Regulators and Promoters of Genetically Modified Foods in the Government of Canada: An Organizational and Policy Analysis

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REGULATORS AND PROMOTERS OF GENETICALLY MODIFIED FOODS IN THE GOVERNMENT OF CANADA: AN ORGANIZATIONAL AND POLICY ANALYSIS

By

Michael J. Prince

Executive Summary

This report describes and assesses the interaction between regulators and promoters of GM food products within the federal government. Focusing on Agriculture and Agri-Food, Canadian Food Inspection Agency, and Health Canada, the paper proceeds through seven steps:

1. the presentation of an analytical framework with which to examine the separation and integration of government functions;
2. a discussion of the horizontal or government-wide policy context for biotechnology decision processes;
3. a description of the mandates and missions of the core federal organizations involved with the regulation and promotion of GM foods;
4. a case study of the current roles and responsibilities for plant protection in the CFIA to explore this issue;
5. a look at biotech federalism, especially the promotional roles provinces carry out and the collaborative intergovernmental mechanisms in place to manage interdependencies;
6. an examination of international experiences on the governance for regulating GM foods; and,
7. some concluding observations and reform issues and options.

At the heart of concern regarding the relation between regulating and promoting GM foods is the work of the CFIA. The paper illustrates this debate by examining the relation between the Plant Biosafety Office (PBO) and the Office of Biotechnology, both of the CFIA. The PBO is located within the Plant Protection Program, one of 14 programs that the Agency currently manages. The goals of the plant protection program are to prevent the introduction and spread of plant pests and diseases, and to control and eradicate any plant pests and diseases. The Office of Biotechnology, by contrast, is not involved in regulation or safety assessments at all. Rather, the Office of Biotechnology serves an interdepartmental relation role providing a link to the Canadian Biotechnology Secretariat in Industry Canada, and a communications function. Having these two functions housed within a single organization like the CFIA, but separate in their operations would seem to be adequate separation for the scientific integrity and autonomy of the PBO. Yet, at the overall level of the Agency, the Office of Biotechnology presents challenges for the public accepting that the CFIA is totally and only a regulatory organization concerned with matters of health and safety.

Having an office within the CFIA that produces information materials criticized as promotional represents a variant of role conflict. That is the dilemma of performing two roles, each perhaps important in their own terms, but incompatible from a public confidence judgment when combined in a single agency.

Organizational and governance reform issues for the Canadian regulatory system for GM foods and biotechnology include:

- what the mandate and mission of the CFIA should be with respect to trade promotion and or trade policy development on biotechnology issues;
- how to strengthen the transparency of, and public involvement in regulatory decision making for GM products; and
- whether or not the Office of Biotechnology should remain within the CFIA or be relocated to another federal organization or portfolio.

The continued status of this Office within CFIA appears to be a problematic one, not due to internal difficulties, but to expectations and reactions externally to what is, and what should be, the primary and proper role of the CFIA. While the Office can be said to be performing a proper function and with a competent group of staff, there is considerable merit in reflecting seriously on whether it is situated in the most appropriate place within the federal government.

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INTRODUCTION

The ability of science to introduce novel traits into plants has changed the way we grow food as well as the characteristics of the food products we eat. It may also affect intra-governmental and intergovernmental relations within Canada as well as trade relations between and among nations. The genetic modification (GM) of foods is one of the most controversial areas of biotechnology.[1] Underlying these concerns is an expressed lack of confidence in the regulatory capacity of governments to deal with this relatively new technology. Some individuals and groups express concern that regulatory capacity may be compromised in countries where governments also promote GM foods and crops as part of their economic growth agenda. The objective of this research paper is to describe and assess the interaction between regulators and promoters of GM food products within the federal government. A central analytical interest is to examine the extent and nature of independence of the regulatory processes from the promotional agencies and activities, enabling risk assessment and product approval decisions made on scientific evidence.

The paper has seven main purposes and corresponding sections. The first is to outline and examine several core functions of governments in science and technology policy, including biotechnology. Against this wider backdrop, the primary focus will be on the two functions of regulation and promotion as policy goals, processes and organizational arrangements. The second purpose is to summarize the horizontal or government-wide policy context for the food regulatory regime, thus highlighting the overarching policy instruments and stance of the federal government. The third is to summarize the legislative framework, mandates and missions of the core federal departments and agency with respect to the regulation and promotion of GM foods. These are Agriculture and Agri-Food Canada (AAFC), the Canadian Food Inspection Agency (CFIA), and Health Canada. Closely related, the fourth purpose is to examine selected current roles and responsibilities of the CFIA that speak to the concern of inadequate separation between regulatory and promotional activities. The paper's fifth purpose and section is to examine biotech federalism. Provincial regulatory and promotional roles are identified along with areas of actual and potential intergovernmental conflict and collaboration. The sixth section places the operations of the Canadian regulatory for GM food technology in the context of selected international practices.

The final purpose is to offer conclusions and directions for reforms to the governance of the federal biotechnology regulatory system, with a view to enhancing its effectiveness and legitimacy and raising public awareness and confidence.

THE SEPARATION OF FUNCTIONS IN GOVERNMENT: THEORY AND PRACTICE IN CANADA

The theory and practice of separating governmental roles relates to the political, organizational and managerial contexts of biotechnology decision making. What functions to specialize in and separate, why, and administratively how, are among the most significant

[1] *Biotechnology* includes a range of techniques, from fermentation to plant and animal breeding, antibiotic production and genetic engineering. It is defined in federal regulations as "the application of science and engineering to the direct or indirect use of living organism, or parts or products of living organisms, in their natural or modified forms." *Novel foods* are products that have never been used as a food; foods which result from a process that has not previously been used for food; or, foods that have been modified by genetic engineering. *Genetic engineering*, also called *genetic modification* or *recombinant DNA technology*, is achieved by changing the code or organization of the genetic material (DNA or RNA) of an organism. This includes moving a gene or genes from one organism to another. According to the *Food and Drug Regulations*, genetically modify signifies "to change the heritable traits of a plant, animal or microorganism by means of intentional manipulation."

classical questions of organizing and managing the public sector. These questions and our responses to them raise the further issues of how to coordinate the various separate functions to ensure some consistency and accountability to overall governmental priorities and plans.

Overall Government Roles in Science and Technology

The potential and actual roles of the government in science and technology are manifold and can be described in a variety of ways (de la Mothe, 2000; Doern and Reed, 2000a; Jarvis, 2000; Leiss, 2000; Lindquist and Barker, 2000). Drawing from this wide literature, and adapting it to the purpose of this study on GM foods, six government functions may be identified as follows:

- Policy development and law making;
- Communicating government policy, decisions and risk;
- Promoting biotechnology industry and trade;
- Regulating;
- Science support of regulation, including risk analysis; and,
- Auditing and evaluation of the process.

Policy development and law making entail at least three activities. These are the formulation of public policies on biotechnology and science more generally; the development of regulations and guidelines, codes and practices, often referred to as standard setting; and the negotiation and establishment of intergovernmental and international conventions and trade protocols. At the government-wide level, this function involves setting out mandates for specific ministerial portfolios and articulating a strategy or set of strategies. Communicating policy relates to the role of government as information provider, collector, and listener. In this field, it involves not only risk communication, but also the provision of information on existing and proposed laws and regulations, specific decisions, and the governance arrangements and practices themselves. An important element of communication is in fostering compliance with rules and laws. Audiences include other federal officials and parliamentarians, farmers, consumers, the public, the media, non-governmental organizations, business clients and partners, students and teachers, provincial and foreign governments, and others. It may also involve consultation exercises on policy reviews. This function bears directly on both the regulation and promotion functions by contributing to consumer protection and public confidence along with facilitating trade access.

Promoting the biotechnology industry is but a recent example of the longstanding practice of public authorities in Canada and elsewhere in assisting, encouraging and partnering in industrial development and economic growth. Indeed, one of the motives in renewing the federal biotechnology strategy in the late 1990s was to improve the government's capacity to promote Canadian biotechnology industries, among other aims. The National Biotechnology Advisory Committee (NBAC), the predecessor to the CBAC, recommended in its last major report that the Minister of Industry should champion biotechnology, "recognizing that Canada's ability to adopt biotechnology and pursue its application and development will significantly determine the country's future economic status and its role in world affairs" (NBAC, 1998). Promotion is of not only the few hundred biotechnology firms currently existent in Canada, but also farmers, fishers and other sectors of the economy. Ideas on government's role as promoter include supporting further research and development, issuing intellectual property rights (patents), and encouraging the commercialization of biotechnology products. They also include marketing and securing market access around the world, and, streamlining biotechnology product approvals so that regulatory systems are competitive with our major trading partners. Leiss and Chociolko (1995:259) have argued that by actively promoting industrial development, some in business and

in government are "risk-promoters" – with "a direct interest in exaggerating benefits and underestimating risk," hence interfering with the perception (and reality) of government as a neutral assessor of risk.

The concept of promotion, however, is more complex and nuanced. It is rich both in theory and in practice, with several shades of meanings and possible activities, ranging from micro private interests to a larger public interest. The focus of the promoter role by government might be a particular application or product developed by a single firm; a local or cluster of biotechnology firms, for example such as in Saskatchewan; biotechnology as a particular sector (for instance, health care or food) or a Canadian industry; and even biotechnology as a direct contributor to the attainment of other federal, provincial or intergovernmental public policy objectives. In other terms, the aim of promotion can be innovation by individual firms, regional economic development, and industrial or trade policy at the sector or national level, or some notion of quality of life and sustainable development.

Government as regulator equally has more gradations than often acknowledged. "Regulation draws on the most fundamental resource a government has, its capacity to command and prohibit" (Pal, 1997: 109). This definition of regulation, a conventional one, by emphasizing a negative policing role, implies that regulation is both detached from and intrinsically antagonistic to the promotion of economic activities. Regulation, thus defined, is regarded as circumscribing and restricting the behaviour of individuals and institutions, but this means excluding important areas of, and roles for regulation. By contrast, political reality itself errs on the side of breadth in understanding regulation as does increasingly academic studies (Doern, Hill, Prince and Schultz, 1999). If regulations are, generically, rules of behaviour backed by the sanctions of the state then they can be, in the view of different interest, rules expressed:

- as constitutional or quasi-constitutional rules (e.g., the Charter of Rights and Freedoms or the 194 Internal Trade Agreement);
- in statutes (e.g., The Canadian Environmental Protection Act);
- in delegated legislation or 'the regs' (e.g., eligibility rules, reporting requirements);
- as domestic or international guidelines (e.g., Health Canada guidelines for novel plants or WHO and FAO guidelines); or
- as standards and codes (e.g., for professional ethics).

Since regulation has a multifunctional nature, it is simplistic to characterize regulation wholly as negative and reactive, with the intent and effect of hindering innovation, impeding economic growth and thereby weakening competitiveness. Of course, *policing* the behaviour of firms and industries is an old and still important function of the state. Inspection, enforcement and compliance activities are familiar illustrations of this function. Yet regulatory bodies in Canada have also engaged in *promoting* the economic welfare of firms and sectors subject to regulations and participated in *planning* by directing economic activities toward public policy aims. As Schultz and Alexandroff (1985) have pointed out, each of these roles has a distinctive decision making style and a narrower or more comprehensive scope of policy goals. They note also that, depending upon the configuration of interests and power in a given sector and time, these promoting and planning activities may be private interest dominant or public interest-led, reflecting different degrees of corporate autonomy and political intervention. While the philosophy of the day may create a dominating interest, there are usually competing interests and conflicting objectives even at any given time.

Science support is another critical function performed by government in the biotechnology regulatory system. Doern and Reed (2000a: 5) define science-based policy and regulation making as, "where scientific knowledge and personnel constitute significant or effective inputs into, or are distinctive features of, the relevant decision-making process."

Science activities and tasks in and for government include assessing risks and undertaking tests; evaluating scientific evidence regarding a new product or process; answering questions and explaining the science basis of decisions or test results; conducting basic research; publishing findings; engaging in peer review and consulting with colleagues around the world; developing new technologies that may be commercialized; monitoring the environment as well as the implementation of and compliance with regulations; and, assessing the consequences of regulations for biodiversity, including animal, plant and human life.

What should be the organizational context for this science? Should all scientific activity be done outside of government? The science can come from several different sources, namely, internal to the federal government; one or more provincial governments; from regulated companies; on contract from university labs or research facilities; and from scientists in other countries working in the public or private sector. Should some, and perhaps more, be done inside the federal government? Moreover, if done inside the government, should the science support for regulation (and promotion) be located within regulatory organizations or located in a separate scientific agency, at arms-length from the regulatory decision making? Contending and varied positions are apparent in the Canadian literature (de la Mothe, 2000; Doern and Reed, 2000b; Jarvis, 2000; Leiss, 2000).

The last, but far from least, government function we need to consider with respect to GM foods and the biotechnology regulatory regime is auditing and evaluation. This feedback or response function involves monitoring the actual administration and implementation of food safety inspection programs and industry regulatory systems. Performance measurement and results reporting are important management tools here for purposes of accountability and transparency. As noted above, scientific knowledge and work are central to the successful carrying out of these monitoring tasks. This function is a key feature of the "checks and balances" approach to food safety standard setting, inspection and auditing between Health Canada and the CFIA (Prince, 2000a).

How and Why the Relation between Government Regulation and Promotion of Biotechnology is an Issue

The relationship between the federal government's role as regulator of risks and its role as promoter of the biotechnology industry is seen by many, inside and outside both the government and the scientific community, as problematic. This perspective holds that government science and or government regulators are not always objective and impartial in the execution of their work, or in the ultimate reception given to their advice, because it is unduly influenced by bureaucratic, political or commercial interests (Hutchings et al., 1997; Jarvis, 2000; Leiss, 2000).

Two recent events clearly demonstrate the prominence of this topic. One concerns the proposed Canada Food Safety and Inspection Act, known as Bill C-80 in the previous session of Parliament, where it died on the order paper. For the government, the bill proposed a simple consolidation and modernization of several existing food and agriculture laws. However, political opposition from various NGOs alleged that the new bill would weaken food safety protection and alter the division of responsibilities, the "checks and balances," between the Minister of Agriculture and Agri-Food, who is responsible for the CFIA, and the Minster of Health. A year later, the bill has yet to be reintroduced in the House of Commons. The second event is the petition filed by the Sierra Legal Defense Fund, in May 2000, under the sustainable development provisions of the *Auditor General Act*, for a review of the federal regulatory structure for biotechnology in the context of sustainable development. Among the questions the petitioners asked was the following: "Does the existing regulatory system for biotechnology provide for the clear separation of regulatory and promotional roles among different agencies involved in the promotion and regulation of biotechnology?"

From a sociology of organization viewpoint, the problem raised by these events is one of role conflict. Certain officials, or a given institution or indeed the government as a whole is faced with performing what are perceived, by at least some in society, as contrary or incompatible policy aims and program activities. Three variants of this role conflict can be identified in relation to GM foods and to biotechnology more generally. One is that public awareness and or governmental expectations are unclear and too poorly formulated to provide a consensus and coherent direction to policy making and regulation. The lack of effective citizen engagement in establishing new structures and policies can contribute to this lack of consensus. Moreover, the nature of risk regulation itself is bound to generate at least some controversy regarding expectations and awareness, given differing perceptions of risk, uncertainties, and the inability to completely eliminate risk.

A second kind of role conflict is that groups disagree over what the government's proper role should be, if one at all, with respect to the science/regulation/promotion trilogy of activities. Even if there is agreement that government ought to perform all of these functions, the third version of this role conflict concerns whether a particular government department or agency, like the CFIA, has two roles within its own mission and mandate, such as safety regulation and trade promotion, which raise honest doubts as to whether both roles can be suitably performed in a consistent manner.

In part, this issue is about the role of science in regulation and whether biotechnology product assessments ought to be shaped by social, political and economic criteria. In part, it is about the public service values of professionalism, integrity and neutrality. More broadly, it is about our understanding of the public interest and private interests and their proper relationship. As Jarvis (2000: 316) expresses it: "The public interest, in this case, the protection of citizens and stewardship of common resources, and private interests, determined in part by access to markets and international competitiveness, are the yin and yang of science-based regulations. These two sets of interests provide the tension that forms the basis for policy choices in this area, as they do in many areas of public policy." This comment is instructive in pointing out that the regulator-promoter issue is not unique to the GM food or biotechnology area, nor is it a new issue on the policy agenda. There are lessons and useful practices to be found in other quarters of government.[2] For Jarvis, these sets of interest, while competing, are not fundamentally contradictory, and so the challenge and opportunity for governments is to find a balance between them. This stance is similar to the federal government's position under the 1998 Canadian Biotechnology Strategy.

In addition to the obvious challenges associated with managing the politics of contending interests, this issue is critical for other reasons too. The nature of the separation or, conversely,

[2] A recent example is the reorganization at Health Canada. In April 2000, Health Canada announced a fundamental restructuring in order to ensure it has the capacity to deliver high quality services to Canadians while also rebuilding the confidence of Canadians in the Department. In recent years, the Department was under significant criticism and legal challenges for its management of a number of files and services, specifically Canada's blood services. As well, the scientific community criticized the Department for influencing the findings of its scientists. In addition, the contamination of the blood system called into question Health Canada's "promotional" role versus its fundamental role of protecting the health of Canadians. Because of growing political and public pressure, the Department separated the *protection* and the *promotion* responsibilities into different branches. The Health Protection and Health Promotion and Programs branches were re-aligned into three new branches: Health Products and Foods (which includes biologics and related biotechnology); Environmental and Product safety; and Population and Public Health. Also included in the restructuring was the introduction of the Office of the Chief Scientist in order to protect the scientists' ability to "speak truth to power" within the Department. While the context and drivers of this example, may be unrelated to biotechnology and GM foods, the lessons and actions from it are important and instructive, and form part of the wider context in which biotechnology is debated. More information on this realignment is on Health Canada's website.

the integration of regulation and promotion, has implications for ministerial responsibility and organizational design. The more the separation of functions, the wider the span of controls for senior management and the greater the need for coordination and supervisory tools.

The nature of governmental functions and their combination within an agency's mandate - rule making, enforcement, adjudicating disputes - are important considerations in administrative law and judicial review. Courts in Canada apply different tests for natural justice and procedural fairness, depending on the function(s) exercised by a public authority. A higher standard is applied to judicial and quasi-judicial powers than for legislative and policy-making powers. Moreover, where the tribunal members or tribunal staff exercise overlapping functions in a mulit-tiered decision process, investigation and adjudication for example, courts have held that such situations may lead to a reasonable apprehension of "institutional bias" in a substantial number of cases (Jones and de Villars, 1999). The result is that there is a real or perceived absence of independence and a sense that final decisions are predetermined.

Separating Regulation from Promotion: Rationales and Forms

Separating biotechnology regulation from biotechnology promotion activities within government relates to relationships between the state and market, citizens and governments, elected politicians and appointed officials, scientists and managers, and different kinds of knowledge. Our focus here is to look at the reasons put forth for such a division or specialization of labour within a bureaucracy, and the various types and organizational expressions for differentiating regulatory work from other kinds. Table 1 summarizes the discussion that follows. The organizational forms range approximately from least to most insulation from direct ministerial and legislative control.

Table 1
Separating Governmental Functions by Structures

Organizational Form	Rationale	Functions Possibly Performed	Regulation-Promotion Relationship
Departments	Direct Ministerial control and accountability, Specialization	Policy development Communication Science support Regulation Auditing/evaluation	Tend to give emphasis to one or other.
Central agencies	Horizontal management across government, and support to Cabinet	Policy development Communication Setting Auditing/evaluation standards	Not involved directly in either but interested in their individual results and their interface.
Advisory councils	Representation of interests, outside expertise, credibility, public participation	Policy development Communication Science advice Policy evaluation	Through policy advice, could have an indirect input on either regulation or promotion.
Commercial Crown corporations	Entrepreneurship, representation of business interests/expertise	Policy development Communication Science advice Promotion	Give emphasis to promotion function. Subject to regulation by other public bodies
Regulatory boards and appellate bodies	Impartiality, expertise and natural justice, flexibility in operations	Policy development Communication Regulation Evaluation	Intended to focus on regulation but may also serve promotional and planning purposes.
Special operating agencies and other alternative delivery mechanisms	Innovation, power sharing, smaller and perhaps smarter government	Policy development Communication Promotion Regulation	Likely to focus on promotional activities.

In traditional public administration, the separation of various governmental functions related to workload concerns, representation of interests, entrepreneurship, and natural justice (Hodgetts, 1973). These rationales served to justify the creation of a large number of non-departmental bodies in the federal public service, in the form of advisory councils, Crown corporations and regulatory boards. A general reason for all these forms was to manage better the

expanding workload and increasing technical complexity of the tasks facing government. Another form of assistance to Ministers collectively is, of course, central agencies, which include the PMO, PCO, Treasury Board Secretariat, and Finance. For advisory councils, the rationale has been to recruit experience, expertise and perhaps some representativeness of the public for gathering information, seeking public input, and providing policy advice.[3] For Crown corporations, especially commercial ones, it has been to facilitate a private enterprise culture and style of management and decision making, informed by "sound business" precepts. To realize such a culture, the thinking was that public enterprises needed to be separate from direct political and central agency controls. For regulatory boards, it is to ensure objectivity and impartiality in the determination of rights and the adjudication of disputes.

The concept of institutional bias, mentioned earlier, closely ties to natural justice. Institutional bias, as Jones and de Villars (1999: 372) explain, is when bias or a reasonable apprehension of bias is "generated by the structure of an institution, rather than from the words or actions of an individual." They add that: "if the system is structured in such a way as to create a reasonable apprehension of bias on an institutional level, the requirement of impartiality is not met. The appearance of impartiality is important for public confidence in the system."

In the New Public Management, a recent alternative paradigm for restructuring and operating governments, the rationale for separating functions is to overcome the dysfunction's of large bureaucratic systems, thus encouraging innovation and greater cost effectiveness and responsive services. The division of labour, achieved by contracting out, privatization and other forms of alternative service delivery, is, in a sense, a form of debureacratization. The reasons advanced for this type of separation of functions include promoting experimentation, emphasizing accountability for results, preserving flexibility in responses, and keeping costs down by using competition between service providers (Osborne and Gaebler, 1993).

A fundamental argument for insulating regulation from the promotional activities on biotechnology is reminiscent of the classic argument for regulatory commissions and tribunals to be at arms-length from cabinet-parliamentary government and politics. To accord with rules of natural justice, the regulatory activity, especially if a mixed mandate with quasi-judicial powers, ought to be separate to be impartial. As Schulz (1978: 129) has written: "the adjudicative function of regulatory agencies … [the power to decide in individual applications] provides the only compelling argument for agency independence. Regulatory agencies must be independent when they are called upon to make decisions affecting competitive proprietary interests, as in licensing applications." The causal theory underlying this reasoning is that the arms-length structure helps to produce impartiality, which over time leads to legitimacy, which brings about general public confidence.

What we can call *the regulation-promotion dichotomy* is a descriptive and prescriptive model of risk management and decision-making. The model holds that science-based regulation should be, and in large measure is, removed from promotional activities within government. While it may be quite legitimate for governments to promote trade and market access in regards to science and technology policies, such aims ought to be distinct from the personnel, criteria and decision processes used for making assessments of biotechnology products.[4] This is not to suggest that science and regulating are self-contained realms, or that scientific analysis and advice should be disconnected entirely from management decision making. Rather, the intent is to ensure

[3] Viewed broadly, advisory bodies encompass Royal commissions, task forces; permanent councils attached to departments or central agencies. Beyond these bodies to advise government, are parliamentary committees set up by Parliament to conduct the business of the legislative branch.

[4] Some commentators would push the dichotomy even further. On the federal biotechnology strategy, Leiss (2000:71-2) has said: "why anyone thinks that the same government that is supposed to regulate the relevant risks should be a huckster for the industry is a mystery – especially when it is abundantly clear that private industry is doing a perfectly adequate job of promotion all by itself."

that determinations of the quality, safety and efficacy of GM foods be based first and foremost on scientific tests and state-of-the-art research and evidence, in compliance with statutory provisions.

The organization of Canadian governments demonstrates the presence of several forms of separation of functions (Kernaghan and Siegel, 1999). In recent decades, efforts to restructure the federal public service and policy processes have frequently entailed the separation of certain activities. These include: program evaluation from administration, policy advising from policy-making, long term planning from day to day management, and the management of the economy (Finance) from the management of the government (Treasury Board). The reinventing government movement (Osborne and Gaebler, 1993) also urges separating policy making and strategic management (called 'steering') from service provision and delivery (called 'rowing'). Contemporary practice in the biotechnology field similarly reveals a great deal of delegation and differentiation of authority and responsibility.

Organizational options for separating various functions include the following:

- functions are housed in different sections within a particular department or agency;
- functions are located in different organizations within a particular ministerial portfolio;
- functions reside in different ministerial portfolios;
- functions are divided between one or more portfolios and central agencies; and,
- functions are attached to Parliament as legislative officers.

The Regulation Promotion Nexus

Even if regulatory and promotional activities are separate at the operational and case-by-case decision making level, they need to be coordinated and considered together at the level of policy and governmental mandate. In reality, regulation and promotion rendezvous in a number of ways and arenas of the federal government.

1. Other governmental roles that we have reviewed, like communications and scientific support, can bolster both regulation and promotion. Research and development (R&D), for instance, may well advance the growth of innovative products and technologies, and produce new insights, data and tools for the assessment of environmental impacts. R&D will also create information for new or adjusted regulation, including feeding into problem identification and the analysis of options.
2. During major consultation processes with stakeholders and multiple publics, such as the 1997-98 renewal process of the Canadian biotechnology strategy, both functions are frequently raised and debated about with respect to their relationship.
3. The recently formed coordinating committees on biotechnology, at the senior management and ministerial levels are intended to be important places for addressing the regulation-promotion interface.
4. Horizontal policy initiatives, such as the government-wide Sustainable Development Strategy, explicitly endeavour to balance economic, social and ecological concerns in science and technology as well as all other federal policy fields. The House of Commons Standing Committee on Environment and Sustainable Development, in a study of the biotechnology and the federal regulatory regime, sought in its work and recommendations "to ensure that regulatory decisions made with respect to biotechnology would protect the health of Canadians and the Canadian environment, but at the same time would not produce a regulatory climate that would unfairly hamper the development of the industry in Canada" (House of Commons, 1996: 1)
5. In the field of external affairs and international trade, regulation and promotion meet on an ongoing basis through the federal government's efforts to "[e]stablish and negotiate standards

in order to harmonize Canadian and international regimes to protect Canadians and to provide a favourable business climate" (de la Mothe, 2000:44-45). This illustrates the point made earlier that regulation and promotion are not a simple either/or situation. Regulation can defend and advance the interests of firms and industries, whether by granting patents, protecting commercial secrets, or assuring consumers of the continued inspection and certification of products.

6. Government budgets not only allocate financial resources; they are simultaneously an accommodation of diverse values, a set of plans and a set of signals. Recent budgetary choices reflect the way in which biotechnology is rising as a federal priority and the way in which the scientific support, regulation and promotion functions are being addressed. The 1999 federal budget allocated $55 million over three years for biotechnology R&D. The 2000 budget highlighted biotechnology as "poised to be a major engine of the new economy," committing $160 million to fund the activities of five genome science centres across the country. This same budget stated that biotechnology products "require careful scrutiny and regulation," giving a permanent increase of $90 million over the next three years in the budgets of the federal departments and agencies that regulate biotechnology development (Finance Canada; 2000: 111).

The regulation-promotion nexus, therefore, is multifaceted in the number and variety of interconnections evident in the federal government. This nexus is embedded within, and shaped by, horizontal policy, managerial, legal and constitutional systems.

THE COORDINATION OF GOVERNMENT FUNCTIONS: BIOTECHNOLOGY AS A HORIZONTAL POLICY FIELD

As a set of governmental functions, biotechnology is structured along departmental and agency lines. As a policy field, with a complex bundle of inter-linked ideas, instruments and interests at play, biotechnology cuts across ministerial portfolios and agencies, and their mandates, clients and stakeholders. Likewise, it cuts across levels of government within Canada and with other nation states and international bodies. As biotechnology is a series of techniques, based in science and engineering, and not a type of product, it has a wide scope of actual and possible applications, each with benefits and risks, that affect the mandates and authorities of several federal organizations. Each of these organizations is the custodian of a mix of values and goals, each a part of the "public interest," that pertain to the cultural, ethical, economic, social, scientific and political aspects of biotechnology. The scientific disciplines, professionals and expertise relevant to biotechnology and GM foods are distributed over several government and non-governmental organizations. In the language of Ottawa central agencies, biotechnology has a high degree of "horizontality" or interdependence to it as a policy field.

Five levels of horizontal policy management applicable government-wide are identifiable. These are: the government's overall agenda; policy frameworks and strategies; coordinating organizations for the government generally and for biotechnology more specifically; legislation of across-the-board application; and, constitutional rules and norms.

Table 2

Five Levels of Horizontal Context for Biotechnology Policy
Governmental Agenda Throne Speeches Budget Plans
Policy Frameworks and Strategies Sustainable Development Strategy Canadian Biotechnology Strategy Regulatory Policy and the Regulatory Process and Management Standards
Coordinating Organizations Parliamentary offices Central agencies Interdepartmental bodies
General Legislation *Privacy Act* *Criminal Code* *Auditor General Act*
Constitution Rules and Norms Rule of Law Division of Powers Charter of Rights and Freedoms

These levels are distinguishable in relation to the nature of their processes and their propensity for change. They range highly public and political processes, with significant symbolic and rhetorical content, and fairly flexible in the short run, to those that are more legalistic and relatively more stable, providing many of the "rules of the game" for the other levels and for vertical activities of government. Each can be briefly outlined, with illustrations from the Canadian biotechnology policy field.

Government's Overall Agenda

The government's overall agenda embraces the top priorities of the government, and those initiatives and themes with high visibility. Government organizations must position themselves in relation to this context. This macro political agenda finds expression in pre-election policy books, throne speeches, and budget speeches and plans. These documents and processes establish a policy context which influences all the biotechnology departments and agencies in their own organizational priorities, planning environments, and inter-organizational and perhaps intergovernmental relations. The 1999 Speech from the Throne, for example, contained commitments to a stronger food safety program, action on environmental health issues, and modernized health protection. These all are important themes for the regulatory organizations like CFIA, Health, and Environment. Still other themes in the Throne Speech - of building a dynamic economy, supporting strong communities and working internationally to advance Canada's place

in the world – resonate for the promotion-oriented federal organizations like Agriculture and Agri-Food Canada, Industry Canada, and International Trade.

Strategies and Framework Policies

Strategies and framework policies customarily refer to an identified group of more or less interconnected policies, programs and activities directed toward a shared purpose, approach or target group. In recent years, strategies and frameworks are increasingly linked to the idea of partnership, that is, of sharing resources and responsibilities across federal organizations, and between the federal government and other governments or sectors (Pal, 1997). They span the full width of government activities and interests, from the Federal Aquaculture Development Strategy to the Social Union Framework Agreement. Three strategies stand out as especially relevant to the matter of GM foods, those on sustainable development, science and technology advice, and biotechnology. Under the *Auditor General Act*, as amended in 1995, federal departments and agencies were required to develop sustainable development strategies by the end of 1997 and are to present an updated version by the end of 2000. An emerging policy paradigm (Doern and Conway, 1994), sustainable development calls for growth that meets the needs of the present without compromising the ability of future generations to meet their own needs. Economic, environmental and social objectives are to be integrated into policy thinking and organizational decision making. This has prompted federal organizations to consult with one another and with their stakeholders; review existing activities and operationalize sustainable development based on their mandates.

In April 2000, the federal Cabinet approved a new *Framework for Science and Technology Advice: Principles and Guidelines for the Effective Use of Science and Technology Advice in Government Decision Making* (Canada, 2000a). The Framework is based on ideas and direction from the Council of Science and Technology Advisors, an external body of experts created in 1998 to provide the federal government with advice on internal science and technology issues of government-wide importance. The Framework includes six science advice principles and guidelines along with a series of implementation measures to promote the adoption of the Framework; ensure accountability for adherence to it; and evaluate its effectiveness.

The federal government has had an explicit strategy on biotechnology since the early 1980s. In 1983 the first National Biotechnology Strategy was introduced and focused on the development of scientific capacities and promoting the commercial environment for this up-and-coming economic sector. Building on this strategy, a policy framework for regulating products of biotechnology was announced in 1993, arising from an agreement among federal regulatory departments and agencies. The principles contained in the Federal Regulatory Framework for Biotechnology are:

- Maintaining Canada's high standards for the protection of the health of workers, the general public and the environment;
- Using existing legislation and regulatory institutions to clarify responsibilities and avoid duplication;
- Developing clear guidelines for evaluating biotechnology that are in harmony with national priorities and international standards;
- Providing a sound scientific knowledge base on which to assess risk and evaluate products;
- Ensuring that the development and enforcement of Canadian regulations are open and include consultation; and

- Contributing to the prosperity and well-being of Canadians by fostering a favourable climate for investment, development, innovation and adoption of sustainable Canadian biotechnology products and processes.

In comparison to the earlier statement, this framework articulates several principles that stress the regulation function relatively more than the promotion function, though both functions are contained.

A renewed Canadian Biotechnology Strategy (CBS), replacing the 1983 version while reaffirming the 1993 framework, was released in 1998. As a horizontal policy framework, the renewed CBS contains a vision statement, four guiding principles, eight objectives and ten themes from concerted action. The vision is "To enhance the quality of life of Canadians in terms of health, safety, the environment, and social and economic development by positioning Canada as a responsible world leader in biotechnology." The guiding principles are to: reflect Canadian values; engage Canadians in open, ongoing, transparent dialogue; promote an innovative economy, sustainable development, competitiveness, public health and scientific excellence; and ensure responsible action and cooperation domestically and internationally. Interestingly, while reiterating the core ideas of (a) health, safety and environmental protection, and (b) innovation, economic development and commercialization, the 1998 Strategy places new and enhanced attention on public participation and confidence; communication; ethics; and the scientific capacity of the system in terms of knowledge and personnel. The fact that there are eight goals and ten action themes point to a maturation of the biotechnology sector, the elaboration of issues and the changed political setting of today that confronts this policy sector and others. The image of the federal government's role that emerges here is as the "responsible leader" balancing risks and benefits, and addressing multiple values and goals on both the domestic and world stages.

Horizontal Mandate Structures

Horizontal mandate organizations have responsibilities that extend across the government to coordinate some particular crosscutting public values and policy purposes. By definition, central agencies and offices of parliament, have mandates that are broadly horizontal in nature and possess the authority to have input in most if not all departments and agencies. The Office of the Auditor General, an agent of Parliament, has regularly reviewed the federal government's science and technology management practices and the use of resources. Attached to the Auditor General's is the Commissioner of the Environment and Sustainable Development, whose work is supported by a host of other structures. These institutions have various functions and relationships, and include the interdepartmental network on sustainable development strategies; the Sustainable Development Committee of deputy ministers; the National Round Table on the Environment and the Economy, an advisory body to the government; and, the House of Commons Standing Committee on Environment and Sustainable Development, a parliamentary committee whose job is to hold Ministers to account for what they have (and have not) done in matters environmental. Other notable parliamentary agencies are the Offices of the Information and Privacy Commissioners. The Treasury Board Secretariat (TBS) and the Privy Council Office (PCO) are principal horizontal organizations in and around the cabinet and Prime Minister.

For managing the renewed biotechnology strategy, a series of structures have established. A Biotechnology Ministerial Coordinating Committee has been set up, chaired by the Minister of Industry and comprised also of the Ministers of Agriculture and Agri-Food, Health, Environment, Fisheries and Oceans, Natural Resources, and International Trade. An eight member coordinating committee of Biotechnology Deputy Ministers and Agency Heads (the deputies of the seven core departments and the head of the CFIA supports this committee). Below this, is a nine member coordinating committee of Assistant Deputy Ministers; and, a small secretariat headed by an

executive director. As needed, working groups of officials will deal with particular issues (Canada, 1998: 11).

An external structure is the recently formed Canadian Biotechnology Advisory Committee (CBAC). A key component of the renewed strategy, the CBAC is "an expert, arm's-length panel to advise ministers on biotechnology issues, raise public awareness and engage Canadians in discussions on biotechnology matters." A fundamental rationale for the CBAC is impartiality and expertise, and one of its main roles will be communication and consultation with the public.

Legislation of General Application

The fourth level of the horizontal policy context concerns legislation of a general application. Many of these statutes are authorities of the Treasury Board and provide the framework for government management. Significant laws of general application are the *Access to Information Act*, *Financial Administration Act*, *Privacy Act, Public Service Staff Relations Act,* and *Real Property Act.* Other important laws under the responsibility of other central agencies include the *Auditor General Act,* the *Criminal Code,* and the *Statutory Instruments Act* and *Regulations.* This last statute provides for the examination, publication and scrutiny of regulations and other statutory instruments. With some exceptions, new and revised regulations proposed by federal departments and agencies are transmitted to the Clerk of the PCO for registration. In examining regulations, the Clerk may consult with the Minster of Justice for advice. If approved, regulations are published in the *Canada Gazette,* the official periodical publication of the federal government, giving notice of current rules and orders. Once published, copies of the regulation are distributed to each member of the House of Commons and Senate, and are deemed to be "judicially noticed." Annually, all new regulations are sent to a parliamentary committee for scrutiny.

Constitutional Rules and Norms

Constitutional rules and norms that define and shape the regulatory state include the rule of law, the Charter of Rights and Freedoms and the distribution of powers between the federal and provincial orders of government.[5] The doctrine of the rule of law holds that every official act must be justified by some legal authority; that no law may be applied retroactively; that there be equal treatment under the law, implying freedom from excessive and unfair state action; and, that all agencies of the state are subject to operate under the law in compliance with the procedural requirements of "natural justice." The Charter of Rights is one of the overarching institutions of the Canadian political system and regulatory state. It applies to the actions of the federal, provincial, territorial, and municipal levels of governments as well as other public bodies, including administrative tribunals exercising statutory authority.

Federalism is another overarching institution in our constitutional order. In Canada's federal system, legislative powers are divided between the federal and provincial governments. Each level has a series of responsibilities enumerated in the constitution. The eleven regulatory states under Canadian federalism function with a mix of separate and shared authority.

In relation to science and biotechnology policy and to food safety regulation, the federal government has exclusive legislative powers to make laws in relation to peace, order, and good government; the regulation of trade and commerce; navigation and shipping; sea coast and inland fisheries; weights and measures; quarantine; patents and copyrights; and the criminal law. It is the criminal law power in particular that authorizes laws for food and drugs and the protection of

[5] Other fundamental constitutional dimensions of the regulatory state in Canada include cabinet government and the supremacy of parliament. See Prince (1999) for details.

health (Hogg, 2000). The provinces derive their authority to legislate and regulate from exclusive powers in relation to property and civil rights; nonrenewable natural resources; forestry resources; and generally all matters of a local and private nature in the province. The provinces and the federal Parliament have concurrent powers to make laws in relation to agriculture and interprovincial trade in non-renewable resources, with federal paramountcy. This means that where federal law and provincial law coexists in these policy fields and are inconsistent, the federal law prevails.

MANDATES AND MISSIONS OF FEDERAL ORGANIZATIONS INVOLVED IN GM FOODS

On the question of whether the existing regulatory system for biotechnology provides for the clear separation of regulation and promotion roles among different organizations, a recent official response by several ministers responsible for biotechnology states:

> The Government of Canada recognizes the importance of separating its regulatory and promotional functions. As the government fulfills a number of roles in relation to any technology, including biotechnology, Canadians expect that in addition to safeguarding the environment and the health of Canadians and animals, the Government of Canada will work to promote sustainable economic development consistent with the SDSs [Sustainable Development Strategies] of federal departments and agencies. The Government also has a responsibility to inform Canadians about the regulation of products derived from biotechnology. The Government fulfills each of these roles yet keeps the regulatory and promotional functions separate by assigning different and distinct mandates to departments and agencies. These mandates are voted on by Parliament, and Ministers are accountable back to Parliament for the performances of Departments and Agencies in fulfilling their assigned duties (Canada, 2000b: 4).

This authoritative presentation of the existing system is a useful starting point for a fuller analysis. It speaks to the regulation and promotion roles as well as to the importance of communication and auditing roles, and accountability mechanisms. The regulation-promotion nexus model is implicit in the references to Canadians' expectations that the government will in fact perform all of these multiple roles, and that the roles are performed within a horizontal policy framework of sustainable development. Explicitly, the statement is far closer to the regulation-promotion dichotomy, by emphasizing that different federal organizations have responsibility for different roles in regards to biotechnology, and by highlighting the constitutional principle of individual ministerial authority and responsibility to Parliament for legislation and programs.

Looking at mandates and missions provides useful information on the authorities, aims, and ambits of federal departments and agencies directly concerned with biotechnology and, more specifically, GM foods. In terms of statutory powers and duties, five federal organizations are regulators of biotechnology products. Table 3 summarizes the legislative responsibilities of these organizations and the biotechnology product types they regulate.

Table 3
Federal Structures and Mandates for the Regulation of Biotechnology

Organization	Legislation	Products Regulated
Canadian Food Inspection Agency (CFIA)	*Feeds Act, 1997*	Feeds, including novel feeds
CFIA	*Fertilizers Act, 1997*	Fertilizer supplements, including novel chemical and microbial supplements
CFIA	*Fish Inspection Act, 1997*	Fish and marine plants
CFIA	*Health of Animals Act, 1990*	Veterinary biologics
CFIA	*Plant Protection Act, 1997*	Plants in the agricultural and forestry sectors
CFIA	*Seeds Act, 1997*	Plants, including plants with novel traits and trees
Health Canada	*Food and Drugs Act, 1997*	Foods, drugs, cosmetics and medical devices
Pest Management Regulatory Agency	*Pest Control Products Act, 1995*	Pesticides, including organic functions of chemicals and organisms
Department of Fisheries and Oceans	*Fisheries Act, 1999*	Transgenic aquatic organisms
Environment Canada Health Canada	*Canadian Environmental Protection Act, 1999*	All animate products of biotechnology for uses not covered under other federal legislation

Source: Adapted and expanded on from Canada (2000b: 7-8).

With respect to GM foods in particular, the relevant regulators are the CFIA and Health Canada, and the primary promoter is Agriculture and Agri-Food Canada, so these will be the prime focus here.

Canadian Food Inspection Agency

Created in 1997, the mandate of the CFIA involves the delivery of all federally mandated food inspection and quarantine services as well as animal health and plant protection programs.[6] The CFIA is a departmental corporation, meaning it has independent legal status, established under its own statute, with a corporate board form of management and somewhat more autonomy than a regular operating department. For purposes of ministerial responsibility and parliamentary accountability, the Agency reports to the Minister of Agriculture and Agri-Food. In addition to an annual report, the Agency must submit, at least once every five years, a "corporate business plan" to the Minister for approval. The Minister, in turn, must table a copy of the plan in both the House of Commons and the Senate. For purposes of human resources, the CFIA has separate employer

[6] For detailed discussion of the origins and operations of the CFIA, see Prince (2000a) and (2000b).

status under the *Public Service Staff Relations Act.* This means the Agency is at arm's length from the personnel controls of central agencies, granting it relatively more flexibility in devising and implementing the terms and conditions of employment. A President who can appoint analysts, graders, inspectors, veterinary inspectors and other officers to implement the Agency's mandate heads the CFIA.

The CFIA is responsible for the administration and enforcement of 11 Acts and their regulations. This includes the acts listed in Table 3 and the *Agriculture and Agri-Food Administrative Monetary Penalties Act, Canada Agricultural Products Act, Canadian Food Inspection Agency Act, Meat Inspection Act,* and *Plant Breeders' Rights Act*. In addition, the CFIA is responsible for the enforcement of the *Consumer Packaging and Labelling Act* as it relates to foods, the enforcement of the *Food and Drugs Act* as it relates to food, and the administration of the provisions of the *Food and Drugs Act* as they relate to food, except provisions that deal with public health, safety or nutrition.

This exception is noteworthy in that section 4 of the CFIA legislation stipulates that it is "the Minister of Health who is responsible for establishing policies and standards relating to the safety and nutritional quality of food sold in Canada." Furthermore, the Health Minister is designated as responsible for "assessing the effectiveness of the Agency's activities related to food safety." This section thus gives statutory expression to the concept of a "checks and balance" relationship between the CFIA and Health Canada.

In terms of statutory powers contained in its enabling legislation, the Minister or

CFIA may:

- enter into contracts, memoranda of understanding and other agreements with a federal government department or agency, a provincial government or any other person or organization;
- negotiate and enter into international agreements for the implementation of technical requirements for the international movement of products or other things regulated under an Act or provision that the Agency enforces or administers;
- bring or take actions, suits or other legal proceedings, including applying to a judge for an interim injunction enjoining any person from contravening an Act or provision that the Agency enforces or administers;
- procure goods and services from outside the public service of Canada, with the approval of Cabinet given on the recommendation of the Treasury Board;
- issue, license, sell or otherwise make available any patent, copyright, industrial design, trade-mark or other similar intellectual property right under any Act or provision that the Agency enforces or administers;
- fix fees, not exceeding the actual cost, to be paid for a service, product, right or the use of a facility provided by the Agency;
- serve orders that a product be recalled or sent to a designated place when it is believed, on reasonable grounds, that a product poses a risk to public, animal or plant health; and,
- enter into agreements with one or more provincial governments for the provision of services or the formation of a joint corporation, for carrying out of activities within the Agency's responsibilities, or the collection of fees for services or use of facilities, with the approval of Cabinet on the recommendation of the Minister of Finance.

This simple listing of powers tells us a good deal about the intentions behind creating the CFIA and the government's vision for the Agency. First, the CFIA is the federal government's lead regulatory organization for the food safety system, as illustrated by the extensive number of laws for which it is responsible. Secondly, the rationale for creating a non-departmental structure

was to capture some of the benefits of flexibility coming from an agency form. These benefits include greater discretion in procuring goods and services, in managing the Agency's personnel, and in handling matters of intellectual property rights. Thirdly, while separate from AAFC, requirements of ministerial responsibility, cabinet control and parliamentary oversight do condition the Agency. The influence of the horizontal policy context is apparent in the requirements for approvals from Treasury Board and the Department of Finance for certain actions. Fourthly, alongside the theme of relative autonomy within the federal public service, is the image of the CFIA as connected in a network of relationships with provinces, possibly the courts, private sector organizations, consumers, and international bodies.

Critical in understanding the regulation-promotion debate is the working relationship between the Minister of Agriculture and the President of the CFIA. In formal terms, the Minister has the principal policy role for the Agency while the President has the lead management role. The Agency, for instance, takes responsibility for drafting the *Corporate Business Plan* while the Minister has the opportunity for input, which the Minister has taken and the authority for final approval of the *Plan*. To date there has not been a case in which the Minister intervened in a regulatory decision made by the CFIA. The Minister of Agriculture has no role in reviewing and approving the environmental assessments of GM foods conducted by the CFIA. As a rule, Ministers prefer not to become involved in science-based regulatory decisions. Moreover, there is no appeal mechanism of CFIA decisions, set out in the legislation, to either the Minister of the Cabinet. Conversations do occur between the Minister and the President in the gray area where policy and regulation connect. An example, would be when the regulatory decision is to destroy certain animals for reasons of public health, while the policy question is whether the existing level of financial compensation to farmers is adequate. The Agency decides the appropriate safety course of action, and the Minister would review and perhaps alter the compensation rate. Labeling offers another example. The enforcement of consumer package labeling, under existing legislation is done by CFIA staff, with no involvement by the Minister. The issue of whether mandatory labeling of GM foods should be required or not under Canadian law, is a policy question on which both the Minister of Agriculture and Health have been publicly active.

Applying the analytical framework of governmental roles, we can observe that the CFIA is a multifunctional organization. The Agency develops policies, legislation and regulations; has a significant in-house scientific capacity of laboratory services and testing centres; and, administers a range of inspection, establishment registration, product certification, licensing, enforcement and compliance programs. As well, the CFIA engages in risk communication; offers consumer education services; and, audits the implementation of detection systems and risk analyses done by industry (Prince, 2000a).

What, however, about promotion? Is the CFIA, as a regulator, involved also in promotional activities related to GM foods and biotechnology?

The federal governments own response to this question is unequivocal. "The creation of the CFIA" the government recently stated, "has organizationally separated this agency from any part of the government involved in research and development of biotechnology products. In addition, the CFIA is separated from other arms of the government responsible for trade promotion, market information and policy related issues such as farm income and rural development" (Canada, 2000b: 9). This is a strongly worded version of the regulation-promotion dichotomy.

Other government messages and experience have not been so clear cut, providing reasonable grounds for debate on this issue. The preamble to the *Canadian Food Inspection Agency Act, 1997,* touches on this question. Among other considerations, by creating a food inspection agency, the preamble speaks of the Canadian government's "wishes to promote trade and commerce." Such powers of the CFIA as for consumer packaging and labelling, negotiating international arrangements for the movement of products, and the issuing of intellectual property rights, could be seen as relating to the <u>active promotion</u> of trade and market privileges. The act of

not collecting fees or setting them well below the true cost of providing services to a firm or industry could be understood to be a form of passive promotion. The Agency's first *Corporate Business Plan*, for the period 1997 to 2000, describes the mission of the CFIA as "safe food, market access, and consumer protection." The mandate and the mission are expressed in terms of three objectives: "(1) To contribute to a safe food supply and accurate product information. (2) To contribute to the continuing health of animals and plants for the protection of the resource base. (3) To facilitate trade in food, animals, plants and their products."

Closely reflecting the mandate and mission, the *Plan* identifies four priorities for the Agency. These are effectiveness and efficiency of the inspection system, domestic and international market access, consumer protection, and intergovernmental cooperation. Under each priority is a set of strategies and planned actions for the 1997 – 2000 period. According to the *Plan,* the CFIA strives to achieve the priority of facilitating trade by participating in regional and international standard setting organizations, and through involvement in the negotiation of trade agreements, such as at the World Trade Organization (WTO).

Osbaldeston (1992: 144) notes that it can take three to five years to implement significant organizational change in the federal government, and even longer where "major adjustments in organizational culture are necessary." The CFIA is just in its fourth year of existence as an organization, having to amalgamate what used to be the Food Production and Inspection Branch of AFFC, along with parts of Health Canada, Industry Canada, and DFO.

The formation of the CFIA is a significant organizational reform that does involve modifications in Agency culture. Indeed, the latest CFIA documents signal a learning process on the relation between regulation and promotion, marking the abandonment of the objective of facilitating trade and market access. Prominent references to trade and markets are apparent in the original *Corporate Business Plan,* the *1997-98 Annual Report,* and the *Estimates* from 1997-98 through to 1999-2000, in the Minister's message, and descriptions of CFIA's mandate, mission and objectives. This is not surprising given the intent that the CFIA would be a more entrepreneurial form of public sector governance (Prince, 2000b). Moreover, about three-quarters of the Agency's staff came from the Food Production and Inspection Branch of AAFC, forming the dominant culture, at least in the early years.[7]

A textual analysis of CFIA records reveals that from mid- or late 1999 onward, promotional activities and objectives no longer appear in documents describing the plans, priorities, essential result commitments and related activities of the Agency. In the executive summary of the *1998-99 Annual Report,* the Agency's President offered the following clarification of facilitating market access:

> Not to be confused with "trade promotion", market access refers to the Agency's measures to protect important Canadian resources – Canada's food supply, its animals and plants – through measures that help prevent the spread of food-borne illness and maintain a healthy animal and plant population. We contribute to safe food by inspecting and certifying producers and importers, thereby protecting Canadians and helping to build international confidence in Canadian-produced foods and animal and plant products; and influencing international inspection standards and encouraging adoption of Canadian requirements (CFIA, 1999: 2)

Here, market access is represented as an outcome of regulation rather than as a policy objective. Enhanced trade is the result of CFIA's primary business of inspecting food, animals

[7] The program objective of the Food Production and Inspection Branch in AAFC was "to enhance the marketability of agricultural and food products." The Branch, which numbered about 4,000 full-time equivalent staff, was responsible for setting and enforcing standards to, among other aims, "facilitate national and international trade."

and plants. Importers and producers are regulated for the purposes of protecting and maintaining a safe and healthy food system. Following on this, the *2000-2001 Report on Plans and Priorities* for CFIA contains no references to trade or market access. In fact, the report notes that "CFIA intends to submit a new Planning, Reporting and Accountability Structure in the incoming fiscal year [that is, 2000-01] to formalize wording changes in the Program Objective and Business Line Objective" (CFIA, 2000a: 9). The proposed new Program Objective, in effect a revised mission statement, is "to deliver effective and efficient federal inspection and related services for food safety, consumer protection, plant protection and animal health."

If words have significance, then this shift in the textual presentation of CFIA's mandate suggests a desire to emphasize the separation of regulation from trade promotion. Gone are references to market access and the facilitation of trade. The Agency wishes to be perceived by stakeholders and the public as a science-based regulatory organization concerned foremost with the safety and quality of food products.

Health Canada

From the *Department of Health Act*, derives the mission of Health Canada, which is "To help the people of Canada maintain and improve their health." The department's vision for the Canadian health system, shared by other ministries of health and other stakeholders, is "improving the health of the population, and providing modern health services efficiently and equitably." The formal mandate of Health Canada comes from several pieces of legislation, including, for biotechnology uses in agriculture, the *Food and Drugs Act* and *Regulations, Hazardous Products Act* and *Controlled Products Regulations, Pest Control Products Act* and *Regulations,* and, possibly, the *Quarantine Act.*

Under the *Department of Health Act,* the statutory powers and duties of the Minister of Health encompass the following matters:

(a) the promotion and preservation of the physical, mental and social well-being of the people of Canada;
(b) the protection of the people of Canada against risks to health and the spreading of diseases;
(c) investigation and research into public health, including the monitoring of diseases;
(d) the establishment and control of safety standards and safety information requirements for consumer products and of safety information requirements for products intended for use in the workplace;
(e) the protection of public health on railway, ships, aircraft and all other methods of transportation, and their ancillary services;
(f) the promotion and preservation of the health of the public servants and other employees of the Government of Canada;
(g) the enforcement of any rules or regulations made by the International Joint Commission relating to boundary waters and questions arising between the United States and Canada, in so far as they relate to public health;
(h) subject to the *Statistics Act,* the collection, analysis, interpretation, publication and distribution of information relating to public health; and
(i) co-operation with provincial authorities with a view to the coordination of efforts made or proposed for preserving and improving public health.

The Health Minister is also granted what may be called a "safety net" role or, in legal terms, residuary power (Hogg, 2000). The Minister's duties and powers include the administration of any federal laws and regulations not assigned by law to any other department or minister that relate, in any way, to the health of the people of Canada. Hence, along with the

powers enumerated above, the Health Minister holds the residue of federal powers as they pertain to public health.

With respect to biotechnology and GM foods, Health Canada's authority comes directly from the *Food and Drugs Act.* Under this law, food is defined as, "any article manufactured, sold or represented for use as food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever." Health Canada's authority is to assess and control the nutritional value, quality, and safety of food, the safety and effectiveness of human and veterinary drugs and therapeutic devices, and the safety of cosmetics. The regulation making authority is wide, with the Department able to establish conditions for the manufacture, labelling, sale, advertisement, and importation and inter-provincial movement of food products. The sole purpose of the *Food and Drugs Act* and *Regulations* is said to be consumer protection (Canada, 2000b), although environmental protection would appear to be a purpose as well. The Act is very much a regulatory instrument with considerable detail devoted to the inspection, seizure and forfeiture of products, and the powers of inspectors and analysts. Contravention of the *Act* or *Regulations* as it relates to food, can result, on conviction by indictment, in a fine up to $250, 000 and or imprisonment for a term up to three years.

Health Canada has three major areas of responsibilities: protection and promotion, health care policy, and First Nations and Inuit health. Underpinning these is "an *integrated health infostructure* that supports the generation, organization and dissemination of information and knowledge for making better health policy, program and medical decisions" (Health Canada, 2000: 14). The area of most interest for this study is the protection and promotion component. In this area of responsibility, the role of Health Canada entails "preventing and reducing the incidence of illness and injury by direct regulatory or other actions to manage risks over which individuals have little or no control by themselves." Further, it involves "providing individuals, groups, communities and the general population with information and tools (or access to them) so that they can make informed decisions about their health" (Health Canada, 2000: 13-14). Current departmental priorities and strategies for health protection include:

- focussing and investing in the in-house science capability and technical expertise;
- strengthening programs for food safety, environmental health and the regulation of health products;
- developing modern health protection legislation and making the decision making process more open;
- strengthening health protection activities such as disease control and testing of food, drugs and natural health products; and,
- working in partnership with others, both nationally and internationally, in the regulation of biotechnology (Health Canada, 2000: 16).

This survey of powers and priorities helps to highlight the functional nature of Health Canada. Certainly, the core function is regulatory given the emphasis in the mandate and legislation on protection and prevention, and the exercise of criminal law. Related closely to this is policy development on health and food safety. Scientific research and testing, and communication (the generation and dissemination of information and knowledge) are also major functions performed by Health Canada. On the role of promotional activities, the federal government states that, "[r]egulatory organizations within Health Canada have no role in commodity or product marketing, product research or development" (Canada, 2000b: 9).

Health Canada also performs an audit function in the food safety system of CFIA's inspection activities. While the CFIA conducts all federal food inspection activities, the Health Minister is responsible for establishing policies and standards relating to the safety and nutritional quality of food sold in Canada. Health Canada is further responsible for undertaking a systematic

and independent audit of the food safety components of the food inspection program of the CFIA to verify its compliance with Canadian health and safety standards. Again, this illustrates the checks and balances nature of the federal government's food safety system.

Agriculture and Agri-Food Canada

Compared to Health Canada and the CFIA, Agriculture and Agri-Food Canada (AAFC) is not a regulator of GM foods but rather a promoter of agricultural biotechnology. AAFC's departmental vision is that they are "a top performing team committed to global excellence of Canada's farms and food." The current Minister has described his personal mission as "to promote and protect the interests of the Canadian agriculture and agri-food industry … everywhere I go" (AAFC, 1999: 4). A fuller sense of the Minister's promotional perspective is contained in the department's latest *Report on Plans and Priorities:*

> Today, Canada is known around the world for the strength of its agriculture industry and its world-class innovation. Our food safety system is recognized as one of the best in the world. These are things that matter to Canadians. So do jobs. Over 13% of Canadian jobs are in the agriculture and agri-food industry, and our industry provides first-time employment for over half of all young people entering the workforce.
>
> These are the signs of a dynamic industry. In the last half decade, the Canadian agri-food industry has proven its ability to trade on the world stage, breaking all export records. …. [W]e intend to help the agriculture and agri-food sector to continue to grow (AAFC, 2000a: 4).

AAFC's mandate, couched very much in promotional language, is "to maximize agriculture's contribution to Canada by creating a vigorous business environment in which the industry and rural communities can flourish and grow. A strong agriculture and agri-food sector is a growing, competitive, market-oriented sector that is profitable and responds to the changing needs of Canadians" (AAFC, 2000a: 8).

Under the *Department of Agriculture and Agri-Food Act 1994,* the powers and duties of the Minister include matters relating, of course, to agriculture; products derived from agriculture; and, research related to agriculture and agricultural products, including the operation of experimental farm stations. The Minister may designate any person as an inspector for providing inspection services for the enforcement of any Act under the Minister's responsibility. In recent years, the Minister of Agriculture has been also Minister for Coordinating Rural Affairs, serving as the advocate for rural Canada.

Within the AAFC portfolio, the Minister is responsible for the administration of 16 Acts and regulations. These include the *Farm Income Protection Act, Farm Improvement Loans Act, Agricultural Products Marketing Act, Experimental Farm Stations Act,* and the *Farm Products Agencies Act.* In addition to the department itself, the portfolio includes, besides the CFIA, the Canadian Dairy Commission, Canada Grain Commission, Canadian Wheat Board, and Farm Credit Corporation. Each of these organizations has a constituent piece of legislation, a board form of management, and a mandate to operate in the interests of producers while ensuring a dependable commodity or service.

The plans and priorities of the AAFC include:

- opening doors to trade, and nurturing and expanding markets for Canadian products;
- improving international trade rules at the WTO for agricultural products;
- ensuring greater income stability for many farmers;

- fostering rural development and strong rural communities; and
- investing in agricultural biotechnology research and innovation to foster a progressive agri-food economy (AAFC, 1999, 2000a and 2000b).

The governmental functions performed by AAFC primarily centre on promotion and scientific research, supplemented by a trade policy making role at the international level; all supported by a communication function.

INSIDE THE CFIA: CAUSE FOR CONCERN?

Perhaps at the heart of concern regarding the relation between regulating and promoting GM foods is the work of the CFIA. We can illustrate the current debate by examining the relation between the Plant Biosafety Office and the Office of Biotechnology, both of the CFIA.[8] The plant products program is the crucible for this issue because plants with novel traits (PNT's) is an active area of research employing genetic engineering and because the 42 GM foods approved for use in Canada so far include corn, canola, potato, tomato, squash, soybean, flax, and cottonseed oil. These are all plant products derived from biotechnology. In addition, the Plant Biosafety Office (PBO) has a memorandum of understanding with the PMRA in Health Canada, in which the Office does the safety assessments of pest control products for the PMRA, before the commercial use of such products is allowed (Krupa, 2000).

The PBO is central to the CFIA's regulatory and science functions. Previously called the Plant Biotechnology Office within what was then called the Plant Health and Production Division, the PBO is located within the Plant Protection Program, one of 14 programs that the Agency currently manages. The goals of the plant protection program are to prevent the introduction and spread of plant pests and diseases, and to control and eradicate any plant pests and diseases (CFIA, 2000a). The PBO has four responsibilities: it assesses the potential risk of adverse environmental effects of PNT's in Canada; authorizes import permits for plants with novel traits; authorizes confined field trials and the unconfined release of plants with novel traits; and, manages the certification of seeds and the registration of varieties of field crops. Its core legislative authority comes from the *Seeds Act* and *Regulations* supplemented by regulatory directives and guidelines. The PBO comprises scientists and regulators who oversee confined field trials and conduct safety assessments. Since the late 1980s, confined field trials in Canada have been carried out on numerous GM plants, including alfalfa, broccoli, canola, sugar beet, sweet pepper, tobacco, and wheat.
In the words of the PBO:

> An important element of the regulatory system is the use of confined field trials which are intended to give developers of PNT's the opportunity to evaluate these plants under controlled conditions. Confined field trials are designed in a manner to mitigate any potential environmental impact of PNT's and to prevent their introduction into feed and food systems until full assessments have been accomplished.
>
> When a developer wishes to market a PNT, information required to undertake full environmental safety assessment must be provided to the Plant Biosafety Office. Detailed information about the novel trait, the method used to introduce the novel trait into the

[8] A possible second issue might be the role of the CFIA in international negotiations and trade disputes. Potentially this seems to a field of activity that could blur the roles of technical advice, policy advocacy and trade promotion. To the extent this happens, it challenges the idea of the regulation-promotion dichotomy. Under the federal government's Regulatory Process and Management Standards, enforcement staff can be involved in the development of new standards or requirements.

> plant and any risks of adverse effects resulting from the release of the plant into the environment must be provided. Potential adverse effects could include the plant becoming a weed of agriculture or invasive of natural habitats; novel traits passing to wild relatives through gene flow; the plant or it's gene products adversely effecting non-target organism (including humans); and the plants impact on biodiversity (CFIA, 2000c).

In 1997-98, the Plant Protection inspection program had 417 full-time equivalent staff, close to a $34 million budget, and conducted 39,700 laboratory tests that year (CFIA, 1999). Much more detail could be provided in describing the operations of the PBO, but the point has been sufficiently made that the Office is a science-based and risk-based regulatory unit for agricultural products.

The Office of Biotechnology within the CFIA was transferred from AAFC and was formerly called the Biotechnology and Strategies Coordination Office. The Office of Biotechnology does not contain a scientific staff engaged in inspection or lab activities. It is not involved in regulation or safety assessments at all. Rather, the Agency's Office of Biotechnology serves an interdepartmental relation role providing a link to the Canadian Biotechnology Secretariat in Industry Canada, and a communications function.

It is the later function that has attracted some public criticisms and raises questions about whether there is sufficient separation between regulation and promotion within the CFIA or if the Office of Biotechnology should even be within the Agency. The web site for the Office of Biotechnology contains a main page and then pages on consumer information, technical information, and related sites. Under the consumer and technical information pages are further pages with more detailed material on such topics as labelling, plant biotechnology and food safety.

A conceivable problem arises when the communication of information by the Office of Technology is considered promotional in intent or effect; when the telling (information) becomes selling (promotion). Drawn from the Office's web site Table 4 sets out examples of what constitute the provision of information. Alongside are examples of communications that appear to cross some line-of-neutrality, becoming the promotion of the technology, of a particular policy stance, or the Canadian industry.

Telling becomes selling when the message communicated, as in the first case, accentuates the advantages and benefits of biotechnology but downplays or fails to mention possible harms and risks. This is an example of what Leiss and Chociolko (1995) call "risk-promotion" by some in government. In the second case, critical perspectives available on various web sites are not included. Whether or not intended, this could be construed as an indication of biases inherent in the Office. In the third case, the slippery slope is that describing the policy equals defending the policy equals debating and discrediting other approaches, pointing out concerns and difficulties of policy alternatives, such as mandatory labelling of GM food products. Magazine articles, radio commentaries, and news releases by the Agency all run the risk of appearing to take sides. Data for some audiences may be dictum for others. In the fourth example, the depiction of regulation goes beyond the classical policing and protection role to encompass suggestions of the promotion of firms, products or sectors as a purpose of regulation (Schultz and Alexandroff, 1985).

These examples serve to remind us that promotion is a complex and nuanced activity. At times, there is a thin line; admittedly difficult to detect in advance, between information and promotion while, at other times, the hazard of crossing over from telling to selling may seem more obvious.

Table 4
When Does Information Become Promotion?

Information	Promotion
Defining and describing biotechnology, genetic engineering, and other terms. Providing general facts on agricultural products.	Highlighting that there are many benefits, present and future, to products derived from biotechnology, without recognition of limits and concerns.
Listing "Related Sites" on biotechnology on web site.	Including only governmental and industry-based sites as links.
Outlining what is the government's policy on labelling products of GM. Depicting the safety-based approach to regulation.	Defending the current policy and raising concerns about reform alternatives.
Describing the purpose of agricultural regulation.	Extending the regulatory mandate to include assisting Canadian companies to trade internationally.

Source: Based on material from the web pages of the Office of Biotechnology, Canadian Food Inspection Agency, as of October 2000.

The communication activities of the Office of Biotechnology in CFIA do not compromise the scientific quality of the work and decisions of the PBO. Having these two functions housed within a single organization like the CFIA, but separate in their operations would seem to be adequate separation for the scientific integrity and autonomy of the PBO. Yet, at the overall level of the Agency, the Office of Biotechnology presents challenges for the public accepting that the CFIA is totally and only a regulatory organization concerned with matters of health and safety. Having an office within the CFIA that produces information materials criticized as promotional represents a variant of role conflict discussed earlier. That is the dilemma of performing two roles, each perhaps important in their own terms, but incompatible from a public confidence judgment when combined in a single agency. I will return to this issue in the final section.

BIOTECH FEDERALISM: THE ROLES OF THE PROVINCES AND INTERGOVERNEMENTAL RELATIONS

Biotech federalism refers to the federal-provincial domain of biotechnology policy and administration, including the nature and significance of intergovernmental relations for the regulation and promotion of GM foods. In Canada, biotechnology is an area mainly of divided jurisdiction, with some shared jurisdictions between the two senior orders of government. Relevant federal powers relate to criminal law, inter-provincial and international trade and commerce, and treaty powers; and provincial powers relate to ownership of natural resources, and property and civil rights. Agriculture, as noted earlier, is a shared jurisdiction between the two levels, but with federal paramountcy.

As a technology, as an industry, and as a public policy interest among governments, biotechnology is a pan-Canadian phenomenon. Biotechnology firms are located in every

province, with the greatest concentration in Quebec, Ontario and British Columbia (Canada, 1999). Commercial applications predominate in three areas: health care, agriculture, and environmental protection. Health care and pharmaceuticals comprise about half of the industry, with agri-food the second largest segment with about 28 per cent of the Canadian biotechnology market. In the agriculture sector, biotechnology firms are located in every major economic region of the country.

> In Atlantic Canada, the focus is on plant and animal health, whereas the focus shifts to animal health in Ontario and Quebec. On the West Coast, advances are taking place in micropropogation, as well as pest control products. The greatest concentration of Canada's ag-biotech companies is found in the Prairie provinces, particularly Saskatchewan, where the work centres on genetic engineering in crops and animals (BIOCON, 1997: 12).

The pan-Canadian nature of the industry is reinforced through actions by federal agencies such as ACOA, WEDC, and the NRC along with governmental budget measures. The 2000 federal budget announced an investment of $160 million in Genome Canada, a new non-profit corporation, "to fund the activities of five genome science centres to be located in Atlantic Canada, Quebec, Ontario, the Prairies and British Columbia. These centres will provide laboratory services to researchers from universities, government and the private sector and serve as focal points to accelerate genomic research in Canada" (Finance Canada, 2000: 111).[9]

Provincial governments figure in biotechnology in several ways, with promotional functions more extensive than a regulatory role. Canada's food inspection system appears complex from a jurisdictional perspective, with federal, provincial, territorial and municipal governments potentially involved. Provincial governments, for example, have food safety and consume protection legislation. Provincial laws and regulations that pertain to agriculture biotechnology as industrial activities typically include occupational health and safety; transport of dangerous goods; environmental protection and or waste material disposal. All provinces participate in the Workplace Hazardous Materials Information System as well (Bravo, 2000). Relevant government organizations are departments of environment, labour and transportation as well as workers' compensation boards. Provincial and local medical officers of health and public health inspectors perform regulatory activities related to food quality and safety, supported by provincial laboratories and departments of health. They inspect food processing plants and retail store outlets; investigate food-borne disease outbreaks and conduct product removals; analyze and assess the quality of food products; and communicate health hazard alerts to the public, industry and other governments. These legislative and regulatory activities are all examples of "social regulation," that is, state rules designed to make the marketplace a safer and fairer space for workers, customers, and firms; and, for protecting the natural environment from potential adverse effects from industries (Doern, Hill, Prince and Schultz, 1999).

On regulating GM foods, however, the jurisdictional question is relatively apparent: the federal government is the sole authority under the *Food and Drugs Act* and the criminal law power. The move to a single agency for food safety and inspection, with the creation of the CFIA in 1997, was designed to clarify this federal responsibility.[10]

The role of provinces in biotechnology goes well beyond that of stakeholders in federal consultative processes. Most, if not all, provincial governments, in all regions and of all political persuasions, recognize the real and potential economic benefits of biotechnology. Promoting

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[9] "Genomic science", as the 2000 federal budget stated, "is key to the advancement of biotechnology. It is the study of the genetic code in people, plants and all other living things" (Finance Canada, 2000: 111).

[10] Issues of intra- and intergovernmental relations continue to be worked out. See the Auditor General's 1999 report, chapter 15, on the management of a food-borne disease outbreak.

biotechnology is emerging as a significant form of "province-building." Saskatchewan is probably the most advanced example of this promotional approach, having an explicit biotechnology development strategy. Other provinces, including British Columbia and Quebec, have a focus on biotechnology as part of their science and technology strategies. Still others have biotechnology either explicitly or implicitly in their economic development plans and programs (Canada, 1998: 4). Provinces' promotional activities encompass a number of provincial public sector institutions: universities along with agriculture, community and veterinary colleges; teaching hospitals and medical research institutes; provincial government laboratories; provincial Crown corporations and business development and funding agencies. Biotechnology firms in Canada tend to be privately owned, rather than have public shares, are relatively small sized (less than 50 employees), highly skilled and knowledge-based, and with higher than average salaries. Recognizing the economic value and potential of the agri-food industry, provinces are seeking to encourage the formation and expansion of biotech firms and the commercialization of biotech applications (BIOCON, 1997). Like their federal counterpart agencies (AAFC, Industry Canada, NRC, ACOA, and WEDC), provincial promoters may provide technology development support, funding assistance, training programs and brokerage functions, such as promoting partnerships and providing facilities.

What is the possibility of conflict between federal and provincial governments over the regulation or promotion of GM foods? In theory, at least four scenarios of intergovernmental regulatory dispute can be identified in Canadian federalism. One is where provinces would see federal regulatory policy, or specific decisions, as encroaching on their jurisdiction. This situation does not apply in the case of regulating GM foods, though the wider field of biotechnology does touch on provincial matters of health, the environment and industrial activities.[11] A second scenario is federal regulatory actions seen to be contradictory to, or at least overlapping with provincial regulatory efforts and objectives. This situation does not seem to apply because of the federal power over GM foods, although there may be a need for "greater clarification of the regulatory oversight responsibilities among federal, provincial and municipal governments" (Canada, 1998: 20).

Regardless of overlap or clarity, however, one or more provincial governments may be dissatisfied with federal decisions on GM foods for political or tactical reasons unrelated to jurisdiction. A third cause of tension might be if provinces believe they have been inadequately consulted on federal policy processes and regulatory decisions. Generally, provincial governments do not appreciate treatment as just one more stakeholder rather than as fellow governments with sovereign powers and responsibilities. Regarding the confined trail sites for testing novel food traits, provinces are treated differently. While there is no mandatory public notice or information about such trials, the provincial governments involved do get a 30 day notice (Doern, 2000). A fourth scenario is if provinces viewed federal regulatory actions or in-actions as hampering their own promotional goals and strategies. Given the division of functions between the two levels with respect to regulation, and the increasing emphasis given by the provinces to the economic benefits of biotechnology, this is perhaps the likeliest of these forms of intergovernmental conflict.

A variety of bilateral and multilateral mechanisms and processes have been created in recent years for managing intergovernmental relations and for encouraging cooperative activities in food policy, regulation, communications, science and promotion. Illustrations of intergovernmental cooperation across these functional areas are:

- The Canadian Food Inspection Implementation Group. A *Blueprint Document for the Canadian Inspection System*, endorsed by all agriculture ministers in 1994, outlining

[11] See the Minority Report of the Bloc Quebecois Members of the Standing Committee on the Environment and Sustainable Development, on regulating biotechnology (House of Commons, 1996).

a vision for the development of an integrated national program of food inspection based on harmonized standards and supported by an inter-jurisdictional forum. The CFISIG was subsequently formed to help implement the *Blueprint*, and comprises members from federal, provincial, territorial agencies for agriculture, health and fisheries. Upon its creation in 1997, the CFIA became a member of this group. The CFISIG has made progress on a range of initiatives, including a national diary regulation and code, food retail and food services code, and meat and poultry regulation and code.

- The Federal-Provincial-Territorial Inspection Committee. This is a technical and science-based group of officials. The CFIA describes one of the committee's major roles being "to bridge possible gaps between science and policy" dealing with food standards, and technical issues involving animal health, plant protection and farm inputs, among other topics (CFIA, 1999).
- The Federal-Provincial-Territorial Committee on Food Safety Policy. This body focuses on emerging and anticipated food safety issues in order to protect the health of Canadians. "Its members evaluate and promote pertinent standards, policies, and educational programs aimed at increasing public knowledge of health hazards associated with food" (CFIA, 1999).
- Intergovernmental Agreements on Food Inspection. As of June 2000, the CFIA had signed agreements with five provinces and one territory (Quebec, Alberta, Ontario, Prince Edward Island, Saskatchewan, and the Northwest Territories). The agreements have the aims of minimizing duplication of inspections services, bridging potential gaps, and furthering information sharing in order to improve food safety (CFIA, 2000b).

These examples deal primarily with regulation, but instances of biotechnology-related intergovernmental cooperation are evident, too, in science and research support, trade promotion, and the communication of information on agriculture and food biotechnology.[12] Overall, biotech federalism, and more specifically, intergovernmental food safety policy making is notable for the degree of efforts at integration and mutual support among governments. Both levels of government recognize the reality of interdependence and the virtue of accommodating arrangements. Provinces recognize the necessity and legitimacy of federal leadership on food safety, especially in regards to trade policy considerations (Prince, 2000b). The federal government, in turn, recognizes the need to consult and work closely with the provinces in biotechnology matters. Finally, actions by federal promoters of biotechnology, such as the NRC, help to avoid the age-old complaint in Canadian politics that federal policy discriminates in favour of some provinces or region at the expense of others (Schultz and Alexandroff, 1985).

[12] Federal, provincial and territorial agriculture ministers have endorsed ambitious trade goals of doubling Canada's agri-food exports over the 1998 to 2003 period. The renewed Canadian Biotechnology Strategy noted cooperative federal-provincial interactions at the working level, such as co-locations for research in agriculture, health and forestry (Canada, 1998: 9). The Food Biotechnology Communications Network (FBCN), which "offers a range of services including information referrals, a regional network of experts, a website and issues management activities," is supported by Agriculture and Agri-Food Canada. Along with representatives from non-governmental and private sectors, the FBCN has representatives from the Ontario and New Brunswick departments of agriculture on the board of directors. Other provincial members include the Government of Manitoba, and the Saskatchewan Canola Development Commission (FBCN, 2000).

INTERNATIONAL EXPERIENCES

How does Canada's regulatory system of agricultural biotechnology compare to systems in other countries? A recent survey by MacKenzie (2000) of five other countries with established regulatory systems – Argentina, Australia, Japan, the United Kingdom and the United States – reveals that systems around the world are in evolution. The survey also shows that there are national differences, especially at the level of policy and organization design; and, that many elements are common at the technical and scientific levels.

Governance arrangements dealing with genetic techniques or biotechnology have explicitly emerged in just the past 10 to 15 years and continue to evolve with respect to policy frameworks, laws, regulations, and organizational forms. MacKenzie's study shows that Canada stands alone, in comparison to the five other countries surveyed, on the "regulatory trigger" for assessing a food product from biotechnology. While the other countries focus on the process of manufacture, the Canadian system focuses on the product, more specifically, the novel properties of the product under consideration. Related to this, Canada has a unique terminology and set of definitions for terms such as plants with novel traits (PNTs). Another exceptional feature of the system in Canada is the separation of the assessment of food safety function, located in Health Canada, from the actual regulation, inspection and enforcement function of the CFIA. Nowhere else in the world does this division of activities exist (Health Canada, 1999).

Still another distinctive feature of the Canadian system in comparison to this international context, is the relatively modest transparency of the policy development and regulatory decision-making processes. Compared to Australia and the United States in particular, a big weakness (or democratic deficit) in the Canadian system is the absence of public notification and public comment on product approvals before the final regulatory decision is made. Advantages to the regulators of the public having the right to be informed and to comment include the possibility of generating new or additional information about a product as well as legitimating the process and ensuing decision.

At the technical and scientific levels, there are a number of common practices observed by regulatory systems around the world. These include the following:

- government guidelines on health and safety procedures when undertaking research involving GM;
- entrepreneurs are responsible for conducting all of the research and testing of the proposed product;
- some business information and research data are confidential, as defined in large part by the companies involved;
- governments publish risk assessment information requirements;
- mandatory notification and or environmental assessment prior to approval of experimental field trials;
- mandatory pre-market notification;
- safety assessments are done by all regulators, considering similar risk factors, using the concept of "substantial equivalence" and asking the same kinds of questions based on international consensus; and,
- audit, evaluation or review mechanisms are in place in governments, in an independent or arm's length capacity, to assess the performance of the regulators.

These shared practices demonstrate how regulators acquire and exchange information and advice by participating in their wider "epistemic community" (Haas, 1992) of knowledge-based experts with recognized competence in the domain of food safety and risk analysis. This community is composed of natural scientists and other professionals, is trans-national in scope,

and has a relatively shared set of beliefs in policy goals and instruments, causality, and notions of validity. Given reliance of regulatory agencies on the provision of evidence by firms, it is critical that regulators have access to the most current scientific knowledge from different sources. The CFIA's food and animal and plant health programs, for example, receive support from the Agency's own laboratory services along with those of Health Canada. In addition, CFIA regulators access current knowledge through international and national data bases, scientific journals and conferences and contacts with individual experts around the world (Prince, 2000).

While there is a good deal of consensus on scientific and technical matters in regulating biotechnology around the world, there is considerable debate both within and among nations on "non-science issues" or ethical and social questions pertaining to GM foods. A recent review of international approaches to non-science issues in regulating food products of biotechnology (SECOR, 2000) helps to place Canada in a comparative context. Canadian practice is similar to that in nine other countries and the European Union in that science-based considerations are the exclusive or near exclusive regard in the regulatory approval of individual products and techniques. Ethical and other social concerns are not commonly contained in the main laws dealing with biotechnology or food safety. The review found that the nature and degree of the public's ethical concerns over biotechnology varied across the jurisdictions and that the concerns themselves change over time, shaped by religious and cultural beliefs, scientific developments and the role of the media and interest groups. How governments deal with such ethical and social concerns also varied across countries, although all the jurisdictions are reported to be treating these issues as important policy matters (SECOR, 2000: 15).

In most of the countries surveyed, governments have established structures and processes to deal with social and ethical principles in the decision-making systems. These structures typically are bio-ethics advisory bodies separate from the actual regulatory approval processes. Social, ethical and public concerns have also been incorporated through representation on expert scientific advisory committees, consumer committees and other stakeholder groups.

In Canada, the main "non-science issue" relating to biotechnology embrace environmental concerns (e.g., GM seeds pollinating other crops); consumer awareness and acceptance of biotechnology food products in general and GM foods in particular; and, public confidence in, and the transparency of, regulatory agencies and decision processes. As in most other countries, Canada has not codified non-science considerations into legislation governing biotechnology.[13] Instead, like other jurisdictions, the Canadian government has addressed ethical and social principles in framework policies and advisory structures. Examples include the renewed Biotechnology Strategy, the Biodiversity Protocol, and the Sustainable Development Strategy; and the mandate and membership of the CBAC plus advisory councils to specific Ministers (e.g., AAFC, Environment, Health). All these structures are separate from regulatory decision making agencies.

While further examination of the international context lies beyond the scope of this paper, some critical questions are worth asking. Why has Canada chosen a divergent path from many of its international counterparts and what are the implications of these choices? For example, why do other countries focus on the regulation of the process rather than the product? As well, why has Canada chosen to use a different terminology? Have some of these differences contributed to the difficulty Canada has in trading some of its GM foods abroad? Will Canada's choice in how it regulates this industry impact its future trading opportunities?

[13] Indirectly perhaps through the *Auditor General Act* and the role of the Commissioner of Environment and Sustainable Development. See MacKenzie (2000: 50-51) and the discussion earlier in this paper.

CONCLUSIONS

This study has examined, both theoretically and empirically, the link between the regulation and promotion of GM foods in the federal government and beyond, in the context of intergovernmental relations and international practices. To accomplish this, the paper proceeded through six steps:

1. the presentation of an analytical framework with which to examine the separation and integration of government functions;
2. a discussion of the horizontal or government-wide policy context for biotechnology decision processes;
3. a description of the mandates and missions of the core federal organizations involved with the regulation and promotion of GM foods, namely, the CFIA, Health Canada, and Agriculture and Agri-Food Canada;
4. a case study of the current roles and responsibilities for plant protection in the CFIA to explore this issue;
5. a look at biotech federalism, especially the promotional roles provinces carry out and the collaborative intergovernmental mechanisms in place to manage interdependencies; and,
6. an examination of international experiences on the governance for regulating GM foods.

This final section offers some reform issues and concluding observations.

Reform Issues and Directions

One of the biggest challenges raised by non-governmental groups in several countries is whether governments can effectively manage their multiple functions with respect to biotechnology. This is a legitimate and serious issue for Canadian public policy as well. Looking ahead at the prospects for reform in this area, it is instructive to note the federal government's own thinking and stance towards the biotechnology regulatory system. In a number of documents, the government presents an image of the system as rigorously science-based, comprehensive in application, consultative with stakeholders, and efficient and effective in delivery, all resulting in one of the safest systems in the world. As recently expressed: "The Government of Canada considers that the use of existing Acts, which in some cases have effectively protected the environment and the health and safety of Canadians for over a century, has value and a number of advantages over redrafting legislation to address technological advances such as new techniques of biotechnology" (Canada, 2000b). This position rules out other reform proposals, such as those advanced by some experts and groups, that new separate legislation, a so-called "gene law," be created and enforced by Health Canada or by a new agency for this purpose. A related proposal is transferring all regulatory authority for products of biotechnology to Environment Canada and the *Canadian Environmental Protection Act* (House of Commons, 1996).

The federal governments preferred approach to reform is a commitment to continuous improvement of the regulatory system by reviewing and amending legislation and regulations; and expanding public funds for the system to ensure a strong science capacity. It also includes seeking advice from outside experts in the country, such as the Royal Society of Canada; and, consulting with specialists in other countries and in international bodies.

This stance by the federal authorities toward reforming the regulatory system should be informed by, and continually assessed against the principles on biotechnology governance articulated by government over the past decade. In the 1993 Federal Regulatory Framework for Biotechnology, the principles associated with governance speak of using existing legislation and regulatory institutions to clarify responsibilities and avoid duplication; and, ensuring that the

development and enforcement of Canadian regulations are open and include consultation. Of the four guiding principles in the 1998 renewed CBS, one is to reflect Canadian values. Another is to engage Canadians in open, ongoing, transparent dialogue. Compared to the original 1983 national strategy on biotechnology, the 1998 strategy gives greater emphasis to public participation, communications and ethics. Even more recently, the federal government has acknowledged it "has a responsibility to inform Canadians about the regulation of products derived from biotechnology" (Canada, 2000b: 4). The theme running through these principles is fundamentally a democratic ideal. That ideal is that the processes for both the development and the subsequent enforcement of regulations ought to be apparent to the public as well as open to public input and consultation on an ongoing basis.

When considering governance reform issues it is worth remembering other developments on the federal science and food policy agendas. Items to look for in the next Parliament include Health Canada's plans for replacing the *Pest Products Control Act* with a new regulatory system bolstered with greater public involvement. Another likely item is the re-introduction of a *Canada Food Safety and Inspection Act* to consolidate and modernize existing federal food legislation and agricultural inputs legislation, such as on fish, meat or plants. This reform is designed to establish a set of uniform standards and enforcement measures for all agricultural sectors. In 2001, federal departments and agencies must submit their revised sustainable development strategies to the Commissioner of Environment and Sustainable Development. These strategies have the potential of enhancing inter-organizational cooperation and coordination as well as magnifying the role of sustainable development as a policy paradigm that could bridge the regulatory and promotional roles of government.

Another governance trend to watch closely is of course how the CBAC will interpret and implement its mandate. Like the CFIA and other recent organizational reforms, the CBAC will need time to establish its mission and method of operations. Among the issues to observe is how much attention this new advisory committee gives to non-science considerations, that is, social, cultural, and ethical concerns related to biotechnology. Other practices to watch for are the extent to which CBAC engages as well as educates the public on these matters, and provides proactive and independent advice to government (SECOR, 2000). The CBAC is composed of diverse Canadians, including ethicists, theologians, scientists and others, primarily to ensure that it is representative of all views and interests in the area of biotechnology. The degree to which CBAC effectively performs this role will help determine whether a separate ethics advisory body is thought to be necessary.

Organizational and governance reform issues for the Canadian regulatory system for GM foods and biotechnology include:

- what the mandate and mission of the CFIA should be with respect to trade promotion and or trade policy development on biotechnology issues;
- how to strengthen the transparency of, and public involvement in regulatory decision making for GM products; and
- whether or not the Office of Biotechnology should remain within the CFIA or be relocated to another federal organization or portfolio.

The first reform issue concerns the future direction and nature of the CFIA's mandate and mission. A partial clarification of the Agency's mandate is underway, as noted beforehand, with respect to a new Planning, Reporting and Accountability Structure for 2001-02 and other changes in the documentary presentation of the mission and priorities. This desire to extinguish references to promoting market access and international trade would be assisted by also replacing the language of "business lines" and "corporate business plans" with language which instead highlighted the public interest of health and safety. In the area of trade policy, the question can be asked of what role, if any, should the CFIA have in influencing international standards for food

products in order to advance Canadian interests and policy objectives or in challenging the alleged misuse of technical measures to black trade? Certainly, CFIA officials can participate on international delegations and offer technical and scientific advice on standards for safety or quality or the implications of changes in policy. This would seem to respect the regulation-promotion dichotomy. However, should CFIA officials head such delegations and take a direct role in the policy debates and development of trade standards? This would likely raise the apprehension of the CFIA crossing over the line from regulator to promoter.

The CFIA is essentially a department of food inspections by another name. The Minister of Agriculture remains responsible and accountable for what it does. It does differ from a regular department in that it enjoys some greater administrative flexibility than most departments. The important point, though, is that the CFIA is not an arm's length regulator because it reports to a Minister whose department is a key promoter of what it is regulating. This is one of the professed concerns of its critics.

The second reform concerns expanding and institutionalizing opportunities for public participation in the regulatory decision-making process on biotechnology products. One step toward this is the creation of the CBAC. Another step is Health Canada's plan for new legislation to replace the *Pest Control Products Act* (*PCPA*) that will bolster public participation in regulatory decisions. According to the department, strengthening public involvement would cover public inspection of confidential scientific studies submitted in support of pesticide registrations. It would also include "public consultation on major registration decisions; and the right of individuals (not just that of manufacturers, as under the current *PCPA*) to request that the Minister review major registration decisions"(Health Canada, 2000: 31). If passed, this policy would be a positive reform in moving Canada toward best practices on the transparency of biotechnology regulatory decision making as implemented in Australia and the United States. From his survey of international practice, MacKenzie (2000: 3) concluded that while Canada had a scientifically sound system, "increased transparency through public notification and comment is one [issue] that deserves investigation as to its feasibility within the Canadian regulatory framework." MacKenzie has no doubt as to the desirability of such a reform: ""Greater transparency concerning both the risks and benefits of biotechnology products and how government decisions are made is an essential component of building trust in new technologies. Broad disclosure is a stabilizing force not because the general public reads scientific studies or government decision documents, but because opinion leaders and those who intermediate information dissemination do" (2000: 62). The elements in the proposed *PCPA* should be considered, along with a review of Australian and American policies and practices, as a possible template for application to other federal laws and science-based departments and agencies.

Probably the most significant finding from this study with implications for organizational reform is that the CFIA is not totally detached from promotional activities. This conclusion follows from the examination of the Agency's mandate and mission along with an analysis of the communication activities of the Office of Biotechnology. The mandate and mission, as already observed, are under revision to clarify the regulatory purpose and focus of the CFIA. The question remains of what is the most appropriate location for the Office of Biotechnology or at least its promotion function. The continued status of this Office within CFIA appears to be a problematic one, not due to internal difficulties, but to expectations and reactions externally to what is, and what should be, the primary and proper role of the CFIA. A role conflict of sorts has arisen with some individuals and groups perceiving an incompatibility between the CFIA performing its regulation role and carrying out aspects of what is a promotional role. Even if CFIA officials do not recognize or accept that such a conflict does or might exist, stakeholders and other interested parties may well think such a contradiction exists. Certainly, that is the premise behind the Sierra Legal Defense Fund's petition of the federal government in May 2000. For possibly a number of reasons, GM foods is an issue on which many in the Canadian public

have a low tolerance for real or perceived role conflict within the country's principal food safety regulatory agency.

If the location of the Office of Biotechnology within the CFIA endangers public confidence in the Agency, then what might the government do? If the communication role of the Office includes a promotional segment, then relocating the Office or this role to Industry Canada may be appropriate, in keeping with the mandate of that portfolio and the Industry Minster's lead responsibility for the Canadian Biotechnology Strategy. If the intent was to ensure that the Office generated and provided information foremost through a public health and safety lens, then Health Canada might be the best option for repositioning the Office. If the aim was to achieve a balanced approach between human and environmental safety and trade promotion, then maybe the sustainable development paradigm of Environment Canada would be an acceptable portfolio to house the Office of Biotechnology. While the Office can be said to be performing a proper role, there is considerable merit in reflecting on whether the communication function is situated in the most appropriate place within the federal government.

Certainly there exists the potential for broader conflicts of interest beyond the promotional activities of the Office of Biotechnology within the CFIA, which reach beyond GM foods and even beyond biotechnology policy to encompass science policy and industry policy. What the recent difficult experiences of Health Canada and Human Resources Development Canada teach us is that administrative problems and potential conflict of interest and accountability problems need to be resolved before a crisis in public health emerges. The CFIA is not immune from the possibility of becoming the next public crisis, be it in the field of biotechnology or other areas, such as food inspection. Is it the role of government to promote the biotechnology sector or should this be the responsibility of the sector itself? This question applies, of course, to other sectors as well and reinforces general skepticism about government's ability to pick and develop "winning" industries. What are the most effective governance structures, including independent bodies and citizen engagement processes, for holding government accountable for the protection of Canada's food supply? Only through effective public engagement in policy development can decision-makers hope to rebuild the trust of citizens in government.

Final Observations

The focus of this study has been on government organizational roles, mandates and formal authority relationships. To be sure, public confidence in GM foods and biotechnology are shaped by much more than structural arrangements and administrative practices. Nonetheless, institutional designs do matter. They matter in terms of what values they promote, how those values are advanced, the accountability relations forged, and the public perceptions created. No single best set of organizational arrangements likely exists for the promotion and regulation of GM foods within the federal government. There are, however, more or less acceptable and workable structures in light of public expectations, technical requirements and scientific capacities, along with intergovernmental and international practices and commitments.

Institutional designs are mediums for particular ideas, words and concepts, in short, a discourse for both the members of the organization and its task environment and the wider public. To be a genuine dialogue, this discourse requires a shared vocabulary coupled with accessible, timely and intelligible information and meaningful consultations. These elements are essential underpinnings to public awareness and understanding, and to public confidence and accountability.

Further reflection, therefore, is desirable on the meaning and appropriateness of using the terms regulation and promotion and the related concepts of the regulation-promotion dichotomy and the regulation-promotion nexus. These terms are more complex and subtle in meaning than many have assumed. There are multiple perspectives and interpretations of each of these ideas,

which deserve a fuller examination than was possible here. Is promotion the best term for describing the activities concerned with the economic development aspects of biotechnology? Is the idea of separating regulation and promotion the most appropriate way of formulating the issue of ensuring the regulatory system's integrity? Whether we use 'dichotomy' and 'nexus' or other terms, the vocabulary is important politically and organizationally. The concepts we choose to use will refer to activities that need to be structured and managed; concepts that will shape public debates, and provide a standard for evaluating the effectiveness and credibility of the food safety system. Notwithstanding the links and connections between regulation and promotion, it remains important to make a distinction between the regulatory and promotional activities of GM foods. It is important because of the requirement for impartiality, evidence-based decision-making, and the legitimacy of processes and decisions.

While the regulation-promotion dichotomy concerns specialization, division of labour and separation of functions, the idea of the regulation-promotion nexus stresses integration of functions, and organizational coordination and control. Within a large, complex system such as the Government of Canada, there is a simultaneous demand for the dichotomy and the nexus. The fundamental public policy challenge is to achieve some balance between this differentiation and integration of governmental functions; to decide, in other words, which officials and organizations are to do which roles, how and where.

In business administration, classic rationales for the division of labour include enhancing efficiency and the quality and quantity of product outputs, as well as capturing economies of specialization, thereby increasing competitiveness. In public administration, by comparison, the separation of functions is commonly aimed at additional values of impartiality, legitimacy, and a concern with process as much as product, as evidenced by the "checks and balances" between the CFIA and Health Canada. The organizational question, in government, is ultimately about what conditions of separation and coordination are consistent with the need for specialization and objectivity, and, at the same time, for policy consistency and public accountability. The paradigm of 'responsible world leadership on biotechnology' – the emerging federal government expression of Canada's public interest in this field - demands that all of these values be addressed by political leaders.

This challenge will only become more pressing. As biotechnology sectors in Canada, including agricultural products, shift more from a research focus to commercialization, and as trade competition from other countries around the globe increases, more interests and institutions will be involved, with additional issues at stake. The promotion function, and biotechnology itself, will become further politicized as the government's championship role becomes more explicit publicly and more energetic programmatically in response to these trends. *If the regulatory and promotional functions become more sharply differentiated, the more conflict there may be and the more difficult it will be to resolve such tensions. Thus, the more essential it becomes to have structures and procedures in place to achieve integration between the functions.* Government officials should bear in mind this last point in advising Ministers on the proper relationship between regulation and promotion. In this regard, the creation of a coordinating cabinet committee and supporting secretariat, and the establishment of interdepartmental committees of senior officials with responsibilities for biotechnology, are positive developments in building the necessary integrative devices of governance. Ultimately, the challenge for Canadians and their governments is to develop far more effective and democratic institutions for dealing with conflicting public roles and accountabilities.

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