1998). American regulators do, however, point in policy statements to the consistency between the scientific basis of their assessment process and that endorsed by international institutions such as the OECD.

⁸⁸ This is not to say that the policy choices that have been made have no effect on the allocation of costs and benefits. They clearly do, but during policy making, state officials did not openly discuss efforts to direct the allocation of costs and benefits (for example, between the plant biotechnology industry and agricultural producers) as an essential part of the task at hand, although they have made vague statements about the general expected benefits of the products of genetic engineering.

⁸⁹ The use of science as a “neutral arbiter” in trade disputes, as ordained under the Sanitary and Phytosanitary Agreement of the World Trade Organization, is an example of science being used as a programmatic idea in order to achieve the broad economic goal of trade liberalization.

heavily reliant on domestic sources of expertise, were less able to carve out room to manoeuvre from societal pressures. The neutral characterization and dominant role of science was subsequently reinforced by a narrow problem definition and by the limited opportunities and resources, especially in Canada, for those who wished to contest its authority.⁹⁰

At the moment of policy choices, science was chosen as the dominant programmatic idea in the service of economic policy goals. In the US, these goals centered on ensuring the competitiveness of the domestic biotechnology and food industries through relatively rapid commercialization. In Canada, competitiveness was also a goal, although there was more emphasis on ensuring regulatory responses were harmonized in such a way to secure access to important export markets. While contestation has increased since policy choices were made, the dominant role of science in policy choices will continue to privilege those actors within the domestic policy networks with relevant scientific expertise, unless science becomes highly contested. In the US in particular, this result has provided tremendous advantage to the domestic food and plant biotechnology industries.⁹¹

Styles of scientific expertise

Examining the role of science across two countries allows some conclusions about whether there appears to be distinct styles of scientific expertise that can contribute to differing policy choices. Renn outlines an ideal typology of styles of using scientific expertise: adversarial, fiduciary, consensual, and corporatist, and a newly emerging style he calls mediative.⁹² Using Renn's typology, both the FDA and Health Canada in their respective food safety policy networks are closest to the consensual style. A consensual style relies on expert judgment and scientific reputations; and 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. The FDA's somewhat consensual style through the 1980s and 1990s in this case appears to depart somewhat from more general characterizations of the role of science in American regulatory politics which match more closely with Renn's adversarial style. This adversarial style is described 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.

However, as contestation has increased within the American food safety policy network, there are signs that the style of using science is becoming more adversarial. In fact, the closed

⁹⁰ In contrast, biotechnology skeptics have had more opportunities and resources to contest science within environmental release policy networks, especially in the US due to the *National Environmental Policy Act* which permitted court challenges by public interest groups.

⁹¹ These industries, and their Canadian counterparts, have been highly supportive to date of American and Canadian policy choices on food safety assessment and labelling of genetically-engineered food crops and other ingredients. Only in 1999, with increased contestation within the domestic policy network, did some members of the American agri-food industry begin to suggest that the FDA should consider moving from voluntary to mandatory consultations to bolster public confidence.

⁹² Renn (1995) see Table 1, p. 151.

nature of the FDA's policy making in the early 1980s and 1990s may well be more accurately portrayed as a symptom of the huge political pressures toward deregulation that the agency was experiencing than as a representative example of American regulatory science. The greater vulnerability of the FDA combined with the higher level of contestation in recent years, all of which contribute to the politicization of science, is likely to produce a role for science more consistent with the comparison of American and Canadian regulatory styles made by Harrison and Hoberg.⁹³ In summary, the development of responses to the food safety risks of genetically-engineered plants does confirm the possibility of country-specific differences in regulatory styles; at the same time, the somewhat exceptional nature of the American food safety response demonstrates the utility of a closer examination of the use of science within a variety of policy networks.⁹⁴

The variations in the styles of using scientific expertise and especially those in the patterns of exchange of scientific expertise within policy networks help us to understand the differing policy responses to food safety risks in Canada and the US. It is not surprising that Canadian regulators would emerge with greater capacity and discretion, given the role of science in this case study. First, there appears to be a constant tradition, maintained in this case study, of a greater politicization of regulatory science in the US, which in turn increases the vulnerability of scientific legitimacy during policy making. There is little evidence of a similar tradition in Canada, where those who might prefer to contest science lack the same opportunities and resources (scientific and financial) as their American counterparts. Contestation of science appears to be easier in the US, in part due to the generally 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.⁹⁵ The greater availability and diversity of scientific resources in the US also appears to promote the prominent use of science in policy making debates. This result provides a clear example of the phenomenon of the "scientification of politics", as Weingart describes it, which in turn results in the politicization of science, with the ultimate potential effect of delegitimizing science.⁹⁶ The degree of scientific uncertainty contributes to this phenomenon, but cannot be exploited without adequate opportunities and resources.

Second, the neutral characterization of science leading up to and at the moment of food

⁹³ 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 paternalistic, informal, consensual, and closed. There is a preference for case-by-case review rather than reliance on general principles, and more emphasis on science which permits greater flexibility. 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.

⁹⁴ It cannot always be assumed that a regulatory style of science will be consistent across policy issues within a country. For example, Jasanoff concludes from her case studies that there is little consistency across American regulatory agencies in how they use scientific advice. See Jasanoff (1990).

⁹⁵ See Harrison and Hoberg (1994). Jasanoff 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. See Jasanoff (1990): 208.

⁹⁶ However, as Weingart acknowledges, the politicization of science has not yet led to science's total delegitimation because there is no alternative to scientific expertise in terms of the continuing ability to use it to make authoritative knowledge claims. See Weingart (1999).

safety assessment policy choices makes the allocation and location of scientific expertise an important aspect of the dynamics within policy networks. The reliance on international and foreign sources of expertise appears to be a critical component of state capacity and autonomy in Canada. In contrast, the allocation of relevant scientific expertise in the US for food safety, decentralized and largely within the private sector, fuels the perception that regulators have been captured.

LESSONS FOR POLICY CAPACITY

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 capacity⁹⁷, but conclusions from this case study suggest that it rests substantially on three interrelated factors: first, state capacity and autonomy; second, access to independent informational / scientific expertise that legitimizes the use of science and / or other forms of knowledge (scientific legitimacy); and third, 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 (democratic legitimacy). 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. Contestation may well encourage the creation of pluralist policy networks. There is no guarantee, however, that democratic legitimacy will step into the void caused by the weakness or disappearance of scientific legitimacy. It is also possible that market-based ideas will instead dominate. In the case studied here, this latter result may not be to the advantage of biotechnology 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 biotechnology proponents, including economic power.

Ideally, however, scientific and democratic 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. The level of contestation of scientific authority and growing resistance to genetically-engineered food crops in North America in the late 1990s suggests that Canadian and American regulators have achieved limited success in securing scientific and democratic legitimacy to bolster policy capacity. Their responses to the issue of food safety risks were precedent-setting in terms of encouraging more systematic evaluations of new plant varieties. Those responses, however, were not foolproof when it came to guaranteeing consumer acceptance both at home and abroad and have resulted in the loss of export markets. Policy choices have now come under heavy public scrutiny and have been criticized as lacking scientific and democratic legitimacy. These developments illustrate how

⁹⁷ Peters 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 Peters (1996). His discussion focuses on factors which constrain or contribute to policy capacity.

hurdles may change over time for regulators, requiring adaptation and innovation rather than reliance on the status quo.⁹⁸

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. If the procedural elements of policy making (including scientific and democratic legitimacy) 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 the credibility of the policy making process, including long-running political battles which swallow up time and resources, and may result in inconsistent policy making.⁹⁹

The issue of labelling genetically-engineered foods illustrates the stakes. The effort in both countries to insulate labelling policy choices from the “political” aspects of the debate over genetic engineering through the authority of science by linking it to food safety assessment has not been altogether successful. These policy choices have been challenged in both countries in the late 1990s largely because of the lack of both scientific legitimacy and democratic legitimacy during policy making. These weaknesses make it difficult for regulators to justify labelling policy choices that deny consumer choice, especially in a context of growing contestation of science. Further, the lack of an effective political forum appears to have encouraged marginalized interests to turn to the economic forum of the marketplace. In the late 1990s, biotechnology skeptics in Canada and the US appealed directly to consumer self-interest on the issue of food safety risks by encouraging boycotts. 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. The experiences of Canadian and American regulators in the cases of food safety assessment and labelling suggest ways in which policy capacity can be strengthened.

Strengthening policy capacity: scientific legitimacy

⁹⁸ 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.

⁹⁹ Ozawa (1991).

Securing scientific legitimacy may well be an increasingly difficult, but also 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 high technological frontier which absolutely no one completely understands and which generates a diversity of possible futures”.¹⁰⁰ Skeptical and more scientifically-aware citizens raise 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.¹⁰¹ 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 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 (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. Second, regulators must strive to demonstrate and ensure 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 and the exercise of autonomy from societal actors.¹⁰²

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 resources within the Food Directorate of Health Canada and within the Research Branch of Agriculture and Agri-Food Canada, resulting in the loss of many senior scientists.

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

¹⁰⁰ Giddens (1998).

¹⁰¹ A similar prescription can be made for cases that require additional and other types of expertise.

¹⁰² As Doern 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. Doern (1998): 42.

component and thus avoid 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.¹⁰³ 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.¹⁰⁴ Ironically, the more vociferous the claims of the neutrality of science in attempts to exclude or marginalize “political” elements of the debate, the more 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 underlines 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.¹⁰⁵

Science should not be used to exclude the economic, social, and ethical dimensions of a policy issue. Instead, before and during efforts to build a credible and adequate scientific 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, as Jasanoff suggests, forums in which science can be negotiated and compromises can be reached.¹⁰⁶ 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.¹⁰⁷ This mandate would provide a credible scientific foundation for policy debate.

Democratic legitimacy

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. Carroll and Carroll list criteria that provide legitimacy during policy making.¹⁰⁸ These criteria include repeated

¹⁰³ 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. See Salter (1988): 168-169.

¹⁰⁴ Jasanoff (1990): 3, Brunk et al. (1991), and Leiss and Chociolko (1994).

¹⁰⁵ Kneen (1992): 201.

¹⁰⁶ Jasanoff (1990).

¹⁰⁷ Salter (1995).

¹⁰⁸ Carroll and Carroll (1999).

and 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.

One strategy that policy makers could consider is the more productive use of legislatures on regulatory issues likely to generate controversy.¹⁰⁹ 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 evaluate their 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, which have often been criticized as intentionally restrictive in the scope of participation and discussion. One goal in the pursuit of democratic legitimacy 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 to incorporate within regulation, and thus determine what types of expertise will be needed during policy making. Benefits should be scrutinized as extensively as risks and costs to assess the potential for pursuing social utility. For example, 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 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?

Democratic legitimacy will not guarantee democratic outcomes, nor should it necessarily. It is a procedural characteristic of policy making and is not a substitute for accountable political leadership, which must be exercised at the time policy choices are made. That leadership should, however, be prefaced and surrounded by an ongoing democratic public discussion. It should be backed by rigorous measures that make both policy makers and other participants in policy communities accountable for their contribution. These measures should include clear information on who was consulted during policy making, who they represented, and what they said. The basis on which policy options were selected or discarded should be readily available.¹¹⁰

Innovative policy making: providing competitive advantage

In the case of food safety assessment of genetically-engineered plants, Canadian regulators benefit from policy choices that provide much more capacity and potential autonomy than those enjoyed by American regulators. This finding results in the conclusion that the country more exposed to the pressures of economic internationalization in agri-food policy was able to provide

¹⁰⁹ In the case studied here, federal legislative committees have been used occasionally and sporadically in Canada to discuss issues arising from commercialization. There have been more committee hearings in the US, but they have also focused on an oversight role rather than on providing a regular forum for debate encompassing the full range of perspectives.

¹¹⁰ 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

more capacity to its regulators.¹¹¹ 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.¹¹² 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 contribute to competitiveness.¹¹³ In this case, these differences stemmed largely from the capacity and relative autonomy of the Canadian state actor within its policy network. These characteristics in turn result from the traditional wealth of in-house and public sector expertise in agricultural research and regulation and from the longstanding practice of food safety regulators of supplementing their expertise with the recommendations of relatively credible scientific international institutions. Developments in the 1980s and 1990s, however, appear to have eroded the in-house expertise of Canadian regulatory agencies. Canadian policy makers allow this expertise to slip away at the cost of policy capacity, and ultimately the ability to make policy choices in the public interest. Adequate policy capacity should allow policy makers to balance the short-term orientation of democratic government with a longer-term perspective, and produce sustainable policy responses that can simultaneously achieve multiple policy goals such as economic competitiveness, food safety, and environmental protection.

¹¹¹ For example, as of 1996-97, Canada exported about two-thirds of the value of its agricultural production, compared to less than one-third in the US. Canada exported 65 per cent of its wheat crop, 50 per cent of canola, and 40 per cent of oats. The US exported 43 per cent of its wheat crop and 37 per cent of its soybean crop. Exports of food products have grown quickly in both countries in the 1990s. However, Canada is more heavily reliant on a single market for its food products. The US is Canada's major export market for food products, accounting for 71 per cent of all export sales in 1998. In contrast, the largest export market for American food products is Japan, accounting for 18 per cent of all food sales in 1998.

¹¹² Weiss (1998).

¹¹³ This paper takes a broad and longer-term view of competitiveness, considering that it can be a result of the quality or safety of an industry's products, as well as their selling price.

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TABLE 1:

Comparison of policy responses to food safety assessment of genetically-engineered plants, Canada and the United States

CANADA¹

PRINCIPLES

1. Goals

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)

UNITED STATES²

PRINCIPLES

1. Goals

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 US producers in domestic and world markets. (1984)

¹ [Canada. Health and Welfare Canada. Health Protection Branch, 1992 #455], [Canada. Health Canada. Health Protection Branch. Food Directorate, 1994 #151], [Canada. Minister of Supply and Services Canada, 1995 #150]. The principles listed for both countries are either direct quotes or slightly revised for clarity and brevity.

² [United States. Food and Drug Administration, 1992 #326; United States. Food and Drug Administration. Center for Food Safety and Applied Nutrition, 1995 #327]

PRINCIPLES

2. Means

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. Means

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

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

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 arrangements

The Canadian Food Inspection Agency (CFIA) 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.

Amendments to the Food and Drug Regulations created new regulations for “novel foods”. 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.
4. These provisions will not apply to those foods, such as infant formula, already regulated by pre-market notification.

UNITED STATES

Institutional arrangements

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.³ 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 and encourages developers to 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.

³ In the US, the Environmental Protection Agency 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 2:

Comparison of policy responses to labelling of foods with genetically-engineered ingredients, Canada and the United States

CANADA⁴

PRINCIPLES

1. Goals

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)

Harmonization

Domestic and international needs must be considered. Consistency with the principles of major trading partners and international standards should be sought. (1995)

2. Scope

Focus is on novel foods and novel food ingredients. (1995)

It is not necessary to inform consumers through labelling that genetic engineering has been used, unless significant changes have been made. (1995)

Labelling should be understandable, truthful and not misleading; voluntary positive and negative labelling is acceptable, if factual. (1995)

Religious dietary restrictions are outside the current mandate and are adequately addressed by the regulatory framework of religious groups. (1995)

UNITED STATES⁵

PRINCIPLES

1. Goals

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)

2. Scope

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)

Labelling must be truthful and not misleading. (1992)

The consumers' "desire to know" is not on its own an adequate basis for requiring disclosure through labelling. (1995)

⁴ [Canada. Agriculture and Agri-Food Canada. Biotechnology Strategies and Coordination Office, 1995, December 1 #325]

⁵ [United States. Food and Drug Administration, 1992 #326; United States. Food and Drug Administration. Center for Food Safety and Applied Nutrition, 1995 #327]

CANADA

Institutional arrangements

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 currently based on the principles of the guidelines outlined above and the general labelling requirements of the *Food and Drug Act* regulations.

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 arrangements

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".⁶ 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.

⁶ [United States. Food and Drug Administration, 1992 #326]

TABLE3: Plant biotechnology regulation policy communities, Canada and the United States

CANADA

AGRI-FOOD INDUSTRY

AGRICULTURAL PRODUCER ASSOCIATIONS

General

Canadian Federation of Agriculture
National Farmers Union

Commodity

Canola Council of Canada
Canadian Grains Council
Flax Council of Canada

BIOTECHNOLOGY ASSOCIATIONS

BIOTECCanada

FOOD PROCESSING ASSOCIATIONS

Food and Consumer Products Manufacturers of Canada

SEED INDUSTRY

Canadian Seed Trade Association

PUBLIC INTEREST GROUPS

Consumer

Consumers Association of Canada

Environmental groups

Canadian Environmental Network, Biotechnology Caucus
Canadian Institute for Environmental Law and Policy

AGRICULTURAL RESEARCH COMMUNITY

Canadian Agri-Food Research Council
Plant Biotechnology Institute, NRC
Research Branch, AAFC
Individual public and private sector scientists

UNITED STATES

AGRI-FOOD INDUSTRY

AGRICULTURAL PRODUCER ASSOCIATIONS

General

American Farm Bureau Federation
National Family Farm Coalition

Commodity

American Soybean Association
National Corn Growers Association
US Grains Council

BIOTECHNOLOGY ASSOCIATIONS

Biotechnology Industry Organization

FOOD PROCESSING ASSOCIATIONS

Grocery Manufacturers of America
National Food Processors Association

SEED INDUSTRY

American Seed Trade Association

PUBLIC INTEREST GROUPS

Consumer

Consumer Policy Institute, Consumers Union

Environmental groups

Environmental Defense Fund
Environmental Law Institute
National Wildlife Federation
Union of Concerned Scientists

AGRICULTURAL RESEARCH COMMUNITY

Agricultural Research Service, USDA
Board of Agriculture, National Research Council, National Academy of Sciences
Individual public and private sector scientists
National Association of State Universities and Land-Grant Colleges

TABLE4: Food safety and labelling policy networks, Canada and the United States
INDICATORS OF STATE AUTONOMY AND CAPACITY

Agency	Institutions	Ideas / Mandate	Capacity	Interdepartmental	Total
Health Canada (FS)	M	H->M	M->L	M	M
FDA (FS)	L / M	L	L / M	L	L / M
AAFC / CFIA (LABEL)	L	L	M	H	L / M
Health Canada (LABEL)	L	L	M	L	L / M
FDA (LABEL)	M	L / M	M	L	L / M

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 groups	M	L	N/A	L	L
US envtl groups	M	L	N/A	M	M
Cdn consumer groups	M	L	L	L	L
US consumer groups	M	L	M	M	M

L=low, M=medium, H=high

POLICY NETWORKS

CANADA

Concertation (weak)

UNITED STATES

Clientele pluralism

TABLE 5: Consultation strategies, Canada and the United States

CANADA

Mechanisms

selective multistakeholder meetings
informal consultations through mailings
formal (*Canada Gazette*)
conferences and meetings for other purposes

Scope

scientific / technical

Composition

food industry, consumer organizations, health professionals
Canada Gazette-open to all those able to participate

UNITED STATES

Mechanisms

closed scientific workshops
closed and open scientific advisory committee meetings
formal (*Federal Register*)
public meetings (1999)

Scope

scientific / technical
(The scope of the 1999 public meetings was circumscribed somewhat by a set of questions the FDA prepared to guide discussion.)

Composition

scientific experts
public meetings-broad spectrum of interest groups and individuals
Federal Register-open to all those able to participate

TABLE6: Variations in the characterization of science

adapted from Linder (1995)

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.

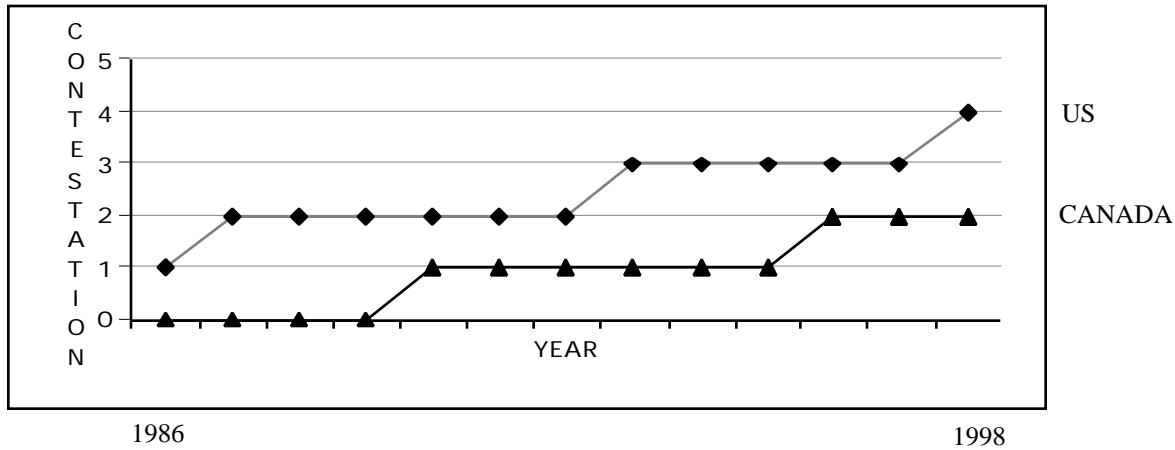
Authoritative

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.

TABLE 7: Characterization of science within food safety policy networks in Canada and the United States



SCALE=DEGREE OF CONTESTATION

1=NEUTRAL
5=HIGHLY CONTESTED

CANADA

1990=starting point
1996=commercialization, labelling debate visibility grows

UNITED STATES

1986=starting point (Coordinated Framework allocates responsibility to FDA)
1987=FDA receives questions about food safety
1993=responses to 1992 policy statement
1998=lawsuit against FDA, labelling debate grows

TABLE 8: Scientific resources and policy networks

CANADA

Allocation of scientific expertise

*Industry (domestic, multinational)

*Academic (domestic, foreign)

*International institutions

Regulators

Policy network

Concertation (weak)

*=dominant location of expertise

UNITED STATES

Allocation of scientific expertise

*Industry (domestic)

*Academic (decentralized)

Regulators

International institutions

Policy network

Clientele pluralism