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THE ROLE OF FEDERALISM IN PROTECTING THE PUBLIC'S HEALTH

Intergovernmental Relations in Food Biotechnology Governance: Complementary Disentanglement in Regulation with Collaboration in Food Safety and Inspection

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> Good governance is essential for creating and maintaining a regulatory regime that protects the health and safety of citizens and of the environment. As well, it inspires confidence in its efficiency and effectiveness. Good governance entails both legislated accountability and a commitment to transparency, and effective separation of regulatory functions from other potentially conflicting functions of government. (CBAC 2002, viii)

Food safety is a cross-cutting and cross-border issue, involving a variety of policy sectors and levels of governance. It is also increasingly recognized as important to the promotion and protection of public health (WHO 1999). Food crises affecting human food and animal feed, for example the spread of 'mad cow' disease (Bovine Spongiform Encephalopathy – BSE) and its transmission to consumers through beef consumption, have exposed serious flaws in governments' food safety and inspection systems and highlighted the intergovernmental nature of risks (Ugland and Veggeland 2006, 611).[1] In response, many national and other jurisdictions have undergone changes in their governance approaches to food safety. Alongside these developments have been the advent of modern food biotechnology and the adaptation of governance to manage related benefits, costs and risks. In particular, novel applications of biotechnology to plants and related foods has created the potential for additional adverse effects on feed and food supplies and the need for effective, regulation and multi-governmental responses, such as illustrated in the transterritorial Starlink, genetically modified (GM) corn episode. Since many governments are both the regulators and promoters of food biotechnology, there are also growing governance challenges to balance food safety and public health objectives with other important economic, trade and competitiveness considerations.

This chapter focuses on an examination of intergovernmental relations in food biotechnology governance in Canada, part of which involves analysis of the interrelated food safety and inspection system. Historically, federal and provincial/territorial governments (F/P/T)[2] have faced immense but different challenges in both the promotion and regulation of GM foods. The federal government's first initiative in the promotional area was the development of the 1983 National Biotechnology Strategy.* This strategy was later accompanied in 1993 by a Regulatory Framework for Biotechnology. The Canadian Biotechnology Strategy and the Canadian Regulatory System for Biotechnology aimed to ensure

an appropriate balance between ensuring protection in relation to human, animal, and environmental health and safety, and securing the practical benefits of biotechnology processes/products and the global competitiveness of the sector (Industry Canada 1998, 12; Doern 2000, 4). In the spring of 2007, a new Science and Technology Strategy and governance structure replaced the Canadian Biotechnology Strategy, while the Canadian Regulatory System for Biotechnology remains in place.

In the current biotechnology framework, the federal government acts as both the promoter and regulator of GM foods. In contrast, provinces primarily function independently in the promotional area. Intergovernmental relations in food biotechnology regulation can therefore be described as disentangled. The federal government takes the leadership in regulation, and relations among the orders of government are generally characterized by independence and non-hierarchy. In contrast, the form of intergovernmental regime that best characterizes the linked area of food safety and inspection is collaborative, characterized by interdependence and non-hierarchy.

Up to this point, federal leadership in food biotechnology governance, blended with the extant collaborative food safety and inspection system, has been generally considered a success in terms of its impacts on principles of federalism. The federal government perceives their leadership role as constitutionally and legislatively legitimate. Perhaps more importantly, it is also viewed as necessary because of the specialized expertise required to assess safety and risks, the tremendous resource commitment, trade policy considerations and the need to harmonize with international guidelines and standards. From provincial governments' perspectives, the federal role in GM food regulation is viewed as advantageous: Provinces can actively pursue economic development and promotional ambitions with the federal government ultimately accountable for regulatory risks, costs and good governance. Moreover, the collaborative apparatus in food safety and inspection generally facilitates a good working relationship between the orders of government and the sharing of information about food biotechnology governance.

These complementary forms of federalism in the two linked policy domains have also been generally effective and democratic in achieving the goals of the Canadian Biotechnology Strategy/Regulatory Framework for Biotechnology. In particular, the collaborative relationship in food safety and inspection has enabled the disentangled regulatory system to work more effectively and democratically, and ,for example, could be essential to deal with national

spillovers in the future such as GM food crises affecting Canada's feed and food supplies. However, this overall positive assessment of the impacts of intergovernmental relations in food biotechnology regulation does not mean that there are not challenges for good governance at the federal level. On the contrary, core challenges for Canada's food biotechnology governance regime concern effectiveness and respect for fundamental principles of democracy such as accountability, transparency and public participation.

This argument develops in the chapter as follows. The chapter begins with an overview of food biotechnology as a public health concern. The case study then describes the evolution of intergovernmental and interagency relations in food biotechnology governance since the 1983 National Biotechnology Strategy. The structure and allocation of responsibilities in food biotechnology regulation and then in food safety and inspection are discussed, utilizing in the latter area the provinces of Ontario and Saskatchewan as illustrative examples. The case study then examines more closely the disentangled form of intergovernmental relations in food biotechnology regulation, and compares this form to F/P/T collaboration in food safety and inspection. Finally, the predominantly positive consequences of the current form of intergovernmental relations in food biotechnology policy for principles of federalism are described, and then the governance regime is evaluated in terms of policy effectiveness and democracy. It is argued that, in many ways, the complementary collaborative relationship in food safety and inspection enables the disentangled regulatory system to work more effectively and democratically.

Methods
Drawing on the framework in the introduction to the working paper series, the case study describes the evolution of intergovernmental and interagency relations in food biotechnology governance since the 1983 National Biotechnology Strategy. The methodology involved extensive primary and secondary research and telephone and personal, semi-structured interviews with a total of sixteen policy actors from March to April 2005: ten federal, five provincial and one expert. Interviews were conducted with officials from Agriculture and Agri-Food Canada, the Canadian Food Inspection Agency, Health Canada, Saskatchewan's Department of Agriculture, Food and Rural Revitalization and Ontario's Ministry of Agriculture, Food and Rural Affairs.

A PUBLIC HEALTH CONCERN

Biotechnology "…refers to the use of recombinant DNA techniques to identify genetic material that expresses a desired trait, isolating that material, and inserting it into the target organism" (Moore and Skogstad 2001, 3-4).[3] The rapid development of biotechnology for the creation of GM foods in the past decade in Canada raises a number of public health concerns. Most of all, food biotechnology is a public health issue because of the potential and immediate impacts on the safety of the food supply (OPHA 2001, 5). First, foods with genetically-engineered components may contain new or elevated levels of allergens or toxins, thus presenting increased risks or threats to human health (Yarrow 2000, 10). Second, there is considerable scientific uncertainty regarding the effects on humans (among other species) of long-term consumption of GM food (Moore and Skogstad 2001, 4). Of major concern is that any unexpected or unintended effects may not be discovered for years in jurisdictions introducing mandatory segregation, labeling and traceability systems. Third, in jurisdictions without such systems, such as Canada, some experts worry that if any harm does occur from eating GM crops, GM-fed livestock or other GM food products, it will be difficult or impossible to trace it (Clark 2002). Finally, like conventional and organic food hazards and emergencies, any GM food crisis is likely to produce threats to human health and economies that cross political borders and thus any response is likely to necessitate multi-jurisdictional action.

Since plants typically have been the targets of genetic modifications in the Canadian food sector, this case study focuses on plant biotechnology and related GM foods. The 'first generation' of alterations has entailed the addition of one or two commercially useful traits from one plant species to another (transgenic), for example, to enhance productivity or nutritional value or create pesticide or disease resistance in crops. Specifically, from 1988 to 2007, the Canadian Food Inspection Agency has assessed and authorized the unconfined environmental release of about 70 plants with novel traits (PNTs) (over half were transgenic) (Yarrow 2000, 13; CBAC 2002, 26; CFIA 2008).[4] Roughly the same amount of novel (and transgenic) crops have been approved for use in livestock feed (CBAC 2002, 26: CFIA 2008b). Further, from May 1994 to January 2008, Health Canada (2005, 15-19; 2008) has assessed and authorized over 100 GM food products for marketing in Canada.[5] However, since GM crops are not separated from traditional plants or other plants with novel traits in Canada, accurate information about "the

exact percentage of products…containing GM ingredients is not available" (Toronto Board of Health 2000, 4). In 2000, it was estimated that 60 to 70 per cent of food products currently on grocery store shelves in Canada contain GM ingredients (Curry 2000). Of importance is that with the so-called 'second generation' of alterations, there is great potential for increased complexity of GM food products in the future, which will bring pressure to bear on the regulatory and pre-market approval system (Government of Canada 2001, 1).

THE EVOLUTION OF FOOD BIOTECHNOLOGY PROMOTION AND REGULATION IN CANADA

The 1983 National Biotechnology Strategy deemed biotechnology "a national priority for economic development." Its central objective was "to provide federal policy guidance and programme support to encourage the concerted action necessary to make commercial progress" (NBAC Annual Report 1984 cited in Abergel and Barrett 2002, 138). Accordingly, the federal government allocated $11.9 million per annum for two years to foster the industrial development of biotechnology and over $100 million to fund national biotechnology research centres (Bjorkquist and Winfield 1999, 17). Hence, economic concerns were paramount and the main goal of the National Biotechnology Strategy was to promote biotechnology product development in Canadian industries to ensure global competitiveness in areas of strategic focus. Indeed, regulating biotechnology products to protect public health was not a central or even secondary objective.[6]

Culminating a process to address this perceived gap, in January 1993, the government formally announced the Federal Regulatory Framework for Biotechnology. The national approach to regulation and the safety assessment of GM and other novel food products is based on:

- the characteristics of the product
- the use of science-based risk assessment, and
- the protection of human health and environment meeting performance standards.

The rationale for this approach is threefold:

- the application of genetic engineering does not pose novel or greater risks to human health or the environment compared to traditional plant breeding or mutagenesis

techniques; as such, the emphasis of safety assessment should be on the GM product, rather than the process

- safety assessment should focus on establishing the 'substantial equivalence' of a GM product to conventionally-derived products that have a history of safe use (involving an examination of the same risk factors that have been established for the conventional food); only if 'substantial equivalence' cannot be established should a more extensive safety assessment be necessary, and
- risk assessment should be governed by sound science (CBAC 2002, 8-9).

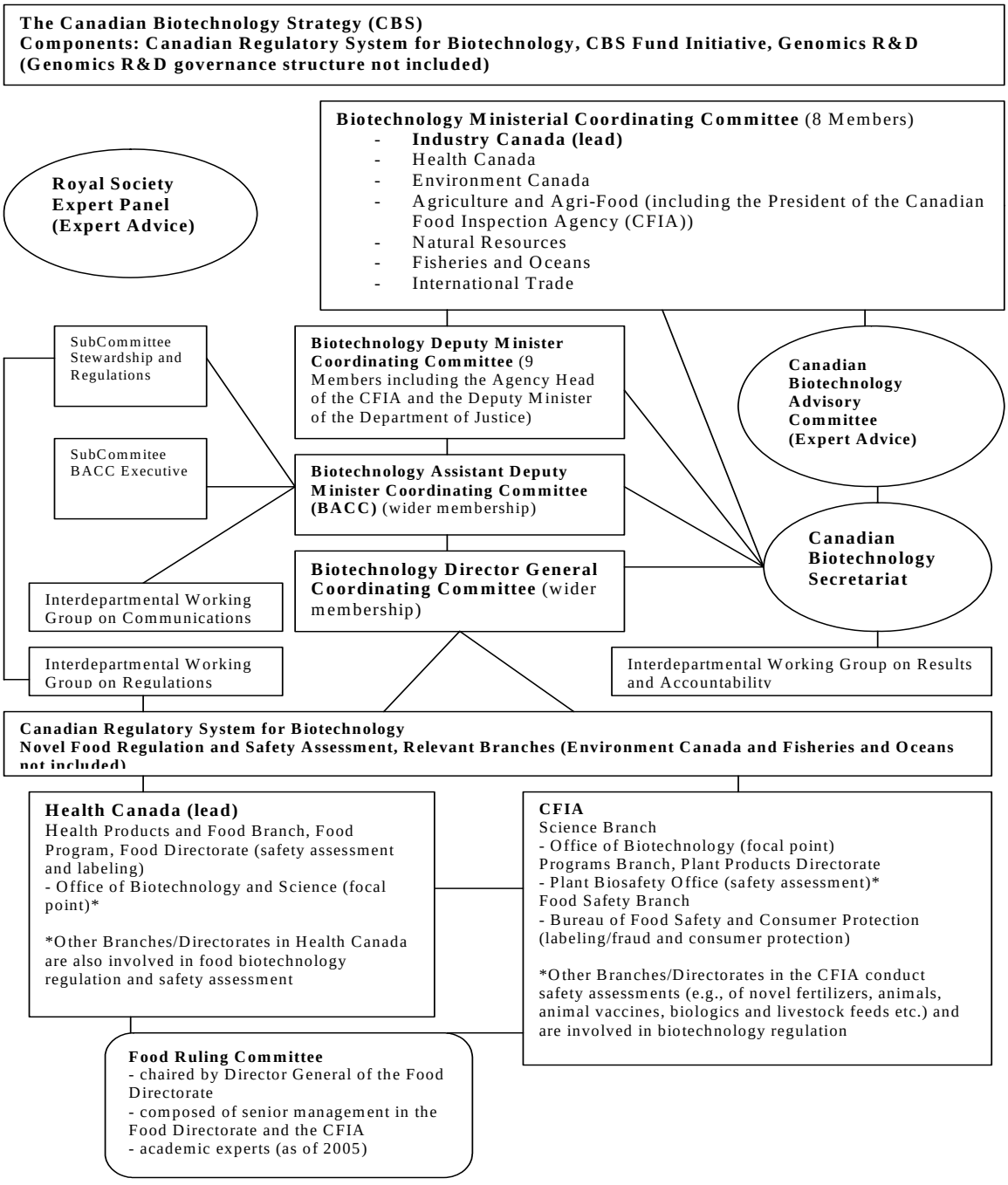
Given this 'product-based' approach, this means that GM foods in Canada are regulated in essentially the same manner as conventionally-derived food products. In contrast, a 'process-based' approach, based on the assumption that the genetic modification of food poses unique risks and therefore requires special precautionary regulation and institutions, has historically prevailed in jurisdictions such as the European Union (EU) (Bernauer and Meins 2003, 651).

Shortly after the release of Canada's regulatory framework, the Minister of Industry was put in charge of revising the National Biotechnology Strategy (Industry Canada 1998, 3). In August 1998, the renewed Canadian Biotechnology Strategy was released and new institutional structures were created to further its actualization (See Appendix A for the story of the evolution of the strategy). Central to the strategy were six principles to guide federal officials in agencies/departments that were involved in the safety assessment of GM foods and other biotechnology products for commercial use. They obligated actors to:

- maintain high standards for protecting the human health of Canadians and the environment
- use existing laws and regulatory departments to avoid duplication
- develop clear guidelines for evaluating biotechnology products that are in harmony with national priorities and international standards
- provide a sound, scientific knowledge base on which to assess risk and evaluate products
- ensure that the development and enforcement of Canadian biotechnology regulations are open, transparent and include consultation, and
- contribute to the prosperity and well-being of Canadians by fostering a favourable climate for investment, development, innovation and the adoption of sustainable Canadian biotechnology processes/products (Industry Canada 1998, Annex C).

Therefore, unlike the original National Biotechnology Strategy, these principles better address both the economic benefits of new biotechnology processes/products and the protection of human, animal and environmental health and safety. Further, in support of these principles, the Canadian Biotechnology Strategy promoted nine specific goals, ten workplan themes and an underlying array of core Canadian values, notably including "public health" and "the promotion of safer, more nutritious and healthful foods" (Industry Canada 1998, 15). However, core economic goals of the National Biotechnology Strategy still appeared to take precedence in the Canadian Biotechnology Strategy. The governance structures for the Canadian Biotechnology Strategy and Canadian Regulatory System for Biotechnology are depicted in Figure 1.

Figure 1: The Canadian Biotechnology Strategy and Canadian Regulatory System for Biotechnology: Food Biotechnology Governance Structure



Source: Gabler 2006

In May 2007, the federal government released a new Science and Technology Strategy, Mobilizing Science and Technology to Canada's Advantage. Part of the policy framework aims to streamline the federal science and technology regulatory regimes so Canada can become "a best in class regulator" (Industry Canada 2007c). Accordingly, when the policy authority for the Canadian Biotechnology Strategy came up for renewal in June 2007, it was ended (Industry Canada 2007b). The main governing structure of the Canadian Biotechnology Strategy, the Canadian Biotechnology Advisory Committee, was also jettisoned, along with other advisory councils, in favour of a broader advisory body called the Science, Technology and Innovation Council, which reports to the Minister of Industry (Industry Canada 2007c, Chapter 6). What remain in place and funded, at least for the 2007-2008 period, are the Canadian Regulatory System for Biotechnology and the Canadian Biotechnology Fund (Industry Canada 2007a and 2007b).[7] These ongoing initiatives constitute the current domain of federal food biotechnology regulation.

FOOD BIOTECHNOLOGY FEDERALISM

"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 food" (Prince 2000, 25). In Canada**,** the federal government is the main actor in the regulation of food biotechnology, while the provinces are largely inactive. In contrast, both federal and provincial orders of government play active, independent promotional roles, with instances of intergovernmental cooperation also evident in areas such as science, innovation, R&D and commercialization and trade promotion. The following sections focus on an overview of the relevance for federalism of food biotechnology regulation and food safety and inspection, rather than the promotional aspects of policy.

THE FEDERAL ROLE IN THE REGULATION OF FOOD BIOTECHNOLOGY

HEALTH CANADA

The responsibility for establishing science-based policies and standards pertaining to the nutritional composition, quality and safety of food, including GM foods, lies solely with Health Canada in the Food Directorate, Food Program, Health Products and Food Branch. The *Food and Drugs Act* makes illegal the manufacture or sale of dangerous, adulterated or misbranded

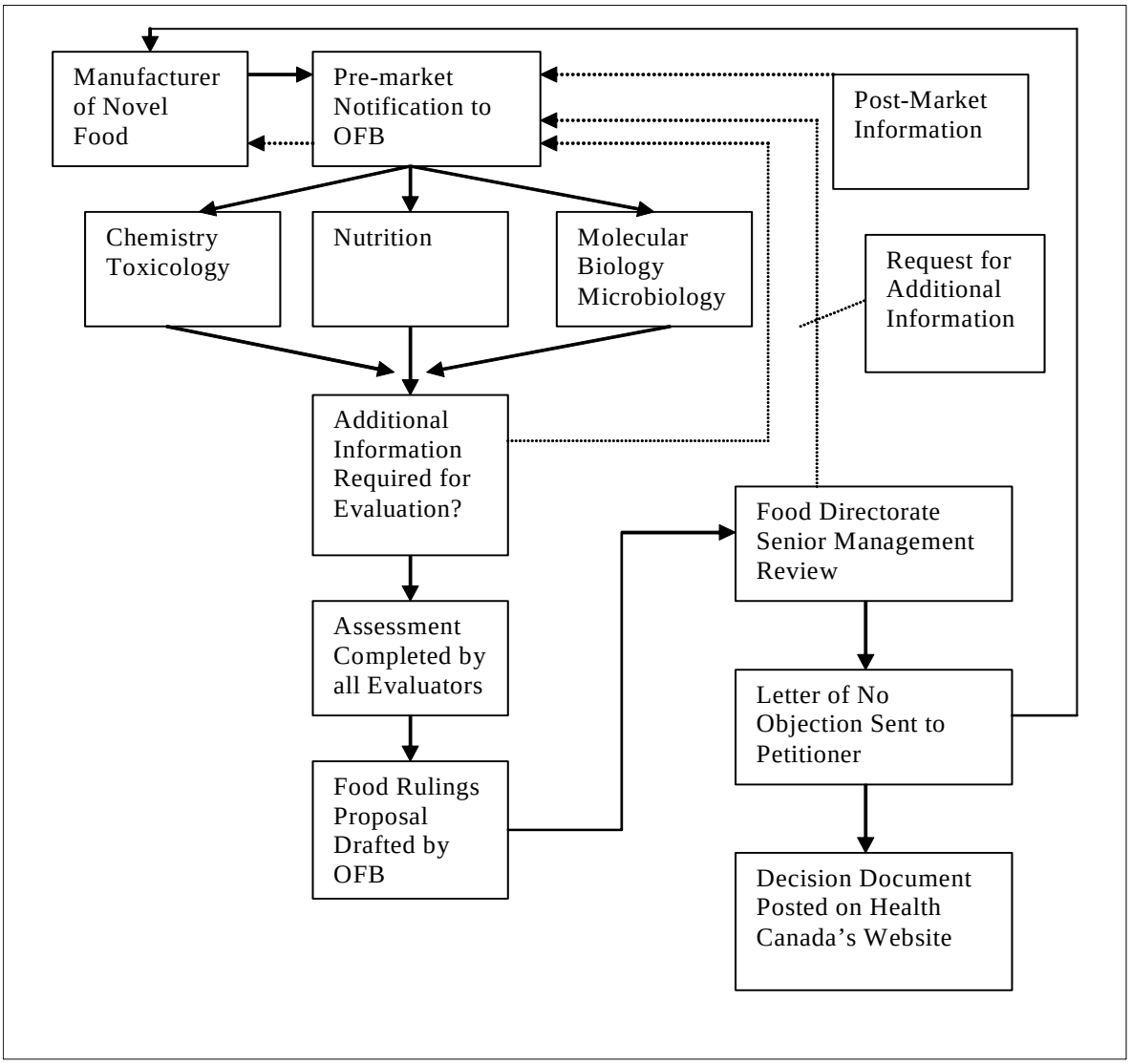
products. Accordingly, Health Canada's legislative powers to regulate GM foods come from this Act. In terms of constitutional authority, subsection 91(27) of the *Constitution Act* gives federal Parliament exclusive authority to legislate with regard to 'criminal law.' This allows Parliament to create criminal legislation directed at legitimate public health evils (Jackman, 2000, 99-102).

Since amendments to the *Food and Drugs Act* in October 1999, GM foods come under the *Novel Food Regulations*. They define novel foods and set the time frame for the government's review of manufacturers' assessments of the safety of their products. The other instructive documents are entitled *Guidelines for the Safety Assessment of Novel Foods, Volumes I and II* (1994a; 1994b). Collectively, these guidelines detail provisions for the pre-market notification, classification, safety assessment and approval of novel foods.[8] Moreover, many of them are based on scientific principles developed through expert consultation in international policy and standard setting organizations such as the Food and Agricultural Organization/World Health Organization's joint Codex Alimentarius Commission and the Organization for Economic Development and Cooperation (OECD).[9]

The formal process for evaluating the safety of GM and other novel food products is depicted in Figure 2. It involves an Office of Biotechnology and Science which coordinates an assessment that is ultimately reviewed and decided upon by a Food Ruling Committee. The Office of Biotechnology Science is located in the Health Products and Food Branch and also acts as a focal point for interdepartmental coordination. The length of this process normally takes anywhere from six to 18 months, involving about 80 to 100 person-hours on average (Doern 2000, 13). As Doern (2000, 10) reports, "…the core of science officers work on biotechnology products consists of not much more than ten experts in Health Canada and ten in the Canadian Food Inspection Agency (for its aspects of biotechnology in plants, feeds, seeds and feeds) with perhaps another twenty or so experts within the science-establishment whose expertise is drawn on in a more periodic basis." If there are any disputes among the evaluators over the science, "…dispute resolution can move up the hierarchy within Health Canada or [the] Canadian Food Inspection Agency to Director or higher level official[s]" (Doern 2000, 13). Due to commercial secrecy requirements, data on the pre-market product notification, evaluation and approval of GM foods are normally kept confidential, unless plant biotechnology developers agree to voluntarily release their notices of submission for public comment and review (see for example, Health Canada, the Canadian Food Inspection Agency and Croplife Canada's pilot

Biotechnology Transparency Project (CFIA 2008a)). Here, Health Canada's final decisions are advertised on its website, but there are no formal appeal or review processes once a decision has been made. There is also no systemic program for the post-market surveillance and review of GM food products (Doern 2000, 15-24). Therefore, although scientific peer-reviewed literature, expert reports and outside academics can be drawn upon in the process on an ad hoc basis, there can be no external, independent peer review and no public involvement.

Figure 2: The Safety Assessment and Approval Process for Foods Derived from Biotechnology



Source: Health Canada. Presentation by Brian Harrison. *Regulating Novel Foods in Canada*. http://apec.biotec.or.th/pdf/RegulatingNovelFoodsinCanada.pdf (accessed 6 September 2005).

Note: Office of Biotechnology (OFB)

THE CANADIAN FOOD INSPECTION AGENCY

Although Health Canada takes the lead in the regulation of GM foods for human consumption, the Canadian Food Inspection Agency is responsible for GM seeds, crops and livestock feed.[10] The Canadian Food Inspection Agency's legislative powers come from the *Feeds Act*, the *Fertilizers Act*, the *Seeds Act*, the *Plant Protection Act*, the *Health of Animals Act* and the *Pest Control Products Act*.[11] In the regulation of GM plants for food production for humans, the *Seeds Act* (environmental release and variety registration) and the *Plant Protection Act* (importation) are the most important. The federal government has obtained the authority to pass such legislation from the *Constitution Act*'s sections 95 (concurrent powers in agriculture, with federal paramountcy) and 91 (2) (the power to make laws in relation to the regulation of "trade and commerce") (Moore and Skogstad, 1998, 129, Footnote 7).

The Canadian Food Inspection Agency's Programs Branch, Plant Products Directorate, Plant Biosafety Office conducts the environmental safety assessments of GM plants with legislative authority derived from the *Seeds Act*. It also authorizes import permits for GM plants (*Plant Protection Act*) and manages the certification of seeds and the registration of varieties of field crops (*Seeds Act*). The Plant Products Directorate further has responsibility for the regulation and approval of contained (laboratories) and field (confined, unconfined) trials for GM plants. While manufacturers and other laboratory/research bodies largely self-regulate the contained stages, science evaluators from the Plant Products Directorate assess industry and other applications for field trials, and once approved, field staff monitor the trials and related records (Doern 2000, 11). Importantly, there is no mandatory public notification about, or public information on the location of, confined/unconfined field trials. Provincial governments are given a 30 day notice with regard to the commencement of confined trials within their jurisdictions. Like Health Canada, the Canadian Food Inspection Agency has an Office of Biotechnology Science that coordinates its safety assessment efforts and acts as the interdepartmental liaison.[12]

The Canadian Food Inspection Agency also has the responsibility for all federal inspection programs related to safeguarding food, plant and animal health, as well as for the enforcement and administration of many of the regulations relating to the *Food and Drugs Act.* In theory, this responsibility includes enforcement of the policies and standards established by Health Canada as they relate to the safety of GM foods. However, many questions remain with

regard to the practicalities of implementing these federal and other intergovernmental arrangements. Ultimately, Health Canada is responsible for assessing the effectiveness of Canadian Food Inspection Agency activities related to GM food safety, inspection and enforcement (Canadian Biotechnology Advisory Committee 2002, 8).

SHARED RESPONSIBILITIES BETWEEN HEALTH CANADA AND THE CANADIAN FOOD INSPECTION AGENCY

Health Canada and the Canadian Food Inspection Agency share responsibility for GM food labeling policies under the *Food and Drugs Act*.[13] Health Canada is responsible for establishing GM food labeling policies with respect to health and safety matters, while the Canadian Food Inspection Agency is responsible for the development of non-health and safety labeling regulations. In the former case, Health Canada would only require mandatory labeling of GM foods in line with the *Food and Drugs Act* when nutritional or compositional changes are made to products, or when specific health concerns exist, such as the presence of possible food allergens (Steiner 2000, 157). In the latter case, the Canadian Food Inspection Agency is accountable for protecting consumers from misrepresentation and fraud with respect to food labeling, packaging and advertising and for prescribing basic food labeling and advertising requirements applicable to all foods (Canadian Food Inspection Agency 2004, 1). In April 2004, the federal government announced that a voluntary, national labeling standard for GM foods was adopted by the Standards Council of Canada, permitting both positive (does contain) and negative (does not contain) labeling (Canadian Biotechnology Advisory Committee 2005). Thus, unlike other jurisdictions such as the EU, Canada does not have a comprehensive, mandatory labeling scheme for GM foods and food ingredients (Bernauer and Meins 2003, 652). Table 1 summarizes the Canadian Regulatory System for Biotechnology for all biotechnology products. Table 2 highlights the delineation of regulatory responsibilities among Health Canada and the Canadian Food Inspection Agency in the Canadian Regulatory System for Biotechnology.

Table 1: The Canadian Regulatory System for Biotechnology*

Department/ Agency	Products Regulated	Relevant Legislation	Regulations
Health Canada	Foods, including novel foods, drugs, cosmetics, medical devices Pest control products Baculovirus, pesticides, biocides	Food and Drugs Act Canadian Environmental Protection Act (CEPA) Pest Control Products Act	Food and Drugs Regulations Novel Foods Regulations Medical Devices Regulations Cosmetics Regulations New Substances Regulations Pest Control Products Regulations
Canadian Food Inspection Agency	Plants and seeds, including those with novel traits Livestock feeds, including novel feeds Animals, animal vaccines and biologics, fertilizers	Seeds Act Plant Protection Act Food and Drugs Act Consumer Packaging and Labelling Act Feeds Act Health of Animals Act Fertilizers Act	Seeds Regulations Food and Drug Regulations Feeds Regulations Health of Animals Regulations Fertilizers Regulations
Environment Canada	Products under CEPA, including biotechnology products (e.g., microorganisms used in bioremediation, waste disposal, mineral leaching or enhanced oil recovery)	CEPA	New Substances Notification Regulations (These regulations apply to products not regulated under other federal legislation)
Department of Fisheries and Oceans	Fish, including transgenic fish	Fisheries Act	Under development

Source: Table adapted from Leiss and Tyshenko 2002.

FEDERAL FUNDING OF THE

Table 2: Delineation of Regulatory Responsibilities among Health Canada and the Canadian Food Inspection Agency (CFIA) within the Canadian Regulatory System for Biotechnology

Public Health Area	Health Canada	CFIA
Human Health and Food Safety		
• Review of safety assessment and approval of novel foods	*	
• Nutritional content	*	
• Allergens	*	
• Potential presence of toxins	*	
Food Labelling Policies		
• Nutritional content	*	
• Allergens	*	
• Special dietary needs	*	
• Fraud and consumer protection		*
Plant and Animal Health and Safety Assessment		
• Seeds		*
• Plants		*
• Livestock Feeds		*
• Animals		*
• Animal vaccines and biologics		*
• Fertilizers		*

Source: AGBIOS. *The Canadian Regulatory Framework for Biotechnology Products.* http://www.agbios.com/cstudies.php?book=REG&ev=CANUSA&chapter=Canada&lang=EN (accessed 6 September 2005).

CANADIAN BIOTECHNOLOGY STRATEGY AND THE CANADIAN REGULATORY SYSTEM FOR BIOTECHNOLOGY

The funding of the regulatory system for GM foods has been purely a federal responsibility. From 1999 to 2008, the federal government has provided a total of $467.9 million to the three initiatives of the Canadian Biotechnology Strategy: the Canadian Biotechnology Strategy Fund ($65.1 million from April 1999 to June 2007), the Canadian Regulatory System for Biotechnology ($228.4 million from April 1999 to 2007) and the Genomics R&D Program ($17.4 million from April 1999 to March 2008) (Industry Canada 2007b). In addition to regular program budgets, the Treasury Board continues to allocate separate program funding through the Canadian Regulatory System for Biotechnology to the relevant agencies/departments to enhance their regulatory capacity.[14] As the Treasury Board Secretariat reported in 2007b (3), the objectives of the Canadian Regulatory System for Biotechnology are to:

- "meet technical capacity and human resource needs;
- improve public awareness of, and confidence in, the regulatory system;
- increase efficiency, effectiveness and timeliness of the regulatory system; and
- generate knowledge to support the regulatory system."

Here, the Canadian Regulatory System for Biotechnology is horizontally managed by the interdepartmental Working Group on Regulations, which reports to the Biotechnology Coordinating Committee. In the past, the Canadian Biotechnology Strategy Fund (and the Secretariat) supported the relevant agencies/departments in areas such as horizontal management, policy development, research, innovation, risk management and stewardship. Federal funding for the Canadian Biotechnology Strategy from 1999 to 2007 is outlined in Table 3.

Table 3: Federal Funding of the Canadian Biotechnology Strategy (CBS) 1999-2007

Fiscal Year Actual Spending+	**CBS Fund/ CBAC/CBSec**	**Canadian Regulatory System for Biotechnology**	**Genomics R&D**	**Total**
1999-2000 *2001-2002*	28, 560.00	*2000-2003* 90,000.00++		
2002-2003	9,171.26	35,000.00	19,900.00	64,071.26
2003-2004	9,173.50	33,097.50	19,900.00	62,171.00
2004-2005	12, 984.99	35,480.00	17,900.00	66,364.99
2005-2006	8,397.45	34,600.00	19,900.00	62,897.45
2006-2007	4,670.00	34,600.00	19,900.00	59,170.00
2007-2008+++	1,800.00++ CBAC/CBSec funding unknown End Date of CBS: June 15, 2007 End Date of CBS Fund: June 30, 2007	34,680.00++	19,900.00++ Will be seeking program renewal from April 2008 to March 2011	Unknown

+Spending thousand ($000)
++ Reports of planned rather than actual spending
+++ For the 2007-2008 period, $1.75 million additionally allocated to ensure biotechnology is well positioned with the new Science and Technology Strategy objectives

Sources:

AAFC et al. 2002. *Canadian Biotechnology Strategy Overall Performance Report* 1999-2002. July; Treasury Board of Canada. 2005. *The CBS*. http://www.tbs-sct.gc.ca/rma/eppi-idrp/hrdb-rhbd/cbs-scb/description (accessed 2 September 2005); Industry Canada. 2006a. *CBS Horizontal DPR 2004-05.* http://www.ic.gc.ca/cmb/welcomeic.nsf/532340a8523f33718525649d006b119d/cf027598cd20dfaa852570ab006cf65d!OpenDocument (accessed 19 June 2006).

Industry Canada. 2006b. *Industry Canada Performance Report – For the period ending March 31, 2006.* http://www.ic.gc.ca/cmb/welcomeic.nsf/532340a8523f33718525649d006b119d/5cc96db1852fb3d68525722f00749030!OpenDocument (accessed 1 March 2008).

Industry Canada. 2007a. *2007-2008 Estimates. Report on Plans and Priorities.* http://www.ic.gc.ca/cmb/welcomeic.nsf/532340a8523f33718525649d006b119d/e8ed6d3c991df93e852572ad0055bbf9!OpenDocument (accessed 1 Mar 2008).

Industry Canada. 2007b. *Performance Report — For the Period Ending March 31, 2007.* http://www.ic.gc.ca/epic/site/ic1.nsf/en/00309e.html (accessed 1 Mar 2008).

INTERNATIONAL ASPECTS

The federal government has the power to negotiate and sign international agreements which can directly impact food biotechnology policy. Officials from Health Canada and the Canadian Food Inspection Agency actively participate in international policy and standard setting bodies such as the Codex Alimentarius Commission[15] and the OECD. To arrive at national positions and oversee Canada's involvement in these bodies internationally, contact points in the federal government coordinate interdepartmental and intergovernmental consultation through informal mechanisms or formally in the existing F/P/T food safety and inspection committee structure (see discussion below). [16]

In particular, trade agreements such as the World Trade Organization's (WTO) *Agreements on Sanitary and Phytosanitary (SPS) Measures and Technical Barriers to Trade* and the *North American Free Trade Agreement* reference Codex standards. Thus, federal officials need to ensure federal legislation is harmonized or in compliance with them to minimize negative impacts on trade. Under the WTO's *Sanitary and Phytosanitary Agreement*, then, Canada would have to justify its GM food standards on scientific grounds if they deviated from the relevant international standards and resulted in a greater restriction of trade.

Other nations' regulatory frameworks, and policy and scientific consultations with their officials, are also influential. For example, Canada has adopted a similar 'product-based' approach to the regulation of food biotechnology as the US. Canada also has been on the winning side of a WTO trade dispute with Argentina and the US against the EU's *de facto* moratorium on GM foods. (On 29 September 2006, the WTO ruled that the EU's moratorium on biotechnology products between June 1999 to August 2003 was illegal under international trade rules (WTO 2006)). It has thus become important to the federal and provincial governments to harmonize key aspects of their GM food regulatory system with their most important trading partners. For example, in July 1998, the Government of Canada committed to harmonization with the US on the regulation of agricultural biotechnology with regard to the pre-market safety assessment and approval of plants with novel traits (Royal Society of Canada 2001, 37). In December 2001, the *Canada and U.S. Bilateral Agreement on Agricultural Biotechnology* was finalized.

COMPARISON WITH CANADA'S FOOD INSPECTION SYSTEM AND ITS RELEVANCE FOR FOOD BIOTECHNOLOGY GOVERNANCE

Based on the discussion above, the federal government is solely responsible for the regulation of food biotechnology in Canada, working with international jurisdictions and trading partners. Thus, jurisdictional questions are clear in the regulation of GM foods (federal leadership), with shared jurisdiction among the two orders of government in food biotechnology promotion.

In contrast, Canada's food inspection system is much more of a "complex animal" in terms of intergovernmental relations (Confidential Interview 18 March 2005). Responsibility for food inspection falls to both the federal and provincial governments, with the inspection roles of municipalities, regional health authorities and local health units varying from province to province. Overall, F/P/T governments have enacted over 77 Acts, which set standards for the health and safety of food and enable governments to enforce them and carry out food inspection. Municipal governments also enact and enforce by-laws that affect food safety/inspection or play more limited roles of enforcing standards that have been developed at the provincial level. To perform these roles, F/P/T governments invest substantive amounts of money in food safety and inspection systems. In most cases, municipalities derive partial funding from provincial Ministries in addition to traditional sources of revenue such as property taxes (CFISG 2000, 6).

The Canadian Food Inspection Agency has the sole responsibility for federal legislation related to food inspection performing this role closely with Health Canada (the standard setter), Agriculture and Agri-Food Canada and the Department of Fisheries and Ocean. At the provincial level, responsibility for food safety and inspection is generally divided among Ministries responsible for health, agriculture, fisheries, environment and natural resources. The distinction made in roles is that the federal government is responsible for the safety and inspection of food products that move between provinces and internationally, while provincial governments are responsible for those food products that are sold within their jurisdictions, including local food processing, the food service industry, and the food retail industry (Moore and Skogstad 1998, 130). As Doern (2000, 26) summarizes:

> Provincial and regional/local medical officers of health and public health officers 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.

In the case of GM foods, for example, some provincial governments and regional health authorities/local public health units have developed policy recommendations and information materials that address their public health implications (Toronto Board of Health 2001, 2003).

Accordingly, under the Canadian Constitution, jurisdiction is shared for food safety and inspection activities. Provincial legislatures have obtained the authority to pass food inspection legislation from their powers over "property and civil rights," which have come to be interpreted as intra-provincial trade and commerce (section 92(13)). In terms of food safety legislation, provinces have used their authorities over matters of a "local or private" nature (section 92(16)) and agriculture (section 95). Of course, these provincial powers have to be accommodated with the federal government's powers to enact food safety and inspection legislation in relation to the regulation of "trade and commerce" (section 91(2)), criminal law (section 91(27)) and agriculture (section 95) (Moore and Skogstad 1998, 129-130).

In Ontario, the Ministry of Health and Long-Term Care is responsible for developing food safety standards and policies for food premises, while food safety inspection is delegated under the *Health Protection and Promotion Act* to the province's 37 local public health units. The Ministry of Health and Long-Term Care has the power to take measures to protect public health, for example to condemn food, lay charges, order establishments closed and issue food recalls and tickets. Local health units inspect non-federally registered food processing plants, free-standing meat processing facilities and other food premises, respond to food-related complaints and provide food safety information. The Ministries of Agriculture and Food (now Ontario's Ministry of Agriculture, Food and Rural Affairs) and Natural Resources also administer and enforce a number of food safety and inspection provincial statutes, e.g., related to meat, livestock, dairy products, oils, vegetables, fruits and fish. Further, as part of an ongoing review of Ontario's food safety system, the 2001 *Food Safety and Quality Act* modifies the extant food-related Acts. Reforms were primarily to: ensure consistent food safety and quality standards and requirements; enhance enforcement actions, and; assist with the "…timely and

effective response to a food safety crisis, including the introduction of a traceability system to 'trace back' to find the source of a contaminated food, and 'trace forward' to determine where it has been distributed" (Ontario's Ministry of Agriculture, Food and Rural Affairs 2004).

In the event of food recalls and food borne illness outbreaks *within* Ontario, the following would happen. In the first case, the Canadian Food Inspection Agency would normally be in charge and carry out the food recall (although the Ministry of Health and Long-Term Care has equal authority to issue food recalls under the *Health Protection and Promotion Act*). In the second case, the Ministry of Health and Long-Term Care would take the lead as Chair of the Ontario Outbreak Investigation Coordinating Committee, of which the Canadian Food Inspection Agency and Health Canada are partners. Local public health units, Ontario's Ministry of Agriculture, Food and Rural Affairs and Ministry of Natural Resources would also be involved where appropriate (Ontario's Ministry of Agriculture, Food and Rural Affairs 2005). In particular, since Ontario's Ministry of Agriculture, Food and Rural Affairs led in the development of the 2001 *Food Safety and Quality Act*, and is responsible for its implementation, it may assume a greater role here in the future.

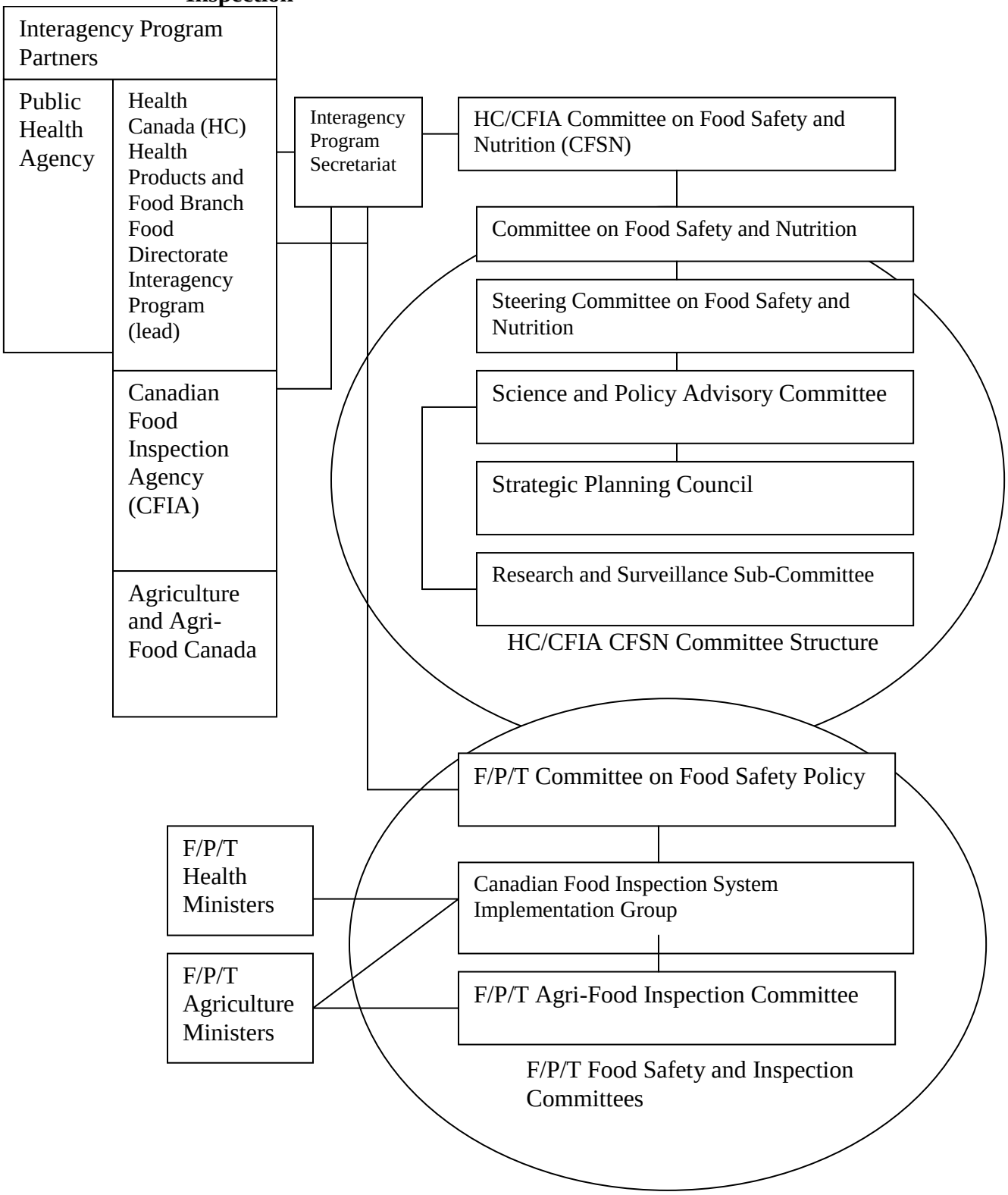
In Saskatchewan, Saskatchewan Health has the primary responsibility for food safety policy development, but through the 1994 *Public Health Act* and sanitation regulations delegate enforcement authority to regional health authorities (Health Canada, 2004). Regional inspectors license and monitor non-federally registered facilities and investigate health hazards and complaints. Saskatchewan's Ministries of Agriculture (formerly known as Saskatchewan's Department of Agriculture, Food and Rural Revitalization) and Environment (formerly Environment and Resource Management) are also responsible for a variety of food specific inspection Acts and commodity-related programs as are its analogous departments in Ontario. The lead agencies to investigate and mitigate a foodborne illness outbreak *within* Saskatchewan are the Regional Health Authorities and Saskatchewan Health, involving the Ministry of Agriculture, the Canadian Food Inspection Agency and Health Canada as necessary (Health Canada, 2006).

To produce an integrated food inspection system and enhance food quality and safety systems across Canada, participating governments committed to the 1994 F/P/T *Blueprint for a Canadian Food Inspection System* and the 2002 F/P/T *Agreement on Agricultural and Agri-Food Policy for the Twentieth-First Century* (including their Bilateral Action Plans and

Implementation Agreements).[17] The vision of the first intergovernmental initiative is "an integrated food inspection system which is responsive to both consumers and industry" (Joint Steering Committee of the Canadian Food Inspection System 1994, 4). The goals of the Blueprint are to: ensure the safety and quality of the food supply and a risk-based inspection system, harmonize standards, improve cost-effectiveness, enhance access to international markets, and prevent economic fraud (Joint Steering Committee of the Canadian Food Inspection System 1994, 4).

The implementation of the Blueprint is the responsibility of the Canadian Food Inspection System Implementation Group, with a membership that is intergovernmental and interdepartmental. It reports to the F/P/T Ministers with food safety and inspection responsibilities and develops model regulations and codes of practice to move Canada toward a unified food inspection system. In particular, the Canadian Food Inspection System Implementation Group works with interagency and F/P/T committees to achieve the goals of the Canadian Food Inspection System *Blueprint*. For example, as part of the Interagency Program at the federal level, there is the Health Canada/Canadian Food Inspection Agency Committee on Food Safety and Nutrition (Committee on Food Safety and Nutrition) and the Steering Committee on Food Safety and Nutrition (among other Councils/committees). The two main F/P/T technical food committees are the Committee on Food Safety Policy and the Agri-Food Inspection Committee. Importantly, interagency and intergovernmental information-sharing and coordination on food biotechnology policy issues is done through this existing committee structure as depicted in Figure 3. For example, in the regular biannual and other F/P/T Committee on Food Safety Policy meetings, there are formal agenda items on GM and other novel foods. Notably, there is also a 2001 F/P/T *Protocol on Information-sharing and Collaboration on Food Safety Matters*.

Figure 3 The Interagency and F/P/T Governance Structures in Food Safety and Inspection



Source: Gabler 2006

The second intergovernmental initiative, the 2001 *Agricultural Policy Framework*, builds upon the Canadian Food Inspection System *Blueprint.* It committed governments to work toward the following food safety and quality goals: to "…protect human health by reducing exposure to hazards,…increase consumer confidence in the safety and quality of food produced in Canada,…increase industry's ability to meet or to exceed market requirements for food safety and food quality, and…provide value-added opportunities through the adoption of food safety and food quality systems" (Government of Canada et al. 2001, 20.1.1-20.1.4). Management goals for the integrated Canadian food safety system include to: "…work with industry towards the development and implementation by industry of government-recognized food safety and food quality process control systems throughout the agri-food continuum,…increase significantly the quality, quantity and availability of data or other information to support the development of risk management strategies and industry-led food and food quality process control systems, and…establish governance systems to allow for integrated policy development and legislative harmonization among the Parties" (Government of Canada et al. 2001, 20.2.1-20.2.3). Some more specific food safety initiatives under the *Agricultural Policy Framework* are to: support industry activities to improve on–and-off farm food safety, traceability, and food quality, develop an integrated food safety information technology infrastructure, harmonize provincial codes/standards with national codes/standards, and improve food safety surveillance and public health surveillance, information sharing and dissemination (Government of Canada et al. 2001).

As part of the December 2003 *Agricultural Policy Framework Bilateral Implementation Agreement*, the federal government committed $39.75 million to this food safety pillar over the five-year life of the agreement and the Ontario government has committed $40 million. The Saskatchewan government has received $26.74 from the federal government. These bilateral agreements are set to expire in the spring of 2008. Accordingly, F/P/T Ministers of Agriculture agreed in June 2007 on a new initiative, *Growing Forward*, the basis from which their governments, in partnership with stakeholders, will negotiate a new policy framework. However, for now, F/P/T Ministers are seeking authorities from their governments to continue extant programs under the current *Agriculture Policy Framework* while the *Growing Forward* framework is being developed and implemented (Government of Canada et al. 2008).

Finally, with the creation of the new Public Health Agency of Canada in 2004, it is the first point of contact within the federal government for issues related to public health

surveillance and actual or potential foodborne illness outbreaks involving more than one P/T or having an international dimension. In particular, the Public Health Agency's Center for Infectious Disease Prevention and Control is responsible for public health surveillance and manages the Canadian Integrated Outbreak Surveillance Centre. In an investigation of a multi-jurisdictional foodborne illness outbreak, the Center for Infectious Disease Prevention and Control would lead an Outbreak Investigation Coordination Committee with the affected P/T or international partners and organizations. In 2004, the *Canadian Foodborne Illness Outbreak Response Protocol to Guide a Multi-jurisdictional Response* was endorsed by the F/P/T Committee on Food Safety Policy, the Council of Chief Medical Officers of Health and the F/P/T Deputy Ministers of Health. It outlines the roles and responsibilities between F/P/T, regional and local jurisdictions in such food safety emergencies. The forms of federalism in food safety and inspection and food biotechnology regulation are now characterized and compared.

THE FORMS OF FEDERALISM IN FOOD INSPECTION AND THE REGULATION OF FOOD BIOTECHNOLOGY

"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 food" (Prince 2000, 25). In Canada**,** the federal government is the main actor in the regulation of food biotechnology, while the provinces are largely inactive. In contrast, both federal and provincial orders of government play active, independent promotional roles, with instances of intergovernmental cooperation also evident in areas such as science, innovation, R&D and commercialization and trade promotion.

COLLOBORATION IN FOOD SAFETY AND INSPECTION

The current relationship in food safety and inspection between the three orders of government is interdependent. F/P/T governments and regional health authorities/local health units must work together to ensure that Canada has a comprehensive and integrated food safety and inspection system. Indeed, in the more extreme case of a multi-jurisdictional food safety emergency, such as a food recall or foodborne illness outbreak, a successful response ultimately depends on clear communications and coordinated actions among all levels of government.

The relationship between the F/P/T governments in food safety and inspection is also non-hierarchical. Currently, the federal government, through Health Canada and the Canadian

Food Inspection Agency, has the explicit legislative authority to ensure and enforce the safety of food products sold interprovincially and internationally and to undertake federal-provincial cooperative efforts in the area. However, the provinces are equally responsible for introducing and implementing legislation to ensure the safety and quality of food products sold intraprovincially. In addition, all three levels of government participate in food safety regulation and assessment, inspection and information provision, and albeit to different extents, pay for the cost of these measures. Thus, many observers characterize the relationship between the F/P/T governments in food safety and inspection as non-hierarchical and as a true "…partnership…based on the equal status of participants [:]…the goal has been to create national – not federal – standards and an integrated – not single-level – system…" (Moore and Skogstad 1998, 146-7).

At the same time, it is important to point out that the F/P/T relationship in inspection can be more vertical, where the federal government passes legislation that creates unwanted financial burdens at the P/T level as well as for industry. For example, in July 2003, the federal government in consultation with P/T and industry partners amended the *Food and Drug Regulations* and *Health of Animal Regulations* to enhance BSE controls by preventing specified risk material (SRM) from cattle from entering food for human consumption. In particular, the new policy required that all SRM be removed at the time of slaughter and diverted from the food supply, which meant a greater role, and increased costs for inspection, for industry and for the CFIA and P/T agencies responsible for federally-registered and non-federally registered establishments respectively (Food Directorate, Health Canada 2003). Without significant new funding to P/T governments to accompany the new legislative commitments, however, from provinces' perspectives the problem of an unfunded mandate arose (Confidential interview 31 March 2005). Likewise, the relationship between the provinces and regional health authorities/local health units can at times be hierarchical, as the latter must implement safety measures legislated by the former, but only partially paid for. Indeed, this emergence of unfunded mandates across levels of government in food safety and inspection can at times introduce a degree of hierarchy into an otherwise collaborative relationship.

Looking back historically, however, it is clear that provincial governments assumed a major role in the *Canadian Food Inspection System Blueprint's* 1994 negotiation. Accordingly, the *Canadian Food Inspection System Blueprint* has been characterized as a cooperative,

intergovernmental initiative, based on a partnership of governments and industry. (Moore and Skogstad 1998, 146-7). Provinces and the federal government equally supported the major goals of the *Canadian Food Inspection System Blueprint*, especially the need to harmonize regulatory measures interprovincially and internationally to minimize negative impacts on trade. Moreover, the Interagency Program and F/P/T governments continue to work together in food safety and food quality through the *Canadian Food Inspection System Blueprint's* intergovernmental structure and initiatives such as the *Agricultural Policy Framework's* pillar on integrated policy development and legislative harmonization. As one federal official explained, "…it's very interdependent,…non-hierarchical…and collaborative" (Confidential Interview 1 April 2005).

DISENTANGLEMENT IN FOOD BIOTECHNOLOGY REGULATION

In contrast, the form of intergovernmental regime that best characterizes the historic and current relationships surrounding food biotechnology regulation is disentanglement. First, the initial development of the National Biotechnology Strategy, and then the later regulatory framework and Canadian Biotechnology Strategy, were all federal initiatives. As such, no real interdependence exists in this form of federalism, with the federal government being the only active player in the regulatory area. Agenda-setting and policy development occurs at the federal level and internationally. The federal government is solely responsible for introducing legislation and regulation pertaining to plants with novel traits and novel foods, while taking into account international principles and standards. The provinces might be consulted in agenda setting formally through the existing food safety and inspection F/P/T structure or informally, but do not play major roles. The Canadian Biotechnology Strategy/the new Science and Technology Strategy and the Canadian Regulatory System for Biotechnology are also entirely funded by the federal government, with instances of cost-recovery introduced by agencies/departments such as the Canadian Food Inspection Agency to fund aspects of the regulatory process.

Second, the relationship between the federal government and the provinces in food biotechnology policy is non-hierarchical. Although the federal government clearly takes a leadership role in the regulatory area and has the legislative authority to enforce its safety standards, up to this point, it has not had to rely on any coercive measures to gain provincial cooperation. Due to their economic interests in agriculture and food biotechnology promotion, and the specialized "expertise" and "extraordinary resource commitment" involved in the

regulation of GM food products, provinces are generally content that this is clearly an area of federal responsibility and authority (Confidential Interview 8 April 2005). Equally, provinces have strong interests in inter-provincial and international trade promotion and want the federal government to continue its work in international fora to develop harmonized, international standards for the regulation, safety assessment and labeling of GM foods (Standing Committee on AFE 2005b, 11). Moreover, the federal government alone bore the financial burden of the Canadian Biotechnology Strategy, and continues to fund the regulatory system, which provincial governments for now see as a "fair distribution of costs" across the orders of government (Confidential Interview 8 April 2005).

Table 4 summarizes the allocation of roles and responsibilities in the regulation of food biotechnology in Canada. In contrast, Table 5 outlines the roles and responsibilities of the orders of government in food safety and inspection. Tables 6 and 7 summarize the forms of federalism in food biotechnology policy and food safety and inspection respectively.

Table 4 Allocation of Roles and Responsibilities in the Regulation of Food Biotechnology

Activities	Federal	Provincial/ Territorial	Local	Supranational
Agenda/standard setting	X			X
Legislative authority	X			
Regulation and/or safety assessment	X			
Funding responsibilities	X			
Inspection and enforcement	X	Potential	Potential	
Promotion and related funding	X	X	X	
Information provision	X	X	X	

Table 5 Allocation of Roles and Responsibilities in Food Safety and Inspection

Activities	Federal	Provincial/ Territorial	Local	Supranational
Agenda/standard setting	X	X		X
Legislative authorities	X	X		
Regulation and/or safety assessment	X	X	X	
Funding responsibilities	X	X	X	
Inspection and enforcement	X	X	X	
Information provision	X	X	X	

Table 6 Nature of the Intergovernmental Relationship in the Regulation of Food Biotechnology

	Hierarchical	Interdependent	*Form of Relationship*
Federal-provincial	No	No	Disentangled
Federal-local	No	No	Disentangled
Provincial-local	No	No	Disentangled

Table 7 Nature of the Intergovernmental Relationship in Food Safety Inspection

	Hierarchical	Interdependent	*Form of Relationship*
Federal-provincial	No	Yes	Collaborative
Federal-local	No	Yes	Collaborative
Provincial-local	No	Yes	Collaborative

GM FOOD CRISES

Although the relationships between F/P/T governments and local players have been characterized as disentangled in food biotechnology regulation, some uncertainty exists about what would happen if an unauthorized or unfit plant with a novel trait was released into the environment or an analogous GM food was released into the feed or food supply. For example, under the *Food and Drugs Act*, it would be a criminal offense if a manufacturer knowingly sold a GM food that had not gone through Health Canada's pre-market notification and safety assessment process and received a letter of no objection. Here, the Canadian Food Inspection Agency takes the lead in the implementation and enforcement of federal plants with novel traits

and novel foods legislation, but provinces/localities would be presumably obligated to participate within their jurisdictions as required in terms of food safety and inspection.

For example, if the Canadian Food Inspection Agency initiated a recall of a GM food product (e.g., contaminated with an unauthorized novel protein or for reasons related to unforeseen elevated levels of allergens), provincial Ministries of health and regional health authorities/local health units might be called on to participate.[18] In these situations, Canadian Food Inspection Agency inspectors presumably would actively lead such GM food safety inspection and enforcement, at the manufacturing (e.g., federally-registered establishments) and even retail level. However, the provinces/localities might participate in inspecting and removing the recalled GM food product from other food operations such as processing plants (e.g., not federally-registered), restaurants and retail food stores. A useful question here is whether and to what extent provincial and local actors would have the scientific, technical, financial or other capacity to contribute to Canadian Food Inspection Agency efforts in such a GM food emergency.

Similarly, if there was a multi-jurisdictional or even jurisdictional food-borne illness outbreak related to a GM food product (e.g., for reasons related to unexpected elevated levels of toxins), provinces and localities would likely participate with the relevant federal agencies/departments in efforts to investigate and control it. This might include the destruction of any GM food within their jurisdictions that is deemed 'unfit' for human consumption. Ostensibly, where appropriate, industry would play a major role in ensuring the safety of GM food products in terms of self-regulation. Therefore, in the administration and enforcement of Health Canada and Canadian Food Inspection Agency legislation pertaining to the safety of plants with novel traits and GM foods, there are elements of interdependence and perhaps the need for more collaborative intergovernmental arrangements to be worked out in the future. As a federal official explained, there are currently no special intergovernmental arrangements or Memoranda of Understandings (MOUs) to outline the roles and responsibilities of the orders of government in situations of accidental releases of GMOs into the environment, runaway GM crops (transgenic movement) posing food-safety risks, or unauthorized/unfit GM products into feed and food supplies (Confidential Interview 7 April 2005). Moreover, without segregation, mandatory labeling, monitoring, tracking or recall systems for GM food distribution in Canada, it is very hard to imagine how such emergency scenarios would play out in practice.

There is a multi-jurisdictional example pertaining to GM seed that might shed light on these questions if it was investigated further. In 1997, Monsanto Canada Inc. recalled 60,000 bag units of GM canola seed in Canada when it discovered an unapproved novel trait in the product (Bjorkquist and Winfield 1999, 30; Scoffield 2000). Monsanto, not the Canadian Food Inspection Agency, discovered the error. Earlier, the Canadian Food Inspection Agency had approved only one of two novel traits for unconfined environmental release found in the product. As such, the seed had to be traced back through retailers, collected and then buried in landfill sites in Western Canada; hectares of canola already planted by farmers also had to be destroyed (Scoffield, 2000). However, what remains unclear from reports is the extent of industry, federal, provincial and local involvement in the recall process and how effective industry and government(s) were at tracking down the seed and ensuring its disposal.

Another example is the well-known 2000 US-Canada StarLink corn recall episode. It demonstrated a gap in the federal regulatory system, highlighting the potential risks to public health in approving GM products with human food counterparts that carry restrictions on their use for non-food purposes.

Textbox

In 1998, StarkLink corn, containing a novel pest-resistant protein, was approved by the US Environmental Protection Agency for use in animal feed, but not for human consumption. However, US government efforts to segregate StarLink corn and keep it out of the human food supply failed. As such, US corn exports and exported food products made from the corn came to contain the novel protein.

At the time, Starlink corn had not been approved by the Canadian Food Inspection Agency (CFIA) or Health Canada for production or sale for any use in Canada (CFIA 2001; CFIA 2002-2003). Health Canada had also conducted a prior health-risk and safety assessment on food products containing the novel protein under the *Novel Foods Regulations*, and concluded that the novel protein was resistant to digestion and, as a consequence, may have allergic potential for some persons (CFIA 2002-2003). Thus, any food product derived from StarLink corn was in violation of the *Food and Drugs Act*.

Accordingly, in 2000, the CFIA initiated a Class II recall of all associated raw or finished, retail food products derived from yellow corn CFIA also began a pre-entry border program for corn and corn-based commodities coming into Canada from the US, including Starlink related testing documentation requirements (CFIA 2004). To carry out these programs, CFIA Operations Branch staff, evaluators and other specialists of the various CFIA Programs Branch commodity groups (including the Plant Biosafety Office and the Feed Section), the technical staff of the Laboratories Directorate, and officers of the OFB worked collaboratively together. In addition, the CFIA worked with the Canada Customs and Revenue Agency and the Canadian Grain Commission (CFIA 2001-2002).

In 2002 and 2003, CFIA inspectors reported that they did not detect any StarLink novel protein in any food or seed in Canada in nearly two years of testing (CFIA 2002-2003; CFIA 2003). However, the CFIA did find the presence of the StarLink novel protein in feed shipments entering Canada (CFIA 2003; Confidential Interview 14 April 2005). Unfortunately, public confidence in novel foods and in Canada's food biotechnology regulatory system was substantially shaken from media reporting of the Starlink corn episode (CFIA 2002-2003). Starlink corn remains prohibited for import to or use in Canada (CFIA 2004).

IMPACT OF FORM OF FEDERALISM ON THE DEVELOPMENT OF THE CANADIAN BIOTECHNOLOGY STRATEGY AND CANADIAN REGULATORY SYSTEM FOR BIOTECHNOLOGY

The Monsanto GM canola seed and StarLink corn recalls are examples that highlight why there are concerns about the policy effectiveness of the Canadian Regulatory System for Biotechnology in protecting the safety of the food supply. Equally, concerns about the democratic nature of the Canadian Biotechnology Strategy and regulatory system resulted from recognition that the federal government's roles and responsibilities as regulator and promoter of biotechnology might be in conflict. Accordingly, there is the potential for the federal government to better represent in regulatory processes the economic interests of industry rather than the broader public health concerns of citizens.

In contrast to these concerns about good governance at the federal level, the disentangled relationship in food biotechnology regulation, blended with the extant collaborative relationship in food safety and inspection, has generally had positive impacts upon principles of federalism. These complementary forms of federalism in the two linked policy domains have also been generally effective and democratic in achieving the goals of the Canadian Biotechnology Strategy/Canadian Regulatory Framework for Biotechnology. Of course, there remain some notable areas for improvement and of uncertainty in the workings of the intergovernmental arrangements, for example surrounding the effective handling of future GM food problems. Table 8 summarizes the overall effectiveness of the set of intergovernmental forms.

RESPECT FOR PRINCIPLES OF FEDERALISM

First, federal and provincial officials interviewed perceived that the current governance regime in food biotechnology generally respects the formal divisions of powers contained in the Constitution as well as the political sovereignty of the orders of government. The disentanglement allows provinces the freedom to pursue their promotional roles, while the federal government is ultimately accountable for the potentially uneasy relationship between promotion and regulation. Here, P/T governments remain in agreement with the chosen, and arguably less stringent, 'product-based' approach to the federal regulation of food biotechnology because of its compatibility with international standards, trade commitments and economic interests. Theoretically, and as long as provincial legislation was carefully crafted to not conflict

with or contradict any current federal legislation or regulations, provinces could adopt more stringent approaches (exceed standards) to the regulation of certain aspects of agriculture and food biotechnology. For example, legal opinion solicited by the Standing Committee on Agriculture, Forestry and Environment of the Legislative Assembly of Prince Edward Island (2005a, 6) confirmed that the production of GM organisms could be legitimately banned by legislation in their province.[19]

> There are no laws passed by Parliament and no federal regulations currently in force that would preclude the passage of provincial legislation that might ban or restrict the use of (planting of) GMOs in the province.

However, the international harmonization of GM food science and safety standards in WTO and NAFTA-approved fora, such as the Codex Alimentarius Commission, essentially has acted to narrow the possible range of trade-friendly, regulatory options, and thus has reduced potential areas of action and disagreement among the F/P/T governments in the short term. This F/P/T consensus on the current federal leadership role could undergo flux in the long term, for example should one or more P/T governments' economies/trade interests or the health of their populations become impacted deleteriously by federal GM food legislation or regulations and/or Health Canada/Canadian Food Inspection Agency decisions (in)actions/ (non)decisions. Areas where F/P/T interests could potentially conflict in the future, for instance, could be regarding evolving economic and trade interests in GM and other novel foods versus federally and provincially certified organic food products (e.g., how to manage the co-existence of GM and non-GM crops and foods in local/provincial, national and global markets) (CFIA 2008).

Second, the federal government is not only solely responsible for the relevant GM food legislation, but also for the funding of the Canadian Biotechnology Strategy/the new Science and Technology Strategy and the Canadian Regulatory System for Biotechnology. This means that problems of unfunded mandates that occur at times in the collaborative area of food safety and inspection presently are not a salient issue in the current disentangled arrangement in food biotechnology governance (Confidential Interview 31 March 2005). At the same time, federal leadership actions in any major multi-jurisdictional GM food safety crisis, which could

potentially place unwanted fiscal pressures on the P/T governments in inspection, could change the current perception that costs are fairly distributed among the orders of government.

Third, due to the extant F/P/T committee structure for food safety and inspection, there appears to be an effective system in place to support – at a minimum the biannual - sharing of information about food biotechnology governance. In the past, this is how the federal government has formally informed the provinces on GM food matters, in addition to informal, intergovernmental mechanisms of communication and co-ordination and other formal stakeholder consultations. Hence, the existing, linked, collaborative apparatus in food safety and inspection appears to currently support a good working relationship between the orders of government so that data can be shared in GM food regulation.

However, it is important to note that some provincial officials interviewed felt that these F/P/T mechanisms in food safety and inspection are not as frequently or well used in relation to food biotechnology policy. Thus, they expressed interest in additional means to increase the quantity and quality of information flowing to the provinces/territories from the federal government (Confidential Interview 8 April 2005).[20] And although intergovernmental relations in food biotechnology policy have experienced relatively "calm waters" to date, the establishment of dispute-settlement mechanisms to address any future concerns would likely be beneficial (Boucher et al. 2002, 35). In general, however, the current, disentangled intergovernmental arrangement in food biotechnology policy, blended with the extant collaborative system in food safety and inspection, was generally perceived by interviewees to have positive impacts on principles of federalism.

POLICY EFFECTIVENESS

In terms of effectiveness, the Canadian Biotechnology Strategy and the Federal and Canadian Regulatory Frameworks for Biotechnology can be considered successes in that they created the first national system to regulate and conduct the safety assessment of GM and other novel food products. Before these federal leadership initiatives, the common concern of separate federal and provincial biotechnology strategies was economic development and there was a gap in the regulation of new biotechnology products in order to protect public health and ensure the safety of the food supply. In particular, the Canadian Regulatory Framework for Biotechnology, primarily through the players of the Health Canada and the Canadian Food Inspection Agency,

now provides avenues for the regulation of novel foods and plants with novel traits respectively, where none existed effectively before. In the linked area of food safety and inspection, the Canadian Food Inspection Agency provides a single window of food inspection delivery at the federal level, and the extant, collaborative relationship among the orders of government continues to move provinces toward harmonization of practice in inspection with rather supportive institutional structures to ensure coordination of activities and information sharing. In cases of actual or potential foodborne illness outbreaks involving more than one P/T or having an international dimension, the new Public Health Agency has further become the lead agency of coordinated F/P/T response. So if there is ever a transterritorial GM food crisis, federal regulatory authority and the lead agencies will potentially allow for effective responses. However, the extant collaborative, intergovernmental arrangement in food safety and inspection needs to be relied on to effectively solve GM food problems; a necessary 'capacity' complement to the current classical arrangement in food biotechnology regulation.

Further, although controversy still surrounds the federal government's decision to adopt a 'product-based' approach versus a 'process-based' approach to GM food regulation, in doing so, it aligned itself effectively with powerful trading partners and the harmonized, standards set by relevant international organizations. Indeed, this strategy addresses trade competitiveness concerns, assuring compliance with international trade rules and agreements and that Canadian GM food producers and processors will be less vulnerable to trade challenges. Most of all, one set of food biotechnology regulations applied nationally and rationalized to those of Canada's trading partners and international organizations has prevented a patchwork of dissimilar provincial regulatory approaches/institutions or lower-than-federal/international standards from arising. Similarly, the Canadian Biotechnology Strategy and Canadian Regulatory Framework for Biotechnology's 'scientifically-grounded', product-based approach using existing laws and regulatory departments avoided duplication and overlap by deeming a whole new set of federal precautionary and 'process-based' regulations and institutions as unnecessary.

In terms of other gaps and overlaps in the Canadian Biotechnology Strategy and Canadian Regulatory System for Biotechnology, past and current problems related to policy effectiveness in food biotechnology regulation, as opposed to inspection activities, are more about the challenges of good governance. Some of the main criticisms of seminal reports from a Royal Society of Canada Expert Panel on the Regulation of Food Biotechnology (2001), the

Canadian Biotechnology Advisory Committee (2002) and the Office of the Auditor General (2005) were that the Canadian Biotechnology Strategy and the federal regulatory regime for GM foods needed to: reduce gaps and overlaps in the regulatory system, better ensure its interagency roles and responsibilities are not in conflict, develop specialized tools and institutions for interagency co-ordination, and adapt flexibly the system to new technologies and future generations of alterations.

First, although those interviewed stressed the clear allocation of regulatory authority to the federal government, these reports pressed the relevant agencies/departments to review the efficiency and effectiveness of their standard operating principles, policies and processes in order to avoid potential gaps and overlaps within the regulatory system. This included specifying clear procedures and mechanisms for the coordination of the assessment and approval/registration of GM seeds/crops/feeds and foods, and related inspection, enforcement, surveillance and monitoring activities (Canadian Biotechnology Advisory Committee 2002, xiii).[21] In particular, the Canadian Biotechnology Advisory Committee (2002, xiii-xiv) stressed the need for organizational change to ensure better interagency coordination of activities at the federal level.[22]

Second, most interviewees seemed satisfied that the federal government has been successful in separating its regulatory duties from its promotional roles. However, the Royal Society and Canadian Biotechnology Advisory Committee reports strongly criticized Canadian regulatory agencies/departments for not clearly segregating such functions.[23] Here, the initial impetuses for the National Biotechnology Strategy and the Canadian Biotechnology Strategy/Canadian Regulatory System for Biotechnology were to make the regulatory process as efficient and timely as possible, thereby minimizing burdens on industry in securing product approvals and creating a positive environment in Canada for innovation and investment. Accordingly, critics expressed reservations that Industry Canada, with its promotional mandate, took the lead in the Canadian Biotechnology Strategy, as well as housed the Canadian Biotechnology Strategy governance structure (e.g., the Canadian Biotechnology Secretariat). This relationship continues with the new Science and Technology Strategy and Council. Furthermore, although Agriculture and Agri-Food Canada's regulatory function was taken over by the Canadian Food Inspection Agency, some observers still felt that the latter's regulatory mandate was mixed with promotional functions. Agriculture and Agri-Food Canada and the Canadian Food Inspection Agency also both report to the Minister of Agriculture, who is

ultimately responsible for ensuring that the agriculture sector is "efficient, effective and internationally competitive" (Canadian Biotechnology Advisory Committee 2002, 15). Similarly, Health Canada has been criticized in the past for industry and promotional biases (Canadian Biotechnology Advisory Committee 2002, 15). Therefore, the current organization of food biotechnology governance at the federal level in Canada has been criticized for underplaying the importance of an independent and autonomous, regulatory system that prioritizes the safety of human health over other objectives.

Another cause for concern about the Canadian Biotechnology Strategy and Canadian Regulatory System for Biotechnology revolved around the question of whether the federal agencies/departments involved possess sufficient scientific capacity to ensure effectiveness in GM food safety assessment decision-making. For example, in the mid 1990s, the federal government slashed science capacity by approximately 20 per cent, and it is well-known that in-house capacity has not recovered from the loss (Boucher et al. 2002, 4). Speaking to such concerns, the federal officials interviewed in the Canadian Food Inspection Agency and Health Canada expressed reservations about the upcoming second generation of GM products (among other technological innovations) and the scientific capacity of regulators to deal effectively with their cumulative impacts. Indeed, given that rapid changes in biotechnology can affect health, safety, the environment, and the economy, it is important that the current governance regime and regulatory bodies respond to such developments in effective and timely ways. For example, the Expert Panel and Canadian Biotechnology Advisory Committee reports make clear the need to continually update Canadian legislation and regulatory approaches and protocols as product complexity increases (e.g., in the safety assessment of GM foods for risks related to allergenicity and nutritional/toxicological composition). In the short term, this includes the need for further elaboration of effective and appropriate applications of the principles of substantial equivalence and precaution (Expert Panel 2001; Canadian Biotechnology Advisory Committee 2002). In the long term, processes for the systematic and rigorous, post-market surveillance and review/testing of GM foods are required.

Of concern is that although the Auditor General's (2005, 4.21) report recognized some of the positive responses of management and working-level officials in this area, it revealed the lack of top-level leadership for the Canadian Biotechnology Strategy and Canadian Regulatory System for Biotechnology, including the non-response of Ministers so far to the expert advice

received. Further, with the cancellation of the Canadian Biotechnology Strategy, and the new Science and Technology Strategy lacking much in the way of detail while discarding the Canadian Biotechnology Advisory Committee, it is now even less clear how the federal government intends to solve such issues relating to good governance and policy ineffectiveness.

RESPECT FOR PRINCIPLES OF DEMOCRACY

Other core challenges for the current food biotechnology governance regime are respect for fundamental principles of democracy such as accountability, transparency, and public participation. First, in the current form of disentangled federalism, it is clear that the federal government is ultimately accountable as the regulator of GM and other novel food products and would take the lead in a transterritorial GM food problem. However, public awareness of this federal leadership role in regulation/emergency response is lacking, and further confused by the F/P/T roles in promotion, which could create political accountability issues for all orders of government in the face of a GM food crisis (See Boucher et al. 2002, 14, 19-20, 36). The collaborative roles in food inspection among the orders of government and industry are also complex and confusing to the public and can lack transparency as the case of the Monsanto GM canola seed recall demonstrate.

Further, at the federal level, the 2005 Auditor General's report criticized the Canadian Biotechnology Strategy for limitations in its accountability governance structure. The Auditor General (2005, 4.53) summarized that "…it was not always clear which federal organizations were involved and how they were to participate. This weakens accountability arrangements, and ultimately, reporting on outcomes and learning by federal organizations." Specifically, the Auditor General (2005, 4.58-4.63) argued there was a lack of planning for overall performance measurement and thus weak reporting to Parliament with regard to accountability and management frameworks, approval processes, and funding arrangements.[24] Thus, it was very difficult for Parliament, and in turn the citizenry, to get a picture of the main achievements (and weaknesses) of the strategy and regulatory system. This is not surprising given that the Auditor General (2005) found that the Privy Council Office, Treasury Board Secretariat and relevant Ministers and agencies/departments were not giving adequate attention to the initiative. Moreover, the new Science and Technology Strategy chooses not to address them at all.

Second, the Canadian Regulatory Framework for Biotechnology and disentanglement in food biotechnology regulation positively provides the public with a single opening to access the policy process (Health Canada and the Canadian Food Inspection Agency), rather than having to go through P/T governments. It also facilitates federal leadership in trade negotiations and in the harmonizing work of the relevant food safety international organizations, with the complementary collaborative arrangement in inspection supporting informal and formal consultations in the F/P/T committee structure. However, as a consequence, it creates a regulatory apparatus at the federal level that risks criticism in terms of being more susceptible to lobbying from powerful interest groups. In the past, for example, the Expert Panel (2001) and Canadian Biotechnology Advisory Committee (2002) criticized the Canadian Regulatory System for Biotechnology for perceptions of conflicts of interest and for close government-industry ties, deeming that regulatory decisions could be viewed as balancing client interests over broader public ones.

Specifically, the Expert Panel (2001) and the Canadian Biotechnology Advisory Committee (2002) criticized Health Canada and the Canadian Food Inspection Agency of inadequately consulting with the expert scientific community and the public, while favouring industry, in GM food safety assessment and approval processes. In addition, they cited a lack of transparency in the regulatory process as normally the detailed scientific and technical data informing decisions were not released to the public and did not undergo independent, scientific peer review. Of course, the problems of biased consultation and transparency here are partially consequences of the trade-off between keeping business information confidential (so as not to jeopardize firm or industry competitiveness) and allowing for independent scientific and public scrutiny (CBAC 2002, xiv). At the same time, both the Expert Panel and Canadian Biotechnology Advisory Committee recommended that the relevant authorities alter the democratic nature of regulatory decisions in terms of increasing scientific standards of objectivity, openness to full peer review and the overall transparency of the process. In particular, the Expert Panel proposed the creation of an external and independent panel of scientists to review the science and rationales underlying all safety assessments and regulatory decisions.[25] Thus, industry involvement in the regulatory process, in the absence of significant independent expert and other public participation, could potentially create pressures to prioritize efficiency concerns over the protection of the food supply and its long term safety and quality.

Finally, while past processes to revise the regulatory framework and renew the Canadian Biotechnology Strategy included laudable efforts toward diverse public participation, the past initiatives of the Canadian Biotechnology Advisory Committee and responding Government of Canada Action Plans predominantly entailed consultations with those federal government actors themselves selected as stakeholders (Hartley and Skogstad 2005, 314). For example, the Canadian Biotechnology Advisory Committee's multi-stakeholder consultations on the regulation of GM foods were by invitation only and were not open to the broader public. As a result, most groups involved represented industry and agricultural producers and very few represented consumers, public health and the environment (Abergel and Barrett 2002, 152). In fact, key stakeholders such as public interest and environmental NGOs boycotted the entire Canadian Biotechnology Advisory Committee consultation process on the grounds that "…the remit…was too narrow and it lacked independence from government" (Hartley and Skogstad, 2005, 314). Thus, it appears as though groups that represent broader public interests could be more involved in the future evolution of the regulatory framework and of the Science and Technology Strategy. Table 8 recaps the overall effectiveness of the set of intergovernmental arrangements. Table 9 summarizes some of the challenges for good food biotechnology governance at the federal level.

Table 8 Effectiveness of Intergovernmental Arrangements in the Regulation of Food Biotechnology

	Summary
Policy Effectiveness	
Health Economic	• Canadian Biotechnology Strategy and Canadian Regulatory Framework for Biotechnology successful in terms of addressing the gap in the regulation of new food biotechnology products • the Canadian Food Inspection Agency provides a single window of food inspection delivery at the federal level, and the collaborative relationship among F/P/T governments continues to move provinces toward harmonization of practice in inspection with rather supportive institutional structures to ensure coordination of activities and information sharing • In the case of a transterritorial GM food crisis, federal regulatory authority and the lead agencies may potentially allow for effective responses; however, the collaborative, intergovernmental arrangement in food safety and inspection needs to be relied on to effectively solve multi-jurisdictional GM food problems • Trade competitiveness concerns are met by the strategy/regulatory framework: the decision to adopt a 'product-based' approach to food biotechnology regulation is compatible with powerful trading partners' policies, international trade agreements and the harmonized, standards set by the relevant international organizations • One set of food biotechnology regulations applied nationally and rationalized to those of Canada's trading partners and international organizations prevents overlap and duplication by P/T governments
Democracy	• Strategy/regulatory framework provides the public with a single opening to access the policy process (Health Canada and the Canadian Food Inspection Agency), rather than having to go through P/T governments; however, it creates a regulatory apparatus that is more susceptible to lobbying from powerful interest groups
Federalism	• Current governance regime in food biotechnology in principle respects jurisdictional sovereignty • Provinces are generally satisfied with the federal leadership role; the international harmonization of food biotechnology standards in WTO and NAFTA-approved fora narrows the possible range of policy options and has reduced potential areas of disagreement among the F/P/T governments in the short term; however, this does not mean the F/P/T consensus will remain static in the long term in the face of economic and other challenges • Provinces allowed to pursue promotional ambitions unfettered by regulatory concerns about risk, uncertainty and good governance; however, this strategy could back fire in the case a future transterritorial GM food crisis accompanied by a lack of public awareness of the

	accountability structure among orders of government • Facilitates federal leadership in trade negotiations and in the harmonizing work of the relevant international organizations, with the complementary collaborative arrangement and intergovernmental committee structure in inspection supporting informal and formal F/P/T government and other stakeholder consultations • Federal government alone bears burden of current regulatory costs; however, federal leadership actions in a multi-jurisdictional GM food safety crisis could potentially place **unwanted** fiscal pressures on the P/T governments in inspection • Extant F/P/T food safety and inspection committee structure could be used more frequently for information-sharing in food biotechnology policy realm • No clear dispute-resolution mechanisms within the regulatory system or in the context of F/P/T relations

Table 9 Effectiveness of the Canadian Biotechnology Strategy and Regulatory System for Biotechnology

	Summary
Policy Effectiveness	
Health Economic	*Federal Level* • Potential conflicts of interest between regulatory and promotional functions • In some areas, interagency roles and responsibilities still require clarification • Need for improved coordination of interagency activities • In the past, efficiency concerns have impacted upon the Canadian Biotechnology Strategy and regulatory system; risk of public health and safety considerations becoming secondary in importance • Advantages of cost-sharing arrangements in regulatory system with industry partners
Democracy	*Federal Level* • Federal government clearly accountable, but accountability limitations still exist in the regulatory system horizontal governance structure • Minorities (e.g., industry) better represented than majorities (e.g., the public health of citizens, consumers) • Trade-offs between commercial secrecy and transparency in the regulatory system • Minimal participation of experts in the regulatory system; public participation in the past Canadian Biotechnology Strategy governance structure also minimal

CONCLUSION

GM food regulation is clearly a federal responsibility. The present intergovernmental relationship in food biotechnology policy resulting from the Canadian Biotechnology Strategy and its regulatory framework is best described as disentangled federalism. To date, the federal government solo approach to regulation has been generally considered successful in terms of respect for principles of federalism. Ottawa and the provinces generally agree on the significant potential for economic development and other benefits of food biotechnology, and as a result, they typically operate in the promotional area. At the same time, they view a federal leadership role in regulation and stewardship as most appropriate given the extant powers and legislation, scientific and technical capacity, resource demands and international dimensions. Ultimately, it is the federal government that bears the accountability burden for regulatory risks, costs and good governance.

The Canadian Biotechnology Strategy and its regulatory framework can also be generally considered successful federal initiatives in terms of policy effectiveness and democracy, with some notable areas for improvement. Importantly, as this chapter has shown, the success of disentanglement in GM food regulation depends on the extant, complementary collaborative relationship in food safety and inspection. In the face of a future GM food crisis with national spillover effects, for example, federal authority and leadership would be necessary, but so too would cooperation with the provinces/territories in the inspection component. In many ways, then, the complementary collaborative relationship in food safety and inspection permits the disentangled regulatory system to work more effectively and democratically. However, this overall positive evaluation of the impacts on federalism, policy effectiveness and democracy of the intergovernmental arrangements does not mean that the federal leadership strategy and regulatory framework is free of its own challenges for good governance. Indeed, such governance challenges would seem to warrant further research into food biotechnology regulation in Canada, and in the policy vacuum left behind by the cancellation of the Canadian Biotechnology Strategy, further deliberations and action among F/P/T officials and relevant stakeholders.

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Appendix A

The Creation of the Canadian Biotechnology Strategy and its Governance Structures

The Canadian Biotechnology Strategy (CBS) consultation process took place from March to May 1998. Provinces were treated as stakeholders (along with industry, academia, citizens, non-governmental organizations (NGOs) and other interests). The Minister of Industry Canada coordinated federal consultations through a CBS Task Force (involving Health Canada, Agriculture and Agri-Food Canada, Environment Canada, the Canadian Food Inspection Agency, Natural Resources, Fisheries and Oceans, and Foreign Affairs and International Trade, among fifteen other federal actors). Biotechnology Task Forces were also formed within federal agencies/departments to facilitate internal consultations and contribute to the CBS renewal process. Federal Ministers participated in two stages of consultations with stakeholders: roundtables and sector-based consultations. Provincial government representatives attended both fora. In total, more than 5,000 Canadian organizations and individuals participated in the CBS consultation process (Industry Canada 1998, 3). As the CBS (1998, 10) states, "many consultation participants underlined that the federal government should continue to play a leadership role."

The centerpiece of the CBS was the establishment of a federal structure for management and improved horizontal coordination: the Biotechnology Ministerial Coordinating Committee (BMCC). The BMCC comprised the seven federal Ministers whose portfolios dealt most with regulatory matters related to biotechnology (the Ministers of Agriculture and Agri-Food Canada, Environment Canada, International Trade Canada, the Department of Fisheries and Oceans, Health Canada, Industry Canada, Natural Resources Canada), as well as the President of the Canadian Food Inspection Agency. It was chaired by the Minister of Industry and set the policy priorities for the CBS. Here, all Ministers shared accountability for the CBS, with each Minister additionally responsible for the specific areas under their mandate. A CBAC of about 20 independent experts (plus a Chair) was further established to advise the BMCC on policy concerning regulatory matters and serve as a forum for citizen engagement (Greenberg 2001, 13).

In addition, a number of biotechnology coordinating committees, subcommittees, interdepartmental working groups and a Canadian Biotechnology Secretariat (CBSec) were created to support the BMCC's work. Coordinating committees existed at the levels of Deputy

Ministers/Agency Head (chaired by Industry Canada), Assistant Deputy Ministers (co-chaired by Industry Canada and a rotating Minister from another department), and Director Generals (chaired by the Executive Director of the CBSec). The CBSec provided support to the biotechnology Ministerial and other coordinating committees, as well as the relevant subcommittees (i.e., Intramural Genomics R&D, Stewardship and Regulations). The Secretariat's main job was to "…ensure effective horizontal work, policy development and coordination across CBS departments and agencies" (Treasury Board Secretariat 2005). The CBSec was housed in Industry Canada and reported on the overall results of the strategy and the CBS Fund's financial performance.

[1] Food safety refers to the establishment of policies for the safety and the monitoring of the food supply. Food inspection includes all activities related to "the safety and wholesomeness of food products including standard setting, audit, detection of non-conformances, control of hazardous products, training and development of human resources, assessment based on risk, laboratory support, investigational activity, compliance enforcement including licensing, product detention, seizure and recalls, animal and plant health control measures" (CFIA 1997, Annex 5, Glossary of Terms).

[2] Hereon after the term provincial government is used to refer to the provincial/territorial governments in Canada.

[3] The terms biotechnology, genetic engineering and genetic modification are used interchangeably.

[4] Novel plants are those with new traits, but not all plants with novel traits are transgenic or genetically modified through modern biotechnological applications, since traditional breeding or mutagenesis techniques are capable of imparting novel traits into plants (Yarrow 2005, 5). Canada's regulatory system focuses on the introduction of novel traits into plants, regardless of the technique used. The *Seeds Act* defines plants with novel traits as "…a plant variety/genotype possessing characteristics that demonstrate neither familiarity nor substantial equivalence to those present in a distinct, stable population of a cultivated species of plant in Canada and that has been intentionally selected, created or introduced into a population of that species though a specific genetic change" (CBAC 2002, 6).

[5] A novel food is defined "…as any food that does not have a history of safe use as a food, or has been manufactured or packaged in a way not previously applied to that food and causes a significant change in the food's properties. [One]…category of novel foods is GM foods" (BMCC 2002, 6).

[6] The institutional structures that were created to support the National Biotechnology Strategy reflected the initial marginalization of public health concerns, such as the National Biotechnology Advisory Committee. This was a group of 25 senior executives from the industry and finance communities, consumer interests and academia. It provided advice to the Minister of State for Science and Technology and the Interdepartmental Committee on Biotechnology. The Interdepartmental Committee consisted of seven Assistant Deputy Ministers, whose job was to review progress on the National Biotechnology Strategy and coordinate biotechnology policy. The interdepartmental committee was solely chaired by the Minister of State for Science and Technology. The regulatory departments with primacy in areas related to plant-related

food biotechnology were Agriculture Canada and Health Canada. However, at this time, no department had established formal regulations for plants with novel traits or novel foods.

[7] Although a pillar of the original Canadian Biotechnology Strategy, the Genomics R&D program and governance structure (also renewed in the short term) are not discussed in this paper.

[8] Volume I provides guidance in classifying a product as 'novel' and Volume II contains specifications to manufacturers regarding the data they must provide to regulatory authorities in order to demonstrate the safety of their product. Notably, some of the guidelines have been revised and are periodically reviewed (Government of Canada 2001, 6).

[9] For example, the OECD's principle of substantial equivalence from the 1993 report, *Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles*, was highly influential in informing Canada's approach.

[10] Environment Canada under the *Canadian Environmental Protection Act* shares some responsibilities for the environmental assessment of GM organisms with the Canadian Food Inspection Agency and Health Canada. The role of the Department of Fisheries and Oceans is also not examined in this chapter, but is important for understanding the regulatory regime as a whole.

[11] The Canadian Food Inspection Agency shares some responsibilities under the latter Act with Health Canada.

[12] Environment Canada also has an Office of Biotechnology Science that coordinates environmental risk assessments within Environment Canada, as well as interdepartmentally with Health Canada and the Canadian Food Inspection Agency.

[13] Various regulations under the *Consumer Packaging and Labelling Act* also regulate the labeling of food products.

[14] The relevant agencies/departments of the Canadian Regulatory System for Biotechnology are Health Canada, the Canadian Food Inspection Agency, Environment Canada, Fisheries and Oceans Canada, Industry Canada and Natural Resources Canada.

[15] The Codex Alimentarius Commission is a joint FAO/WHO body under the United Nations Food Standards Programme that develops food codes of practice, standards and guidelines. Nation-state governments created the Commission in 1963 to manage the Codex Alimentarius, known as the international code of food standards. Over

time, the Commission has set up a complex system of specialized committees that create draft standards related to specific food issues, which are then approved in meetings of the whole. The main purposes of the Commission and code are to protect the health of consumers and ensure fair trade practices in the food trade. With universal uniform food standards, for example, there is less risk that consumers will be harmed or that governments will use them in discriminatory ways or as barriers to trade. Further, by referencing Codex standards in the 1994 Uruguay Round multilateral trade agreements, governments have made them the benchmarks against which national food measures and regulations are legally evaluated in international trade.

[16] Codex Alimentarius Commission activities in committees and task forces that focus on foods derived from biotechnology are coordinated by the Codex Bureau of Food Regulatory, International and Interagency Affairs in Health Canada's Food Directorate. For example, one of the relevant task forces is the Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology. A similar contact point exists in Health Canada's Food Directorate with respect to the OECD's Task Force on Safety Assessment of Novel Foods and Feeds. The exception here is Canadian activities in the Codex Committee on Food Labeling and its Working Group. These are led by officials in the Canadian Food Inspection Agency's Bureau of Food Safety and Consumer Protection. Environment Canada takes the lead in coordinating the Canadian position in the *Convention on Biological Diversity* and *Cartagena Protocol on Biosafety* (Environment Canada 2004).

[17] More recently, interagency and F/P/T players have also made attempts in the relevant committees to launch consultations on a *National Food Safety Strategy*.

[18] Responsibility for food safety regulations and inspections vary between the provinces. For example, in some provinces departments of agriculture inspect certain provincially regulated plants and processing facilities, while in others the departments of health are responsible for these activities (Greenberg 2001, 4).

[19] In the end, the Standing Committee did not propose that the province become a GM free agricultural zone.

[20] One identified area in which communication and co-ordination could be improved and where conflict occurs is the case of commercial secrecy, and in turn, federal secrecy surrounding confined field trials. The provincial officials, representing their governments who have responsibilities for land use, desired to know more information about the trials such as their specific site locations (Confidential Interview 10 March 2005). Section 92(5) of the *Constitution Act*, provides provincial governments with power over the management and sale of public lands (belonging to the province).

[21] For example, the Expert Panel (2001, xii, 4.6, 5.0) and Canadian Biotechnology Advisory Committee (2002, ix) reports recommended Health Canada and the Canadian Food Inspection Agency coordinate to close the gap on approvals of crops for animal feed but not for human food, as well as create stronger regulatory measures for the propagation of GM plants in laboratories and greenhouse facilities.

[22] The Canadian Biotechnology Advisory Committee (2002, xiii-xiv) report called for *either* the establishment of: an Office for the Coordination of the Regulation of GM Food and Other Novel Foods (regulatory officers and managers), a Committee of Assistant Deputy Ministers drawn from federal regulatory bodies, *or* a new agency responsible for all regulatory activities pertaining to GM foods, including a senior authoritative officer who would be responsible for the coordination of official communications and a centralized consumer food information service.

[23] For example, the Canadian Biotechnology Advisory Committee (2002, xii) report recommended that: "the mandates, internal operations of the regulators of GM foods…, and their relationships with stakeholders be carefully reviewed and modified…to ensure the highest degree of integrity and independence in the conduct of regulatory functions and to avoid the perception of mandate conflict or of conflicts of interest in operations[;] there be effective independence of regulatory functions for GM foods…unencumbered by other government functions and responsibilities, including, but not limited to, policy, economic development, negotiation of international policy and trade rules, and trade promotion[; and,] an assessment be undertaken to determine whether it would be advantageous to apply this recommendation more widely to other facets of the food safety system."

[24] Although the three components of the CBS all have accountability frameworks, the strategy itself does not. The CBSec also only tracks results and outcomes for the CBS Fund, not the CRSB or genomics R&D program activities. In addition, although the Auditor General (2005, 4.62) recognized that the CBSec improved horizontal performance with reports in 2002-2003 and 2003–2004, it noted that these reports were not tabled in Parliament and did not assess the overall contribution of the strategy.

[25] In response, an Action Plan (2001, 5) and federal interviewees discussed options of having an external expert participate in Health Canada's Food Rulings Committee and launching a voluntary pilot project with Health Canada, the Canadian Food Inspection Agency and Crop Life Canada, which would encourage petitioners (the manufacturers) to disclose information about individual submissions under review. They also discussed the importance of communicating impartially to the public about how risk assessments and decisions about approvals are done. These initiatives are now underway.

