SPECIAL SERIES:
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 cr

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

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

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

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).

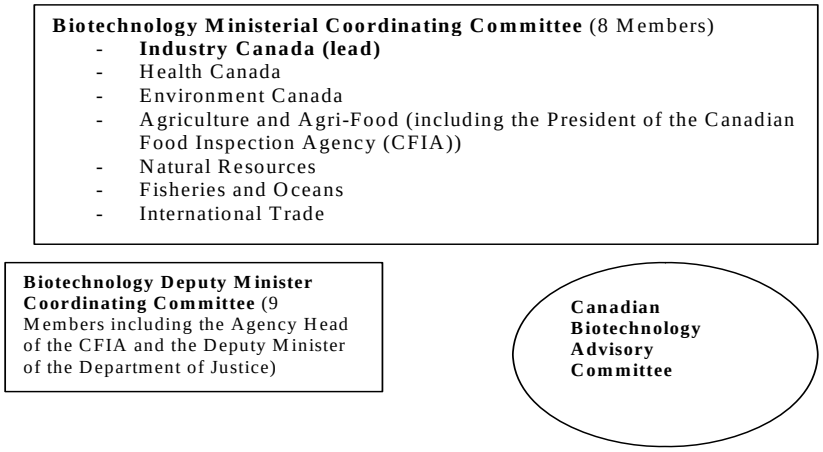
Given this 'product-based' approach, this means that GM foods in Canada are regulated in essentially the same manner as conventionally-derived food products. In contrast, a 'process-based' approach, based on the assumption that the genetic modification of food poses unique risks and therefore requires 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



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

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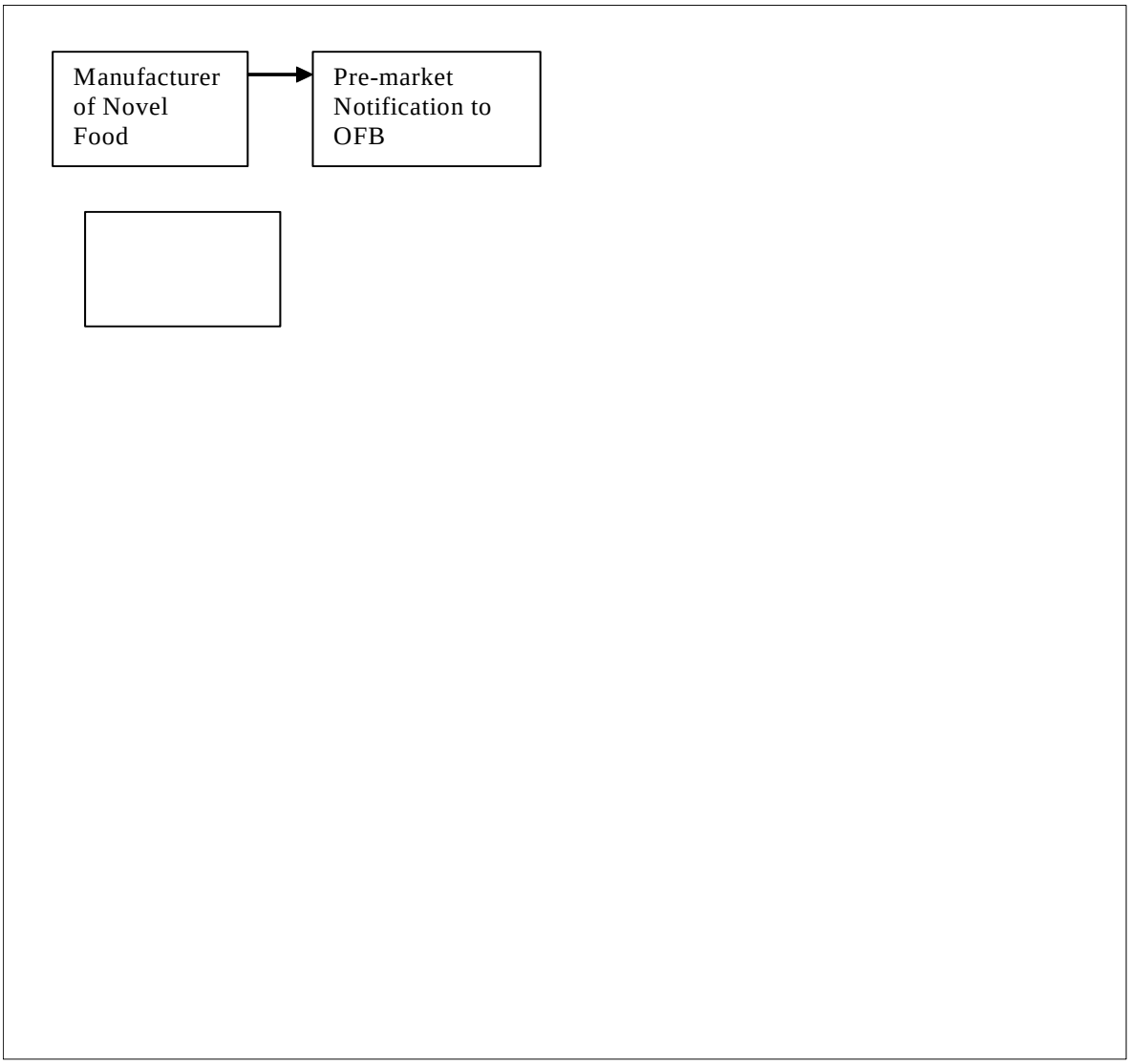
products. Accordingly, Health Canada's legislative powers to regulate GM foods come from this Act. In terms of constitutional authority, subsection 91(27) of the *Constitution Act* gives federal Parliament exclusive authority to legislate with regard to 'criminal law.' This allows Parliament to create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

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



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 plantsonfineajh2gi595 2 0 0 12 yfport pere and variety sac0.00rsned the au1(confined, unconfined8-0.0001

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 pres

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).

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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

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/cf027598cd20dfaa852570a

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.

> 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

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*.

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

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 examplTitiovlct

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 Biotechnolo

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	

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

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

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

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

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]

Se.29cul1 0 6 ost 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. Further1 0 6 ore, 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 1 0 6 andate wasl1 0 6 ixed with promotional functions. Agriculture and Agri-Food Canada and the Canadian Food Inspection Agency also both report to the Minister of Agriculture, who is

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.

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	*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
Economic	¢ 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 ¢

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

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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.

time, the Commission has set up a complex system of specialized committees that create draft standards related to

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